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Assessing the effectiveness of hepatitis C self-testing distribution models in Vietnam

Submission date
24/08/2022

Recruitment status
No longer recruiting

Registration date
08/09/2022

Overall study status
Completed

Last Edited
05/02/2025

Condition category
Infections and Infestations

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims

Hepatitis C is a liver infection caused by the hepatitis C virus (HCV). As many as 43 million people globally do not know their HCV status and of those that are diagnosed, only about one-quarter have been treated. Vietnam faces a high burden of HCV disease, with the highest prevalence observed among people living with HIV (PLHIV) and key populations (KPs) including gay men, transgender women, drug users and sex workers. HCV self-testing (HCVST) has been identified as an innovative approach to increase uptake and diagnosis among people at high risk of HCV and link them to care and treatment to achieve the elimination of HCV by 2030. This study aims to add to the evidence base on optimal approaches for delivering HCVST and priority populations for HCVST programs by evaluating the relative effectiveness of three types of HCVST models in reaching first-time HCV testers as compared to routine provider-led testing.

Who can participate?

Key populations (people who inject drugs, gay men and other men who have sex with men, transgender women, and female sex workers) and PLHIV who are 18 years or older and of any gender. Participants must have an unknown HCV status or have not been tested for HCV within the last 6 months.

What does the study involve?

Participants are asked to join this study when seeking HCV testing services at a health facility, community-based organization (CBO) or online. The study will offer participants a choice of (1) HCV testing options, i.e., provider-led or self-testing; (2) HCV self-test type, i.e., a fingerprick blood test or oral test using a mouth swab, and (3) support in using the test, i.e., with assistance from a healthcare provider or without direct assistance from a healthcare provider. These options will be offered through three models: (1) facility-based distribution (i.e., at clinics and health facilities); (2) community-based primary and secondary distribution at CBOs; and (3) virtual distribution via an online ordering platform. Data will be collected through a cross-sectional survey, programmatic monitoring, cost records, focus group discussions and in-depth interviews with clients, service providers, and program leaders to assess the effectiveness, acceptability, preferences, feasibility, and willingness to pay for HCVST; measure linkage to care; and analyze cost-benefit of an HCVST intervention in Vietnam.

What are the possible benefits and risks of participating?
There are no direct benefits to study participants when they participate in this study. However, participants will have the chance to learn if they are infected with HCV, and infected individuals will be able to receive free confirmatory testing and treatment services. In terms of risks, study participants may feel discomfort when using the finger prick as it may cause a little pain and bleeding or may feel discomfort when swabbing themselves for saliva. The participants may also feel uncomfortable with some of the questions that will be asked. Finally, there is a risk that participants' involvement in the study could become known to others and that social harm may result (i.e., because participants could become known as HIV- or HCV- infected or at "high risk" for HIV/HCV infection).

Where is the study run from?
PATH (Viet Nam)

When is the study starting and how long is it expected to run for?
July 2022 to January 2024

Who is funding the study?
Unitaid (Viet Nam)

Who is the main contact?
Dr Bao Ngoc Vu, bvu@path.org

Contact information

Type(s)
Principal investigator

Contact name
Dr Bao Ngoc Vu

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Assessing the relative effectiveness of three models of hepatitis C (HCV) self-testing as compared to routine provider-led testing in reaching first-time HCV testers among key populations, people living with HIV and their partners in Vietnam

Acronym
AEHV

Study objectives
This is an observational study and thus no hypothesis is available. This study aims to add to the evidence base on optimal approaches for delivering hepatitis C self-testing (HCVST) and priority populations for HCVST programs.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 30/11/2022, Center for Creative Initiatives in Health and Population Institutional Review Board (No. 48, Alley 252/8, Nguyen Khang, Yen Hoa, Cau Giay, Hanoi, Vietnam; (+84) 24 3577 0261; ccihp@ccihp.org), ref: IRB00006980
2. Approved 17/12/2022, WHO Ethics Research Committee (20, Avenue Appia, CH-1211, Geneva 27, Switzerland), ref: ERC.0003830
3. Approved 22/12/2022, Vietnam National Ethics Committee in Biomedical Research (138A Giang Vo Street, Kim Ma Ward, Ba Dinh District, Hanoi, Vietnam; (+84) 24 3384 6688; iecmoh@gmail.com), ref: 235/CN-HDDD

Study design
Two-phase mixed-method multicenter observational implementation science study

Primary study design
Observational

Study type(s)
Screening

Health condition(s) or problem(s) studied
Screening for hepatitis C virus (HCV) among key populations, people living with HIV and their partners who have unknown HCV status

Interventions
The study will be implemented through two phases, i.e., Phase I (active study phase) and Phase II (routine HCVST delivery).

