STUDY REPORT

OPERATIONAL RESEARCH OF HIV SELF-TESTING ACCEPTABILITY AMONG MSM AND PWID **IN GEORGIA**

GHRN
ზიანის შემცირების ქსელი
GEORGIAN HARM REDUCTION NETWORK

#sos_project

Alliance for Public Health

Georgian Harm Reduction Network 2020

CONTENTS

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ABBREVIATIONS

AIDS	Acquired Immunodeficiency Syndrome
FSW	Female Sex Workers
GHRN	Georgia Harm Reduction Network
HIV	Human Immunodeficiency Virus
HIVST	HIV self-test(ing)
IDI	In-depth Interview
IFU	Instructions for Use
KP	Key Population
MSM	Men who have Sex with Men
NSP	National Strategic Plan
PLHIV	People Living with HIV
PWID	People Who Inject Drugs
WHO	World Health Organization

BACKGROUND

Georgia remains to be a low prevalence country with a concentrated epidemic among men who have sex with men (MSM). Even though the prevalence remains low in the general population (with the estimated prevalence of 0.4% [0.3%-0.5%]), there is a risk that the epidemic could worsen because of a growing number of new cases among the key populations (KP) representatives, especially MSM and people who inject drugs (PWID). Female partners of these groups' representatives might serve as bridges to the general population[1] and should also be considered and taken into account in the relevant research and project planning activities and general situation analysis.

At the initial phase of the HIV epidemic in Georgia, injecting drug use was the major mode for HIV transmission accounting for more than 70% of all cases. Over the last few years, HIV transmission through sexual contacts has become dominant: as of 2019, 46.7% of all cases are attributed to heterosexual contacts while homo and bi-sexual contacts accounting for 11.3% of all registered HIV cases[2].

Research-based evidences indicate that the HIV epidemic is concentrated among key affected populations, especially MSM. According to the latest size estimation study, there are approximately 18,500 MSM in Georgia[3]. HIV prevalence in this group in Tbilisi has increased dramatically over the last decade: from 3.7% in 2007 to 21.5%[4] in 2018. Batumi and Kutaisi have also revealed high prevalence among MSM — 15.6% and 9.6% respectively. The recent MSM cohort study conducted by the National AIDS Center, showed very high incidence of HIV infection in this population: up to 6 new infections per 100 person-years of observation. This contributes to the explanation of the rising prevalence of HIV[5].

Based on the latest population size estimation survey conducted among PWIDs in 7 cities of Georgia (2016–2017), the national prevalence estimates for problem drug use in adult population is 2.24% (2.13–2.39)[6], which is the third highest estimate in the world and the second in the EECA region[7]. Based on the National Experts' consensus, the estimated size of the PWID population was set at 52,500 (50,000–56,000) which indicates a 5% increase of the population size since 2014. HIV prevalence in PWID has not changed since 2009, and it varies between 2.4 (95% CI 1.56–3.46) and 2.3 (95% CI 1.63–3.12)[8].

Analysis of national data on the Fast-Track 90–90–90 targets shows that the significant gap in the cascade of the HIV care continuum is at the stage of HIV diagnosis with 64% of the estimated

1 HIV/AIDS National Strategic Plan for 2019-2022
2 https://aidscenter.ge/epidsituation_eng.html
3 Population Size Estimation of Men Who Have Sex with Men in Georgia, 2018; https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0147413
4 http://www.unaids.org/en/regionscountries/countries/georgia
5 Chokoshvili O, Kepuladze K, Tsintsadze M et al. High prevalence and incidence of HIV, syphilis and viral hepatitis among men who have sex with men in Georgia: Findings of the Georgian MSM Cohort. 16th European AIDS Conference. Milan, Italy; 2017.
6 Population Size Estimation of People Who Inject Drugs in Seven Cities of Georgia, 2016-2017, Bemoni Public Union(BPU); Curatio International Foundation (CIF)
7 World Drug Report 2017
8 HIV/AIDS National Strategic Plan for 2019-2022

number of people living with HIV aware of their status[9].

The most recent HIV/AIDS National Strategic Plan (NSP) highlights the importance of addressing the challenge of timely detection and progression to care. The proposed activities mainly aim to expand the coverage of preventive services, including HIV testing, among the KP representatives and make these services more attractive to them. The NSP acknowledges that the introduction of self-testing and saliva testing might expand the testing uptake. Consequently, Georgia is planning to introduce self-testing among KPs that, in turn, will require the establishment of an effective system to ensure that positive cases are captured by the surveillance system, and those persons tested positive are not lost to follow up. In addition, the system should be designed in a way that provides full protection and safety of personal data.

HIV self-testing is a potential strategy to overcome disparities in access to and uptake of HIV testing, particularly among KPs[10]. HIV self-tests (HIVST) have been in development since 1996 with the goal of reducing the number of HIV-infected persons[11]. HIV self-testing is a process where an individual collects his/her own sample and conducts the HIV test privately without a required presence of a medical worker or any other party. Newer tests that are also easier to perform and are more user-friendly and modernized have since been developed. Their main advantages are acceptability, confidentiality, accuracy after the three-month window period and accessibility[12,13]. The purpose of these self-tests is to minimize the number of HIV-infected persons who would not otherwise subject themselves to testing in healthcare facilities. It has potential to substantially scale up acceptability and access to testing both in the general population as well as in the hard-to-reach populations.

In Georgia, HIV testing, as an essential service and entry point to HIV prevention services, is provided under the State and the Global Fund programs for the following groups of people:

- Patients with signs and symptoms of HIV/AIDS;
- Sex/needle partners of people living with HIV (PLHIV);
- Hepatitis B/C infected persons;
- PWIDs, MSM, female sex workers (FSWs) and their sex partners;
- Pregnant women;
- Blood donors;
- Prisoners;

9 https://www.unaids.org/sites/default/files/media_asset/2020_aids-data-book_en.pdf
10 https://www.who.int/hiv/pub/hiv-self-testing-litreview/en/
11 US Food and Drug Administration. http://www.fda.gov/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/PremarketApprovalsPMAs/ucm311903.htm
12 Krause J, Subklew-Sehume F, Kenyon C, Colebunders R. Acceptability of HIV self-testing: a systematic literature review. BMC Public Health. 2013;13:735 [PMC free article] [PubMed] 10.1186/1471-2458-13-735 [PMC free article] [PubMed] [CrossRef] [Google Scholar]
13 Pant Pai N1, Sharma J, Shivkumar S, Pillay S, Vadnais C, Joseph L et al. Supervised and unsupervised self-testing for HIV in high- and low-risk populations: a systematic review. PLoS Med. 2013;10(4):e1001414 [PMC free article] [PubMed] 10.1371/journal.pmed.1001414 [PMC free article][PubMed] [CrossRef] [Google Scholar]

- Military servants and other;
- Patients who should undergo surgery.

The present study was carried out in the frames of the three-year multi-country project "Sustainability of Services for Key Populations in Eastern Europe and Central Asia" (SoS Project) funded by The Global Fund and coordinated by the Alliance for Public Health, in a consortium with the 100% Life (All-Ukrainian Network of PLWH), the Central Asian HIV Association and the Eurasian Key Populations Health Network. In Georgia the project is being implemented by the Georgian Harm Reduction Network.

The present operational research was aimed at determining the acceptability of HIV self-testing among MSM and PWID in Georgia for two types of HIVSTs: (1) oral fluid and (2) blood-based test kits.

The OraQuick® HIVST is a single-use, qualitative immunoassay to detect antibodies to Human Immunodeficiency Virus Type 1 (HIV-1) and Type 2 (HIV-2) in oral fluid. It is assembled in Thailand and is WHO prequalified.

Autotest VIH® is an immunochromatographic assay that detects antibodies in human blood that are produced following infection with HIV. It is a single-use in vitro diagnostic test with the CE Marking. Autotest VIH® is a very reliable tool designed for general public use and secure for the user thanks to its immunological control line. It was awarded by the prestigious Prix Galien France 2016 and Prix Galien International 2018. It is manufactured and distributed by AAZ-LMB.

These tests are not currently registered in Georgia, they were donated by the manufacturers directly for this study and were used for research purposes.

STUDY AIMS & OBJECTIVES

The overall aim of the study was to determine the acceptability of HIV self-testing to improve testing uptake and linkage to care by distributing oral fluid and blood-based test kits to MSM, and PWID in Georgia.

The study had the following specific objectives:

1. To assess the ability of targeted KPs (MSM and PWID) to understand and interpret the instructions for the use of HIVSTs;
2. To explore the reasons for using the HIVSTs;
3. To explore the factors associated with using the HIVSTs;
4. To evaluate the linkage to care among individuals who tested positive;
5. To explore the pros and cons of the HIV self-testing practice and acceptability among study participants.

DESIGN, METHODS & PROCEDURES

Study Design

A mixed-methods study was implemented to achieve the above-mentioned specific objectives. The study had both quantitative and qualitative components.

The quantitative study involved distribution of self-test kits to MSM and PWID. Two weeks later the study participants were contacted for a small follow up survey to assess the acceptability of self-testing, as well as linkages to care services.

MSM and PWID with self-reported HIV negative or unknown statuses were selected for the study.

Within the qualitative component of the research, respondents participating in both stages of the quantitative survey (baseline and follow-up) took part in in-depth interviews (IDIs) on their experiences, attitudes and practices and asked to explore additional factors associated with self-testing and linkage to care.

For the IDIs study participants were consecutively selected from the pool of quantitative study participants of each group: MSM and PWID. During the follow up communications, respondents were asked to participate in IDIs. Those who agreed to share additional details on their experience of the self-testing approach were recruited for participation in the IDIs. The participants were recruited and interviews conducted until saturation of information was obtained.

Population

The study had two target groups: (1) MSM and (2) PWID.

Inclusion/exclusion criteria

Eligibility criteria (MSM/PWID):

- Age 18 or older (legal age of consent)
- Representatives of target populations (MSM/PWID)
- Willing to provide a personal mobile phone number
- Individuals with self-reported negative or unknown HIV statuses
- Willingness to share their HIVST result
- Willing to provide written informed consent for the participation (including consent for possible future contact)

- The ability to speak, read and understand Georgian language
- Exclusion criteria:
- Individuals with self-reported HIV positive status

Individuals with self-reported mental health related problems or any other illness preventing comprehension of the study procedures or providing the informed consent.

Location

The study was conducted in Tbilisi, the capital of Georgia, with the highest number of HIV cases registered in the country, as well as in regions, where provision of preventive services is in place. Social workers of the GHRN service sites recruited PWIDs in Tbilisi and 12 regional sites of Georgia delivering harm reduction services to PWIDs (Batumi, Kutaisi, Zugdidi, Poti, Borjomi, Gori, Akhaltsikhe, Telavi, Rustavi, Samtredia, Ozurgeti), while the trained staff of the community based organization Equality Movement and Center for Information and Counseling on Reproductive Health "Tanadgoma" working with MSM population recruited MSM in Tbilisi, Batumi, Zugdidi and Kutaisi.

Social/outreach workers of the selected organizations ensured distribution of test-kits and data collection.

Data collection, Methods & Tools

Study participants were recruited by the social/outreach workers of the above mentioned organizations using consecutive sampling method, during the outreach session as well as facility based visit /consultation. The social/outreach workers distributed the oral and blood based test kits interchangeably in a systemic way. During the first outreach session, they offered oral fluid self-test kits, while blood based kits were provided during the next outreach session. In addition, participants were given supporting materials (detailed user manuals [Annexes 1 and 2], pre and post-testing counseling information [Annexes 3 and 4], lists of service centers and "helpline" number, which they could call for further information, counselling or support).

The study participation involved completing two sets of questionnaires twice within the two-week period: first — on the day of recruitment (baseline questionnaire — Annex 5) and the follow up cell phone survey, presumably after they have used the self-test kit (follow up questionnaire — Annex 6). If a respondent had not taken the test at the time of follow-up interview, she/he was contacted repeatedly after one week. The maximum number of follow-up attempts was 3.

The baseline survey included questions about participants' demographic characteristics, sexual health behaviors and past experience of HIV testing, while follow-up questionnaire collected information on the testing process, experience, and acceptability, as well as the results of HIVST.

