Supplementary Annex 1 Study information form and informed consent form

Hepatitis C Study Information Sheet

Title of Study

Randomized controlled trial of home-based hepatitis C self-testing in key populations in Georgia

Participating Organizations

NCDC, Equality Movement, Tanadgoma, Tbilisi New Way HRS, Batumi Imedi HRS, Foundation for Innovative New Diagnostics

Introduction

Hepatitis C is a liver infection caused by a virus that can lead to serious liver damage, cancer, and even death. You are being invited to take part in this study to help understand different ways people can be tested for hepatitis C.

Purpose

The purpose of this study is to evaluate different models of hepatitis C testing

Study Procedures

If you take part in the study, you will only have to sign the consent form, take two surveys, and consider getting tested for hepatitis C. You will be randomly selected for testing models: a) to either receive a hepatitis C testing kit delivered to your home or b) receive information about how to get tested for hepatitis C at a local clinic or community center.

If you are selected for the hepatitis c self-test it is a simple procedure using oral fluids. If you are selected for the hepatitis C self-test group you will either be placed in the group that gets the hepatitis C self test delivered by Glovo delivery or be placed in the group that will have the test delivered to your house by a peer outreach worker or a social worker

Your information will be reviewed by the study personnel and grouped with all other persons in the study.

Benefits

As a participant in this study, you may learn if you have been exposed to hepatitis C or not and be offered care and treatment if you have hepatitis C.

Risks

There is minimal discomfort with hepatitis C testing. There is a minimal risk that you could encounter social harms from this study.

Framed in the study the observational team is set up to identify any social harm associated with participation in the study and testing. They will give you recommendations and to get the appropriate services as needed.

You can contact the study coordinator for the information how to contact this group (*The phone numbers will be provided by Arms*)

Compensation and Costs

There are no costs to you for participation in this study. All participants will receive a phone credit voucher of 10 GEL for completion of the first follow up questionnaire to enter test result and another phone credit voucher of 10 GEL when the finish the second study survey. You will receive the phone credits to the phone number that you provide on the online platform approximately 7 days after you complete each survey. You will be offered hepatitis C testing but are not required to be tested for hepatitis C to receive compensation.

Confidentiality

All information collected about you during the course of this study will be stored without any personal identifiers. No one will be able to match you to your information. No one will be able to determine your identity in the frame of the study. Only study personnel will have access to the information.

Voluntary Participation/Study Withdrawal

Taking part in this study is completely voluntary. You are free to withdraw at any time. Whether or not you are part of this study does not in any way affect your medical or preventive care.

Questions

If you have any questions about the study, you may ask the study staff at any time.

The name and phone number of the study personnel of the relevant center will be indicated.

Online informed consent form

Project title: Randomized controlled trial of home-based hepatitis C self-testing in key populations in Georgia

I confirm that I have read and understood the information as provided in the information sheet for the above project and have had the opportunity to ask questions.

I understand that the project team may look at my health records for the current study. I agree to this access. I understand that my identity will not be revealed in any information released to third parties or published. I understand that I may freely withdraw from this project at any time. I agree to be a part of the above project.

Supplementary Annex 2

PARTICIPANT FOLLOW-UP SURVEY #1

These forms will be provided to the participants in Georgian language STUDY ID: automatically inputted and date and timestamped by the platform SURVEY DATE: automatically generated/timestamped by the platform

INFORMATION TO PARTICIPANTS

This questionnaire will be anonymized before being analyzed and your name will never appear in the database. Your answers will be used to better understand hepatitis C testing in Georgia.

SECTION A - STUDY TESTING AND FOLLOW-UP

A1. Did you complete the hepatitis C testing that was offered to you as part of this study?

- 1. Yes
- 2. No

A1ai. (if answered Yes to question A1, version of question for arm 3 and 5) What was the result?

- 1. Positive
- 2. Negative
- 3. Don't know, have forgotten
- 4. Do not want to disclose

A1aii. (if answered Yes to question A1, version of question for arm 1,2 and 4) What was the result?

- 1. Positive
- 2. Negative
- 3. Test did not work
- 4. Don't know, could not read the test
- 5. Do not want to disclose

A1b. (If answered No to question A1) If no, why not?

