Study Protocol
Cover Page

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

NCT Identification Number:
NCT06634342

Date of Document:
September 11, 2024

Principal Investigator	Study Sponsor
Sara Glick, PhD, MPH Associate Professor, Department of Medicine: Allergy and Infectious Diseases University of Washington Epidemiologist, Public Health – Seattle & King County, HIV/STI/HCV Program Phone: 206-263-2044 snglick@uw.edu	Cepheid Mindy Cheng Director, Global HEOR 904 E. Caribbean Dr., Sunnyvale, CA 94089 (925) 872-2764 mindy.cheng@cepheid.com
IRB approval: University of Washington IRB Committee, 9/11/2024, IRB ID: STUDY00021203	

1. Summary of the project

The HOT (HCV One-step Test) Study will evaluate the use of a recently FDA-approved point-of-care RNA test for hepatitis C virus (HCV) in a sample of clients of a syringe services program (SSP). The *GeneXpert IV Xpress System* machine will be provided by the study sponsor Cepheid. This will be a single site, observational prospective study with two data collection components: HCV testing with quantitative data collection (Aim 1), and qualitative data collection (Aim 2). All research activities will be conducted at the Robert Clewis Center (RCC), an SSP operated by Public Health-Seattle & King County (PHSKC).

2. Background

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 (i.e., rapid HCV RNA test) will function in SSPs with PWUD to minimize this barrier. We hypothesize that PWUD who receive one-step HCV testing at SSPs will be more likely to receive their HCV test results and begin treatment.

3. Project goals and objectives

The HOT Study is a single-site, observational prospective study to demonstrate the clinical utility of a one-step HCV testing algorithm at an SSP using Xpert HCV. 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 testing in an SSP.

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

4. Participant eligibility

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.

5. Recruitment and sampling
Printed flyers will be available at the RCC and study talking points will be given to SSP staff. (APPENDIX A1)

a. *HCV testing component*: SSP staff will have one-on-one discussions with SSP participants to tell clients about the study, conduct an initial screening for age eligibility, and refer potential participants to the HCV testing nurse. The HCV testing nurse will determine final eligibility. Enrollment goal: 200 SSP participants in HCV testing.

b. *Qualitative interviews with testing participants*: Qualitative interviews will be conducted with a subsample of participants who completed HCV testing. We will interview 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. To identify the sample of participants who tested HCV-negative, the HCV testing nurse will identify participants on randomly selected days when the qualitative interviewer is available. To identify the sample of participants who were HCV-positive and received HCV treatment, the project nurse will invite all participants who complete treatment to complete the follow-up qualitative interview until the team has reached its quota.

To identify the sample of participants who were HCV-positive but did not return for treatment, we will ask participants during the initial consent process to voluntarily provide contact information to the project nurse which can be used to be contacted for future studies. Periodically throughout the study, the PHSKC HCV epidemiologist will extract a REDCap dataset based on criteria described above to identify a sample of study participants who received HCV testing, had a positive RNA test result, but have not accessed HCV treatment. The epidemiologist will select a random sample and share the participant's name and contact information with the study nurse, who will contact participants and invite them to participate in a qualitative study. This will continue until we meet our sample size goal.

Enrollment goal: 12 HCV testing participants for qualitative interviews.

c. *Qualitative interviews with professionals*: SSP staff and other professional stakeholders will be recruited by PHSKC staff based on their involvement in the project. Enrollment goal: 15 SSP and health care professionals for qualitative interviews.

6. Informed consent to participate and incentives
The consent process for the HCV testing procedures will occur in the HCV testing nurse's office, which is also where the HCV testing will occur. The HCV testing nurse will follow an informed consent guide to explain the study aims, procedures, and participant rights. Participants will be given time to ask questions about both the research and HCV testing. Specific consent will be obtained for: HCV testing, sharing deidentified data with the University of Washington (UW) team, and permission to be contacted during the study to participate in qualitative interviews (if randomly selected).

Due to the illegality of most drug use in WA, we do not want to link a participant's name to a document describing a study focused on substance use and HCV. Therefore, the testing nurse will get verbal consent from participants and document each activity with an X in REDCap.

Participants who choose not to enroll in the HOT Study will be offered the option of receiving the standard HCV testing algorithm (rapid HCV antibody test and phlebotomy for laboratory testing for HCV RNA) at the study site.

For qualitative interviews, the informed consent process will occur in the interview room, which may be an office in the SSP or a nearby conference room. UW research staff will facilitate these interviews and conduct the informed consent process following an informed consent guide, allowing time for all participants to ask questions about research procedures. These staff will review the consent form with each participant, and if the participant consents, they will be asked to give oral consent.