The overall acceptability of the HIVST was assessed by two outcome variables: (1) Would you recommend HIVST to others? and (2) Overall how acceptable does introducing HIVST seem to you?. Both variables were dichotomized and associations with the main demography and self-testing experience characteristics of the entire sample were analyzed.

The qualitative data were collected through in-depth interviews according the guide (Annex 7) consisting of open-ended questions with the focus to collect additional information on barriers and facilitators to uptake of self-testing and the self-testing experience, best approaches for distribution of HIV self-test kits, views on linkage to prevention and care services following HIV self-testing. The average duration of the interview was 40 minutes. The interviewer explained the aim and purpose of the study to the participants before the beginning of each interview. The discussions were tape-recorded without identification of the participants. Digital audio recordings of the discussions were uploaded to a password-protected computer after which the recordings were erased from the audio recorder. The recorded information was used to prepare transcripts for further analysis.

DATA ANALYSIS

For the quantitative component of the study, the overall description of participants was performed in terms of demographic characteristics, economic status, HIV risk behavior and HIV testing history and linkage to care practice using SPSS software. Bivariate analyses were used to summarize and compare characteristic across different target groups using different kind of test kits. For this purpose, the chi-square test was used to calculate p-values for categorical variables. A two-sided p-value < 0.05 was considered statistically significant throughout the analyses.

For the qualitative component, the in-depth interview recordings were transcribed using a predefined coding scheme that was in line with the survey instruments used for collecting data. By using predefined codes, information was organized and followed by contextual analysis, presented below in the results section.

ETHICS

Appropriate ethical considerations were adopted in conducting the research. Prior to implementing the study, IRB approval was sought from the Georgian nongovernmental organization (NGO) "Health Research Union" IRB (#2019–08).

Study participants of both quantitative and qualitative components were provided with an information sheet explaining the objectives of the study, and all participants signed paper informed consent forms prior to participation (Annexes 8 and 9).

RESULTS

Quantitative component

Distribution and Study Participation

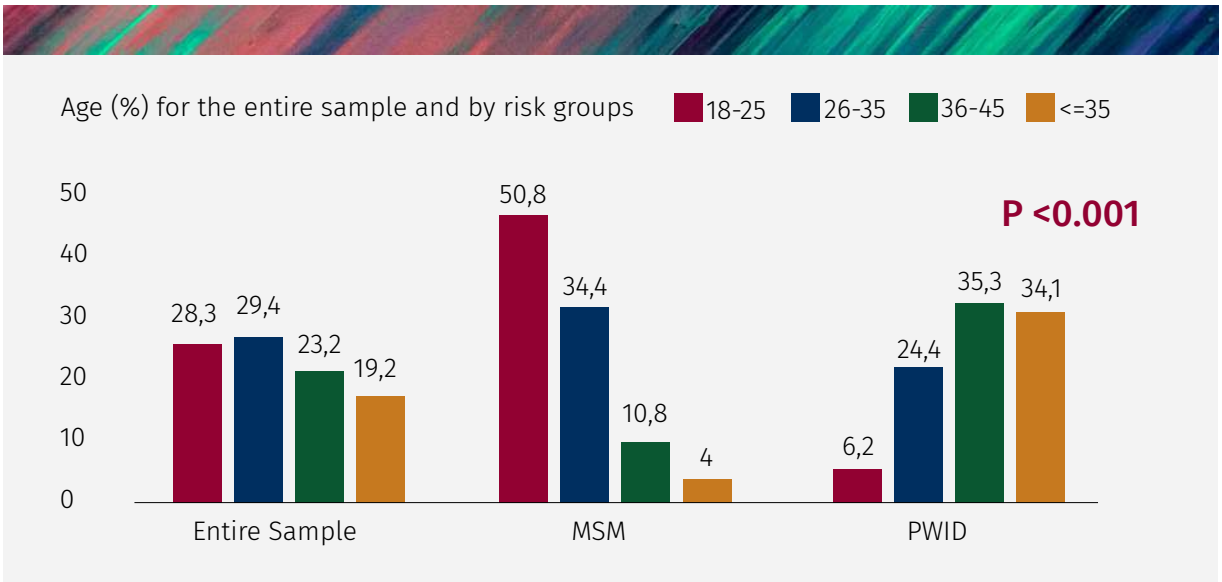
A total of 805 HIVST kits (401 oral fluid and 404 blood based test kits) were distributed between February 2020 and June 2020. All participants completed the baseline pre-test questionnaire before receiving the HIVST. 97,5% (785/805) agreed to participate in the follow up post-test questionnaire, 1.6% refused participation and 0.9% were lost to follow up. Among those who refused participation (13 respondets), the majority did not state any reason for refusal or they did not want to disclose their status.

Study participants characteristics

Demographic characteristics

Two groups of KPs — MSM and PWID — were equally represented in our sample (49.6%/50.4%). In the entire sample 92.2% were male, while 2.7% were female and 5.1% reported being transgender. The age distribution between our two groups was different — 85.2% of MSM were 35 years and younger, while 69.4% of PWID were over 36 years old and this difference was statistically significant.

Chart 1. Participants' age (%) for the entire sample and by risk groups



54.2% of respondent in the MSM group had university degrees and 57.6% were currently employed compared to the PWID group where only 32.2% reported having higher education and 29.0% being employed and these differences were also statistically significant. Having higher monthly income was also more common among MSM group and this difference was also statistically significant; although it should be noted that considerable amount of participants in PWID group did not answer the question regarding the monthly income.

Chart 2. Participants' education (%) for the entire sample and by risk groups

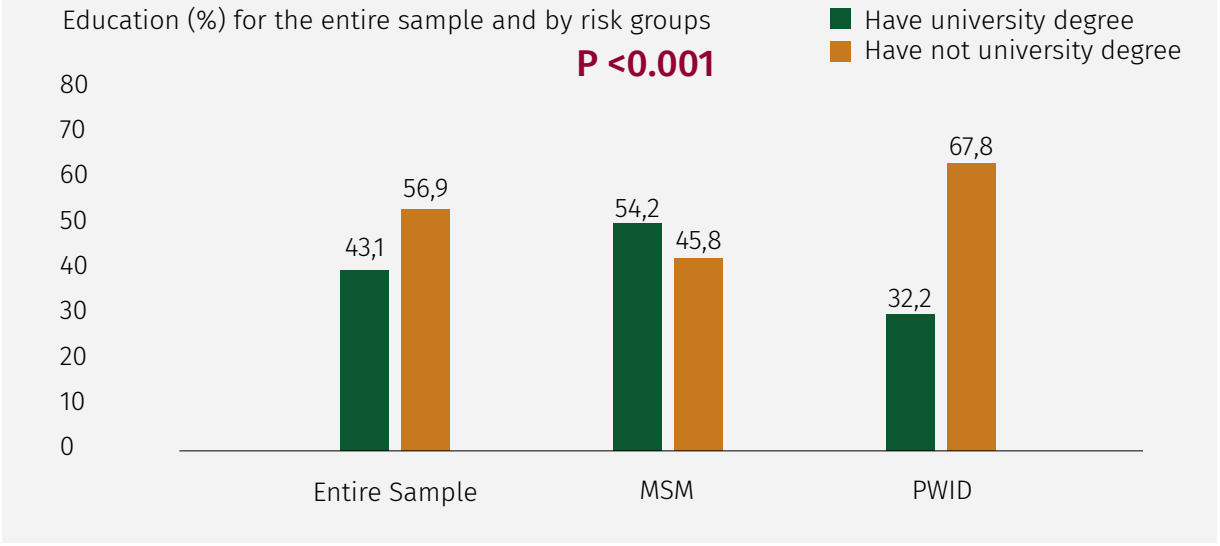


Chart 3. Participants' occupation (%) for the entire sample and by risk groups

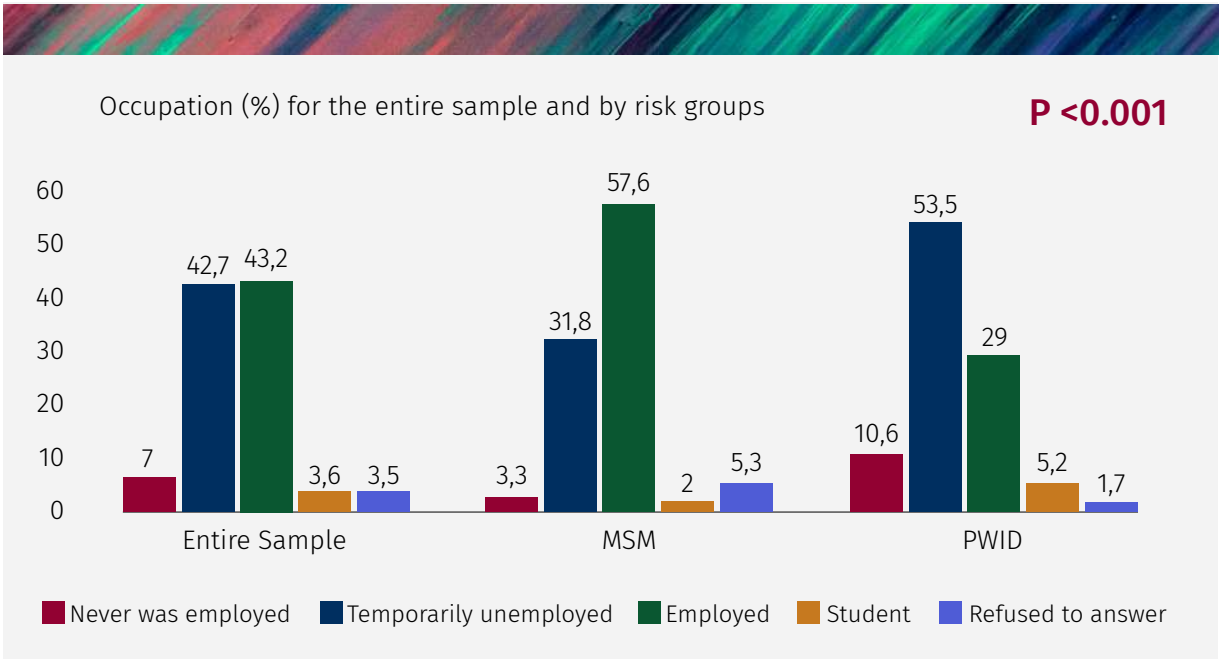
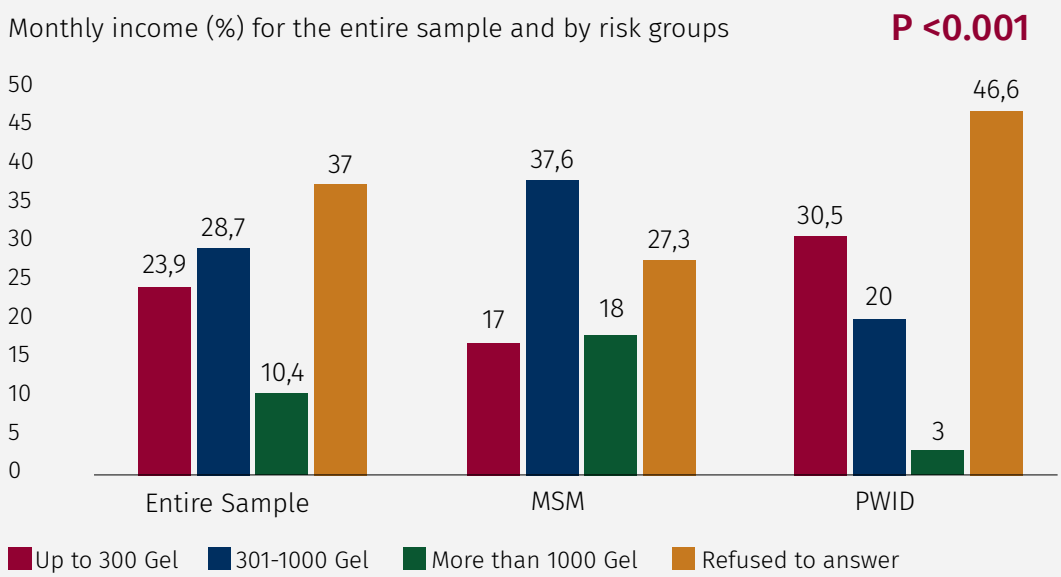


Chart 4. Participants' monthly income (%) for the entire sample and by risk groups



Risky behaviors

The baseline questionnaire collected information regarding the participants' risky behaviors in terms of needle and injecting paraphernalia sharing, condom use and number of sexual partners during the last 12 months. Safe injecting practice was more common in the MSM group and more MSM reported always using a condom during the last 12 months compared to PWID. On the contrary, having 6 and more sexual partners during the last 12 months was more frequent in the MSM group. All differences between the groups were statistically significant. More detailed information on the risky behaviors for both groups are presented in Table 1.

