Expanding HIV self-testing capabilities among key, vulnerable groups and their partners in Ukraine using the Mylan HIVST kit for HIV self-testing

DEMONSTRATION PROJECT REPORT, VERSION 1

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TERMS AND ABBREVIATIONS

Demonstration project (DP)	The project testing and measuring the program's impact in real-time
Convenient sample	The selection of respondents for the study, which consists in establishing contacts with all "convenient" sampling units that meet the criteria for inclusion in the study
Key populations (KP)	Certain population groups that, due to specific types of high-risk behavior, are prone to an increased risk of HIV infection, regardless of the type of epidemic or the local context
Persons who inject drugs (PWID)	individuals who engage in the practice of injecting psychoactive substances into their bodies, often using syringes or needles.
Lay provider	Any person performing functions related to the provision of health care who has the skills to provide specific services but does not have a formal qualification or university degree
Non-governmental organization (NGO)	A non-governmental organization legalized or registered under the legislation of Ukraine
Reactive (positive) test result	Serological test result when there is a reaction indicating the presence of an analyte, i.e., p24 HIV-1 antigen and/or antibodies to HIV-1/2 in the case of HIV
Health care facility (HCF)	Legally recognized location where medical services are provided to individuals. They serve as essential resources for individuals seeking healthcare services at various stages of life and for different health needs.
HIV Testing Services (HIVTS)	A range of approaches and methods used to detect HIV infection in individuals to promote early detection of HIV infection, link individuals to care and treatment services if they test positive and reduce the transmission of HIV within communities.
HIV self-test (HIVST, ST)	A procedure where a person takes a sample for analysis (oral fluid or blood), then performs an HIV test and deciphers the result; as a rule, it takes place in a private setting, and the testing can be conducted either alone or with someone whom the person trusts
Sex workers (SW)	Persons of both sexes who provide sexual services for remuneration
Men who have sex with men (MSM)	Biological males who practice oral or anal sexual contact with another biological male

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Introduction

HIV self-testing (HIVST) has been implemented in Ukraine since 2019 using both unassisted and assisted options. Current legislation, including the Ministry of Health of Ukraine order No. 2092 "On Approval of the Standards of Medical Care "HIV Infection"" of 16.11.2022, the Ministry of Health of Ukraine order No. 1465 "On Amendments to the Standards of Medical Care "HIV Infection"" of 15.08.2023 and the Law of Ukraine "On Amendments to the Law of Ukraine "On Counteracting the Spread of Diseases Caused by the Human Immunodeficiency Virus (HIV) and Legal and Social Protection of People Living with HIV" permit HIVST, including unassisted options, as a screening tool. Until recently, only one kind of HIVST kit, the oral fluid OraQuick® HIV ½ Antibody Test used to detect antibodies to HIV 1 and HIV 2, was available in Ukraine. Thereafter, a second HIVST kit, Mylan blood based, was registered in Ukraine in 2021. The USAID/PEPFAR funded Community Action for HIV Control Project (Project) implemented a demonstration project to explore the acceptability and feasibility of the Mylan kit for HIV screening among key populations (KP) and other priority populations in Ukraine with the aim of expanding different HIV testing options.

KP, including men who have sex with men (MSM), sex workers (SW), people who inject drugs (PWID), and transgender individuals, and priority populations, including sexual partners of people living with HIV (PLHIV), are at increased risk of HIV and face unique challenges accessing HIV prevention, testing, treatment and care due to stigma. Offering different options for HIV services that meet the needs and preferences of these populations is most likely to increase testing demand and uptake.

The demonstration project aimed to assess the feasibility and acceptability of the blood-based Mylan HIV Self-Test and expand the HIVST options for KP and PP in Ukraine. The project had multiple components, including:

(1) adapting the existing materials about the new test kit to the context and language of Ukraine; (2) studying the feasibility and acceptability of introducing the new test kit among clients of non-governmental organizations (NGOs); (3) expanding HIVST capacities through test kit use training; (4) integrating HIVST with other testing modalities (index and social/risk network testing); (5) diversifying distributing HIVST kits through a network of partner NGOs and civil society organizations (CSOs).

Demonstration Project Description

This demonstration project employed mixed methodologies including a quantitative component to assess the feasibility of blood-based HIVST, a qualitative component to assess the acceptability of blood-based HIVST among KP and PP in Kyiv, Zaporizhzhia, Poltava and Chernihiv, as well as support for targeted secondary distribution of Mylan tests in the "client-recruiter and social worker-mentor" interaction system to expand access to HIV self-testing among key and vulnerable groups in selected regions of Ukraine – Zaporizhzhia, Poltava, Chernihiv, Dnipropetrovsk, Cherkasy Oblasts and in Kyiv City.

The demonstration project was introduced as part of the 2022–2023 work plan by

the Project team and implemented in collaboration with NGO HIV service providers, KP beneficiaries and professionals in the field of sociological and epidemiological research were involved in the implementation of the demonstration project.

Participating partners included:

1. European Institute of Public Health Policy, LTD
2. Reference laboratories for the HIV/AIDS diagnosis, viral and particularly dangerous pathogens, State Institution Public Health Center of the MOH of Ukraine
3. Charitable Organization “100% Life. Kyiv Region”
4. Charitable Organization “Svitlo Nadii” (Light of Hope)
5. Chernihiv Branch of Charitable Organization All-Ukrainian Network of People Living with HIV/AIDS
6. Charitable Organization “100% Life Network. Zaporizhzhia”
7. Charitable Organization FREE ZONE

Implementation stages

The demonstration project was implemented in three stages:

1. Stage 1: Introducing the blood-based Mylan HIVST kit for use by non-governmental organizations (NGOs), adapting the instructions and materials to the Ukraine context, and orienting NGOs to the kits’ use (Stage 1).
2. Stage 2: Exploring the feasibility and acceptability of the Mylan HIVST kit for HIVST in NGOs through assisted test kit use and a qualitative survey (Stage 2).
3. Stage 3: Disseminating Mylan HIVST kits among NGOs for targeted distribution to PWID, SW, MSM and other key and priority populations to expand HIVST options (Stage 3).

All three stages of the demonstration project were implemented between February and October 2023

STAGE 1.

Information support for the implementation of the Mylan HIVST kit for HIV self-testing based on non-governmental organizations

In Stage 1, the Project prepared initial data for information support for the implementation of the Mylan HIVST in Ukraine. Providers of NGO-based HIV testing services, as well as NGO clients engaged in HIV index testing services and HIV testing in social/risk networks, were the target audience for the development and dissemination of information materials and instructions. Information materials developed in Stage 1 were distributed to regional partners for internal use and further dissemination to KP and PP clients.

The initial preparation included:

- Collecting, reviewing, translating and adapting test kit information materials, instructions, brochures, booklets, and videos on the procedure of using the Mylan HIVST kit. The main source of information is the official instructions and information materials about the Mylan HIVST kit, which are available in the public domain (in particular, on the website https://www.ez2uzhivselftest.com/). The Ukrainian translation, completed by the project, is available at the following link: https://tr.ee/zYTBxO24y-.
- Developing the scenario and shooting the video instruction on the proper use of the Mylan HIVST kit, adapted to the Ukrainian environment (based on publicly accessible video materials, in particular, on the website https://www.youtube.com/channel/UCGgXQ_X8tily5WjFM5LC4w). The resulting adapted video is available at the following link: https://www.youtube.com/watch?v=SYDXV_bYURY&t=4s
- The project team also developed the protocol for the interaction between the social worker and the recruiter as part of the implementation of an enhanced approach to the secondary distribution of HIVST kits for HIVST among KP and vulnerable populations (Stage 3). The developed document is available at the following link: https://tr.ee/b1ZPOEiRib.
- All adapted materials were distributed to partner NGOs, and are available on the Project website and can be accessed at linktr.ee/hiv.innovations (“Mylan Test Kit” section).

Stage 2.

Explore the feasibility and acceptability of the Mylan HIV Self-Test among PWID, SW, MSM and other key and priority populations

To fulfill Stage 2, the Project involved the European Institute for Public Health Policy (EIPHP) and representatives of the Diagnostics and Reference Laboratory for HIV/AIDS, Viral and Particularly Dangerous Pathogens of the State Institution Public Health Center of the MOH of Ukraine. The EIPHP staff developed a detailed protocol for research and analytical work, and forms and tools for data collection, and organized the process of recruiting respondents, collecting and analyzing the data, and presenting the results.

The objectives of this stage were as follows:

1. To determine the acceptability of assisted self-testing using the Mylan test kit — project data.

2. To assess the ability to understand and interpret the Mylan test kit's instructions — structured interviews with service recipients.

3. To find out the main issues at the stages of conducting and interpreting the results — monitoring of testing by service providers.

4. To determine user attitudes and preferences regarding assisted HIVST using the Mylan test kit — in-depth interviews among service recipients.

5. To determine the possibilities of HIVST implementation using the Mylan test kit — in-depth interviews with service providers and other NGO representatives.

The field stage of the demonstration project lasted from July 24, 2023, to August 29, 2023.

There were two parts of Stage 2: assisted HIVST kit use among NGO clients and in-depth interviews with a subset of those who used the test kit. For the first part, trained social workers held role of the assistant at this stage is to record how the client uses the test system, whether he or she follows the instructions and all the steps. Individual cases of assistance - physical features of the client

Meeting the project goal, 240 individuals participated in the assisted Mylan HIVST kit use. These individuals were engaged through the NGO's risk network referral intervention, which elicits individuals at risk of HIV with unknown status from a PLHIV or at risk KP's social network. The average age of participants was 34.7±9.7. The youngest participant was 19 years old, and the oldest one was 58 years old. Age groups of 18–24 and 25–34 were evenly represented, 54 (22.5%) and 57 (23.8%) respectively. The most represented age group was 35–44 (38.8%), and the least represented group was 45+ — 38 (15.0%) participants.

More than two-thirds of the participants were men — 187 (77.9%) people. Among 187 men, more than half had sex with men — 98 (52.4%). The majority of 89 (90.8%) had no other risk of HIV infection than sex with men. Forty-two (22.5%) had both injection drug use and sexual contact with users of injection drugs, and 34 (18.2%) solely injected drugs. Only one participant reported having sex with men and having injected drugs. Thus, the MSM and PWID were two main and substantially separated KPs among men.

The participants mostly included people who reported one type of risky behavior — 148 (61.2%), but quite often, there were those who reported two or more types of risky behavior — 92 (38.3%). While most men reported one type of risky behavior — 128 (68.4% out of 187 men), most women, by contrast, had a combination of risky behaviors — 33 (62.3% out of 53 women). Among 187 men, more than half had sex with men — 98 (52.4%). Most of them had no other risks of HIV infection than sex with men — 89 (90.8% out of the total number of MSM or 47.6% of the total number of men) (Table 3). Representatives of the other largest category of men either injected drugs — 34 (18.2%), or, in addition to drug use, had sexual contacts with injecting drug users — 42 (22.5%) The total number was 76 persons (40.6% out of the total number of men). Other combinations of risky behaviors among men were less common. Only one participant reported having sex with men and having injected drugs. Thus, MSM and PWID were two main and substantially separated KPs among men.

Table 1 Combinations of risky behaviors among male participants (n=187)

Combination No.	Injecting drugs at least once during the last 30 days before the project	Receiving money, goods or services in exchange for sex in the past 6 months	At least one oral or anal sexual contact with a man in the last 6 months	At least one sexual contact with PWID in the last 6 months	At least one sexual contact with SW in the last 6 months	The number of persons with relevant combinations	
						Absolute number	%
1.			X			89	47.6
2.	X			X		42	22.5
3.	X					34	18.2
4.	X			X	X	6	3.2
5.					X	4	2.1
6.		X	X		X	2	1.1
7.		X	X			2	1.1
8.			X	X		2	1.1
9			X		X	2	1.1
10.				X	X	1	1.1
11.	X	X	X	X	X	1	0.5
12.				X		1	0.5
13.	X	X		X		1	0.5

The five most common risk behavior combinations among women were: (1) injected drug use + sexual contacts with PWID — 16 (30.2%); (2) paid sex + sexual contacts with PWID — 8 (15.1%); (3) sexual contacts with PWID — 8 (15.1%); (4) paid sex — 6 (11.3%); and (5) injected drug use — 5 (9.4%) (Table 2).