Incentives

- Participants will receive a $15 gift card after they complete HCV testing and return to receive their test results. The payment will not be pro-rated; participants must complete specimen collection and receive their results to receive the payment.
- Participants will receive a $40 gift card for participating in the qualitative interviews following their participation in HCV testing.
- Water and snacks will also be provided for participants while they wait for test results and or take part in the qualitative interview.
- SSP staff and other stakeholders will not receive an additional incentive.

7. HCV testing procedures

Nearly all testing procedures and data collection for people participating in this study will be the same as the procedures typically used for people receiving HCV testing at the SSP.

- Collect sample and initiate analysis in the *GeneXpert IV Xpress System* machine.
- Describe what the potential results could be and what they mean.
- Collect standard testing intake information (e.g., name and birthdate) along with additional study questions (e.g, HCV risk behaviors, substance use).
- Complete the HIPAA Authorization Form.
- Give instructions for where/how long participants can wait, or return later, to receive their results.
- Give results to participant:
  - If negative:
    - Explain results and educate on ways to reduce risk of HCV infection.
  - If positive:
    - Explain results and offer HCV treatment services.
    - Link with HCV treatment services.
    - Record testing and linkage results in REDCap.
  - If indeterminate:
    - Perform a second fingerstick and test.
- Issue gift card for receipt of results.

8. Qualitative interviews

During the six months of the testing project, we will also conduct qualitative data collection with three stakeholder groups: participants, SSP staff, and partner health systems. First, UW staff will conduct 12 in-depth interviews with participants who were involved in the testing component of the study. These interviews will be conducted with participants who reflect a diversity of outcomes, including those who received negative HCV RNA results, those who received positive HCV RNA results and were not linked to care, and those who received positive HCV RNA results and started HCV 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 HCV testing nurse will use purposive sampling to recruit participants. (See detailed sampling protocol in section 5.b above.) 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.

Second, UW staff will conduct in-depth interviews (1-1 or in small groups) with staff at the PHSKC SSP 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.

Third, UW staff and SSP staff will work in collaboration to collect qualitative data from partner health care organizations (including the health department itself). The goal of this data collection effort will be to describe the facilitators and barriers of implementing point-of-care HCV RNA testing and connecting individuals who test positive with HCV treatment.

9. Data Collection and Management

The HCV testing nurse will collect identifiers and other data during the testing process and enter these data into the testing REDCap database. During the informed consent process, the HCV testing nurse will use the PHSKC HIPAA Authorization form to obtain verbal HIPAA authorization to allow the study team to access the participant's PHI for research purposes.

<u>Extraction</u>

Prospective HCV Testing and Treatment Data

The UW study team will request a subset of deidentified data extracted from the pre-existing data collection tools used for HCV testing at the PHSKC SSP, modified with a handful of new questions to ensure that data needed to answer research questions is available for analysis.

1) Demographics: Includes some participant demographics, reason for visit, and contact information for follow-up.
    - UW will extract: age, gender/sex, race/ethnicity, zip code (first three digits only), housing status, health insurance, other support services
2) Appointment and Incentive Tracking: Includes information about each appointment, HCV screening test results, and incentives provided.
3) Medical Care: Includes information about the participant's primary care provider and any mental health care providers.

4) Testing and Immunizations: Includes information about HIV testing, past HCV testing history, and vaccination history for hepatitis and HPV.
5) Risk Assessment/Substance Use: Includes information about HCV risk factors and substance use
6) Medication Tracking: Includes information about HCV treatment prescription and initiation and completion dates.

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. Then, she will search the PHSKC HCV surveillance database to determine whether/when participants attended a HCV care visit, whether/when participants began HCV treatment, and if they achieved cure (i.e., sustained viral response at 4 weeks). No other information will be requested or recorded from health care providers.

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.

A formal Data Sharing Agreement will be signed between PHSKC and the University of Washington.

10. Confidentiality protections

Participants will give HIPAA authorization to obtain and use the following PHI: Name, contact information, HCV RNA test result, HCV treatment history. This will be documented electronically. The HCV testing nurse will have access to names and personal health information of participants who consent to HCV testing. To protect the privacy of research participants, the UW study team will have access only to deidentified data extracted from the pre-existing data collection tools used by the PHSKC SSP HCV testing team.

No names will be collected in the qualitative interviews.