- Did not want to test/was not interested
- 2. Forgot to get tested
- Afraid of testing
- 4. Did not have time
- 5. Others, specify:

A1c. (If answered Yes for question A1, for arm 3 and 5 only) Where did you go to get the hepatitis C test done?

(select from drop down list the name of the facility)

(For participants who live in Tbilisi)

- Tbilisi Tanadgoma center
- 2. Tbilisi Equality movement center
- 3. Tbilisi New Way HRS
- 4. Tbilisi ID Hospital
- 5. Neo Lab clinic

	6. 7.	Hepa clinic Other:
(For parti	cipants	who live in Batumi)
	1. 2. 3. 4. 5. 6.	Batumi Tanadgoma center Batumi Equality movement Batumi Imedi HRS Batumi ID hospital Batumi Mary time hospital Other:
	do you 1. advice 2. 3. 4.	in question A1aii, for arm 1,2, and 4 only) If you had tested positive think your next steps would have been? To go to a community-based organization for more information and To go to a healthcare clinic for a confirmation test To go to a hospital for a confirmation test I would not do next step Don't know Others, specify:
	er step to 1. informa 2.	of work or Don't know in question A1aii, for arm 1,2 and 4 only) Have of get a second test done? Yes, have gone to a community-based organization for more ation and advice Yes, have gone to a clinic and asked for another test No, I have not made next step Others, specify:
A1h. (If answered N	1. 2.	estion A1g) If you do not made any next step, why not? Did not want to test/was not interested Forgot to get tested Afraid of testing Did not have time Transportation was too expensive Others, specify:

A2a. (*version of question for arm 3 and 5 group*) Did you ask anyone any question about process of hepatitis C testing?

- 1. Yes, online through the support offered on selftest.ge platform
- 2. Yes, online through searching the internet
- 3. Yes, person who performed the test
- 4. Yes, friend or family member

5.	Yes; others, specify:		
6.	No, I have not asked the question		
A2b. (<i>version of questio</i> C testing?	n for arm 1) Did you ask anyone any question about process of hepatitis		
1.	Yes, online through the support offered on selftest.ge platform		
2.	Yes, online through searching the internet		
3.	Yes, friend or family member		
4.	Yes; others, specify:		
5.	No, I have not asked the question		
A2c. (<i>version of question</i> C testing?	on for arm 2 and 4) Did you ask anyone any question about hepatitis		
1.	Yes, online through the support offered on selftest.ge platform		
2.	Yes, by asking the peer deliver who dropped of my test		
3.	Yes, online through searching the internet		
4.	Yes, friend or family member		
5.	Yes; others, specify:		
6.	No, I have not asked the question		
How easy was the testing Not very convenient How convenient was the Not very private How private did you thing Not very trustworthy How much do you feel you not very secure	Average Very convenient		
How stressful was the te Not very easy Ave	Average Very stressful string process? 1 2 3 4 5 arage Very easy re, how easy was it to access it? 1 2 3 4 5 Did not need it		

A4ai. (If answered Yes in question A4, version of question for arm 1,2 and 4) What do you think have helped you to understand the result of your test (select all that apply)?

A4. (If answered Yes in question A1) Did you feel you could understand the result of your test?

1.

2.

Yes

No

- 1. The printed instructions for use that came with the HCV self-test
- 2. Video instructions on how to perform a self-test
- 3. Being able to communicate with the selftest.ge team
- 4. Other; specify: _____

A4aii. (If answered No in question A4, version of question for arm 1,2 and 4) Why do you think you were unable to understand the result of your test? Select all that apply

- 1. The printed instructions for use that came with the HCV self-test were not easy to understand
- 2. Video instructions on how to perform a self-test was not easy to understand
- 3. Communication with the selftest.ge team were not easy to understand
- 4. Others; specify:

A5. (If answered Positive, test did not work or Don't know in question A1aii) Did you feel you knew what steps you needed to take to be further linked to hepatitis C care after you got the result of your test?

- 1. Yes
- 2. No

A6. (If answered No in question A5) What do you think would have helped you to know what steps you need to take to be further linked to care?

- 1. A list of clinics near me that provide HCV care with their contact information
- 2. More information on how community-based organizations near me could help me navigate how to be linked to care
- 3. A video explaining how I could get linked to care
- 4. Others; specify:_____

A7. In the future, where would you prefer to be tested for hepatitis C?