Table 4 Combinations of risky behaviors among female participants (n=53)

Combination No.	Injecting drugs at least once during the last 30 days before the project	Receiving money, goods or services in exchange for sex in the past 6 months	At least one sexual contact with PWID in the last 6 months	At least one sexual contact with SW in the last 6 months	At least one sexual contact with a man having sex with men	The number of persons with relevant combinations	
						Absolute number	%
1.	X		X			16	30.2
2.		X	X			8	15.1
3.			X			8	15.1
4.		X				6	11.3
5.	X					5	9.4
6.	X	X	X	X		2	3.8
7.	X	X	X			2	3.8
8.			X	X		2	3.8

9		X	X	X	X	1	1.9
10.	X		X	X		1	1.9
11.	X			X		1	1.9
12.				X		1	1.9

The overwhelming majority of participants resided permanently in the project territory — 224 (94.6%). Almost two-thirds reported that they had never been married — 154 (64.2%) and quite a large number were widowers and widows — 63 (26.3%). Almost half of the participants reported running a household on their own or with a cohabitant — 112 (46.7%). 196 (81.7%) of respondents reported complete general and a higher level of education. A fairly large number of participants had permanent jobs — 96 (40.0%), but the number of unemployed and those having odd jobs was also high — 31 (12.9%) and 77 (32.1%), respectively. Personal monthly income averaged UAH 12,429.

Most participants, 194 (80.8%), reported having a previous negative HIV test result (more than a year old), the majority of whom, 120 (61.9%), through HIVST. Forty-six (19.2%) of participants did not know their HIV status because they had never been tested for HIV.

Most participants, 194 (80.8%), were not regular NGO clients. Most of them, 153 (78.9%), reported knowing where to go for HIV testing and 135 (69.9%) were tested through HIVST. Conversely, among the 46 NGO clients, 41 (89.1%) reporting knowing where to go for HIV testing and 32 (82.6%) knew about HIVST kits.

All 240 participants successfully performed HIVST, with 236 (98.3%) non-reactive or negative results and 4 (1.7%) reactive results. Test results reported by the participants and those recorded by the assistant matched in all cases. The average HIVST duration was 24±6 minutes.

All 240 participants were informed of the option to participate in an in-depth interview about the Mylan HIVST experience. Of those who agreed, 40 were randomly selected by an independent review using their client codes and participated in semi-structured qualitative surveys administered by experienced independent interviewers from July 31 to August 24, 2023. This included 10 participants from each four cities (Kyiv, Poltava, Chernihiv, Zaporizhzhia). All interviews were conducted remotely using telephone or messenger calls. Two respondents had a one-minute technology-related interruption during the interview, while all others had no interruption. The average length of the interview was 25 minutes. Annex 1 included details on the interview and survey questions and results.

The survey respondents were aged between 19 and 58, and 31 were men and 9 were women. Thirty-one were not NGO clients (did not have a plastic card or were not in the NGO client registration system). All 40 survey participants received a negative test result more than a year ago, half through HIVST (21), of which 4 were NGO clients.

More than half of the respondents had basic higher or completed higher education (n=23), the rest had basic secondary or complete secondary education (n=16), and one participant had primary education. Less than half of the participants had a permanent job (n=18); the rest had odd jobs (n=7), had no jobs or were disabled (n=13); or students (n=2).

Process organization and general impression of assisted HIV self-testing using Mylan test kits

Involvement and motivation

Clients learned about the possibility of undergoing the HIVST from acquaintances or friends, NGO workers or social networks. Respondents were interested in learning

about their HIV status free of charge and through a new approach. For some, the compensation for time and travel costs was the most motivating factor to participate. All participants were aware of the possibility of undergoing HIV testing in a medical facility or using an HIVST kit, but not all of them were aware that HIV testing was available at NGOs with the assistance of the social worker.

There is mistrust or reluctance on the part of some participants to test for HIV at the medical facility and testing outside the HCF (ST or assisted ST) is perceived by clients as the most comfortable way to obtain information about their health.

The activity was facilitated by NGOs, with social workers and clients helping to recruit participants. When respondents referred to NGOs to participate in testing, participants were given instructions on the use of the Mylan HIVST kit. There was an assistant (social worker) who could explain the details or adjust the steps of participants in the testing process, as needed. In general, respondents' attitudes towards assisted testing using the Mylan HIVST kit did not deteriorate after participation (i.e., as expected by the client) or changed for the better.

Briefing

According to client respondents, the role of assistants was limited to providing verbal guidance; they were not permitted to touch or physically assist the client or test kit use. One respondent reported that the assistant had given very detailed information about the testing procedure, like how to use the test and where to drip the buffer. Some respondents noted that assistants had told them that the participant had to read the instructions and follow them rather than just watch the pictures.

General impression

Respondents noted good communication with the assistants, who helped when needed, comforted clients in the process of waiting for results, and advised on the results of directly assisted self-testing. Most reported that it was good to have someone around who knew how to do the right thing and could guide, prompt and advise. Some noted that the presence of assistants was necessary only for the first time to explain the algorithm and instructions, and they felt being able to re-do such self-testing on their own for the second time. Others reported the assistance unnecessary. Some shared their excitement about using the Mylan kit for the first time. Some respondents were anxious about making a mistake or doing something wrong and worried about the test results. Having received such first experience, the prevailing opinion among clients was that the presence of assistants was necessary only for the first time to explain the algorithm and instructions, and they felt being able to re-do such testing on their own for the second time.

Two respondents were uncomfortable and expressed their negative attitude to the presence of a stranger during the testing process.

Respondents generally liked testing with the Mylan HIVST kit because it was easy, fast, and convenient, and they did not have to wait in lines. However, some respondents needed a lot of help; not everyone was ready to read the instructions and tried to understand the sequence and content of actions from the pictures. The presence of assistants who, if necessary, accompanied the whole process in more detail was a positive factor for many.

Clients still had hesitation regarding HIVST. There were opinions that the test was difficult and unclear, and there was no one to help. In contrast, some reported that they would have preferred to do the HIVST at home on a convenient day and time rather than waste time planning and traveling to an NGO or HCF for that purpose. Some other observations were that some clients did not comply with the instructions which invalidated the testing, did not independently interpret the result correctly and some with reactive test results were not clear on next steps.

Participants' perception of their ability to use the Mylan test kit

Ease of use

Most respondents (n=39) noted their interest in the Mylan HIVST kit and its ease of use. Compared to other HIV blood testing with which they had previous experience, clients liked the configuration of the HIVST kit with the presence of all necessary components (lancet, blood collection tool, reservoir for blood analysis with buffer) and all attached in one unit. All the details were thought out, which allowed clients to use this HIVST kit in almost any premises or places that were comfortable for the client.

The finger puncture was almost imperceptible for respondents, with one respondent reporting not feeling it. Several preferred the oral fluid test because it did not require finger puncture. There were several opinions about more confidence in blood-based HIV testing.

Some usage issues

Noting the ease and comprehensibility of using the Mylan HIVST kit, some respondents openly reported some technical subtle differences they did not understand (n=15). Despite the fact that respondents noted that they were willing to be fully self-tested with the Mylan HIVST kit, some clients felt being able to act as assistants for their acquaintances and close people, but experience using the HIVST kit for the first time showed that even the simplest HIVST kit needed some getting used to it and being understood. The presence of the assistant in this process reduces the number of errors and incorrectly used tests. Just one respondent considered that the whole mechanism of this HIVST kit only complicated the testing process.

Respondents had technical difficulties with the lancet button (how hard and up to what point to press), the blood tube and manipulating the blood drop; some participants did not immediately understand that they needed to open the lancet on one side of the kit; some were not accustomed to reading the instructions; therefore, the ST was somewhat for them unusual and required additional effort.

Participants followed the pictures but did not always read the accompanying text; in this case, assistants emphasized the importance of reading the accompanying text for the correct performance and obtaining the correct result of the HIV test.

Fears about the testing process and applying for the service of assisted self-testing for HIV using Mylan test kits

Respondents shared their anxieties and fears about seeking testing, finding out the test result, privacy risks, and the myths, misconceptions and stigma about HIV testing among their communities. The most frequently reported reasons for not seeking HIV testing were fear of test result, fear of finger prick (and related fears of blood and needles), fear of confidentiality breach or that someone would see them at the testing site, fear of privacy loss, fear of not learning of HIV status in time, stigma about HIV and fear of trying something new.

Mylan assisted testing approach for different kp's

Trusting the assistant

According to respondents, the assistant should be a person with knowledge of the rules and techniques of the HIVST kit use, have the relevant experience, be able to provide psychological support, strictly observe the rules of confidentiality and

non-disclosure of results, have knowledge of where to go in case of HIV reactive test, or correctly provide information about safe behavior and harm reduction. The preference for type of professional to assist with HIV testing differed, with some trusting medical professionals and considering their opinion authoritative and others preferring social workers, persons from their KP (peer-to-peer) and relatives to prevent any disclosure. Some respondents were indifferent and would accept either medical professional or social workers in this role.

Further support after self-testing

Respondents agreed that social workers should have information about the HCF or a doctor for referral in case of a reactive self-test result but in no case should they disclose the result.

In case of reactive self test result, respondents expressed their opinion that the assistant should maintain contact with the client, repeat the HIVST, accompany them to the HCF, if possible, and provide ongoing psychological support until the client receives confirmatory information about their HIV status and begins ART treatment.

If the HIV test result is negative, respondents believe that the assistant should first provide affirmation to the client and note the importance of maintaining health and negative HIV status. Respondents indicated that social worker must advise on HIV prevention including PrEP, offer index and network testing, recommend coming back for repeated testing after six months, and maintain contact periodically, reminding the client about approaches to HIV prevention and recurrent testing.

Willingness to recommend Mylan test kit to friends

Respondents appreciated their experience with the Mylan HIVST kit. Despite the previously announced minor technical difficulties during the demonstration, respondents reported confidence in using the test kit by themselves and would recommend the kits to their friends since it is clear and easy to use.

Respondents noted the need to inform the population about the importance of HIV testing and distribution of this HIVST kit for free, including distribution at workplaces and HCF. Some respondents were proactive in recommending or sharing the Mylan HIVST kit with acquaintances and friends. Some respondents felt that incentives would help motivate individuals for HIV testing including ST kit use, and such incentives could be monetary or other.

The overall impression of respondents about the Mylan HIVST kit was positive, except for two participants who were uncomfortable with HIV testing in the presence of another person. Clients were willing to re-test and recommend it to friends.

A complete descriptive report on Stage 2 implementation of the demonstration project can be found in Annex 1: General Report on the Implementation of Stage 2 of the Demonstration Project.

Stage 3.

Distribution of Mylan HIV Self-Tests among regional partners (NGO) for targeted distribution to PWID, SW, MSM and other key and priority populations to enhance self-testing capabilities among customers and their communities

Mylan HIVST kits were distributed to regional partners (NGOs) to target key and vulnerable populations to whom HIV testing or index testing services or testing in social/risk networks are offered during Stage 3 of the demonstration project (July – October 2023).

This stage involved an enhanced approach to secondary distribution of Mylan HIVST kits by key and vulnerable population representatives among their sexual partners (distribution by clients with newly diagnosed HIV infection in index testing), as well as among social networks characterized by risk of HIV transmission. Representatives of key and priority populations were asked to recruit their partners and social network members and to promote self-testing with Mylan HIVST kits with social and psychological assistance (NGO-based) delivery system and medical (on the basis of specialized health care entities). In selected partner NGOs, social workers skilled in HIV-assisted testing and treatment linkages served as mentors for clients who agree to become recruiters.

Recruiters played a dual role of disseminating information about the availability and importance of HIV self-testing using Mylan HIVST kits to their social environment and assisting during the testing procedure for others who would agree to self-test.