11. Additional ethics considerations

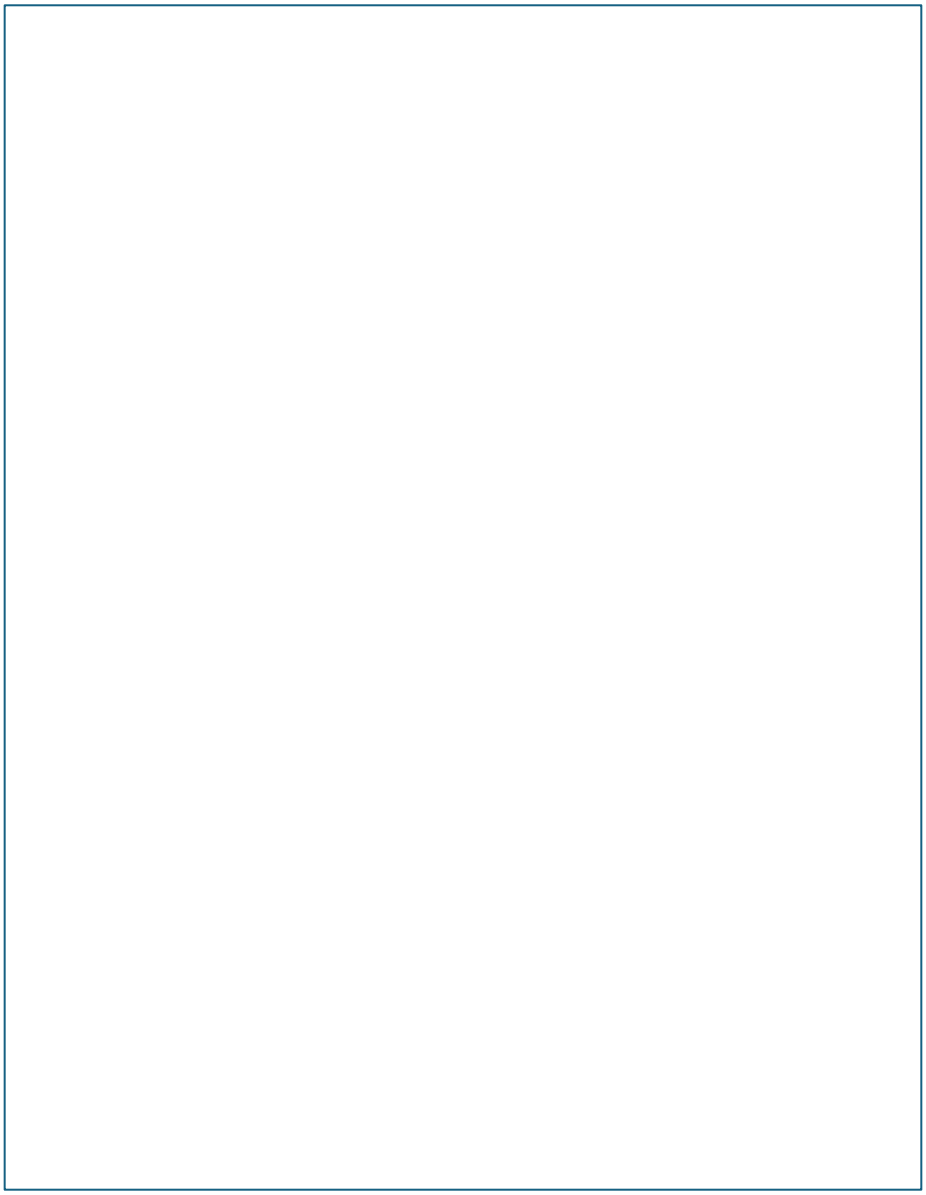
If a participant wants to withdraw their data from secondary use, they must disclose this to the HCV testing nurse who has access to the identifiable data. The PHSKC HCV epidemiologist will then remove their data from the dataset provided to the UW team and create a new analytical dataset. It is not possible for the UW team to do this on its own since there will be no identifiers in the dataset they use.

12. Data analysis and dissemination

The Principal Investigator will store the research data in a secure UW OneDrive folder that only she and other key UW personnel have access to. These data will be stored until the research objectives have been met and study findings are published in a peer-reviewed manuscript.

Data will be used for sponsor reports and published manuscripts.

APPENDIX A1 Recruitment Flyer and Script _DRAFT



Recruitment Script:
The University of Washington and Public Health are conducting a study among our participants about a new kind of rapid test for hepatitis C (hep C). If you are at least 22 years old you could earn a $15 gift card if you are eligible, agree to get tested today for hep C, and then get your results. The test needs only a fingerstick, not a blood draw, and you get your results in an hour or less. You could get tested today and then come back later for the results if you don't want to wait. But you can't get the gift card until you get your results.

Our nurse does the testing here. Do you think you'd like to participate or talk with our nurse about the study?