Phase I: This phase is comprised of a cross-sectional implementation science study that assesses the overall acceptability of HCVST over provider-led HCV testing, HCVST type and distribution model preferences and willingness to pay; uses cascade metrics and visualization to measure the relative strength of linkage from HCV antibody reactivity to confirmation testing and direct-acting antiviral enrollment among those opting for HCVST and routine provider-led HCV testing; and conducts focus group discussions with a key population (KP) and people living with HIV (PLHIV) HCVST users to explore the relative acceptability and preferences for HCVST.

During phase I, HIV-negative or HIV status-unknown KP (people who inject drugs, men who have sex with men, female sex workers, transgender women), PLHIV and their partners living in Ho Chi Minh City (HCMC) or Hanoi will be able to access a choice of HCV testing between provider-led rapid anti-HCV testing (the standard of care) or HCVST (intervention) through three types of distribution models: (1) facility-based, (2) community-based, and (3) online. The facility-based model (n = 9) includes three public-sector methadone maintenance therapy clinics, three public-sector antiretroviral therapy out-patient clinics, and three KP-led private clinics. The community-based sites (n = 8) are KP-led community-based organizations (CBOs) that will offer HCVST as part of the HIV/HCV lay testing or HIVST services they currently offer. The online site is managed by a KP-led social enterprise and they will post information on HCVST on an existing site that offers HIVST orders and home delivery. At the start of the study, the new HCVST service/option will be promoted through the participating facilities, KP-led CBOs and online sites. This will include a study leaflet and study notice posted online through Facebook, sex hookup apps and other platforms.

Clients that seek community- or facility-based HCV testing will be provided with an additional option of HCVST alongside the standard of care of provider-led anti-HCV testing, and those opting for HCVST will be offered an option of either assisted or unassisted HCVST. Clients that test unassisted will be provided with information (e.g., information sheet; video) on how to complete the test. Participants with an HCVST reactive result will be supported by clinic staff to access free HCV confirmatory testing and treatment at KP-led clinics. KP and PLHIV who opt for assisted HCVST will be asked if they'd like to bring an HCVST test to their sexual and/or injecting partners. Those that opt in will be asked to list their partners and will be given the same test type to distribute. If participants consent, study staff will follow up with HCVST participants over the phone to inquire whether their partners accepted the test kit and agreed to participate in a phone interview with study staff. If the secondary testers consent to join the study, the study team will conduct the phone survey, collect any testing results and offer to support linkage to confirmation testing if needed.

For the online HCVST distribution model, clients will be invited to complete the online consent form and the first part of the online survey focused on collecting demographic data. They will then be sent the HCVST test and information on how to complete the test, a link to the rest of the survey to complete after testing, and information on what to do if they test reactive. Study staff will follow up with HCVST participants over the phone and participants with an HCVST reactive result will be supported to access free HCV confirmatory testing and treatment at KP-led and KP-friendly clinics. There is no comparator to routine provider-led testing for the online model.

Focus group discussions (FGDs) will be offered to HCVST users who enroll in the study until the sample is complete. 15 FGDs will be conducted among HCV testers, each of which will comprise between 6-8 people. Two FGDs will also be conducted among HCVST service providers. A quota of service providers representing each service type will be invited to participate in FGDs and to complete the consent process. All FGDs will be held in a private room in the clinic, CBO office or

social enterprise office affiliated with each model. Conversations will be recorded with consent from participants and transcribed for coding.

For the HCV screening-diagnosis and treatment cascade measurement, study staff will track confirmatory testing results (positive, negative, indeterminate, refused to share results, don't know the result or did not do the test), HCV treatment enrolment and completion. Cost data will also be collected using a standard cost element form to measure the relative cost of each HCVST model by the ability to identify new HCV testers and diagnose chronic HCV cases (cost per new diagnosis) as compared to provider-led testing. Cost data will be collected by the research team in collaboration with study clinics, CBOs and online distribution services.

Phase II: The aim of Phase II is to prepare for the country scale-up of HCVST. During this phase, we will expand to three additional facilities (one methadone maintenance treatment [MMT] clinic, one ART-OPC and one pre-exposure prophylaxis [PrEP]), two additional KP-CBOs and an online HIVST ordering platform in Nghe An Province that is managed by two KP-led CBOs. For all twenty facilities, twelve CBOs and two online ordering platforms, only routine monitoring data will be collected. In-depth interviews will be held with national and provincial leaders and service providers. As in Phase I, study staff will track the HCV screening-diagnosis and treatment cascade and cost data will be collected.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
OraQuick® HCV rapid antibody test, OraSure Technologies Inc.