Participating NGOs included:

- Charitable Organization 100% Life Zaporizhzhia (Zaporizhzhia Oblast)
- Chernihiv Branch of Charitable Organization All-Ukrainian Network of People Living with HIV/AIDS (Chernihiv Oblast)
- Charitable Organization 100% Life Network Dnipro (Dnipropetrovsk Oblast)
- Charitable Organization “Svitlo Nadii” (Light of Hope) (Poltava Oblast)
- Charitable Organization “Free Zone” (Cherkasy Oblast)

At the preparatory stage, the Project team developed a training module on the Mylan HIVST kit use for social workers of participating NGOs. The Project team created “recruiter packages,” which included The Mylan HIVST kit, instructions on the use of the kit, action motivational counseling scripts, feedback forms and reporting forms for HIVST kit issue, algorithms for interaction with a mentor, a shoulder bag for tests, and a notepad. To ensure effective communication between mentors from NGO social workers and recruiters, the project team developed “mentor packages” that included instructions for use and accompanying training materials on the use of Mylan HIVST kits for HIV self-testing, recruitment algorithms and rules, mentoring support algorithms, and primary accounting records. See tr.ee/b1ZPOEiRib.

Nine social workers acting as mentors recruited 33 recruits from key populations.

During the activity implementation, 1,965 HIVST (97.5% of the target of 2,015) were distributed, including 1,489 among PWID, 224 among MSM, 140 among SW, 81 among other populations at risk such as ex-prisoners, SW clients and female partners of MSM, and 31 sexual partners of PLHIV. Almost three fourths of test kit recipients (1,393) were male, with 572(29%) female. Of all recipients, 1,533 (78%) persons took HIVST kits for themselves and 432 (22%) for their sexual and/or injecting partners.

Six reactive HIVST results were obtained during the implementation of the project, three of which were confirmed and registered for medical supervision and started receiving ART. Reasons for the other three not being confirmed include:

- Despite the reactive HIVST result, all follow-up testing at the HCF was negative.
- communication with the client was interrupted due to client’s injection drug use and homelessness (work is underway to find the client through risk networks to begin treatment.)
- one client is not yet emotionally ready to consult a social worker to be brought to medical services.

Positive feedback was received about Mylan HIVST kits, including ease of use and mobility of testing and the possibility of performing the test in an environment convenient for the client. Respondents reported a higher level of confidence in blood based self-testing compared to oral self-testing.

Several challenges were reported:

- The step-by-step instructions did not reference treatment of the puncture site with an alcohol wipe, although it is included in the test kit;
- Some PWID participants had difficulties pricking their finger tip due to rougher skin associated with their drug use (searching for “stash points”). In this case, recruiters suggested replacing the HIVST kit or providing an additional blood lancet.
- One test kit may have been faulty; the blood tube could not fill completely due to a blockage.
- Some participants had excess bleeding at the puncture site, and they suggested to include additional gauze and an alcohol wipe.
- Although assistants were instructed not to touch the test kit or physical assist the client, in a few cases due to vision problems or physical disability, assistants needed to help. For these cases, it was suggested by the clients that including rubber gloves with the test kit might be useful.
- Four test results were invalid (no stripes on the HIVST kit). These HIVST were repeated.
- The Ukrainian language instructions are separate from the HIVST kit.
- The tube for blood sampling broke during one test.

A complete descriptive report on Stage 3 implementation of the demonstration project can be found in Annex 1: General Report on the Implementation of Stage 3 of the Demonstration Project.

General Conclusions and Recommendations

NGO clients responded positively to the new Mylan HIVST kit during the demonstration project and successfully followed the Ukrainian translation of the step-by-step instructions, although there is need to reinforce both reading the text and observing the photos. Participants of the qualitative part of the project noted the convenience and compactness of the Mylan HIVST kit and the possibility of using it in any premises where confidentiality can be ensured and where it is comfortable and convenient for all participants in the HIV testing process. Mylan HIVST kits, like other HIVST kits in Ukraine, only require confidentiality, access to KP, and well-trained social workers for those opting for assisted HIVST.

Clients were more open to and more confident with social workers and NGOs than health workers in HCF. Some clients expressed some degree of mistrust in HCF regarding confidentiality, while others perceived HIVST at HCF being more credible or official. Communication with assistants during ST was pleasant, contributing to clients' openness and calmness while waiting for results. At the same time, several clients experienced discomfort and inconvenience because of another person being present during testing. According to the clients, the assistant should be a person with knowledge of HIV and knowledge and experience working with the Mylan HIVST kit. At the same time, they did not care about the assistants' education. Non-disclosure of information, observance of anonymity and confidentiality requirements were the most important criteria of trust.

According to the findings of the demonstration project, the following recommendations are provided for the activities:

- **Organization of the HIVST process**

  1. When organizing the provision of assisted testing services if it is possible — to test clients in private in a separate room at the NGO after the assistant's instructions. In this case, clients who are uncomfortable doing ST in the presence of an assistant could feel comfortable being able to ask a question, if needed.
  2. Develop a step-by-step algorithm for repeated communication with clients who do self-testing. Provide for communication between the social worker and the client to clarify the success of ST and, if necessary, arrange an escort to a HCF.
  3. Develop restrictive policy recommendations concerning ST for persons who have a phobia of medical procedures using needles, fear of blood, perception of the test result, physical limitations for ST (absence of upper limbs, fingers) and poor eyesight.
  4. Adapting the Recruiter Package according to the available feedback when implementing the demonstration project.
  5. Providing recommendations for NGOs in the next project year on strengthening the mapping of recruiters' work in the regions.
  6. The use of depersonalized identifiers (for example, SYREX or CASE++) for the beneficiaries to organize the system of deduplication of services.

- **Learning**

  1. While implementing assisted HIVST using the Mylan HIVST kit, NGOs should ensure the training of social workers (assistants), considering the specifics of this HIVST kit.
  2. Pay attention to training and regularly upgrading the competencies of the assistant providing HIV counseling, testing, and support before starting ART. Training should include not only HIV knowledge, HIV testing, and

ART testing but also communication training, communication skills, and trusting relationships development.

3. Introduce a unified training system for recruiters using existing information and educational materials and/or those designed specifically for the area.
4. Introducing the mentoring support system for NGOs not involved in the distribution of Mylan HIVST kits, with the involvement of experienced social workers from the participating NGOs in the demonstration project through routine interactive meetings or other formats acceptable for participants.
5. Assistants and social workers should know the algorithm of action in case of reactive and non-reactive results or be able to provide medical assistance in case the client does not feel well during the testing process.

- **Using of MYLAN HIVST KIT**

1. Warning that the instruction manual in Ukrainian is separately added to the HIVST kit.
2. Add to the standard set of the HIVST kit another alcohol wipe for use in the "field," off-premise, at the mobile clinic, etc., where there is no access to additional wipes and water in case of excess blood.
3. If needed, indicate in the instructions whether the first drop of blood should be wiped away.
4. If possible, update items 3 and 4 of the instructions. Item 3 should read as follows: "Gently turn the green tip counterclockwise until you hear a distinctive sound, remove the green tip, then discard it." Item 4 should read as follows: "Firmly press the gray button to puncture your finger."
5. Make the text describing the image of the invalid result appropriate (repeated testing following an invalid result): "This is a preliminary test. Contact the health-care facility for further examination," and the text of the instruction "What to do if my result is invalid. The test will show no result if it is performed incorrectly. You will need to repeat the test using a new test device. If you are unsure if you have performed the test correctly, please speak to your doctor."
6. Publish the text of the instructions as follows:

   "Not suitable for people who are afraid of blood and finger puncturing using a needle."

   "The Mylan HIV Self-Test has also correctly identified 99.6% (904/908) of HIV positive samples in the laboratory setting (this is known as the test's sensitivity specificity)".

   The text of the description of Stage 8: "Place the test on the table. Now flip the blood tube into the well." (Stage 5: "Place the test on the instructions next to the result description." The instructions do not further specify that the test should be picked up).
7. Ensure additional marking of HIVST kits with information about their free use ("Not for sale," etc.) to avoid misuse of HIVST kits by clients and recruiters.
8. Add to the the step-by-step instructions step about treatment of the puncture site with an alcohol wipe.

- **Interaction with KP's**

1. The approach to HIV testing among KP is more likely to differ from that for the general population. Testing recruitment and options should consider the characteristics of the KP, their lifestyle, manners of communication, and priorities.

2. During the stage of attracting people for HIV testing, pay attention to the correct delivery of information to potential clients concerning the entire testing process, the way it is performed (in private, with an assistant, the possibility to come with a partner, etc.) to avoid misunderstandings and for better comfort of clients.
3. Involve representatives of communities in the dissemination of information about HIV testing using the Mylan HIVST kit. It needed, provide a system of remuneration and motivation for involvement for recruiters and recruits, if possible, depending on the KP characteristics.
4. Consider the possibility of distributing HIVST kits online through specialized social networks and marketplaces in the category FREE to expand the access of KP to HIVTS and avoid misuse of HIVST kits by clients and recruiters.

Annex 1.
General Report on the Implementation of Stage 2 of the Demonstration Project

EIPHP
EUROPEAN INSTITUTE OF PUBLIC HEALTH POLICY

REPORT

Based on the results of the demonstration project:

Community in action – an assessment of the feasibility and acceptability of Mylan HIV Self-Test to expand the possibilities for HIV self-testing among representatives of key populations and their partners in Ukraine

Kyiv

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Terms and abbreviations

Demonstration project	project testing and measuring the program's impact in real-time
Convenient sample	selecting respondents for the study, which consists in establishing contacts with all "convenient" sampling units that meet the criteria for inclusion in the study
Lay provider	any person performing functions related to the provision of health care who has the skills to provide specific services but does not have a formal qualification or university degree
Reactive (positive) test result	a serological test result when there is a reaction indicating the presence of an analyte, i.e., p24 HIV-1 antigen and/or antibodies to HIV-1/2 in the case of HIV
HIV self-testing (HIVST)	a procedure where a person takes a sample for analysis (perigingival fluid or blood), then performs an HIV test and deciphers the result; as a rule, it takes place in a private setting, and the testing can be conducted either alone or with someone whom the person trusts1
HIV self-testing with direct support (assisted HIV ST)	a situation when specially trained service providers or peer counselors visually demonstrate the procedure for conducting self-testing and interpreting its results to persons undergoing HIV self-testing before or during HIVST; such support is provided in addition to the instructions provided by the manufacturer and other materials included in the ST kit1
Sex workers (SW)	persons of both sexes who provide sexual services for remuneration
Men who have sex with men (MSM)	biological males who practice oral or anal sexual contacts with another biological male
Research Electronic Data Capture (REDCap)	electronic data management platform

1. Rationale

HIV self-testing (HIVST) has been implemented in Ukraine since 2019 using both unassisted and assisted options. Current legislation, including the Ministry of Health of Ukraine order No. 2092 "On Approval of the Standards of Medical Care "HIV Infection"" of 16.11.2022, the Ministry of Health of Ukraine order No. 1465 "On Amendments to the Standards of Medical Care "HIV Infection"" of 15.08.2023 and the Law of Ukraine "On Amendments to the Law of Ukraine "On Counteracting the Spread of Diseases Caused by the Human Immunodeficiency Virus (HIV) and Legal and Social Protection of People Living with HIV" permit HIVST, including unassisted options, as a screening tool. Until recently, only one kind of HIVST kit, the oral fluid OraQuick® HIV ½ Antibody Test used to detect antibodies to HIV 1 and HIV 2, was available in Ukraine. To expand the choice of HIVST kits that can be used by nonmedical professionals in Ukraine, the Community in Action will present the Mylan HIVST kit (a blood-based HIV test kit) as part of the demonstration project. The demonstration project will be based on the existing experience of identifying HIV cases by 1) expanding ST capabilities; 2) integrating with other testing methods (for example, index testing); 3) diversifying the distribution of HIVST kits through a network of partner non-governmental organizations (NGOs) and public organizations; and 4) improving the return of assisted ST results to facilitate referrals to prevention or treatment services. The USAID/PEPFAR funded Community Action for HIV Control Project (Project) implemented a demonstration project to explore the acceptability and feasibility of the Mylan kit for HIV screening among key populations (KP) and other priority populations in Ukraine with the aim of expanding different HIV testing options in the cities of Zaporizhzhia, Kyiv, Poltava, and Chernihiv.