Table1. Risky behavior characteristics by risk group

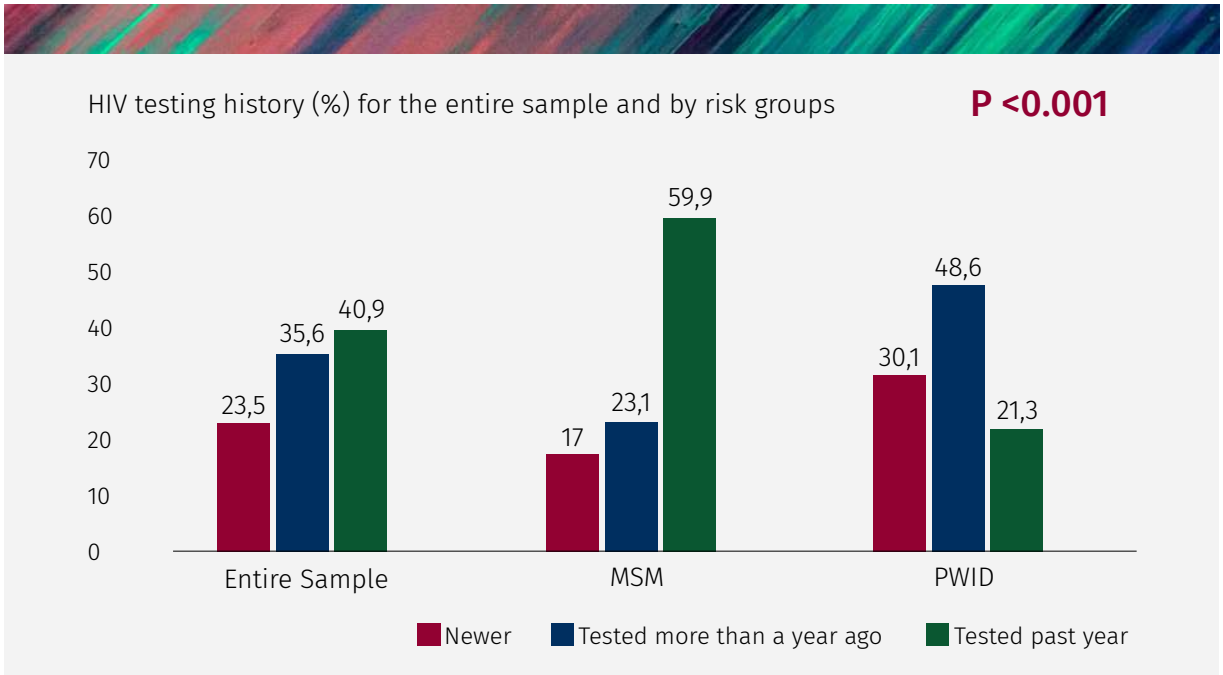
Characteristics	Total		Risk Group				P value
			MSM		PWID		
	N	%	N	%	N	%	
Needle and injecting paraphernalia during last 12 months							
Always	20	2.6	15	3.8	5	1.3	
Occasionally	179	23.0	33	8.4	146	37.8	**<0.001**
Never	578	74.4	343	87.7	235	60.9	

Condom use during last 12 months							
Always	348	43.2	209	52.4	139	34.2	**<0.001**
Occasionally	320	39.8	141	35.3	179	44.1	
Never	80	9.9	19	4.8	61	15.0	
Other/refused to answer	57	7.1	30	7.5	27	6.7	
Number of sex partners in the last 12 months							
0	10	1.2	5	1.3	5	1.2	**<0.001**
1	165	20.5	44	11.0	121	29.8	
2-5	292	36.3	120	30.1	172	42.4	
6-10	133	16.5	97	24.3	36	8.9	
>10	135	16.8	126	31.6	9	2.2	
Refused to answer	70	8.7	7	1.8	63	15.5	

HIV testing history and main reasons for testing

23.5% of the participants were first time testers in our entire sample. When looking into the risk groups separately, the percentage was higher (30.1%) for PWID. Almost 60% of participants in the MSM group reported having had a test in the past year, while this percentage was statistically significantly lower (21.3%) in the PWID group.

Chart 5. Participants' HIV testing history (%) for the entire sample and by risk groups



Having unprotected sex (38.1%) was named as one of the main reasons for getting the HIV test, followed by someone's advice to get tested (15.5%), being a part of regular testing pattern (13.3%) and needle-sharing practice (13.0%).

HIVST use and results

Out of 785 participants who agreed to participate in the follow up post-test questionnaire, all of them indicated that they have used the HIVST. Majority of the participants in both risk groups (75.7% of MSM and 79.6% of PWID) used the HIVST at home. Almost half of the participants used the HIVST immediately upon delivery. MSM were more likely to test alone. In the entire sample, 78.1% of participants became familiar with the pre-counseling information and 74.4% became familiar with the post-counselling information delivered together with the HIVST. PWID were statistically significantly more likely to benefit from these information compared to MSM. Majority of the participants (almost 90%) who got familiar with the pre- and post-counselling leaflets found it useful. 94.8% of the participants in the entire sample provided information about the test results. 4.9% of MSM and 1.5% of PWID had HIV positive self-test results. More detailed information on HIVST use for both groups are presented in Table 2.

Table 2. Self-testing related characteristics by risk group

Characteristics	Total		Risk Group				P value
			MSM		PWID		
	N	%	N	%	N	%	
Where did you of use HIVST							
Home	594	77.7	281	75.7	313	79.6	**<0.001**
The site I received the test	170	22.3	90	24.3	80	20.4	
When did you of use HIVST?							
Immediately	387	49.4	192	49.4	195	49.4	
Within 2 days	249	31.8	136	35.0	113	28.6	**<0.001**
2 days - 2 weeks	148	18.9	61	15.7	87	22.0	
Was anybody present while testing?							
Friend	182	23.2	84	21.7	98	24.7	
Sex partner/spouse/Family member	104	13.3	33	8.5	71	17.9	**<0.001**
Outreach/social worker	107	13.7	45	11.6	62	15.7	
No one	390	49.8	225	58.1	165	41.7	
HIVST result							
Negative	719	91.6	341	87.7	378	95.5	
Positive	25	3.2	19	4.9	6	1.5	**<0.001**
Don't know/Refused to answer	41	5.2	29	7.5	12	3.0	

Did you use the pre-counselling information?							
Yes	604	78.1	272	71.0	332	85.1	**<0.001**
No	169	21.9	111	29.0	58	14.9	
Was the pre-counselling information useful?							
Yes	543	90.0	230	84.6	313	94.6	**<0.001**
No/Somewhat	60	10.0	42	15.4	18	5.4	
Did you use the post-counselling information?							
Yes	573	74.4	262	68.6	311	80.2	**<0.001**
No	197	25.6	120	31.4	77	19.8	
Was the post-counselling information useful?							
Yes	508	89.0	220	84.3	288	92.9	**<0.001**
Somewhat	63	11.0	41	15.7	22	7.1	

Experience and Acceptability of HIVST

The HIVST instructions for use were understandable for 86.0% of participants in the entire sample. There were differences when looking within risk groups and test-kit types. PWID were more likely to understand the instructions for use (IFU) and the IFU for the oral fluid self-test kit were more understandable for the study participants. These differences within the groups were statistically significant. The same tendency and differences were observed regarding the easiness to follow the instructions. The HIVST was convenient to use for 85.3% and easy to use for 83.1% of participants in the entire sample. Again, PWID were more likely to report the convenience and easiness of using the HIVST, compared to MSM and the oral fluid self-test kit appeared to be more convenient and easy to use for the study participants.

Study participants were asked to name the best feature of doing the HIVST and answers were distributed as follows: 61.0% consider the privacy being its best feature, 23.7% think it is convenient and 15.3% named simple operation as the best feature of doing the HIVST. No statistically significant differences were seen regarding this issue neither within the risk groups nor within the test-kit types.

93.9% of the entire sample indicated that they would recommend HIVST to others and 91.8% stated that they would use HIVST again in the future. More PWID expressed the desire to use the HIVST again in the future compared to MSM.

91.6% of respondents consider it acceptable to introduce the HIVST for nationwide implementation. No statistically significant differences were observed concerning this issue within the risk groups, while oral fluid self-test kit appeared to be more acceptable for the participants for wider implementation.

Majority of the participants (75.9%) in both groups indicated that they would prefer to get HIVST

at the same prevention site in the future. 13.6% of the respondents also indicated pharmacy as a preferred place for getting the HIVST.

The tables 5 and 6 bellow provide detailed information regarding the experience and acceptability of HIVST by risk groups and by test-kit types.

Table 3. Experience and acceptability of HIVST by Risk groups

Characteristics	Total		Risk Group				P value
			MSM		PWID		
	N	%	N	%	N	%	
Where instructions for use oral tests/finger prick rapid tests understandable?							
Yes	673	86.0	352	89.8	321	82.1	**<0.001**
Somewhat/no	110	14.0	40	10.2	70	17.9	
Did you find instructions easy to follow?							
Yes	656	83.9	351	89.5	305	78.2	**<0.01**
Somewhat/no	126	16.1	41	10.5	85	21.8	
Did you find it convenient to use HIVST?							
Yes	666	85.3	359	91.8	307	78.7	**<0.001**
Somewhat/no	115	14.7	32	8.2	83	21.3	
Did you find it easy to use HIVST?							
Yes	650	83.1	348	88.8	302	77.4	**<0.001**
Somewhat/no	132	16.9	44	11.2	88	22.6	
What was the best feature of doing HIVST?							
Privacy	474	61.0	236	60.4	238	61.7	**0.31**
Convenience	184	23.7	86	22.0	98	25.4	
Simple operation	119	15.3	69	17.6	50	13.0	
Was it easy to interpret results?							
Yes	684	87.9	357	91.8	327	84.1	**<0.05**
Somewhat/no	94	12.1	32	8.2	62	15.9	
Does the HIVST guarantee confidentiality?							
Yes	704	90.5	353	91.5	351	89.5	**<0.01**

Somewhat/no	74	9.5	33	8.5	41	10.5	
Would you recommend HIVST to others?							
Yes	737	93.9	371	94.6	366	93.1	**0.20**
No/Refused to answer	48	6.1	21	5.4	27	6.9	
Would you use HIVST again in the future?							
Yes	721	91.8	366	93.4	355	90.3	**<0.01**
No/Refused to answer	64	8.2	26	6.6	38	9.7	
Overall how acceptable seems to you introducing HIVST?							
Acceptable	719	91.6	366	93.4	353	89.8	**0.52**
Neutral	56	7.1	25	6.4	31	7.9	
Not acceptable	10	1.3	1	0.3	9	2.3	
Where would you prefer to get HIV ST in the future?							
The same service site	596	75.9	293	74.7	303	77.1	**0.07**
AIDS Center	30	3.8	15	3.8	15	3.8	
Pharmacy	107	13.6	58	14.8	49	12.5	
Online	26	3.3	17	4.3	9	2.3	
Other	26	3.3	9	2.3	17	4.3	

Table 4. Experience and acceptability of HIVST by test-kit types

Characteristics	Total		Type of self-test kit				P value
			Oral fluid		Blood		
	N	%	N	%	N	%	
Where instructions for use oral tests/finger prick rapid tests understandable?							
Yes	673	86.0	312	80.6	361	91.2	**<0.01**
Somewhat/no	110	14.0	75	19.4	35	8.8	
Did you find instructions easy to follow?							
Yes	656	83.9	307	79.5	349	88.1	**<0.001**
Somewhat/no	126	16.1	79	20.5	47	11.9	