- 1. By myself at home
- 2. At home with someone I trust
- 3. By myself at a healthcare clinic
- 4. In a community centre by community-based organization staff
- 5. In a healthcare clinic by a healthcare worker
- 6. In a pharmacy by a healthcare worker
- 7. No preference
- 8. Prefer not to get tested for hepatitis C
- 9. Other, specify:

A8. In the future, would you test yourself at home if you have a hepatitis C self-testing kit and instructions on how to do it?

- Yes
- 2. No
- 3. Don't know

A8a. (If answered Yes in question A8) If yes, how often do you think you would test yourself?

- 1. More than once every 6 months
- 2. Once every 6 months
- 3. Once a year

4.	Once every 2 years
5.	Don't know
6.	Others, specify:

A1d. (If answered Positive in question A1ai or A1aii) Have you taken further steps for hepatitis C care after your positive test? Please select all that applies

- 1. Yes, have gone for confirmation test
- 2. Yes, have had doctor consultation and completed additional testing
- 3. Yes, have started treatment
- 4. others, specify:
- 5. No, I do not plan to take further steps

A1e. (If answered Yes, have gone for confirmation test or Yes, have completed further testing and have started treatment in question A1d) What was the result of your confirmation test?

- 1. I was confirmed active chronic Hepatitis C (viremia)
- 2. I do not have active chronic hepatitis C (viremia)
- 3. Have not been told the results yet
- 4. Do not want to disclose
- 5. Others, specify:_____

A1i. (If answered Yes, have gone for confirmation test or Yes, have completed further testing and have started treatment in question A1d) Where did you go for this further hepatitis C care?

(select from drop down list the name of the facility

(For participants who live in Tbilisi)

- 1. Tbilisi ID Hospital
- 2. Neo Lab clinic
- 3. Hepa clinic
- 4. Other:

(For participants who live in Batumi)

- 1. Batumi Imedi HRS
- 2. Batumi ID hospital
- 3. Batumi Mary time hospital
- 4. Other: _____

SECTION B - RISK BEHAVIORS

- B1. How many times have you or your partner(s) used a condom during sexual contact in the last month?
 - 1. I have not had sexual contact in the last month
 - 2. Always
 - 3. Often
 - 4. Sometimes
 - 5. Never used
- B2. In the last month, have you taken any substance by snorting it?
 - 1. Yes

- 2. No
- B3. In the last month, have you engaged in chemsex (sex under the bioactive substance)?
 - 1. Yes
 - 2. No
- B4. In the last month, have you injected unprescribed drugs?
 - 1. Once
 - 2. More than once
 - 3. Never

B4a. (If answered Once or More than once to question B4) Within the last month, how often did you inject illicit drugs?

- 1. Once a month
- 2. Several times a month
- 3. Once a week
- 4. 2-3 times a week
- 5. 4-5 times a week
- 6. Once a day
- 7. Several times a day
- 8. Don't know

B4b. (If answered Once or More than once to question B4) In the past month, have you ever used a needle/syringe that was used by somebody else before?

- 1. Yes
- 2. No
- 3. Don't know

B4c. (If answered Yes to question B4b) If you have used a needle/syringe that was used by somebody else before in the past month, how many people share it with you?

- 1. (fill in the number of people you shared with)
- 2. Don't know

SECTION C - Help us to make HCV testing accessible to everyone who needs it, your opinion counts!

Please let us know how we can improve HCV testing and care services - your feedback will help to guide how these services can best serve to Georgia population.

Supplementary annex 3:

PARTICIPANT FOLLOW-UP SURVEY #2

STUDY ID: automatically linked and date and timestamped by the platform SURVEY DATE: automatically generated/timestamped by the platform

INFORMATION TO PARTICIPANTS

This questionnaire will be anonymized before being analyzed and your name will never appear in the database. Your answers will be used to better understand hepatitis C testing in Georgia.

SECTION A - STUDY TESTING AND FOLLOW-UP

A1. Did you complete the hepatitis C testing that was offered to you as part of this study?

- 1. Yes
- 2. No

A1ai. (if answered Yes to question A1, version of question for arm 3 and 5) What was the result?

- 1. Positive
- 2. Negative
- 3. Don't know, have forgotten
- 4. Do not want to disclose

A1aii. (if answered Yes to question A1, version of question for arm 1,2 and 4) What was the result?