2. Demonstration Project Description

"Assessing feasibility and acceptability of the Mylan HIVST kit for HIV self-testing to expand the opportunities for HIV self-testing among representatives of key populations and their partners in Ukraine" is the demonstration project based on mixed methodology using quantitative and qualitative components among KPs and their partners in the cities of Zaporizhzhia, Kyiv, Poltava, and Chernihiv.

3. Funding source

The "Community Action for HIV Control" project, implemented by Pact.Inc., FHI 360, and the "AIDS FOUNDATION EAST-WEST" ICF with the support of the US Government through the US Agency for International Development (USAID) within the framework of the U.S. President's Emergency Plan for AIDS Relief (PEPFAR)

4. Objective and tasks

The objective of the demonstration Project is to assess the feasibility and acceptability of the Mylan HIV self-HIVST kit to expand the possibilities for HIV self-testing among representatives of key population and their partners in Ukraine.

The objectives of this stage were as follows:

1. To determine the acceptability of assisted self-testing using the Mylan test kit — project data.
2. To assess the ability to understand and interpret the Mylan test kit's instructions — structured interviews with service recipients.
3. To find out the main issues at the stages of conducting and interpreting the results — monitoring of testing by service providers.
4. To determine user attitudes and preferences regarding assisted HIVST using the Mylan test kit — in-depth interviews among service recipients.
5. To determine the possibilities of HIVST implementation using the Mylan test kit — in-depth interviews with service providers and other NGO representatives.

5. Methodology

Project Design

Cross-sectional data collection with a combination of quantitative and qualitative methodology.

Stages

The demonstration Project consisted of three stages: I – preparatory, II – field, and III – analytical. At the first stage of the Community in Action project, preparatory measures have been made, including:

- developing and approving the activity concept.
- developing the project implementation plan.
- determining ways of recruiting participants.
- developing the data collection system.
- compiling a list of partners NGOs.
- staff recruiting.
- developing project protocol and tools.
- obtaining the protocol approval from the ethics commission.
- delivering HIVST kits to Ukraine.
- distributing HIVST kits among NGOs.
- printing materials.
- developing the REDCap online platform for collecting quantitative data.
- conducting training sessions for representatives of selected NGOs on the correct use of HIVST kits, data collection, quality control and reporting.

The following field activities were held at the second stage:

- involving project participants, obtaining oral informed consent to a structured interview, assisted ST, and possible participation in an in-depth interview among service recipients (n=240).
- collecting basic sociodemographic and behavioral information among service recipients.

- conducting the structured interview and assisted ST among participants.
- completing the checklist for convenient and correct use of the Mylan ST system.
- reimbursing for the time spent.
- collecting qualitative data by conducting in-depth interviews among selected service recipients (n=40).
- recruiting, obtaining verbal informed consent, obtaining qualitative data through in-depth interviews among service providers and other NGO employees, and paying remunerations (n=12).

The third stage involved data analysis, report, and presentation preparation.

Sampling and project geography

The project was implemented in four cities of Ukraine: Zaporizhzhia, Kyiv, Poltava, and Chernihiv, as well as in the surrounding areas (Table 1). These cities were chosen based on the existing experience of implementing ST projects and diversity in terms of the security situation. Two categories of participants were involved in the project: a convenient sample of ST service recipients (KP representatives and their sexual partners) (n=240) and convenient service provider sample and other NGO employees who arrange ST service provision (n=12). A sample size of 240 was suggested based on WHO recommendations concerning a minimum sample size of 200 people to assess the understanding of the manufacturer's instructions.[2]

Table 1. Sample size by methods and territory

	Zaporizhzhia	Kyiv	Poltava	Chernihiv	Total
Structured ST interviews and (service recipients)	60	60	60	60	240
In-depth interviews (service recipients)	10	10	10	10	40
In-depth interviews (service providers and NGO employees)	3	3	3	3	12

Service recipients

INCLUSION CRITERIA:

- Affiliation with KP and their partners:
  - PWID – the experience of injecting drugs at least once during the last 30 days before the project.
  - MSM – at least one oral or anal sexual contact with a man during the last 6 months.
  - SW – receiving money, goods or services in exchange for sex in the past 6 months.
  - KP partners – sexual relations with KP during the last six months (PWID sexual partners, commercial and non-commercial sexual partners of SW, women-sexual partners of MSM).
- 18 years and older.
- Unknown or negative HIV status (test result received more than one year ago).

- Permanent or temporary stay in the territory of project implementation (cities of Zaporizhzhia, Kyiv, Poltava, Chernihiv and nearby raions).
- Fluency in Ukrainian or Russian.
- Verbal informed consent.

EXCLUSION CRITERIA: participation in the project more than once; refusal to provide verbal informed consent; a state of alcohol or drug intoxication that does not allow conducting HIVST and answering the guide's questions, and the respondent's behavior may pose safety risks for themselves or team members.

Service Providers

HIVST project managers and trained employees without special education who conduct assisted ST at the NGO base and are involved in this project and provided oral informed consent.

Project Sites

Project sites for conducting assisted HIVST and in-depth interviews among service providers and recipients were selected according to the following criteria: NGO office, place of preventive service provision, in particular, ST; comfort (to ensure the confidentiality of information, convenience for the respondent and limiting the respondent's distractions). In total, there are ten sites belonging to four organizations that were included in the project (Table2).

Table 2. Project sites

No.	Official name of the organization	Site addresses
1.	Charitable Organization "100% Life. Kyiv Region"	City of Kyiv, 46A Holosiivskyi Ave.
2.	Charitable Organization "100% Life. Kyiv Region"	City of Kyiv, 26B Dniprovska Naberezhna Street
3.	Charitable Organization "100% Life. Kyiv Region"	City of Kyiv, 11B Yaroslavska Street, office 2
4.	Charitable Organization "Svitlo Nadii" (Light of Hope)	City of Poltava, 30 Heroiv Stalinhradu Street
5.	Charitable Organization "Svitlo Nadii" (Light of Hope)	Poltava Oblast, Kremenchuk, 12 Leonova Street, Apt. 44
6.	Charitable Organization "Svitlo Nadii" (Light of Hope)	Poltava Oblast, Myrhorod, 149 Hoholia St, Room 512
7.	Charitable Organization "100% Life. Chernihiv"	City of Chernihiv, 8 Kharkivska St
8.	Charitable Organization "100% Life. Chernihiv"	City of Chernihiv, 14 Kyivska St
9.	Charitable Organization "100% Life Network. Zaporizhzhia"	City of Zaporizhzhia 36A Peremohy St.
10.	Charitable Organization "100% Life Network. Zaporizhzhia"	City of Zaporizhzhia 28 Stalevariv St

Recruiting of Participants

Service recipients will be recruited by representatives of NGOs in contact with representatives of the above-mentioned target groups and clients of NGOs who have acquaintances meeting the criteria for inclusion in the project. NGO employees invited clients of the organization or non-clients who were invited to participate in the project indirectly through the client's acquaintances or social networks. There was focal contact with persons who have never been tested for HIV or who received a negative HIV test result more than one year ago. When clients were interested in participating in the demo project and if the criteria for inclusion were met, verbal informed consent was obtained, and project procedures were fulfilled. The coordinator of the in-depth component selected 40 participants among all the participants who took part in the quantitative part of the project (n=240) who agreed to take part in the qualitative component of the project, with 10 participants from Kyiv, Poltava, Chernihiv, Zaporizhzhia using the method of convenience.

Data Collection

The screening form, the socio-demographic and behavioral information collection form, as well as the structured interview form were programmed and completed electronically on the REDCap secure data collection platform. The screening form and the socio-demographic and behavioral information collection form were filled out by the NGO assistant prior to HIVST.

The structured interview form regarding the understanding of instructions was completed by the NGO assistant before the HIVST based on the participant's words.

The checklist for convenient and correct use of the Mylan HIV Self-Test kit was filled out by the assistant in the paper-based form during the participant's ST. Information from the paper-based form was transferred to REDCap's secure data collection platform after the work with the participant had been completed.

Questions of the interview guide for conducting in-depth interviews among service recipients were intended to determine attitudes and preferences regarding assisted HIVST using the Mylan HIVST kit. The interview guide was demonstrated with the first four respondents, after which some changes were made to its wording.

Questions of the interview guide for conducting semi-structured in-depth interviews of service providers determined the possibilities of ST using the Mylan HIVST kit, the benefits of delivery and the possibility of introducing NGO-based HIV testing services.

Semi-structured in-depth interviews were recorded using a digital voice recorder and transcribed into text.

Data Processing and Storage

The use of encoded participant IDs is dictated by the need to create and maintain the quality of a great number of unique records in the project database by preventing duplication and linking irrelevant data to the participant's record.

All electronic forms have been completed in real-time by NGO assistants and independent interviewers under the supervision of the project central office using REDCap's online data management platform with robust security and backup capabilities.

Data Analysis

Baseline sociodemographic quantitative data among service recipients and service providers, as well as behavioral quantitative data among service recipients, will be analyzed using descriptive statistics. The acceptability of HIVST will be defined as the percentage of persons recruited into the project out of the total number of persons who met the inclusion criteria.

Analysis of quantitative data from structured interviews concerning the understanding of instructions by service recipients involved using descriptive statistics for every HIVST stage and in general. Ten questions repeated the key information of each stage of the test according to the instructions for the HIVST kit. Participants who have answered all ten questions correctly will be considered to have fully understood the instructions.[3]

Quantitative data from the checklist for convenient and correct use of the Mylan HIVST system was analyzed using descriptive statistics for each stage of HIVST and in general. In particular, data on observed errors, difficulties and cases of assistance had been obtained.4 ST was considered successful if a control strip was present and a participant and observer received the result.[4]

Qualitative data obtained through semi-structured in-depth interviews were transcribed from digital audio recordings. Approximately 10% was coded by two researchers following the code system development and identified disagreements were discussed. The remaining transcripts were then coded. The attitudes and preferences of assisted ST recipients were determined by the thematic analysis of in-depth interview transcripts using the MAXQDA software designed to analyze qualitative and mixed data collection methods.[5]

The possibilities of implementing ST using the Mylan HIVST kit were determined by the thematic analysis of transcripts of semi-structured in-depth interviews with service providers and NGO employees using the MAXQDA software designed to analyze qualitative and mixed data collection methods.

Mylan HIVST kit

Mylan HIV Self-Test is pre-qualified by the WHO.6 Mylan HIV Self-Test is a single-use, immunochromatographic, rapid in-vitro diagnostic test for detecting antibodies to Human Immunodeficiency Virus Type 1 (HIV-1) and Type 2 (HIV-2) in whole blood.

The test consists of a paper test strip inside a plastic cartridge. The test is performed by dripping a small drop of blood on the test strip and then applying drops of test fluid (diluent). When the test is completed, two lines may appear on the paper strip. A visible Control Line indicates that the diluent was added and migrated successfully and that test reagents are functioning correctly. The Test Line will only become visible if the applied sample contains antibodies to HIV.

Manufacturer – Atomo Diagnostics Pty. Ltd. _ Level 2, 701–703 Parramatta Rd . Leichhardt , NSW, 2040 Australia atomodiagnostics.com.

Mylan HIV Self-Test is intended for use by untrained lay users in a private setting as a self-test to aid in the diagnosis of HIV-1 and HIV-2 infection based on samples of fresh, whole blood obtained through a finger puncture blood collection technique. The device requires a sample size of 10uL. The test result is qualitative (“your test is reaactive” or “your test is non-reactive”) and is not intended for screening blood donors.

6. Interviewer’s and respondent’s safety in terms of COVID-19 and hostilities

To prevent the spread of the coronavirus disease among project staff and participants, to ensure security due to the hostilities, as well as to create a safe and friendly atmosphere, in-depth interviews will be conducted face-to-face or online using communication channels convenient

for respondents (Zoom, Skype, Viber, etc.). In the event of danger associated with hostilities during an air raid alarm, the interview and all face-to-face field activities were interrupted and resumed after the air raid alarm was canceled, provided the interview could be conducted in a safe environment.