Primary outcome(s)
Effectiveness of HCVST distribution models in reaching first-time HCV testers is measured using a cross-sectional survey in Phase I and an HCV testing e-log book in Phase II

Key secondary outcome(s))
1. Acceptability of secondary HCVST distribution among KP who seek primary HCVST as part of the community distribution model is measured using a cross-sectional survey and HCV testing e-log book in Phase I
2. Linkage of those that test HCV antibody reactive to confirmatory testing, diagnosis, and treatment is measured using an e-logbook and client FGDs in Phase I and an e-logbook and online HCV risk screener in Phase II
3. Acceptability of and preferences for HCVST models are measured using a cross-sectional survey and FGDs with clients and providers in Phase I and an e-logbook in Phase II
4. Operational feasibility of integrating HCVST into HIV and harm reduction services is measured using FGDs with clients and providers in Phase I and IDIs with decision-makers in Phase II
5. Willingness to pay for routine provider-led anti-HCV testing and HCVST tests is measured using a cross-sectional survey in Phase I
6. Relative cost of the three HCVST distribution models as compared to routine provider-led anti-HCV testing is measured using an Excel worksheet in both Phases I and II

Completion date
30/01/2024

Eligibility

Key inclusion criteria
1. 18 years of age or older
2. Unknown HCV status or not tested for HCV within the last 6 months
3. Agreed to provide consent for participation in the study
4. Have access to a reliable phone for follow-up (for those opting for unassisted HCVST)

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
2882

Key exclusion criteria
Individuals who have been diagnosed with chronic HCV and are on treatment

Date of first enrolment
01/09/2023

Date of final enrolment
14/11/2023

Locations

Countries of recruitment
Viet Nam

Study participating centre
Ve Nha CBO
No. 24 Đe To Hoang- Cau Den ward- Hai Ba Trung District
Hanoi
Viet Nam
-

Study participating centre
Mai Am Hoang Mai CBO
No. 20 Lane 1/200 Vinh Hung Str.
Vinh Hung ward
Hoang Mai Dist
Hanoi
Viet Nam
-

Study participating centre
Suc Moi CBO
No. 87 Lane 204
Hong Mai Str.
Quynh Loi ward
Hai Ba Trung Dist.
Hanoi
Viet Nam
-

Study participating centre
Ba Vi CBO
Ba Vi District Health Center
Tay Dang town
Ba Vi
Hanoi
Viet Nam
-

Study participating centre
Glink Hanoi clinic
No. 18, Lane 9 Minh Khai Str.
Truong Đinh ward
Hai Ba Trung Dist
Hanoi
Viet Nam
-

Study participating centre
Nam Tu Liem District Health Center Outpatient Clinic
Inter-agency zone
Cau Dien ward
Nam Tu Liem Dist

Hanoi
Viet Nam
-

Study participating centre
Nam Tu Liem District Health Center Methadone Maintenance Therapy Facility
Inter-agency zone
Cau Dien ward
Nam Tu Liem Dist.
Hanoi
Viet Nam
-

Study participating centre
Tinh Ban 1 CBO
Group 1, Hamlet 4
Vinh Loc A
Binh Chanh Dist.
Ho Chi Minh City
Viet Nam
-

Study participating centre
Niem Tin CBO
A337/8 Nguyen Tran Hien Str.
Ward 18
Dist. 4
Ho Chi Minh City
Viet Nam
-

Study participating centre
Vuot Song CBO
No 72 Road 1
Le Thanh Residence area
An Lac ward
Binh Tan Dist.
Ho Chi Minh City
Viet Nam
-

Study participating centre
Hoa Co May CBO
17/7/2 Thien Ho Duong Str.
Ward 01
Go Vap Dist.
Ho Chi Minh City
Viet Nam
-

Study participating centre
Glink HCMC D10 Clinic
224/38 Ly Thuong Kiet Str.
Ward 14, Dist. 10
Ho Chi Minh City
Viet Nam
-

Study participating centre
Galant Clinic
No. 104, Tran Binh Trong Str.
Ward 1, Dist. 5
Ho Chi Minh City
Viet Nam
-

Study participating centre
HCMC D4 District Health Center Outpatient Clinic
396/27 Nguyen Tat Thanh Str.
Ward 18
Dist. 4
Ho Chi Minh City
Viet Nam
-

Study participating centre
HCMC D4 District Health Center Methadone Maintenance Therapy Facility
396/27 Nguyen Tat Thanh Str.
Ward 18
Dist. 4
Ho Chi Minh City
Viet Nam
-

Study participating centre
Binh Thanh District Health Center Outpatient Clinic
8/104 Dinh Bo Linh Str.
Ward 24
Binh Thanh Dist.
Ho Chi Minh City
Viet Nam
-

Study participating centre
Binh Thanh District Health Center Methadone Maintenance Therapy Facility
8/104 Dinh Bo Linh Str.
Ward 24, Binh Thanh Dist.
Ho Chi Minh City
Viet Nam
-

Sponsor information

Organisation
PATH

Funder(s)

Funder type
Other

Funder Name
Unitaid

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date. The researchers anticipate that datasets may not be made available due to concerns around patient confidentiality. Only aggregate data will be shared in reports or publications.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Plain English results		01/04/2024	05/02/2025	No	Yes