Did you find it convenient to use HIVST?							
Yes	666	85.3	308	79.8	358	90.6	**<0.001**
Somewhat/no	115	14.7	78	20.2	37	9.4	
Did you find it easy to use HIVST?							
Yes	650	83.1	302	78.0	348	88.1	**<0.001**
Somewhat/no	132	16.9	85	22.0	47	11.9	
What was the best feature of doing HIVST?							
Privacy	474	61.0	229	59.9	245	62.0	**0.15**
Convenience	184	23.7	87	22.8	97	24.6	
Simple operation	119	15.3	66	17.3	53	13.4	
Was it easy to interpret results?							
Yes	684	87.9	326	85.3	358	90.4	**<0.01**
Somewhat/no	94	12.1	56	14.7	38	9.6	
Does the HIVST guarantee confidentiality?							
Yes	704	90.5	337	87.8	367	93.1	**0.39**
Somewhat/no	74	9.5	47	12.2	27	6.9	
Would you recommend HIVST to others?							
Yes	737	93.9	362	93.1	375	94.7	**0.45**
No/Refused to answer	48	6.1	27	6.9	21	5.3	
Would you use HIVST again in the future?							
Yes	721	91.8	347	89.2	374	94.4	**0.15**
No/Refused to answer	64	8.2	42	10.8	22	5.6	
Overall how acceptable seems to you introducing HIVST?							
Acceptable	719	91.6	352	90.5	367	92.7	**<0.05**
Neutral	56	7.1	31	8.0	25	6.3	
Not acceptable	10	1.3	6	1.5	4	1.0	
Where would you prefer to get HIV ST in the future?							
The same service site	596	75.9	297	76.3	299	75.5	**0.21**
AIDS Center	30	3.8	11	2.8	19	4.8	
Pharmacy	107	13.6	54	13.9	53	13.4	
Online	26	3.3	18	4.6	8	2.0	
Other	26	3.3	9	2.3	17	4.3	

The overall acceptability of the HIVST was assessed by two outcome variables (Would you recommend HIVST to others? and Overall how acceptable does introducing HIVST seem to you?). Both variables were dichotomized and associations with main demography and self-testing experience characteristics of the entire sample were analyzed.

Participants who used the post-counselling information and found it useful were more likely to point out that they would recommend the HIVST to others. Those who found pre and post-counseling information useful and used the post-counselling information indicated that the introduction of the HIVST was totally acceptable/acceptable. Almost all variables regarding the characteristics of using the HIVST were positively associated with HIVST acceptability (as defined by both outcome variables: Would you recommend HIVST to others? and Overall how acceptable does introducing HIVST seem to you?) in our sample and these associations were statistically significant. In addition, testing positive was statistically significantly associated with the overall acceptability for introducing the HIVST for wider implementation. More detailed information is provided in the tables 7 and 8, respectively.

Table 5. Acceptability of the HIVST by "would you recommend HIVST to others?"

Characteristics	Total		Would you recommend HIVST to others?				P value
			Yes		No/Refused to answer		
	N	%	N	%	N	%	
Age							
<=35	449	57.3	421	93.8	28	6.2	**1.00**
>35	334	42.7	314	94.0	20	6.0	
Gender							
Female	22	2.8	21	95.5	1	4.5	**0.19**
Male	724	92.2	682	94.2	42	5.8	
Transgender	39	5.0	34	87.2	5	12.8	
Risk group							
MSM	389	49.6	362	93.1	27	6.9	**0.37**
PWID	396	50.4	375	94.7	21	5.3	
Education							
University degree	331	43.2	309	93.4	22	6.6	**0.30**
Have not university degree	436	56.8	412	94.5	24	5.5	
Occupation							
Employed	337	43.0	318	94.4	19	5.6	**0.87**
Unemployed	446	57.0	419	93.9	27	6.1	

Type of HIVST kit delivered							
Oral fluid	392	49.9	371	94.6	21	5.4	**0.45**
Blood	393	50.1	366	93.1	27	6.9	
Accompanying person							
Alone	390	49.7	366	93.8	24	6.2	**1.00**
Other	394	50.3	370	93.9	24	6.1	
Test results							
Negative	719	91.6	677	94.2	42	5.8	**0.55**
Positive	25	3.2	23	92.0	2	8.0	
DK/Refused to answer	41	5.2	37	90.2	4	9.8	
Did you use the pre-counselling information?							
Yes	604	78.1	547	95.0	30	5.0	**0.06**
No	169	21.9	154	91.1	15	8.9	
Was the pre-counselling information useful?							
Yes	543	90.0	518	95.4	25	4.6	**0.16**
No/Somewhat	60	10.0	55	91.7	5	8.3	
Did you use the post-counselling information?							
Yes	573	74.4	547	95.5	26	4.5	**<0.05**
No	197	25.6	178	90.4	19	9.6	
Was the post-counselling information useful?							
Yes	508	89.0	490	96.5	18	3.5	**<0.01**
Somewhat	63	11.0	55	87.3	8	12.7	
Where instructions for use oral tests/finger prick rapid tests understandable?							
Yes	673	86.0	646	96.0	27	4.0	**<0.001**
Somewhat/no	110	14.0	89	80.9	21	19.1	
Did you find instructions easy to follow?							
Yes	656	83.9	639	97.4	17	2.6	**<0.001**
Somewhat/no	126	16.1	95	75.4	31	24.6	
Did you find it convenient to use HIVST?							
Yes	666	85.3	645	96.8	21	3.2	**<0.001**
Somewhat/no	115	14.7	88	76.5	27	23.5	

Did you find it easy to use HIVST?							
Yes	650	83.1	629	96.8	21	3.2	**<0.001**
Somewhat/no	132	16.9	105	79.5	27	20.5	
What was the best feature of doing HIVST?							
Privacy	474	61.0	442	93.2	32	6.8	**0.50**
Convenience	184	23.7	176	95.7	8	4.3	
Simple operation	119	15.3	112	94.1	7	5.9	
Was it easy to interpret results?							
Yes	684	87.9	653	95.5	31	4.5	**<0.001**
Somewhat/no	94	12.1	80	85.1	14	14.9	
Does the HIVST guarantee confidentiality?							
Yes	704	90.5	672	95.5	32	4.5	**<0.001**
Somewhat/no	74	9.5	61	82.4	13	17.6	
Would you use the HIVST kit again in the future?							
Yes	721	91.8	706	97.9	15	2.1	**<0.001**
No/Refused to answer	64	8.2	31	48.4	33	51.6	
Overall how acceptable seems to you introducing HIVST?							
Acceptable	719	91.6	695	96.7	24	3.3	**<0.001**
Neutral	56	7.1	38	67.9	18	32.1	
Not acceptable	10	1.3	4	40.0	6	60.0	

Table 6. Acceptability of the HIVST by "Overall how acceptable does introducing HIVST seem to you?"

Characteristics	Total		Overall how acceptable seems to you introducing HIV ST?				P value
			Acceptable/ Totally acceptable		Neutral/Not acceptable		
	N	%	N	%	N	%	
Age							
<=35	449	57.3	441	91.5	38	8.5	**1.00**
>35	334	42.7	306	91.6	28	8.4	
Gender							
Female	22	2.8	21	95.5	1	4.5	**0.78**
Male	724	92.2	662	91.4	62	8.6	
Transgender	39	5.0	36	92.3	3	7.7	
Risk group							
MSM	389	49.6	352	90.5	37	9.5	**0.30**
PWID	396	50.4	367	92.7	29	7.3	
Education							
University degree	331	43.2	311	94.0	20	6.0	**0.08**
Have not university degree	436	56.8	394	90.4	42	9.6	
Occupation							
Employed	337	43.0	307	91.1	30	8.9	**0.51**
Unemployed	446	57.0	412	92.4	34	7.6	
Type of HIVST kit delivered							
Oral fluid	392	49.9	366	93.4	26	6.6	**0.09**
Blood	393	50.1	353	89.8	40	10.2	
Accompanying person							
Alone	390	49.8	355	91.0	35	9.0	**0.51**
With someone	393	50.2	363	92.4	30	7.6	
Test results							
Negative	719	91.6	662	92.1	57	7.9	**<0.05**
Positive	25	3.2	24	96.0	1	4.0	
DK/Refused to answer	41	5.2	33	80.5	8	19.5	

Did you use the pre-counselling information?							
Yes	604	78.1	559	92.5	45	7.5	**0.20**
No	169	21.9	151	89.3	18	10.7	
Was the pre-counselling information useful?							
Yes	543	90.0	515	94.8	28	5.2	**<0.001**
No/Somewhat	60	10.0	43	71.7	17	28.3	
Did you use the post-counselling information?							
Yes	573	74.4	536	93.5	37	6.5	**<0.01**
No	197	25.6	172	87.3	25	12.7	
Was the post-counselling information useful?							
Yes	508	89.0	487	95.9	21	4.1	**<0.001**
Somewhat	63	11.0	48	76.2	15	23.8	
Where instructions for use oral tests/ finger prick rapid tests understandable?							
Yes	673	86.0	639	94.9	34	5.1	**<0.001**
Somewhat/no	110	14.0	78	70.9	32	29.1	
Did you find instructions easy to follow?							
Yes	656	83.9	632	96.3	24	3.7	**<0.001**
Somewhat/no	126	16.1	84	66.7	42	33.3	
Did you find it convenient to use HIVST?							
Yes	666	85.3	638	95.8	28	4.2	**<0.001**
Somewhat/no	115	14.7	78	67.8	37	32.2	

Did you find it easy to use HIVST?							
Yes	650	83.1	623	95.8	27	4.2	**<0.001**
Somewhat/no	132	16.9	93	70.5	39	29.5	
What was the best feature of doing HIVST?							
Privacy	474	61.0	430	90.7	44	9.3	**0.27**
Convenience	184	23.7	174	94.6	10	5.4	
Simple operation	119	15.3	109	91.6	10	8.4	
Was it easy to interpret results?							
Yes	684	87.9	645	94.3	39	5.7	**<0.001**
Somewhat/no	94	12.1	69	73.4	25	26.6	
Does the HIVST guarantee confidentiality?							
Yes	704	90.5	657	93.3	47	6.7	**<0.001**
Somewhat/no	74	9.5	58	78.4	16	21.6	
Would you recommend HIVST to others?							
Yes	737	93.9	695	94.4	42	5.7	**<0.001**
No/Refused to answer	48	6.1	24	50.0	24	50.0	
Would you use the HIVST kit again in the future?							
Yes	721	91.8	688	95.4	33	4.6	**<0.001**
No/Refused to answer	64	8.2	31	48.4	33	51.6	

Linkage to Care

Among the 785 participants who agreed to participate in the follow up post-test questionnaire, 719 (91.6%) indicated that their HIVST results were negative. 3.4% (27 participants — 16 MSM and 11 IDUs) refused to disclose their status. 3.2% of the entire sample tested positive (4.9% of MSM and 1.5% of PWID). 1.8% (14 participants) stated that they don't know the results of their tests and most of them did not provide any reason. Among those providing explanations, majority said that there were no lines and they were not able to read the test results.

12 (48%) out of 25 participants who tested positive stated that they have taken the HIV confirmatory test and 5 (20%) plan to take it in the nearest future. Only 2 (8%) participants who tested positive said they don't plan to take the confirmatory test, one due to fear and the other one due to the distrust of the HIVST results. The remaining 6 participants (24%) refused to answer the question regarding taking the confirmatory test.

Qualitative component

During the follow up stage of the quantitative survey, each study participant was notified about the possibility of further participation in in-depth interviews. Individuals expressing desire to participate were consecutively selected afterwards. Within each target group, interviewees were randomly sampled until saturation of discursive patterns was achieved. This resulted in a sample of 30 interviews, including 16 among MSM and 14 among PWID.

Disaggregation of respondents by type of tests and target groups:

Target group	Type of HIVST		Total
	Blood sample	Oral fluid	
MSM	11*	5	16
PWID	7	7	14
Total	18	12	30

*among them one HIV positive result

The section below provides the contextual analysis of the IDIs.

Results from IDIs demonstrated that self-tests were generally acceptable to study participants, the tests were easy to use, convenient, private and with easily understandable results.