7. Arranging the project team training

The training with instructions was organized for NGO assistants participating in the ST and structured interviews, as well as for independent interviewers who conducted semi-structured in-depth interviews within the preparatory phase of the project. The training was conducted online.

8. Ethical Principles of the Project

The protocol and research tools were reviewed by the Ethics Committee (IRB) of the Charitable Organization “Ukrainian Institute on Public Health Policy”, conclusion No.09-23 of May 5, 2023. All project participants granted verbal informed consent prior to their participation in the project.

All project staff were trained in participant confidentiality protection procedures. To protect confidentiality, any paper or electronic forms did not contain names or other identifiable information and was linked only by a project identification number.

9. Data Use and Dissemination of Results

Project results will be disseminated by preparing and distributing an analytical report based on the results; holding a presentation for regional/national/international partners to discuss the obtained results.

10. Results

10.1. To determine the acceptability of assisted self-testing using the Mylan HIVST kit – project data

The field stage of the demonstration project lasted from July 24, 2023, to August 29, 2023.

There were two parts of Stage 2: assisted HIVST kit use among NGO clients and in-depth interviews with a subset of those who used the test kit. For the first part, trained social workers

held role of the assistant at this stage is to record how the client uses the test system, whether he or she follows the instructions and all the steps. Individual cases of assistance - physical features of the client.

Meeting the project goal, 240 individuals participated in the assisted Mylan HIVST kit use. (Table 9). These individuals were engaged through the NGO's risk network referral intervention, which elicits individuals at risk of HIV with unknown status from a PLHIV or at risk KP's social network. The average age of participants was 34.7±9.7. The youngest participant was 19 years old and the oldest one was 58 years old. Age groups of 18–24 and 25–34 were evenly represented, 54 (22.5%) and 57 (23.8%) respectively. The most represented age group was 35–44 (38.8%), and the least represented group was 45+ — 38 (15.0%) participants.

The overwhelming majority of participants resided permanently in the project territory — 224 (94.6%). Almost two-thirds reported that they had never been married — 154 (64.2%) and quite a large number were widowers and widows — 63 (26.3%). Almost half of the participants reported running a household on their own or with a cohabitant — 112 (46.7%). 196 (81.7%) of respondents reported complete general and a higher level of education. A fairly large number of participants had permanent jobs — 96 (40.0%), but the number of unemployed and those having odd jobs was also high — 31 (12.9%) and 77 (32.1%), respectively. Personal monthly income averaged UAH 12,429.

More than two-thirds of the participants were men — 187 (77.9%) people. Among 187 men, more than half had sex with men — 98 (52.4%). The majority of 89 (90.8%) had no other risk of HIV infection than sex with men. Forty-two (22.5%) had both injection drug use and sexual contact with users of injection drugs, and 34 (18.2%) solely injected drugs. Only one participant reported having sex with men and having injected drugs. Thus, the MSM and PWID were two main and substantially separated KPs among men

The participants mostly included people who reported one type of risky behavior — 148 (61.2%), but quite often, there were those who reported two or more types of risky behavior — 92 (38.3%). While most men reported one type of risky behavior — 128 (68.4% out of 187 men), most women, by contrast, had a combination of risky behaviors — 33 (62.3% out of 53 women). Among 187 men, more than half had sex with men — 98 (52.4%). Most of them had no other risks of HIV infection than sex with men — 89 (90.8% out of the total number of MSM or 47.6% of the total number of men) (Table 3). Representatives of the other largest category of men either injected drugs — 34 (18.2%), or, in addition to drug use, had sexual contacts with injecting drug users — 42 (22.5%) The total number was 76 persons (40.6% out of the total number of men). Other combinations of risky behaviors among men were less common. Only one participant reported having sex with men and having injected drugs. Thus, MSM and PWID were two main and substantially separated KPs among men.

Table 3 Combinations of risky behaviors among male participants (n=187)

N°	Injecting drugs at least once during the last 30 days before the project	Receiving money, goods or services in exchange for sex in the past 6 months	At least one oral or anal sexual contact with a man in the last 6 months	At least one sexual contact with PWID in the last 6 months	At least one sexual contact with SW in the last 6 months	The number of persons with relevant combinations	
						Absolute number	%
1.			X			89	47.6
2.	X			X		42	22.5
3.	X					34	18.2
4.	X			X	X	6	3.2

N°	Injecting drugs at least once during the last 30 days before the project	Receiving money, goods or services in exchange for sex in the past 6 months	At least one oral or anal sexual contact with a man in the last 6 months	At least one sexual contact with PWID in the last 6 months	At least one sexual contact with SW in the last 6 months	The number of persons with relevant combinations	
						Abso-lute number	%
5.					X	4	2.1
6.		X	X		X	2	1.1
7.		X	X			2	1.1
8.			X	X		2	1.1
9.			X		X	2	1.1
10.				X	X	1	1.1
11.	X	X	X	X	X	1	0.5
12.				X		1	0.5
13.	X	X		X		1	0.5

The distribution of risky behavior combinations among women was more wide than among men. Thus, five most common risky behavior combinations among women were: (1) injecting drug use + sexual contacts with PWID — 16 (30.2%); (2) paid sex + sexual contacts with PWID — 8 (15.1%); (3) sexual contacts with PWID — 8 (15.1%); (4) paid sex — 6 (11.3%); and (5) injecting drug use — 5 (9.4%) (Table 4).

Table 4 Combinations of risky behaviors among female participants (n=53)

	Injecting drugs at least once during the last 30 days before the project	Receiving money, goods or services in exchange for sex in the past 6 months	At least one sexual contact with PWID in the last 6 months	At least one sexual contact with SW in the last 6 months	At least one sexual contact with a man having sex with men	The number of persons with relevant combinations	
						Absolute number	%
1.	X		X			16	30.2
2.		X	X			8	15.1
3.			X			8	15.1
4.		X				6	11.3
5.	X					5	9.4
6.	X	X	X	X		2	3.8
7.	X	X	X			2	3.8
8.			X	X		2	3.8
9.		X	X	X	X	1	1.9
10.	X		X	X		1	1.9
11.	X			X		1	1.9
12.				X		1	1.9

One of the most important inclusion criteria was the unknown or negative HIV status of participants (the result was obtained more than a year ago). Most participants, 194 (80.8%), reported having a previous negative HIV test result (more than a year old), the majority of whom, 120 (61.9%), through HIVST. Forty-six (19.2%) of participants did not know their HIV status because they had never been tested for HIV.

Most participants, 194 (80.8%), were not NGO clients. Most of them, 153 (78.9%), reported knowing where to go for HIV testing and 135 (69.9%) were tested through HIVST. Conversely, among the 46 NGO clients, 41 (89.1%) reporting knowing where to go for HIV testing and 32 (82.6%) knew about HIVST kits.(Table 5).

Table 5 Awareness of participants about the availability of HIV testing and the existence of QT for HIVST in general and depending on the NGO client status.

		NGO client				Total	
		yes		no			
Know where to go for HIV testing	yes	41	89.1%	153	78.9%	194	80.8%
	no	5	10.9%	41	21.1%	46	19.2%
Know about rapid tests for HIV ST	yes	38	82.6%	135	69.6%	173	72.1%
	no	8	17.4%	59	30.4%	67	27.9%
Total		**46**	**100.0%**	**194**	**100.0%**	**240**	**100.0%**

10.2. Assess the ability to understand and interpret the instructions for using the Mylan HIVST kit – a structured interview among service recipients

Results of the structured interview on the ability to understand and interpret the ten stages of the instructions for using the Mylan HIVST kit showed that most of participants – 141 (58.8%) – answered all questions of the structured interview correctly and accordingly demonstrated understanding of these instructions.

As for the understanding of the individual stages, the overwhelming majority of respondents – 216 (90.0%) – understand the first stage of implementation correctly, in particular the impossibility of using the HIVST kit with an invalid expiration date (Table 10).

Almost all participants — 236 (98.3%) — reported on the need to massage the finger before puncturing it to stimulate blood circulation and obtain the necessary amount of blood in the second stage.

Most participants — 226 (94.2%) — also demonstrated an understanding of the need to turn the green tip and remove it for use in the third stage.

Most participants — 223 (92.9%) — correctly understood that the finger puncture in the fourth stage couldn`t be done several times with the same test.

Also, most of participants — 229 (95.4%) — correctly answered that after the finger puncture, it was necessary to place the test in the designated place on the instructions provided for in the fifth stage.

Almost all participants — 237 (98.8%) — noted the need to squeeze the finger, so that blood appeared after the puncture as part of the sixth stage.

Significantly fewer participants — 198 (82.5%) — realized that the test-tube could not be filled with blood only by half in the seventh stage.

The overwhelming majority of participants — 233 (97.1%) — understood that it was necessary to flip the test tube to get the blood into the well at the eighth stage.

230 (95.8%) participants showed understanding that more than one drop of solvent should be added in the well in the ninth stage (the instructions recommend adding four drops of the solvent).

In conclusion, the understanding of the last tenth stage regarding the interpretation of the negative (non-reactive) result when the C strip C appears, and the T strip is missing was shown by 230 (96.8%) participants.

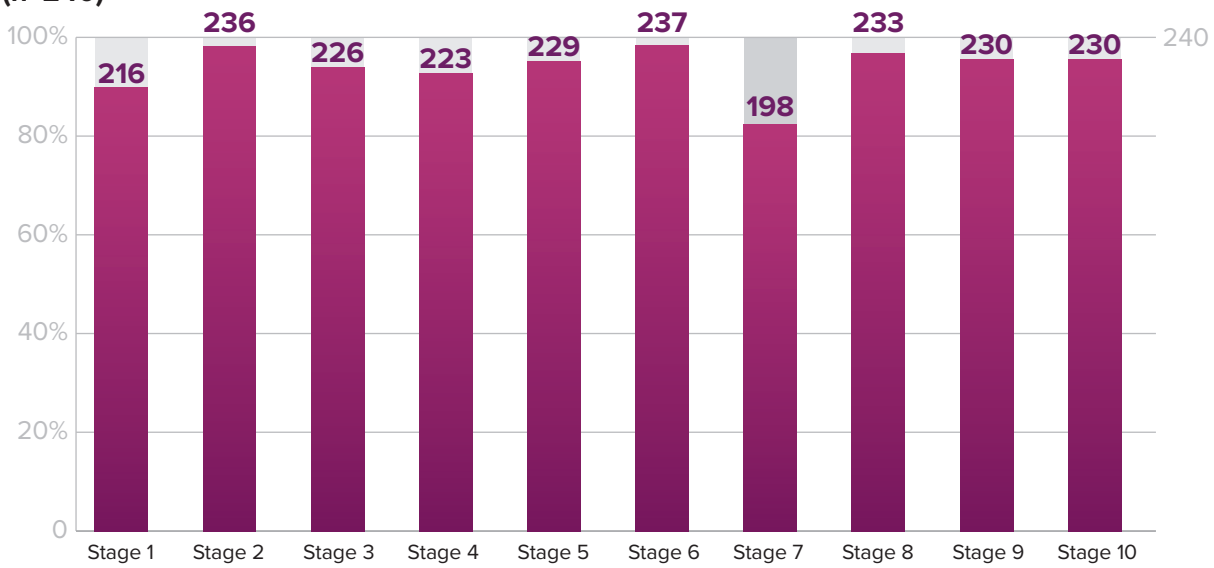
The lowest percentage of participants who understood individual stages of the instructions correctly (≤95%) was observed in stages 1, 3, 4, 7: 216 (90%), 226 (94.2%), 223 (92.9%) and 198 (82.5%), respectively (Figure 1). Thus, the survey question at Stage 1 was formulated as follows *"If a HIVST kit has expired, can this HIVST kit still be used for self-testing?"* The percentage of participants who answered incorrectly or indicated that they did not know about the expiration date of the HIVST kit amounted to 10%. In addition to the universal reason for not paying attention to the instructions, the possible reasons for a relatively high number of incorrect answers may be the lack of understanding of the link between the expiration date and the certainty of the test result, lack of understanding of the need to check the expiry date or check it personally, etc.