- 1. Positive
- 2. Negative
- 3. Test did not work
- 4. Don't know
- 5. Do not want to disclose

A1b. (If answered No to question A1) If no, why not?

- 1. Did not want to test/was not interested
- 2. Forgot to get tested
- Afraid of testing
- 4. Did not have time
- 5. Others, specify:

A1c. (If answered Yes for question A1 for arm 3 and 5 only) Where did you go to get the hepatitis C test done?

(:	select fr	om drop	down lis	t the r	name of	the f	facility)
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(For participants who live in Tbilisi)

- 1. Tbilisi Tanadgoma center
- 2. Tbilisi Equality movement center
- 3. Tbilisi New Way HRS
- 4. Tbilisi ID Hospital
- 5. Neo Lab clinic
- 6. Hepa clinic

7.	Other:
(For participants v	vho live in Batumi)
2. 3. 4. 5.	Batumi Tanadgoma center Batumi Equality movement Batumi Imedi HRS Batumi ID hospital Batumi Mary time hospital Other:
	in question A1aii, for arm 1,2, and 4 only) If you had tested positive think your next steps would have been? To go to a community-based organization for more information and To go to a policlinic for a confirmation test To go to a healthcare clinic for a confirmation test I would not do next step Don't know Others, specify:
you taken any further step t 1.	ot work or Don't know in question A1aii, for arm 1,2 and 4 only) Have o get a second test done? Yes, have gone to a community-based organization for more ation and advice Yes, have gone to a clinic and asked for another test No, I have not made next step Others, specify:
A1h. <i>(If answered No in que</i> 1. 2. 3. 4. 5.	Did not want to test/was not interested Forgot to get tested Afraid of testing Did not have time Test was too expensive Others, specify:
A2a. (<i>version of questi</i> any question about hepatiti 1. 2. 3. 4. 5. 6.	on for arm 3 and 5 group) Did you ask anyone is C testing? Yes, online through the support offered on selftest.ge platform Yes, online through searching the internet Yes, person who performed the test Yes, friend or family member Yes; others, specify: No
	10

A2b. (version of question for arm 1) Did you ask anyone any question about hepatitis C testing?
1. Yes, online through the support offered on selftest.ge platform
 Yes, online through searching the internet Yes, friend or family member
4. Yes; others, specify:
5. No
A2c. (version of question for arm 2 and 4) Did you ask anyone any question about hepatitis C testing?
1. Yes, online through the support offered on selftest.ge platform
Yes, by asking the peer deliver who dropped of my test
3. Yes, online through searching the internet
4. Yes, friend or family member
5. Yes; others, specify:6. No
G. ING
A3. (If answered Yes in question A1) How would you rate the hepatitis C testing you were offered in each of the following categories? Please rate 5 point scale from 1 (weakest) to 5 (strongest)
Not very easy Average Very easy
How easy was the testing process? 1 2 3 4 5
Not very convenient Average Very convenient How convenient was the testing process? 1 2 3 4 5
Not very private Average Very private How private did you think the testing process was? 1 2 3 4 5
Not very trustworthy Average Very trustworthy How much do you feel you can trust the test results? 1 2 3 4 5
Not very secure Average Very secure How secure did you feel during the testing process? 1 2 3 4 5
Not very stressful Average Very stressful How stressful was the testing process? 1 2 3 4 5
Not very easy Average Very easy
If you needed further care, how easy was it to access it? 1 2 3 4 5 Did not need it
A4. (If answered Yes in question A1) Did you feel you could understand the result of your test? 1. Yes
2. No
3. I do not know
A4ai. (If answered Yes in question A4, version of question for arm 1,2 and 4) What do you think

have helped you to understand the result of your test (select all that apply)?