Participants were asked to describe the main aspects influencing the risks for HIV. All respondents stated risky behavior (unprotected sexual intercourse and injecting drug use) as the main predictors for HIV infection.

While discussing the history of HIV testing, 26 respondents reported a previous experience, while only 3 of them were tested first time including the one with the HIV positive result. One participant could not recall his HIV testing experience.

> *"Once every 6 months I took a blood test (complete blood count) and urine tests to control my health, but it turned out that it was not enough. I didn't get tested for HIV before, didn't even think about it. I accidentally heard about the symptoms from my friend and found Tanadgoma's free services"*
>
> **Participant from the MSM group**

The reasons for HIV testing in general were determined by the participants' responses to the question "why did you decide to test or if you have been tested more than once, what were your reasons for repeated testing?". Mostly, the risky behavior and consequent interest to identify the HIV status were the main predictors for HIV testing, however participants mentioned HIV testing being integrated with treatment assessments for Hepatitis C (mainly PWID). Community events offering free and voluntary rapid HIV testing were also mentioned.

The main discussion was focused on the particular decision of the respondents regarding the self-testing approach. Participants mentioned their own interest for testing, offers from outreach workers/peers and better expectations of the self-testing method.

> *"I understand that everything is protected and confidential when others conduct testing, but I was safer when being at home, alone and took the test myself, plus the instructions in the brochure were too easy to follow and clear..."*
>
> **Participant from the MSM group**

> *"When the community organizations were closed during the COVID-19 state emergency conditions, I was looking for some alternatives and my friend suggested this service. It was a very good solution in that situation..."*
>
> **Participant from the MSM group**

Respondents expressed their attitudes towards the advantages of HIVST. They stated that they felt very comfortable, private and safe while using HIVSTs, much more then at facilities or even outreach sessions.

> *"Private environment, reliable response and easy to use..."*
>
> **Participant from the PWID group**

> *"Instructions were very easy to understand, it is an easy to perform and convenient test, reliable result. You can do it whenever you want..."*
>
> **Participant from the MSM group**

> *"I feel safer and calmer while self-testing; it is faster, with higher rate of security and confidentiality..."*
>
> **Participant from the MSM group**

> *"Simple test, very quick and easy procedures, more comfortable. The instructions are also easy to understand..."*
>
> **Participant from the MSM group**

> *"You can do it wherever you want and whenever you want, there is no limitation for time and place. Easy, fast, the instructions are very clear..."*
>
> **Participant from the MSM group**

"It is better than to go to the center [prevention site]. It takes less time..."

Participant from the PWID group

"Simple, highly confidential, I did it alone, I only saw the result and it was very good..."

Participant from the PWID group

"Simple and fast test, you are calm when you are checking the status, no one sees you... I was glad that I did not have to go to the clinic, stand in a long queue. I saved money and time..."

Participant from the PWID group

Almost all participants stated that there are no potential disadvantages of HIVST. Only few (MSM mainly) of them doubted whether the testing will be properly performed, according to instructions, to receive the reliable results.

"Maybe for those who can't prick their fingers themselves blood test will be an inconvenience. There are no disadvantages in total. Well, I would prefer a saliva test in terms of use, but I think a blood test is more reliable, I do not know why..."

Participant from the MSM group

"You should not smoke for 20 minutes before testing and you should read the instructions carefully, in detail..."

Participant from the MSM group

"Maybe someone will do something wrong and receive the wrong answer..."

Participant from the MSM group

"A person may not understand something and be ashamed or afraid to call for clarification..."

Participant from the MSM group

There was only one HIV positive case newly revealed in the course of the study participating in IDIs. According to this participant, he was linked to treatment and care services immediately and received high quality consultation and free medicines. The only inconvenience he mentioned was accessibility to medicines.

"I have to go to the Capital every month from the region to pick up the drugs"

Participant from the MSM group

All participants responses to the question "Would you recommend HIVST to your friends and family?" were positive, most of them had already suggested the HIVST to their partners, friends or peers.

Among the most important factors persuading people to test for HIV, respondents stated the willingness to learn their HIV status, easily accessible tests, isolated and private environment.

"In general, I used to go to the center [prevention site]. I know everyone there and I am happy with the services I receive, but now I prefer to do it by myself. If needed, I will check suspicious results afterwards..."

Participant from the PWID group

"I prefer to do it at home, I have 100% confidence in the result..."

Participant from the PWID group

"At this point, I prefer to test at home, it turned out to be much better and more convenient..."

Participant from the MSM group

"I think that if it comes out positive, I will go to the center for further consultations..."

Participant from the MSM group

Future testing preference was assessed by asking participants to select what kind of testing they would prefer. The majority of respondents prioritized the HIV self-testing approach for future assessments.

As the last part of the study, participants were asked to identify the most important ways, solutions to be undertaken to increase the coverage of HIV testing in their communities. Providing correct and targeted information, popularization of HIV self-testing approach through difference channels of social media were named as main facilitators for improving HIV testing uptake.

"Not many are tested for HIV due to the fear of braking confidentiality, the saliva tests are the easiest to use. Therefore, they should be placed at events for distribution like condoms. It is necessary to advertise so that more people use the test, privately for themselves. Knowing the results will allow them to look after themselves better..."

Participant from the MSM group

"The most important thing is to provide the right information that testing for HIV is safe, easy and very important ..."

Participant from the PWID group

"The popularization of the self-testing approach on social media, among students, not only in the community, but in general. More popularization will allow for more testing..."

Participant from the MSM group

"Promotion, informing and advertising, propaganda. Tests should be distributed and it should be demonstrated how easy it is..."

Participant from the PWID group

DISCUSSION

Although Georgia has made remarkable progress on the right side of the HIV care cascade from diagnosis through viral suppression (First 90: 64; Second 90: 87 and Third 90: 91), 36% of estimated PLHIV remain undiagnosed.[14] Reaching the fast-track 90–90–90 targets will require development and implementation of targeted, intensified and innovative HIV testing approaches in the country. Introduction of HIV self-testing is defined as one of the crucial factors for increasing testing coverage in the Georgia HIV/AIDS National Strategy for 2019–2022. Notably, these approaches should be acceptable and adaptable to a wide range of priority populations.

Results of this study shed additional light to acceptability of HIVST among MSM and PWID in Georgia. However, before making any inferences, study limitations should be considered. Study participants were selected through consecutive sampling; hence, it might have resulted selection bias and more motivated individuals could appear in the sample. In addition, there may be an issue of social desirability bias connected with some of the questions on sexual behaviors and drug use.

The main aim of this study was to explore the acceptability of HIVST among MSM and PWID in Georgia. We assessed the acceptability by examining whether the participants would recommend the HIVST to others and how acceptable its wider introduction seemed to them. The study results demonstrated high acceptability with 93.9% of respondents indicating that they would recommend HIVST to others and 91.6% considering it acceptable for wider introduction.

HIVST is considered as a facilitator for reaching first-time testers, under tested individuals, and individuals who otherwise would not test for HIV.[15] In our sample, 23.5% of the participants were first time testers and this percentage was high for the group of PWID. Thus, expanding access to HIVST may increase the coverage and frequency of HIV testing among MSM and PWID in Georgia.

According to the systematic review, self-testing was preferred to facility-based testing because of its increased convenience and confidentiality, especially among stigmatized populations.[16] HIV self-testing decreased test-associated stigma compared to facility-based testing, and generally empowered people because it provided greater control over individual testing needs[17]. In terms of the HIVST usage experience, the majority of the respondents used the kits at home and they were alone while getting tested, suggesting that MSM and PWID are hesitant to test for HIV in a healthcare facility and may be ideal candidates for the provision of HIV self-testing.

Across a number of studies and populations, participants prefer oral fluid to blood-based HIVST methods, likely because the oral fluid method avoids the need to perform a finger prick15. While primary objective of our study was not to compare preferences of oral fluid to blood-based

14 https://www.unaids.org/sites/default/files/media_asset/2020_aids-data-book_en.pdf

15 Steehler K, Siegler AJ. Bringing HIV self-testing to scale in the United States: A review of challenges, potential solutions, and future opportunities. Journal of Clinical Microbiology. 2019;57(11):e00257–19.

16 Qin Y, Han L, Babbitt A, Walker JS, Liu F, Thirumurthy H, et al. Experiences using and organizing HIV self-testing. AIDS. 2018;32(3):371–81.

17 World Health Organization. Guidelines on HIV self-testing and partner notification: Supplement to consolidated guidelines on HIV testing services. 2016. Available from: https://www.who.int/hiv/pub/vct/hiv-self-testing-guidelines/en/

HIVST kits, it should be mentioned that there were no statically significant differences in terms of the overall acceptability of different types of tests. Although it should be noted that those who used the oral fluid self-tests had a statistically significantly better experience (IFUs were more understandable, test-kits were more convenient to use, etc.) of using the test kits. In addition, MSM who used the blood-based HIVST were more likely to report the prick as a disadvantage.

In the context of HIV self-testing, pre-test information and post-test counselling can be provided in a number of ways, including a directly assisted approach (e.g., in-person demonstration and explanation by a trained provider or peer) or an unassisted approach (e.g., use of manufacturer provided instructions), as well as a number of other support tools, such as brochures, links to Internet or computer-based programs or videos, telephone hotlines, mobile phone applications or text message services. In our study, together with the test kits, the participants were provided with supporting materials, including detailed user manuals, pre- and post-test counseling information, lists of service centers and "helpline" numbers, which they could call for further information, counselling or support. Overall, the participants found the IFUs understandable (86%) and easy to follow (83.9), while very few participants (1.2%) indicated having used the hotline. High proportion of participants used the pre and post counselling brochures and almost 90% of them found them useful. Hence, while planning for an unassisted approach of self-testing, supporting tools should be accounted for as well.

HIV self-testing does not provide a definitive HIV-positive diagnosis because, as with all HIV testing, a single reactive rapid diagnostic test is not sufficient to make an HIV-positive diagnosis17. Thus, linkage to care is an important component, which should be planned appropriately while considering the wider implementation of the self-testing approach. In our study, almost 50% of those who tested positive with the HIVST, self-reported being linked to confirmatory testing. The result suggests that in half of the cases there should be some follow up strategies in place to ensure that those who test positive are not lost and are linked to treatment and care services.