A wrong answer or ignorance of the answers to the question of the survey at Stage 3 *"Can the test be used only if the green tip is turned and removed?"* was given by 5.8% of participants, which may be due to a lack of understanding of the relationship between the performance of actions at this stage and the technical possibility of performing the next stage — the possibility of pressing the gray button to puncture the finger and obtain a blood sample only when the tip is removed.

7.1% of participants answered incorrectly or did not know the answer to the question *"Can the test puncture a finger several times?"* at Stage 4. This error may occur due to a lack of understanding of the HIVST kit's technical features – the possibility of only one-time operation of the automatic finger puncture system.

Finally, the largest percentage of participants did not know the answer or gave a wrong answer to a question at Stage 7 — 17.5% of participants gave a wrong answer to the question *"Do I need to fill the test tube with blood by half?"* A possible reason for many incorrect answers at this stage may be the misunderstanding of the link between adding the required blood volume (fully filled tube) and the reliability of the test result, as well as the ability to perform testing with insufficient blood volume.

Figure 1 The number and share of participants who understood the performance of individual ST stages correctly according to the instructions for using the Mylan test system (n=240)

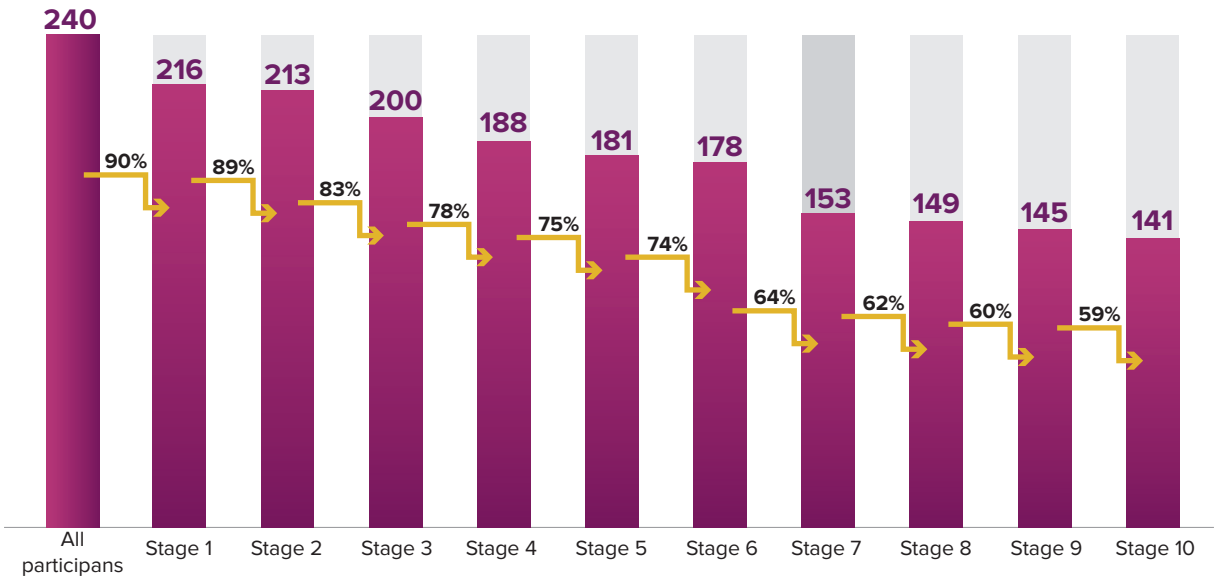


As noted above, participants answered survey questions incorrectly or noted that they did not know the answer 132 times. That is, 99 (41.3%) participants gave incorrect answers one or more times or noted that they did not know the answer (132 times in total). Among these 99 participants, there were the four largest groups, depending on gender and risk behavior (a total of 64 (64.6%)):

- men who inject drugs and have sex with injecting drug users — 25 (25.3% out of 99 participants);
- men who reported oral or anal sex with men — 16 (16.2%);
- men who inject drugs — 14 (14.1%);
- women who inject drugs — 9 (9.1%).

A cascade of participants who have correctly understood the performance of individual ST stages according to the instructions for using the Mylan HIVST kit is represented in Figure 2. As you may see from the cascade, the largest percentage-based reduction in the number of persons who understood the performance of individual stages correctly occurred in Stages 1, 3, 4, 7: (-10%), (-17%), (-22%) and (-36%) respectively. Considering all of this information, it may be said that incorrect or missing responses to the individual ST stages were preferably provided by different participants (at some stages, incorrect or missing answers were provided mainly by some participants, and at other stages by others).

Figure 2 A cascade of participants who have correctly understood the performance of individual ST stages according to the instructions for using the Mylan HIVST kit (n=240)



10.3. To find out the main issues at the stages of conducting and interpreting the results – monitoring of testing

ll 240 participants successfully performed HIVST, with 236 (98.3%) non-reactive or negative results and 4 (1.7%) reactive results. Test results reported by the participants and those recorded by the assistant matched in all cases. One negative result was obtained after repeated testing (the first test was invalid). Test results reported by the participant and those recorded by the assistant matched in all cases. The average HIVST duration was 24±6 minutes. At the end of ST, one participant reported feeling unwell and attributed it to the puncture of the finger and the blood. He subsequently felt better, no medical care was needed All four participants with reactive test results were referred to healthcare entities (HCF). 227 (96.2%) out of 236 participants who tested negative for HIV were referred to preventive care services.

Ten ST stages and 14 substages may be conditionally divided into those that make further ST possible, and those where failure or incomplete performance preserves the ability to perform the following stages. The stages/substages making the following stages possible are:

- **Stage 3 —** gently turn and remove the green tip, then discard it, because *further pressing of the gray button and puncturing the finger is impossible without it.*
- **Stage 4** — press the gray button and puncture the finger; *without pressing the gray button and puncturing the finger, the test tube cannot be filled with blood, pressing the button without puncturing the finger requires repeated testing using a new HIVST kit.*
- **Substage 1 of Stage 7** — fill the test tube with blood, *as without this further testing is impossible; if the test tube is filled with blood only partially, further testing is technically possible but the reliability of the result is reduced.*
- **Substage 2 of Stage 8** — *flip the tube with blood into the well; without this, further testing is impossible.*
- **Stage 9** — add 4 drops of solvent; without this, *further testing is impossible; if you add fewer or more drops, further testing is technically possible but the reliability of the result is reduced.*

The above-mentioned stages/substages were eventually completed by all participants (2 participants used two HIVST kits because after pressing the gray button at Stage 4, they failed to puncture the finger; one participant added 3 drops of solvent and the other one — 6 drops at Stage 9, in both cases the test worked as indicated by the appearance of a strip opposite the letter C). Other stages/substages were sometimes skipped by participants for the reasons that would be specified below. Results of ST observation are presented in Table 11, in particular: (1) performing each individual phase immediately or after receiving the response from the assistant, with notes/comments on the stage completion; (2) questions from participants at each individual stage; and (3) intervention (explanation, information, assistance, etc.) by the assistant during each individual stage.

STAGE 1.

Stage 1 of the ST involves three actions: (1) wash and dry hands; (2) wipe your finger with an alcohol wipe; (3) check the expiration date before opening the foil package. Every step of Stage 1 was performed by 200 (83.3%), 226 (94.2%) and 162 (67.5%) participants respectively. Only 147 (61.3%) participants completed all three steps of Stage 1 immediately or after receiving answers to the questions. Most participants did not check the expiration date of the HIVST kit. The most typical comments from participants were the following: a person said that they have already treated their hands with antiseptic; they have already washed their hands; the alcohol wipe would be needed later; the expiration date should be checked by the assistant during assisted ST. Five participants asked about the performance of the first stage: *Where is the information on the expiration date? (2) Can you puncture my finger? (1) Do you have a wipe? (1) How can I open it; do you have scissors? (1).* Assistants intervened (answered questions, provided explanations, helped, etc.) during the ST of 49 (20.4%) participants. The main interventions were: drawing attention to the instructions; a reminder to follow the sequence of actions; a reminder to wash and dry hands, use alcohol wipes, and check the expiration date; giving scissors.

STAGE 2.

Stage 2 involves finger massage for 5–10 seconds. This action was completed by the vast majority of participants immediately or after receiving answers to follow-up questions — 213 (88.8%). Two participants noted that they did not see any point in completing this step, as their blood could be drawn easily anyway. One participant asked the following questions: *"I wiped my finder with a wipe, then rubbed it, should I perhaps wipe it with the alcohol wipe again?" and*

"Which finger should I draw blood from?" Assistants interfered with the performance of Stage 2 by 12 (5%) participants. The following interventions were made: a reminder to massage the finger and a demonstration of which finger to draw blood from.

STAGE 3.

Stage 3 determines the possibility of further ST. At this stage, you should carefully turn and remove the green tip, then discard it. The overwhelming majority of participants did so immediately or after receiving answers to their questions — 223 (92.9%). Most comments concerning this stage were the following: it was easy; the tip could not be removed the first time (tried to remove the tip without turning it, did not understand which way to turn the tip); could not remove the tip myself; turned the tip carelessly; I was too careful, afraid to break the test. Quite a few participants — 26 (10.8%) — asked questions that mainly referred to the direction in which the tip should be turned and how to remove it. The assistant also interfered with the ST quite often — 34 (14.2%). The intervention mainly concerned the confirmation of the participant's steps; clarification and assistance in turning and removing the tip.

STAGE 4.

Press the gray button and puncture the finger at Stage 4. Almost all participants (238 (99.2%)) pressed the gray button and punctured the finger. Only two participants (0.8%) failed to puncture their fingers. These participants were re-tested using a new HIVST kit. Comments at this stage were the following: It took me long because I was afraid to puncture the finger; the instructions should indicate that the pressure is required until a distinctive sound is heard; I pressed the button not hard enough; at first, I did not really understand where to press. Quite a few participants asked about this stage — 30 (12.5%). The questions mainly concerned how and where to puncture the finger. Some participants did not feel anything following the button click and said, *"Nothing is happening" or "I did not feel anything, did it work?"* There were also questions about an extra wipe. The consultant interfered with the ST of 28 (11.7%) participants. The main interventions were: calming participants; prompting them where and how to puncture the finger; showing how to press the finger, suggesting to press hard; saying that it was necessary to press until the distinctive sound is heard, and then place the test on a table; confirming that puncture; giving another alcohol wipe.

STAGE 5.

At Stage 5, participants had to place the test on the instructions near the description of results, which was immediately made by 223 (92.9%) participants. Only one participant asked where to place the test. Another participant asked about the pipette (meaning the test tube to be filled with blood at the next stage). Interference with the ST process of 16 (6.7%) participants took place at this stage. Interventions mainly concerned reminders of where to place the test.

STAGE 6.

At Stage 6, according to instructions, the participant has to squeeze the finger firmly in front of the puncture site, so that blood comes out. This was done by 229 (95.4%) participants. The most frequent comments at this stage were the following: without compression, the blood was flowing intensively; the participant pressed the site with one finger, so the blood did not come out. 9 (3.8%) participants asked questions like *"Why doesn't the blood come out?", "How much blood should be drawn?", "Do you have an additional wipe?", "Is this blood enough?", "How to draw blood?"* (The last question formally refers to the next stage). The assistant helped 10 (4.2%) participants at this stage. Thus, the assistant advised on how to squeeze the finger to make blood flow; gave an additional wipe to one participant; reminded that the tube should be full and that the blood could be added to the tube if needed (this reminder was made in the context of answers to participants and formally refers to preparations for the next stage).

STAGE 7.