- The printed instructions for use that came with the HCV self-test 1.
- 2. Video instructions on how to perform a self-test was not easy to understand
- Communication with the selftest.ge team were not easy to 3. understand

	4. 5.	Being able to communicate with the selftest.ge team Other; specify:
		uestion A4, version of question for arm 1,2 and 4) Why do you think
you were unable to	unaersi 1.	and the result of your test? Select all that apply The printed instructions for use that came with the HCV self-test
		not easy to understand
	2.	Video instructions on how to perform a self-test was not easy to
	unders	stand Communication with the selftest.ge team were not easy to
	unders	
	4.	Others; specify:
		Invalid or Don't know in question A1aii) Did you feel you knew what be be further linked to hepatitis C care after you got the result of your
	1.	Yes
	2.	No
		estion A5) What do you think would have helped you to know what e further linked to care?
	1.	A list of clinics near me that provide HCV care with their contact
	inform 2.	ation More information on how community-based organizations near me
		help me navigate how to be linked to care
	3.	A video explaining how I could get linked to care
	4.	Others; specify:
A7. In the future, wh	ere wo	uld you prefer to be tested for hepatitis C?
· · · · · · · · · · · · · · · · · · ·	1.	By myself at home
	2.	At home with someone I trust
	3.	By myself at a healthcare clinic
	4. 5.	In a community centre by community-based organization staff In a healthcare clinic by a healthcare worker
	6.	In a pharmacy by a healthcare worker
	7.	No preference
	8.	Prefer not to get tested for hepatitis C
	9.	Other; specify:
A8. In the future, wo		u test yourself at home if you have a hepatitis C self-testing kit and?
	4.	Yes
	5.	No
	6.	Don't know
A8a. (If answered Y	es in qu	uestion A8) If yes, how often do you think you would test yourself?

More than once every 6 months

Once every 6 months

Once every 2 years

Once a year

Don't know

1.

2.

3.

4.

5.

6.	Others, specify:	
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A1d. (If answered Yes to question A1, Positive in question A1a and No in question A1d in Follow-up survey #1, this will be the first question for them in this Follow-up survey #2. After questions A1d and A1e have been answered by this group in Follow-up survey #2, they will proceed to section B. This question is also for those who answered Positive in question A1a in Follow-up survey #2; for this group, they will proceed through the rest of section A following skip patterns based on their answers) Have you taken further steps for hepatitis C care after your positive test?

Please select all that applies

- 1. Yes, have gone for confirmation test
- 2. Yes, have had doctor consultation and completed additional testing
- 3. Yes, have started treatment
- 4. Others, specify: _____
- 5. No, I do not plan to take further steps

A1e. (If answered Yes, have gone for confirmation test or Yes, , have had doctor consultation and completed additional testing and have started treatment in question A1d) What was the result of your confirmation test?

- 1. I have hepatitis C viremia
- 2. I do not have hepatitis C viremia
- 3. Have not been told the results yet
- 4. Others, specify: _____

A1i. (If answered Yes, have gone for confirmation test or Yes, have completed further testing and have started treatment in question A1d) Where did you go for this further hepatitis C care?

(select from drop down list the name of the facility

(For participants who live in Tbilisi)

- 1. Tbilisi ID Hospital
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(For participants who live in Batumi)

- 1. Batumi Imedi HRS
- 2. Batumi ID hospital
- 3. Batumi Mary time hospital
- Other: _____

SECTION B - RISK BEHAVIORS

B1. How many times have you or your partner(s) used a condom during sexual contact in the last month?

- 1. I have not had sexual contact in the last month
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- 3. Often
- 4. Sometimes
- 5. Never used

- B2. In the last month, have you taken any substance by snorting it?
 - 1. Yes
 - 2. No
- B3. In the last month, have you engaged in chemsex (sex under the bioactive substance)?
 - 1. Yes
 - 2. No
- B4. In the last month, have you injected unprescribed drugs?
 - 1. Once
 - 2. More than once
 - 3. Never

B4a. (If answered Once or More than once to question B4) Within the last month, how often did you inject drugs?

- 1. Once a month
- 2. Several times a month
- 3. Once a week
- 4. 2-3 times a week
- 5. 4-5 times a week
- 6. Once a day
- 7. Several times a day
- 8. Don't know

B4b. (*If answered Once or More than once to question B4*) In the past month, have you ever used a needle/syringe that was used by somebody else before?

- 1. Yes
- 2. No
- 3. Don't know

B4c. (*If answered Yes to question B4b*) If you have used a needle/syringe that was used by somebody else before in the past month, how many people share it with you?

- 1. (fill in the number of people you shared with)
- 2. Don't know

SECTION C - Help us to make HCV testing accessible to everyone who needs it, your opinion counts!

Please let us know how we can improve HCV testing and care services - your feedback will help to guide how these services can best serve the people in Malaysia: