Testing Consent Form
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

Public Health-Seattle & King County and the University of Washington invite you to be part of a project about hepatitis C virus (HCV) testing. The information I will give you can help you make a good choice about joining the project.

A. Why we are doing this project

The purpose of this project is to learn about people's experience using a new type of test for HCV. We will use this information to plan better HCV testing and treatment for people in your community. This project is confidential, which means that no one outside of the HCV testing team will know your name or be able to identify you. Being in this project is voluntary.
The study is being paid for by Cepheid, the company that makes this new HCV test.

B. What will happen

If you agree to be in this project, this is what will happen.

1. We will offer you a free HCV test. If you agree to the HCV testing, we will enter your name and date of birth into our computer health records. Then we will stick the tip of one of your fingers to obtain a few drops of blood. We will do a hepatitis C RNA test. We will give you a card with a number that is linked to your specific test. The card will not show your name or date of birth.
2. It can take up to 60 minutes to get the result of your test. You may wait here or you can leave and come back in an hour. You will receive a $15 gift card when you get your results. We will also explain what those results mean.
    a. If the rapid test is negative, that means the test did not find any HCV virus in your blood, and you do not have hepatitis C. You will also learn how to reduce your chances of getting HCV and other infectious diseases.
    b. If the rapid test is positive, that means you have HCV virus in your blood and you have HCV infection. We will offer you the chance to get treated for HCV here or refer you to other HCV health care you might need.
3. If you have a positive test, we will ask you to sign a release of information so we can see what HCV care you had for 6 months after your test. We want to see how many people started and finished treatment, what type of treatment, and how many were cured.
4. We will ask some questions about yourself, including your age, gender, race, and housing status. We will also ask you questions about your past HIV and HCV testing and results. We will also ask you questions about your risk factors for HCV including injection drug use.
5. When testing is complete, we will destroy your blood sample. We will not store or save any samples.
6. Some participants, regardless of testing outcome, may be asked to take part in a 30-minute interview about taking this HCV test (for a $40 gift card).

Personal Information

When you agree to HCV testing, we will enter your name and other personal information into a secure, password-protected electronic health record system at Public Health-Seattle & King County. We will not tell anyone else your test results and you must show us your testing card in order to get those results. We do not share health information with any other health care provider unless you give us permission by signing a release of information form.

During the 6-month study period, the HCV testing staff at Robert Clewis Center will combine information from all participants except participant names to share with the research team at the University of Washington. This "study data" will include data about participants like age, gender, race, drug use, past HIV and HCV testing, HCV risk factors and HCV test results.

We will protect your confidentiality. We will store your name and other identifiable information separate from the study data. Access to your identifying information will be limited to certain members of the study team and individuals from UW or other agencies that may need to audit study records.

We may use data from this study for future analyses. Other collaborators will have access to the interview and testing data but will not be allowed to see any information that could identify you.

C. Things to consider

There are minimal risks from being in this project:

1. Some of the questions we will ask (such as your housing status or drug use) are personal and may make you feel uncomfortable.
2. The fingerstick may cause temporary discomfort from the needle stick, bruising, bleeding, light-headedness, and local infection.
3. You may feel uncomfortable finding out you might have been infected with HCV.
4. If your HCV test results are negative, there is a slight chance that the results are wrong and that you could still be infected.

D. Benefits

You could benefit for being a part in this study. The standard HCV test that has been used before requires a blood draw and it can take up to 2 weeks to get your results. With the new HCV RNA point-of-care test in this study, we only need a fingerstick to collect your sample (no blood draw) and you can get the test results in 30-60 minutes. Therefore, choosing to get tested for HCV in this study will be an easier and faster than getting tested the other way. It will also be easier to connect you with HCV treatment and cure the infection. HCV treatment is provided by the same nurse who will give you the test.

E. Alternatives

If you choose not to take part in the project but would still like to take an HCV test, we can give you another type of HCV test. That HCV is also free. The results from your test and any data you provide will not be linked to this study.

F. Compensation

If you take part in the HCV testing, you will get a $15 gift card after you complete the testing and receive your results.

G. Persons to Contact

This project is run by: Sara Glick at 206-263-2044. You may call her with any questions about being in the project. If you have questions about your rights as a participant or if you feel that you have been harmed, contact the University of Washington's Human Subjects Division at 206-543-0098. If you want one, you will get a copy of this form to keep.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the website will include a summary of the results. You can search this Web site at any time.

H. Confidentiality Statement

Testing and any health care you receive after testing is confidential. The project staff at University of Washington will have access to data about your test result, HCV treatment you receive, and survey responses, but will not be allowed to see any information that could identify you. Your information will be grouped with information from other persons.
If you know me, you may ask for another staff member so that your answers will be fully anonymous.

I. Costs

You will not be charged for counseling, the HCV test, HCV prevention materials, referrals to appropriate agencies, or any other services provided by this project.

J. Right to Refuse or Withdraw

Being in this study is voluntary. This means that you can refuse to sign up. It also means that if you do sign up for the study, you can decide to stop being in the study at any time without penalty.

K. Agreement

Do you have any questions?

Answer any questions before this the next section.

You have read or had read to you the details of this project. You have been given a copy of this form. You have had the chance to ask any questions. You have the right to refuse to join the study. I am going to ask for your permission to take part in this project.

Permission will be documented by the interviewer in REDCap.

Do you agree to take part in the study?

☐ Yes
☐ No

If yes:

Do you agree to hepatitis C testing?

☐ Yes
☐ No

Do you agree to provide your name and birthdate so that we can refer you to treatment services?

☐ Yes
☐ No

Do you agree to let use your data for future analysis?

☐ Yes
☐ No