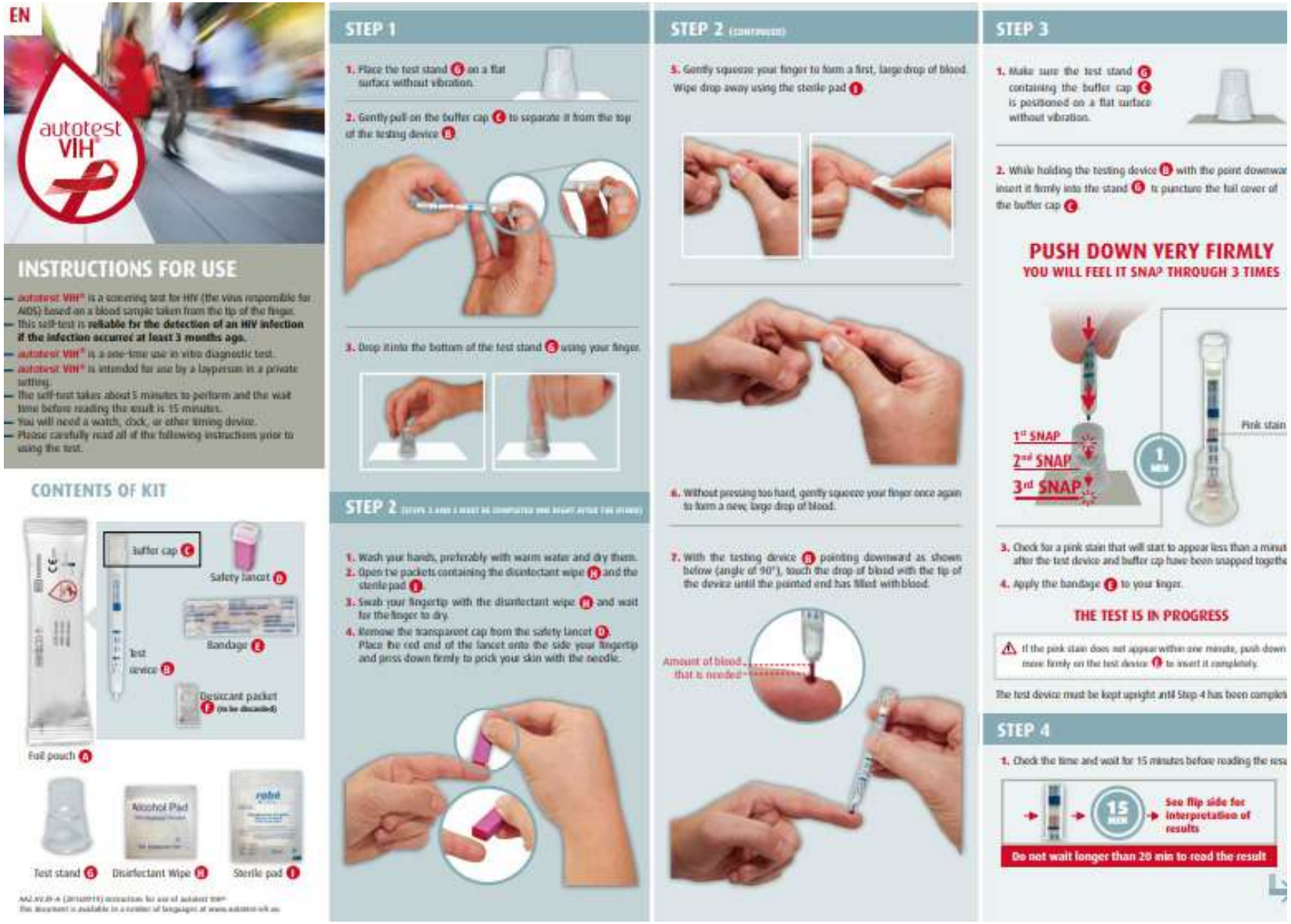
The study additionally intended to identify the preferences of the target groups regarding the sites for receiving the HIVSTs. It appears that the majority of the MSM and the PWID prefer to get HIVSTs at the same prevention site where they usually receive other prevention services. Although some respondents indicated that pharmacies are also an option for them to buy the HIVST. Online delivery and National AIDS Center were also named among the potential sites for receiving self-tests. The results suggest the need for implementing diverse delivery models for self-test kits distribution, as well as promotion of the HIV self-testing approach through all possible communication channels. One of the suggested model of test delivery can be Sigma automatic distribution machines that is being developed within French 5% initiative and the Global Fund project and is being implemented in the capital of Georgia since 2019.

CONCLUSION

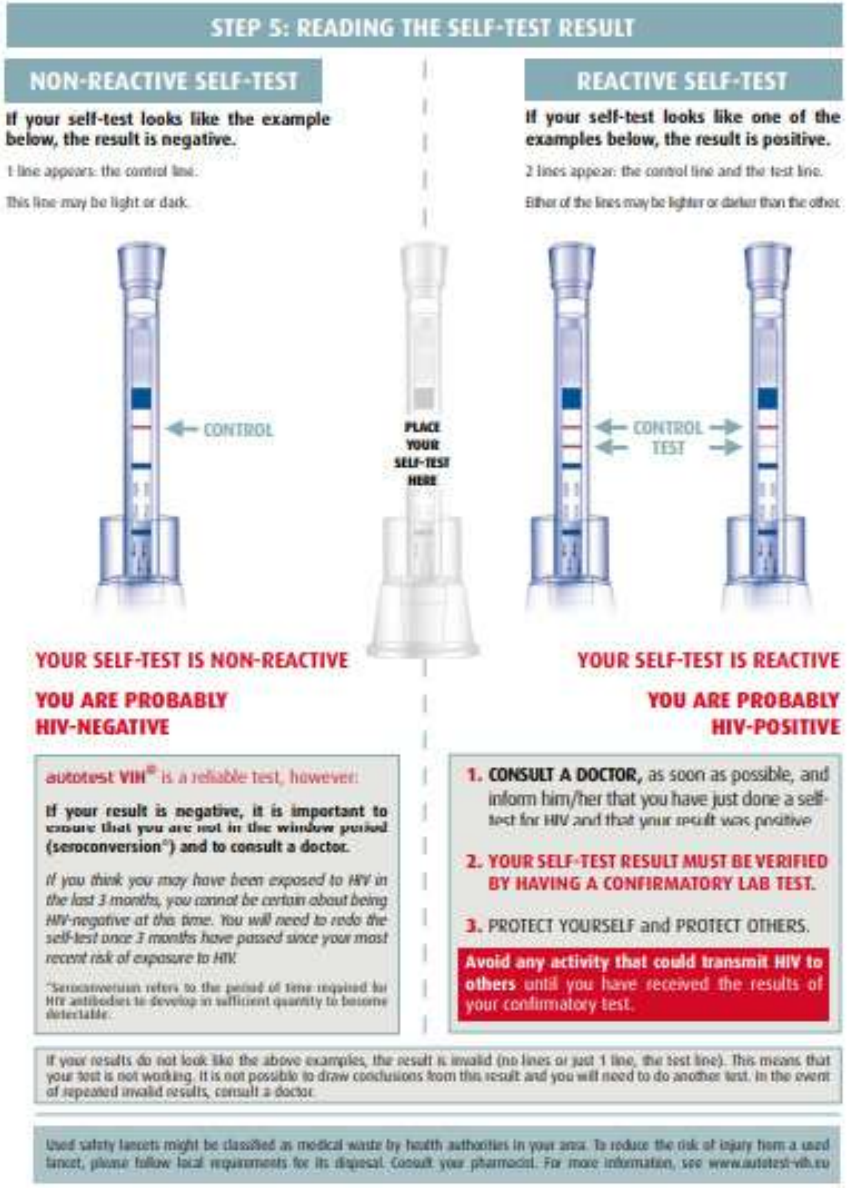
The study achieved its aim and revealed high acceptability of HIVST among MSM and PWID in Georgia. Policy makers ought to adopt various measures to facilitate its implementation and scale-up, as self-testing can serve as a necessary investment to reach the undiagnosed and improve the first step of HIV care continuum in the country.

ANNEX 1: INSTRUCTION FOR USE, ORAL FLUID SELF-TEST KIT

ANNEX 2: INSTRUCTION FOR USE, BLOOD BASED SELF-TEST KIT



ANNEX 2: INSTRUCTION FOR USE, BLOOD BASED SELF-TEST KIT



STEP 5: READING THE SELF-TEST RESULT

NON-REACTIVE SELF-TEST

If your self-test looks like the example below, the result is negative.

1 line appears: the control line.

This line may be light or dark.

REACTIVE SELF-TEST

If your self-test looks like one of the examples below, the result is positive.

2 lines appear: the control line and the test line.

Either of the lines may be lighter or darker than the other.

CONTROL

PLACE YOUR SELF-TEST HERE

CONTROL
TEST

YOUR SELF-TEST IS NON-REACTIVE

YOU ARE PROBABLY HIV-NEGATIVE

autotest VIH® is a reliable test, however:

If your result is negative, it is important to ensure that you are not in the window period (seroconversion*) and to consult a doctor.

If you think you may have been exposed to HIV in the last 3 months, you cannot be certain about being HIV-negative at this time. You will need to redo the self-test once 3 months have passed since your most recent risk of exposure to HIV.

*Seroconversion refers to the period of time required for HIV antibodies to develop in sufficient quantity to become detectable.

YOUR SELF-TEST IS REACTIVE

YOU ARE PROBABLY HIV-POSITIVE

1. **CONSULT A DOCTOR,** as soon as possible, and inform him/her that you have just done a self-test for HIV and that your result was positive.
2. **YOUR SELF-TEST RESULT MUST BE VERIFIED BY HAVING A CONFIRMATORY LAB TEST.**
3. PROTECT YOURSELF and PROTECT OTHERS.

Avoid any activity that could transmit HIV to others until you have received the results of your confirmatory test.

If your results do not look like the above examples, the result is invalid (no lines or just 1 line, the test line). This means that your test is not working. It is not possible to draw conclusions from this result and you will need to do another test. In the event of repeated invalid results, consult a doctor.

Used safety lancets might be classified as medical waste by health authorities in your area. To reduce the risk of injury from a used lancet, please follow local requirements for its disposal. Consult your pharmacist. For more information, see www.autotest-vih.eu

> Need support or guidance?
> Need help with using the test or interpreting the result?
> Questions related to HIV or other sexually transmitted infections?

7/7 8:00-23:00 GMT +1

Sida Info Service

autotest-vih@sis-association.org

PRINCIPLE AND PERFORMANCE

autotest VIH® is an immunochromatographic assay that detects antibodies in human blood that are produced following infection with HIV.

The control line that appears when the test is used serves to confirm that the test is functioning properly.

Sensitivity*: the sensitivity of this test has been calculated to be 100% with a confidence interval of 99.1% to 100%. All HIV-positive individuals in this study obtained a correct result. No false negatives were observed.**

Specificity*: the specificity of this test has been calculated to be to 99.8% with a confidence interval of 99.5 to 100%. 0.2% of HIV-negative individuals obtained an incorrect result, i.e. 0.2% of results were false positive.***

Reliability: a practicability study of the handling of this test by laypeople showed that over 99.2% of participants obtained an interpretable result and over 98.1% correctly interpreted the result. Positive results were interpreted correctly in 100% of cases.

Interferences: no significant interference has been observed upon examination of specimens that contain substances or that present medical conditions with the potential to affect the results of this test.

Detailed information on results from the above-mentioned studies is available upon request at **www.autotest-vih.eu**

*Studies of 335 people (sensitivity) and 1403 people (specificity) from the United States and the European Union.

**False negative: a specimen known to be positive for the target marker and mistakenly classified as negative by the test.

***False positive: a specimen known to be negative for the target marker and mistakenly classified as positive by the test.

WARNINGS AND PRECAUTIONS

- autotest VIH® is strictly intended for private use as self-test for HIV and must not be used for any other diagnosis or purpose under any circumstance.
- autotest VIH® must only be used with a fresh sample of capillary blood. Do not re-use for serum or plasma specimens.
- Store the self-test in its original packaging in a cool, dry location between 8°C and 30°C. Keep away from sunlight.
- autotest VIH® is for single-use only. It should be performed between 18°C and 30°C. Do not re-use.
- Do not open the foil pouch containing the self-test device until you are ready to perform the test.
- This self-test is not intended for use in the context of therapeutic follow-up with patients receiving antiretroviral therapy.
- Individuals who use this self-test should consult their doctor prior to making any medical decisions, regardless of whether the test result is negative or positive.
- False positive results (0.2% in studies of test specificity) or false negative results could be obtained in the following circumstances: exposure to HIV in the 3 months prior to using the test (window period), situations of advanced immunodeficiency or infection by a rare variant, and among HIV-positive people receiving antiretroviral therapy.
- Failure to store as directed or to respect the limits of use could cause the test result to be incorrect.
- Do not use the self-test if the packaging or foil pouch have been opened or damaged.
- Do not use if expiry date printed on the packaging has passed.
- If you have trouble understanding the package insert or instructions for use, **please contact Sida Info Service immediately at: autotest-vih@sis-association.org (7/7 - 8:00-23:00 GMT+1).**
- Keep this self-test and the items that come with it away from children, the components included with autotest VIH® could be harmful if swallowed and could cause irritations.
- autotest VIH® is an additional form of HIV testing that can be used as a complement to other existing options. autotest VIH® is only able to detect HIV infection and cannot be used as a test for other sexually transmitted infections.
- AAZ-LMB expressly disclaims all liability for the use or distribution of autotest VIH® or any of its components, that fail to strictly follow the directions and limits of use as specified in the applicable instructions for use.

Further information and a demonstration video are available at **www.autotest-vih.eu**

Manufactured by AAZ-LMB Saigon 212 - Rhône-Alpes Lyonnais - France

CE 0459

French Manufacturer

Legend of symbols:

carefully read instructions for use

do not reuse

IVD in vitro diagnostic medical device

expiry date

CE - CE marking

store between +8°C and +30°C

Bottle Cap Warning:

ANNEX 3: HIV PRE-TEST COUNSELING INFORMATION

What is HIV infection?