Stage 7 stipulates performing two steps: (1) fill the tube with blood; (2) if the blood tube is not full, squeeze the finger and add the necessary amount of blood. A total of 182 (75.8%) participants were able to fill the tube with blood at once, which is quite a low indicator compared to other stages. However, the remaining participants — 57 (98.3%) — subsequently added the required amount of blood, except for one. Thus, 239 (99.6%) participants ultimately filled the tube with blood. Most comments at this stage were the following: I failed to fill the tube on the first try; the blood flew slowly; there was little blood; it took a lot of time. At this stage, 19 (7.9%) participants asked the following questions: *"Where to add blood?"; "How to transfer the blood into the tube?"; "Should I add the blood directly into the well?"; "How much more blood should I add to the tube?"; "Can I approach my thumb several times to fill the tube?"; "Is the test tube full?"; "What to do to fill the test tube?"; "May I have an extra wipe?"* At this stage, the assistant intervened to help 23 (9.6%) participants. Interventions mainly concerned reminders to squeeze the finger and get a drop of blood; demonstrations of how to squeeze the finger and fill the tube; explanations of where, how and what amount of blood to add; confirming the tube is full; providing the wipe. One participant asked to keep the test on the table because he was missing two fingers on his right hand, and the third finger was injured, so it was inconvenient for him to do ST on his own.

STAGE 8.

Stage 8 consisted of two steps: (1) place the test on the table and (2) flip the tube of blood into the well. 234 (97.5%) participants coped with these steps immediately or after receiving answers to questions. Most comments were the following: I failed to do it the first time, either with the help or after the tip; I did not understand how and to what extent to flip the tube. 20 (8.3%) participants asked the following questions: *"How exactly should I flip the test tube?"; "Which way do I flip the test tube?"; "To what extent do I need to flip the test tube?"; "This way?"; "The participant flipped the test tube halfway and asked if it was done correctly?"; "Do you have an extra wipe?"; "Will the blood splash into my eyes?" Is the blood flowing? Did it coagulate? "How can I understand it?"; "Will the blood get into the well rather than outside it?"* Assistants intervened in the ST of 24 (10.0%) participants. The main interventions were the following: answering that the tube needed to be flipped all the way so that the blood would get into the test hole; giving the alcohol wipe; when the participant raised the test tube to flip it, he was stopped in order to flip the test tube correctly; prompting that it was necessary to flip the tube and the finger shouldn't cover the test tube when flipping, it was necessary to lower it until the blood flew into the well, and it was necessary to flip it more; explaining the mechanism and algorithm of adding blood and solvent.

STAGE 9.

Participants had to add four drops of solvent into the well at Stage 9. The overwhelming majority of participants added four drops of solvent into the well either immediately or after receiving the answers. One participant did not see well, so the assistant added the solvent into the well for them. One participant added three and the other six drops of solvent. Most comments were the following: added three drops; one drop fell past the well; did it after the reminder; asked assistant to help because the participant could not see well; added six drops of solvent. 7(2.9%) participants asked the following questions at this stage: *"Where should I add solvent?"; "How many drops should be added: 3 or 4?"; "Why should I add 4 drops?"* The assistant intervened in the ST of 12 (5.0%) participants. Most interventions were the following: reminding to add the solvent; prompting where and how many solvents drops to add; helping to add four solvent drops (the participant with poor eyesight); and suggesting that the solvent was better to keep perpendicular to the test.

STAGE 10.

The final ST stage involves the following: waiting for 15 minutes, then recording the result; not reading the result if more than 20 minutes passed. 239 (99.6%) participants immediately and correctly complied with this stage. One participant decided that 10 minutes was enough. 6 (2.5%) participants asked the following questions: *"Are the results reliable?"; "The stripe appeared opposite the letter C. Can I stop waiting?", "Why should I wait for 15 minutes if there is a strip opposite the letter C?"; "Should I take the test again in three months?", "How often should I take the test?".* Assistants only intervened to help 4 (1.7%) participants reminding them to record the time.

Therefore, the lowest level of ST (≤95%) immediately or even after receiving answers to their questions was recorded at Stages 1, 2, 3 and 5: 147 (61.3%), 213 (88.8%), 223 (92.9%) and 223 (92.9%), respectively (Figure 3). The lowest share of participants who correctly understood the instructions concerning individual stages (≤95%) was observed at Stages 1, 3, 4, 7: 216 (90%), 226 (94.2%), 223 (92.9%) and 198 (82.5%), respectively. That is, a poor level of understanding and ST performance at the same time was typical of Stage 1 — wash and dry your hands; wipe your finger with an alcohol wipe; check the expiration date before opening the foil package, and Stage 3 — gently turn and remove the green tip, then discard it.

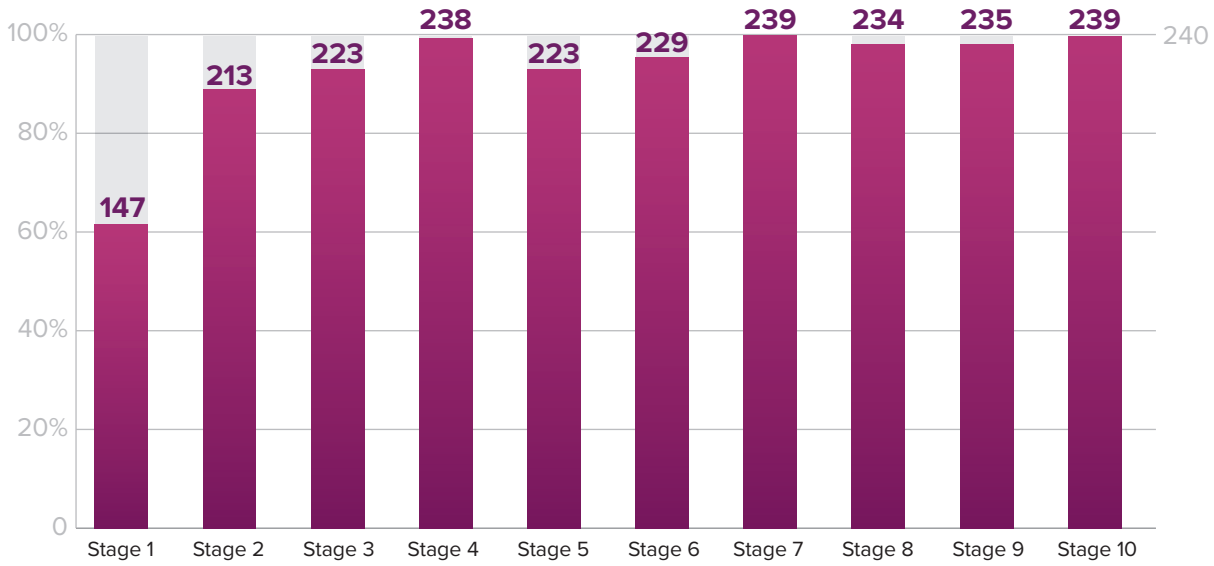
As for Stage 1, additional information had been received as to why participants did not follow the steps of this stage even when they understood them. First, some participants did not need to wash and dry their hands because they had done it before. Many more participants did not check the expiration date of the HIVST kit because they were sure that the assistant — the person providing the HIVST kit — should do it during assisted ST.

The poor level of understanding of Stage 3 steps and, indeed, the poor level of their performance was mainly related to the technical complexity of this stage. That is, they needed to turn the tip in the right direction and to a sufficient angle, then remove the tip after its correct turning. As already mentioned, a significant number of participants (26 (10.8%)) asked a question about performing these steps, and quite often, assistants interfered with ST at this stage — 34 (14.2%) participants.

Stages 2 and 5 were characterized by a poor level of performance but a high level of understanding of the instructions. Many participants massaged the finger for 5–10 minutes only after being reminded by the assistant, but some did not do this even after the reminder, explaining that the blood flow was good. Finally, at Stage 5, a significant number of participants did not immediately place a test on the instructions next to the result description. Yet, later, most did it after being reminded by the assistant.

Surprisingly, 58 (24.2%) participants failed to fill the test tube completely at first. As already mentioned, a smaller share of participants compared to the other stages — 198 (82.5%) understood that at Stage 7, the test-tube could not be filled with blood only halfway. But based on comments and interferences at this stage, participants failed to fill the test tube to the full at once. Eventually, all participants, except one, managed to fill the tube with blood.

Figure 3 The number and percentage of participants who have completed individual ST stages (first time or after answering questions) according to the instructions for using the Mylan HIVST kit (n=240)

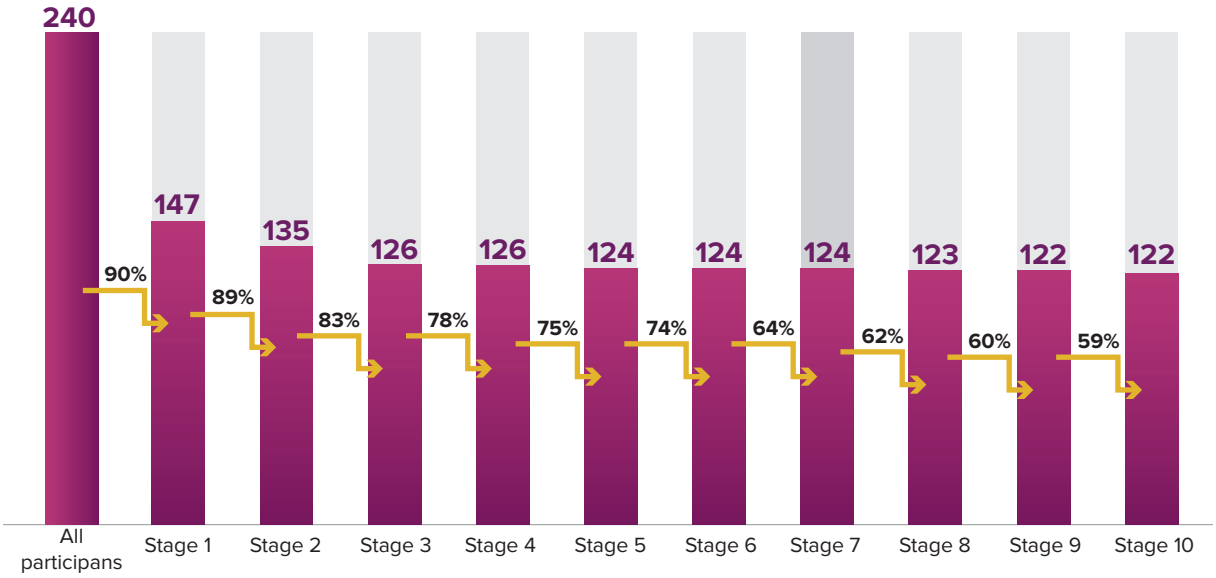


More than half of the participants (122 (51%)) completed all stages of ST immediately or after receiving answers to their questions (Figure 4). Oo\ut of 118 participants who did not complete all stages immediately or after receiving answers to their questions, the four largest groups, depending on gender and risk behavior (a total of 83 (70.3%)) were:

- men who reported oral or anal sex with men — 31 (26.3%);
- men who inject drugs and have sex with injecting drug users — 26 (22.0%);
- men who inject drugs — 17 (14.4%);
- women who inject drugs — 9 (7.6%).

As seen from the cascade, the largest decline in the share of persons who performed individual stages correctly was observed only at Stage 1 — (-39%). At subsequent stages, this decline was 0–3%. Thus, a certain group of participants who did not immediately follow the next steps was formed at Stage 1, and the remaining participants immediately completed all the stages.

Figure 4 A cascade of participants who have completed individual ST stages (the first time or after answering questions) according to the instructions for using the Mylan HIVST kit (n=240)



On the contrary, the cascade about the ability to understand the instructions, which was presented in the previous sections, demonstrates that different groups of respondents were wrong in understanding the different stages of the instructions, mostly these are stages 1, 3, 4, 7: (-10%), (-17%), (-22%) and (-36%), respectively. Thus, we can assume that participants differed in their characteristics in understanding individual steps of the instructions but were conditionally divided into two subgroups based on the ability or inability to immediately perform the individual steps of ST.

Finally, some participants showed both an understanding of all ST stages according to the instructions and fulfilled all ST stages (immediately or after receiving answers to their questions) — 94 of 240 (39.2%) (Table 6).

Table 6 A comparison of the number of participants who understood all ST stages according to the instructions correctly and performed all ST stages (immediately or after receiving answers to their questions) — 94 of 240 (39.2%)

Correct understanding of all ST stages	Completion of all ST stages				Total	
	yes		no			
yes	94	39.2%	47	19.6%	141	58.8%
no	28	11.7%	71	29.6%	99	41.3%
Total	**122**	**50.8%**	**118**	**49.2%**	**240**	**100.0%**

10.4. To determine user attitudes and preferences regarding assisted HIVST using the Mylan HIVST kit — in-depth interviews among service recipients.