HIV is an infection caused by the human immunodeficiency virus (HIV). Once the virus enters the human body, it begins to multiply, which lowers the human immunity over the time. After the decrease of immunity, a person can no longer protect himself/herself from various diseases.

What is AIDS?

AIDS (Acquired Immunodeficiency Syndrome) is the final clinical stage of the disease caused by HIV infection.

There are three main ways of HIV transmission:

1. Through the contact with infected blood — blood transfusion, injections and other manipulations using non-sterile contaminated medical instruments. Most commonly, transmission occurs during drug injections use when sharing syringes, needles, or other paraphernalia contaminated with HIV-infected blood.
2. Through unprotected sexual contact (without a condom) — both during heterosexual (between men and women) and homosexual (between men) contact with an infected person.
3. Transmission from an HIV-infected mother to a fetus/child during pregnancy, childbirth (at the time of delivery) or breastfeeding.

HIV cannot be transmitted through:

1. Handshaking, hug and kissing
2. Sneezing or coughing
3. Sharing food and dishes
4. Using a shared toilet or bathroom
5. Using a public swimming pool
6. The mosquito bites
7. The relation with an HIV-infected person in work, public or household environment.

Why should I get tested for HIV?

HIV has no specific clinical signs, so testing is crucial for its diagnosis. Testing is especially important and necessary in case of experiencing risky behaviors.

Diagnosis

At the initial stage, testing is carried out by simple rapid tests that determine the presence of

antibodies in the blood. Then, it is necessary to conduct a confirmatory test. You cannot be diagnosed with HIV without a confirmatory testing. Hence, the rapid test alone (the answer of which is ready in 15–30 minutes) does not confirm the presence of the virus in the blood; it only gives presumptive diagnosis.

If your rapid test result is negative, you can change your risky behaviors and thus avoid getting infected.

To reduce the risk of infection it is necessary to:

- Practice safe sex (use of condoms);
- Test and treat sexually transmitted infections, including HIV;
- Give up injecting drug use; in case of drug use, use new and disposable needles, syringes and other injecting paraphernalia.

However, it is necessary to make sure that you are not in a so-called "window period". This is the period from the virus entering into the body to the production of response antibodies by the body (specific cells produced directly against the virus). Therefore, if a person is tested at this period, his or her test result will be HIV negative. The window period lasts for 4–12 weeks. Although an infected person cannot be diagnosed during the window period, he/she represents a potential source of infection for other people.

If your rapid test result is positive, you must take a confirmatory test.

After conducting the confirmatory test and getting the HIV diagnosis, the CD4 lymphocyte count and the viral load is determined. The results of these tests will always appear in the medical records of the HIV infected person and represent the bases for treatment initiation and evaluation of treatment effectiveness.

The number of CD4 lymphocytes in the blood determines the state of the body's immune system. The results are calculated by counting the cells within 1 cubic/mm of blood (cell/ml3). CD4 counts range from 400 to 1,600 for people with HIV-negative status, with an average of 500 being considered as «normal».

The viral load test shows how many viruses there are in a small blood sample.

A viral load while on ARV treatment shows how effective your treatment is. The goal of treatment is to achieve a state where the viral load is «undetectable.» **If the viral load is undetectable, it means that ARV medications are effective.**

An HIV-positive person who starts ARV treatment on time and whose viral load is minimal (undetectable) does not pose a risk of spreading the infection to his or her heterosexual or homosexual HIV-negative partner. This approach is called **undetectable = untransmittable**.

By confirming the diagnosis and by timely initiation of treatment, you will be able to prevent the transmission of HIV to others, manage the disease properly and prolong your life.

ANNEX 4: HIV POST-TEST COUNSELING INFORMATION

If your test result is negative

This means that no virus has been detected in your blood and you are not infected with HIV. However, it is necessary to make sure that you are not in a so-called "window period".

If you had HIV risky behavior during the past 3 months before taking the test, it is worthwhile to have another HIV test again after 3 months, as you may be in a so-called «window period». This is the period to produce the right amount of HIV antibodies to make it possible to detect them in the blood.

It is important to remember that **HIV can be transmitted**:

- **Through unprotected sexual contact** with an HIV-infected person both through same-sex relationships (homosexual intercourse) and non-same-sex relationships (heterosexual contact);
- By **sharing a needle, syringe, and other injecting paraphernalia** with an HIV-infected person;
- By **transfusing uncontrolled blood and blood products** of an HIV-infected person;
- Through transmission from an HIV-infected **mother to a fetus/child** during pregnancy, childbirth (at the time of delivery) or breastfeeding.

Since HIV-infected people often look healthy, they may not be aware of their HIV status. The best ways of prevention include:

- It is better to have **one, healthy, regular partner**, otherwise in case of sexual intercourse be sure to use a condom during every occasion;
- **Avoid injecting drug use**, otherwise always use a new needle and syringe (do not use a needle or syringe that has been used by someone else, as well as avoid reusing by yourself). Never use shared injecting paraphernalia or other items (cotton, filter, etc.);
- If you or your friend, relative, etc. needs a blood or blood products transfusion, **request it from the blood bank**;
- If you have frequent unprotected sex, you may be at risk of being infected with various sexually transmitted infections (STIs) (e.g. syphilis, hepatitis B, gonorrhea, etc.). In such case, it is recommended to **get tested for STIs**, as these diseases, as well as HIV/AIDS, can be transmitted through unprotected sexual contact.

Information for women:

- Be sure to get tested for HIV during pregnancy. If you appear HIV positive, you should get special prophylactic treatment to minimize the risk of fetal/neonatal infection;

It is also important to know that HIV is not **transmitted through**:

- Handshaking, hug and kissing;
- Sneezing or coughing;
- Sharing food and dishes;
- Using a shared toilet or bathroom;
- Using a public swimming pool;
- The mosquito bites;
- The relation with an HIV-infected person in work, public or household environment.

If your test result is positive

This means that a virus has been detected in your blood and you are most likely to be infected with HIV. Then, it is necessary to conduct a confirmatory test. You cannot be diagnosed with HIV without a confirmatory testing. To get the information needed for confirmatory testing, you can contact your HIV prevention service provider, AIDS center or call the hotline (all contact information are provided along with the test).

Early initiation of ARV treatment will allow you to maintain good health for a long time. This treatment is free and available to all citizens of Georgia. Timely treatment can stop the development of AIDS and prevent life-threatening complications.

It is well known that HIV infection can be acquired through unprotected sexual contact, and because sexual contact with a spouse and a regular sexual partner is often unprotected, it is necessary to test them on HIV as well. You should notify them about your HIV positive status.

It is also recommended to test people with whom you have had risky behaviors (unprotected sexual contact, sharing needles and syringes, etc.) as early detection of HIV is very important for their health too.

If your test result is unclear

In this case, it is recommended that your take another test after 3 months or take additional tests, by using more sensitive methods. You must contact your HIV prevention service organization or the AIDS Center (all contact information is provided together with the test-kit).

It is important to abstain from risky behaviors that could lead to transmission of infection before getting correct results.

ANNEX 5: BASELINE SURVEY QUESTIONNAIRE

Date: _____

Unique ID code /—/—/—/—/—/—/—/—/—/—/—/—/—/—/—/—/

Organization: _____

Outreach/social worker: _____

Recruitment site: _____

Risk group:

1. MSM
2. PWID

Type of HIV self-test kit delivered:

1. Oral fluid
2. Blood-based test kits

Agree to participate in the survey:

1. Yes
2. No, if no please specify the reason

A. PARTICIPANT'S CONTACT INFORMATION

1. Phone number _____

B. DEMOGRAPHIC CHARACTERISTICS

B.1. Age _____

B.2. Sex

1. Male
2. Female
3. Transgender

B.3. Education the highest level of education attained

1. Didn't attend school

2. Elementary school

3. High school

4. Professional college

5. Secondary school

6. University

7. Post-graduate

99. Refused to answer

B.4. Occupation (Please circle all possible answers)

1. Never was employed

2. Temporarily unemployed

3. Employed

4. Student

5. Other _____ (Please, specify)

99. Refused to answer

B.5. What is your monthly income?

1. up to 300

2. 301–1000

3. more than 1000

4. Refused to answer

C. RISKY BEHAVIORS

C.1. Needle and injecting paraphernalia sharing during last 12 months

1. Always

2. Occasionally

3. Never

4. Other (please specify)

99. Refused to answer

C.2. What is your sexual preference?

1. Heterosexual

2. Homosexual

3. Bisexual

99. Refused to answer

C.3. Condom use during last 12 month

1. Always

2. Occasionally

3. Never

4. Other (please specify) _____

99. Refused to answer

C.4. Number of sex partners in the last year _____

99. Refused to answer

D. HIV TESTING

D.1. HIV Testing history

1. Never

2. Tested more than year ago

3. Tested past year

99. Refused to answer

D.2. Reason for HIVST

1. Engaged in risky behavior

1.1. Had unprotected sex

1.2. Shared needle and injecting paraphernalia

1.3. Had cases of using non-sterile contaminated medical instruments

1.4. I needed to transfuse blood or its products

2. Sex partner engaged in risk behavior

2.1. My sex partner had unprotected sex

2.2. My sex partner shared needle and injecting paraphernalia

2.3. My sex partner had cases of using non-sterile contaminated medical instruments

2.4. My sex partner needed to transfuse blood or its products

3. I was suggested to get tested

4. Part of my regular testing pattern

5. I wanted to learn my HIV status/curiosity

6. HIV testing is easily accessible

7. I needed a certificate of HIV testing

8. Other (please specify) _____

99. Refused to answer

ANNEX 6: FOLLOW-UP SURVEY QUESTIONNAIRE

Date:

Unique ID code /—/—/—/—/—/—/—/—/—/—/—/—/—/—/—/—/

Organization: _____

Outreach/social worker: _____

Recruitment site: _____

Risk group:

1. MSM
2. PWID

Type of HIV self-test kit delivered:

1. Oral fluid
2. Blood-based test kits

Agree to participate in follow-up survey

1. Yes
2. No, if no, please specify the reason _____

A. HIV SELF-TESTING

A.1. Did you use HIVST?

1. Yes
2. No, if no please encourage the participant to take HIV self-test and set the date for repeated call (probe one week) and end the survey.

A.2. Where did you use HIVST?

1. At home
2. At the site I received the test
3. Other (please specify) _____

A.3. When did you use HIVST

1. Immediately
2. Within 2 days
3. Within 2 days and 1 week
4. Between 1 week and 2 weeks
5. Other (please specify) _____

A.4. Was anybody present while testing?

1. Friend
2. Sex partner / spouse
3. Family member
4. Outreach/social worker
5. No one
6. Other (please specify) _____

A.5. What was the HIVST result (Please remind the participant, that the information about his/her status will be kept confidential.)

1. Negative
2. Positive
3. Don't know (please specify what was the problem) _____
99. Refused to answer

A.6. Did you call the helpline?

1. Yes, if yes, what was the reason _____
2. No (go to question 8)
3. Refused to answer

A.7. Was the helpline useful?

1. Yes
2. Somewhat
3. No
99. Refused to answer

A.8. Did you use the pre-counselling information?

1. Yes, go to question 9

2. No, go to question 10

99. Refused to answer

A.9. Was the pre-counselling information useful?

1. Yes

2. Somewhat

3. No

99. Refused to answer

A.10. Did you use the post-counselling information?

1. Yes

2. No

99. Refused to answer

A.11. Was the post-counselling information useful?

1. Yes

2. Somewhat

3. No

99. Refused to answer

A.12. In case of positive test result have you taken the confirmatory HIV test

1. Yes (go to section B)

2. Not yet, but plan to take the test (go to section B)

3. Does not plan (continue)

99. Refused to answer

A.13. Why don't you plan to take confirmatory test?

1. Do not trust to Self-testing result

2. Fear of being diagnosed

3. Fear about disclosure

4. Sceptic about the treatment

5. Already registered at AIDS Center

6. Other, please specify _____

B. EXPERIENCE AND ACCEPTABILITY

B.1. Were the instructions for use oral tests/ finger prick rapid tests understandable?

1. Yes
2. Somewhat
3. No, if no state what was unclear _____
99. Refused to answer

B.2. Did you find instructions easy to follow

1. Yes
2. Somewhat
3. No, if no state the reason _____
99. Refused to answer

B.3. Did you find it convenient to use HIVST?

1. Yes
2. Somewhat
3. No
99. Refused to answer

B.4. Did you find it easy to use HIVST?

1. Yes
2. Somewhat
3. No
99. Refused to answer

B.5. What was the best feature of doing HIV ST?

1. Privacy
2. Convenience
3. Simple operation
4. Other, please specify _____

B.6. Was it easy to interpret results?

1. Yes
2. Somewhat

3. No

99. Refused to answer

B.7. Does the HIVST guarantee confidentiality?

1. Yes

2. Somewhat

3. No

99. Refused to answer

B.8. What did you dislike about HIVST?

1. Please specify _____

99. Refused to answer

B.9. Would you recommend HIVST to others?

1. Yes

2. No

99. Refused to answer

B.10. Would you use the HIVST kit again in the future?

1. Yes

2. No

99. Refused to answer

B.11. Overall how acceptable seems to you introducing HIV ST?

1. Totally acceptable

2. Acceptable

3. Neutral

4. Not acceptable

5. Totally unacceptable

B.12. Where would you prefer to get HIV self-test in the future?

1. At the same prevention center

2. At AIDS center

3. At the pharmacy

4. On-line

5. Other (please specify) _____

ANNEX 7: IN-DEPTH INTERVIEW GUIDE (QUESTIONNAIRE FOR COMMUNITY MEMBERS (MSM/PWID))

Introduction

Moderator introduces him/herself and explains purpose of the interview: I am —— (name, last name) and I work at GHRN. GHRN is the key actor to deliver low threshold harm reduction services to PWIDs in Georgia. Apart from service delivery, GHRN pursues advocacy strategies based on human rights and public health principles.

The aim of this meeting is to discuss your perceptions and experience and factors that influenced your decision regarding self-testing on HIV.

Your views will be used to help us to obtain more detailed information on acceptability of HIV self-testing practices and to elaborate recommendations for future initiatives based on your experience.

Your participation in the interview is voluntary. You have the right to not answer the question if you don't want to. The interview will be recorded and a transcript will be produced in order not to miss important information provided by you.

The interview will last about 40 minutes. All the information given will be treated with confidentiality and be used for the purposes of the study only.

Thank you for agreeing to spend time to answer some more detailed questions about yourself and your views of self-testing for HIV.

A. TARGET GROUP

1. MSM

2. PWID

B. PERCEPTIONS OF RISKS (HIV AND TESTING-RELATED)

B.1. What, if any, concerns do you have about HIV for yourself?

B.2. What, if any, concerns do you have about HIV for your partner?

B.3. What, if any, concerns do you have about HIV for others in your household?

B.4. Can you describe to me what aspects in your current life you consider to be likely to increase your risk of HIV?

B.5. Can you describe to me what aspects in your current life you consider to contribute to your avoidance of HIV?

C. PREVIOUS EXPERIENCE OF HIV TESTING

C.1. Have you ever had an HIV test before? You do not need to tell me the result.

C.2. (If yes) can you please explain why you decided to test or if you have tested more than once, what your reasons for repeat testing were?

Probes: Fears? Own sexual behavior? Partner change? Voluntary versus coercive? Other?

C.3. (If yes) what was the whole experience like?

Probes: Location (Outreach, Facility based)? Confidentiality? Trust in results and provider? Other?

C.4. (If no) can you please explain why you decided not to test?

Probes: Related to risk perceptions? Related to service perceptions? Related to fears and concerns regarding stigma, disclosure or status? Other?

D. HIV SELF-TESTING

D.1. Can you please describe briefly why you made your particular decision regarding self-testing

Probes: Factors related to testing in general? Factors related to self-testing?

D.2. What do you think of this HIVST strategy in general?

Probes: Acceptance for community? Clarity, Presentation and user friendliness in general?

D.3. What in your opinion are the potential advantages and disadvantages of HIV self-testing?

D.4. In case of positive results, Please share your experience regarding linkage to care services.

D.5. Would you recommend HIVST to your friends and family? Why?

E. FUTURE OF TESTING

E.1. In your opinion and whether or not you have tested up to now, what are the most important factors in HIV testing i.e. what factors would persuade you to test?

Probes: Community or facility-based, integrated or stand-alone venues, home-based outreach services (accessibility)? Level of counselling? Provider-client relations/control of testing (self-testing)? Confidentiality? Confidence & trust in results & test? Accessible referral mechanisms to ART?

E.2. If you plan to test in the future, what kind of testing would you prefer?

Thank you very much for the time you have spent in answering my questions today. Please remember that this information is all confidential. I have learnt a lot from our discussion here today and hope that the time has also been useful to you.

In your opinion how can be increased the coverage of HIV testing in your community?

ANNEX 8: CONSENT FORM FOR STUDY PARTICIPANTS

Dear Participant,

You are selected to participate in the study -»HIV self-testing acceptability among MSM and PWID in Georgia «, which is conducted by the non-governmental organization Georgian Harm Reduction network In frames of the SoS project funded by the Global Fund and coordinated by the Alliance for Public Health, in a consortium with the 100% Life, the Central Asian HIV' Association and the Eurasian Key Populations Health Network.

The goal of the study is to determine the acceptability of HIV self-testing to improve testing uptake and linkage to care by distributing oral fluid and blood-based test kits to MSM, and PWID in Georgia.

In case of your approval, you will be provided with HIV self-test kit (oral fluid or blood-based test kits) and invited to complete a short questionnaire now (baseline) and after two weeks (follow-up). Each interview will take approximately 15 minutes. You will be paid 15 GEL for your participation. Researcher will ask you questions about:

- Information about your socio-demographic characteristics;
- Income and economic status;
- Experience of HIV testing;
- Sexual health behaviors.
- HIV test result

The information you provide will only be used to determine the acceptability of HIV self-testing among MSM/PWID in Georgia to improve testing uptake and linkage to care by distributing oral fluid and blood-based test kits to target populations.

The information provided by you will be confidential and will not be disclosed to anyone. It will only be used for research purposes. Your name will not be included in the questionnaire, and only a Mobile phone number will be used for follow-up interview to indicate your HIV test result, experience with self-administered testing and your plans for future testing. The completed questionnaires will be also kept confidential.

This proposal has been reviewed and approved by the Health Research Union IRB (# 2019–08), which is a committee whose task it is to make sure that research participants are protected from harm. If you wish to find about more about the IRB, contact Health Research Union, Tel: +995 32 214447; e-mail: info@hru.ge

Individual benefits of HIV self-testing include increased access to testing and earlier diagnosis for people living with HIV.

There may be some physical/psychological risk to the study targeted KPs participating in the survey associated with the positive results received from self-testing. In addition, there may be minimal psychological risk associated during completing survey questionnaires. Due to sensitive nature of some questions (like risky behaviors) in the survey questionnaire, some participants may experience minor emotional discomfort.

Your participation will be voluntary and you can withdraw from the study after having agreed to participate. You will be free to refuse to answer any question that will be asked in the questionnaire. If you have any questions about this study, you may contact Georgian Harm Reduction network (24 Shartava st, Tbilisi Georgia. Tel: 595 092 950; 599 94 94 04).

Signing this consent indicates that you understand what will be expected of you to participate in this study.

I have been invited to take part in the study -» HIV self-testing acceptability among MSM and PWID in Georgia «.

I have read the foregoing information. I have had the opportunity to ask questions about it and any questions I have asked have been answered to my satisfaction. I consent voluntarily to be a participant in this study and understand that I have the right to withdraw from the interview at any time without in any way affecting my future life and seeking of medical care.

During the follow-up interview I agree to disclose my test result to researcher.

Participant: _____

Researcher: _____ *Date:* ___ / ___ / _____

ANNEX 9: INFORMED CONSENT FORM FOR IN-DEPTH INTERVIEW RESPONDENTS

Organization: Georgian Harm Reduction Network (GHRN)

I am _____, I am doing the study on HIV self-testing approaches. The overall objective of the study is to determine the acceptability of HIV self-testing to improve testing uptake and linkage to care by distributing oral fluid and blood-based test kits to MSM, and PWID in Georgia.

Procedures:

To find answers to some of the questions of interest for our study, we invite you to take part in an in-depth interview. This interview will be moderated by a moderator who will lead the discussion and a facilitator who will handle logistics and take notes.

As you were involved in the study on acceptability of HIV self-testing, now you are being invited to take part in this interview because we feel that your experience can contribute much to the recommendations of the study and factors associated with HIV preventive service distribution among target populations.

The questions discussed during the interview will cover the following key areas:

1. Satisfaction with study participation
2. Reasons to be tested using self administered kits
3. The main questions arising for the period of the study implementation conserning the usage of HIV self-test kits
4. Your feelings about follow-up interviews
5. Attitudes and preferences toward different types of HIV testing
6. Cases of linkage to care services

If you do not wish to answer any of the questions or take part in any part of the interview, you may say so and keep quiet. No one else but the people who take part in the discussion and the moderator will be present during this interview.

The entire interview will be tape-recorded, but **no-one will be identified by name on the tape**. Digital audio recording of the discussion will be uploaded to a password-protected computer at the GHRN office after which the recording will be erased on the audio recorder. The recording will be transcribed, a coding scheme will be created using broad categories to organize the data, in line with key areas described above. Using these predefined codes, information will organized and displayed. The recorded information will be used to ensure that the responses for the study report are correct and in your own words. The information recorded is considered confidential,

and no one else except principal investigator will have access to the record. The audio recording will be destroyed one year (12 months) after the completion of the study.

The expected duration of the discussion is about 40 minutes.

Risks and Discomforts:

There is a slight risk that you may share some personal or confidential information can be shared by chance or that you may feel uncomfortable talking about some of the topics. However, we do not wish this to happen, and you may refuse to answer any question or not take part in a portion of the interview if you feel the question(s) are personal or if talking about them makes you uncomfortable.

Benefits:

There will be no direct benefit to you, but your participation is likely to help us find out more about preferences of HIV self-test kits distribution among target populations and develop recommendation for improving HIV case detection and linkage of newly detected cases to care services.

Incentives:

You will be paid 15 Lari for participation in this interview.

Confidentiality:

The information that we collect from this research project will be kept confidential. Transcript, notes and audio digital recordings will not include your identification information. Instead, you will be given a number to keep your responses private.

Right to refuse or withdraw:

You do not have to take part in this research if you do not wish to do so. You may stop participating in the interview at any time you wish and refusing to participate will not affect your future practice in any way.

Who to contact:

If you have any questions you may ask those now or later. If you wish to ask questions later, you may contact any of the following:

Tamar Zurashvili
Address: 24 Shartava str,
Tbilisi Georgia
+995 595 092 950
tzurashvili@hrn.ge

Tamar Kasrashvili
Address: 24 Shartava str,
Tbilisi Georgia
+995 599 94 94 04
tkasrashvili@hrn.ge

This proposal has been reviewed and approved by the IRB of the Georgian nongovernmental organization “Health Research Union”, which is a committee whose task it is to make sure that research participants are protected from harm. If you wish to find about more about the IRB, please contact HRU IRB +995 32 214447 or email at info@hru.ge.

Sustainability of services for key populations in Eastern Europe and Central Asia region —

#SOS_PROJECT

CERTIFICATION OF INFORMED CONSENT

I have been invited to take part in the research on the acceptability of HIV self-testing among MSM and PWIDs in Georgia. I have been told the purpose and procedures of this study, risks and benefits associated with this research, as well as confidentiality issues.

I have read the foregoing information. I have had the opportunity to ask questions about it and any questions I have been asked have been answered to my satisfaction. I consent voluntarily to be a participant in this study and understand that I have the right to withdraw from the discussion at any time without in any way affecting my future practice.

Print Name of Subject Date and Signature of Subject

_____ _____

___/___/___ *(dd/mm/yy)*

Print Name of Researcher/Moderator Date and Signature of Researcher/ Moderator

_____ _____

___/___/___ *(dd/mm/yy)*