From July 31 through August 24, 2023, experienced independent interviewers conducted 40 semi-structured qualitative surveys of participants. All 240 participants were informed of the option to participate in an in-depth interview about the Mylan HIVST experience. Of those who agreed, 40 were randomly selected by an independent review using their client codes and participated in semi-structured qualitative surveys administered by experienced independent interviewers from July 31 to August 24, 2023. This included 10 participants from each four cities (Kyiv, Poltava, Chernihiv, Zaporizhzhia). All interviews were conducted remotely using telephone or messenger calls. Two respondents had a one-minute technology-related interruption during the interview, while all others had no interruption. The average length of the interview was 25 minutes.

The survey respondents were aged between 19 and 58, and 31 were men and 9 were women. Thirty-one were not NGO clients (did not have a plastic card or were not in the NGO client registration system). All 40 survey participants received a negative test result more than a year ago, half through HIVST (21), of which 4 were NGO clients.

More than half of the respondents had basic higher or completed higher education (n=23), the rest had basic secondary or complete secondary education (n=16), and one participant had primary education. Less than half of the participants had a permanent job (n=18); the rest had odd jobs (n=7), had no jobs or were disabled (n=13); or students (n=2).

Table 7 Socio-demographic and other characteristics of interviewees among KP representatives (n=40)

Indicator	Absolute number
Age, years (min. — 19, max. — 58)	36.3
Sex	
male	31
female	9
Education	
primary education (incomplete 9th grade)	1
basic (incomplete) secondary education (full 9 grades)	2
complete general secondary (or vocational) education (11 grades, etc.), incomplete higher education	14
basic higher education (higher education institution of I-II levels of accreditation, vocational school)	7
complete higher education (bachelor's, specialist's, master's degree) (higher education institution of III-IV levels of accreditation), (university)	16
Primary occupation	
permanent job	18
odd jobs	6
unemployed	10
no other occupation except sex work	1
maintaining a household	1
disabled (person with a disability)	2
vocational school student	1
university student	1
Personal income (UAH) for the last 30 days	
UAH 0 to UAH 5,000	18
UAH 5,000 to UAH 10,000	9
UAH 10,000 to UAH 20,000	6
UAH 20,000 to UAH 30,000	2
above UAH 30,000	5
Marital status	
have never been married	21
married	6
divorced	11
widow/widower	2

Indicator	Absolute number
Cohabitation and maintaining a household	
with parents/relatives	7
with a female partner	5
with a male partner	9
alone (including with roommates in a shared dormitory room, in a rented apartment together with other lodgers, etc.)	16
with children	3
NGO client	
yes	9
no	31
Previous experience with HIVST	
yes	21
no	19

PROCESS ORGANIZATION AND GENERAL IMPRESSION OF ASSISTED HIV SELF-TESTING USING MYLAN TEST KITS

Involvement and motivation

Clients learned about the possibility of undergoing the HIVST from acquaintances or friends, NGO workers or social networks. Respondents were interested in learning about their HIV status free of charge and through a new approach. For some, the compensation for time and travel costs was the most motivating factor to participate. All participants were aware of the possibility of undergoing HIV testing in a medical facility or using an HIVST kit, but not all of them were aware that HIV testing was available at NGOs with the assistance of the social worker.

There is mistrust or reluctance on the part of some participants to test for HIV at the medical facility and testing outside the HCF (ST or assisted ST) is perceived by clients as the most comfortable way to obtain information about their health.

"I don't want anyone to manipulate my data, test results" (DEO2489M)

"If I do need to do it anyway, it is better to do it with a healthcare professional... it will be more reliable" (DOO0278M).

The activity was facilitated by NGOs, with social workers and clients helping to recruit participants. When respondents referred to NGOs to participate in testing, participants were given instructions on the use of the Mylan HIVST kit. There was an assistant (social worker) who could explain the details or adjust the steps of participants in the testing process, as needed. In general, respondents' attitudes towards assisted testing using the Mylan HIVST kit did not deteriorate after participation (i.e., as expected by the client) or changed for the better.

"I liked it, and the device is convenient. And there is no need to wait in lines. I did a check-up myself, and there is no need to run anywhere, shiver from fear, or wait for the test results for a long time." TOV0583F

Briefing

According to client respondents, the role of assistants was limited to providing verbal guidance; they were not permitted to touch or physically assist the client or test kit use. One respondent reported that the assistant had given very detailed information about the testing procedure, like how to use the test and where to drip the buffer. Some respondents noted that assistants had told them that the participant had to read the instructions and follow them rather than just watch the pictures.

Participants did everything themselves, sometimes receiving tips or adjustments. Some respondents noted that they had done everything themselves with their own hands, but used plural: "we got reviewed..., we disinfected the finger..." (MBS2598M), "we opened the instructions..." (VYU1902M).

"I was made to read all the instructions (laughing). And I never read the instructions, to be honest. They showed me what it looked like. Then I did it under his control." TGS1482M

"The instructions I was given... I read them and reviewed them. Everything was clear for me. It was clear, like for the first-grader. Well, the information is presented in a very good way. And the positive aspect is that there are helpful pictures, too." YKO1987M

General impression

Respondents noted good communication with the assistants, who helped when needed, comforted clients in the process of waiting for results, and advised on the results of directly assisted self-testing. Most reported that it was good to have someone around who knew how to do the right thing and could guide, prompt and advise. Some noted that the presence of assistants was necessary only for the first time to explain the algorithm and instructions, and they felt being able to re-do such self-testing on their own for the second time. Others reported the assistance unnecessary. Some shared their excitement about using the Mylan kit for the first time. Some respondents were anxious about making a mistake or doing something wrong and worried about the test results. Having received such first experience, the prevailing opinion among clients was that the the presence of assistants was necessary only for the first time to explain the algorithm and instructions, and they felt being able to re-do such testing on their own for the second time.

"I was sure I'd have a negative result, but still, that 15-minute waiting time... She didn't let me get nervous, she distracted me, she talked to me." INF1987F

"Every time you sit there, your heart... jumps up and down. Because you don't know... How to get on with life? I have no idea. Scary." VLD0102M

Two respondents were uncomfortable and expressed their negative attitude to the presence of a stranger during the testing process.

"To be honest, I wanted to stop a few times because it bothered me, I didn't expect to do it myself... It was difficult that the social worker was there ... or any other person, I was embarrassed." ARN0681M

Respondents generally liked testing with the Mylan HIVST kit because it was easy, fast, and convenient, and they did not have to wait in lines. However, some respondents needed a lot of help; not everyone was ready to read the instructions and tried to understand the sequence and content of actions from the pictures. The presence of assistants who, if necessary, accompanied the whole process in more detail was a positive factor for many.

"Because you don't have to go to the hospital, you don't have to waste time, and it's just really convenient. Because going to the hospital, I mean lines, plus... you have to wait until the test is done, they do not show the result right away, and here, you see it in 15 minutes. There, they ask to come the next day, and there's a line there". DEO2489M

Clients still had hesitation regarding HIVST. There were opinions that the test was difficult and unclear, and there was no one to help. In contrast, some reported that they would have preferred to do the HIVST at home on a convenient day and time rather than waste time planning and traveling to an NGO or HCF for that purpose. "Hence, the advantage is independence from any person" (MBI0696M). Some other observations were that some clients did not comply with the instructions which invalidated the testing, did not independently interpret the result correctly and some with reactive test results were not clear on next steps.

PARTICIPANTS' PERCEPTION OF THEIR ABILITY TO USE THE MYLAN TEST KIT

Ease of use

Most respondents (n=39) noted their interest in the Mylan HIVST kit and its ease of use. Compared to other HIV blood testing with which they had previous experience, clients liked the configuration of the HIVST kit with the presence of all necessary components (lancet, blood collection tool, reservoir for blood analysis with buffer) and all attached in one unit. All the details were thought out, which allowed clients to use this HIVST kit in almost any premises or places that were comfortable for the client.

"I liked the fact that the applicator is located immediately in the tester itself — this is the first aspect. Second, you need to add a drop into a separate cell rather than dripping like before — until you manage to make this drop fit in the hole. It is very convenient." MGY1777M

The finger puncture was almost imperceptible for respondetns, with one respondent reporting not feeling it. Several preferred the oral fluid test because it did not require finger puncture. There were several opinions about more confidence in blood-based HIV testing.

"The puncture was hardly there... we had blood drawn by puncturing the finger, and it hurt more this one. It's nothing. Everything is just perfect. Perfect test." OLM1781F

Some usage issues. Noting the ease and comprehensibility of using the Mylan HIVST kit, some respondents openly reported some technical subtle differences they did not understand (n=15). Despite the fact that respondents noted that they were willing to be fully self-tested with the Mylan HIVST kit, some clients felt being able to act as assistants for their acquaintances and close people, but experience using the HIVST kit for the first time showed that even the simplest HIVST kit needed some getting used to it and being understood. The presence of the assistant in this process reduces the number of errors and incorrectly used tests. Just one respondent considered that the whole mechanism of this HIVST kit only complicated the testing process.

"This mechanism with blood - you're filling, flipping it, whatever... what for? I think it's a complication, not a simplification". YKO1987M

Respondents had technical difficulties with the lancet button (how hard and up to what point to press), the blood tube and manipulating the blood drop; some participants did not immediately understand that they needed to open the lancet on one side of the kit; some were not accustomed to reading the instructions; therefore, the ST was somewhat for them unusual and required additional effort.

"It didn't work at first... I pressed, and the needle did not puncture the finger. Perhaps... I did not press my fingers hard enough. And then it was replaced, and the next time, I succeeded. At once." DEO2486M

"To flip this little green tube... It took me a long time to figure out what to do with it." TOV0583F

"And (laughing) I don't see the applicator with a needle when it's inside. It was the most difficult" TLB3188M

FEARS ABOUT THE TESTING PROCESS AND APPLYING FOR THE SERVICE OF ASSISTED SELF-TESTING FOR HIV USING MYLAN TEST KITS

Respondents shared their anxieties and fears about seeking testing, finding out the test result, privacy risks, and the myths, misconceptions, and stigma about HIV testing among their communities. Some clients called the fear of knowing the test result (n=10) as a potential reason why people around respondents were not tested for HIV. The second type of fear by frequency was the fear of puncturing the finger (n=7), which could be partly due to fear of blood (n=1) or general fear of injections (n=1). In addition to the fears mentioned above, the following ones were also discussed: the fear of leaking information by acquaintances who could potentially see the client near specialized HCFs or in places of HIV testing (n=6), the fear of privacy loss (n=3) mainly in the HCF or lab, but also the fear of being tested with the assistant at the NGO because of the potential loss of privacy (n=1); the fear of not knowing about HIV in time (n=2); and vice versa, the topic of HIV being taboo (n=2); fear of something new, which had not been done before (n=1), and a psychological trauma (n=1).

"For it [about HCF] to be called differently, so that it did not have this name". OMO0374M

"To puncture your finger, this part is a little terrifying. Blood is flowing. Ah! This is my finger." DOO0278M

MYLAN ASSISTED TESTING APPROACH FOR DIFFERENT KP'S

Trusting the assistant. According to respondents, the assistant should be a person with knowledge of the rules and techniques of the HIVST kit use, have the relevant experience, be able to provide psychological support, strictly observe the rules of confidentiality and non-disclosure of results, have knowledge of where to go in case of HIV reactive test, or correctly provide information about safe behavior and harm reduction. The preference for type of professional to assist with HIV testing differed, with some trusting medical professionals and considering their opinion authoritative and others preferring social workers, persons from their KP (peer-to-peer) and relatives to prevent any disclosure, "in case HIV is found" (NAP1665F).

"And if that is a healthcare professional, this should be a person I know or someone I heard positive feedback about, and who did not buy their diploma in exchange for... lard." INF1987F

"I always refer to different centers... specifically to social workers because the atmosphere there is so friendly and unobtrusive. That is nothing like the hospital, where you feel nervous..." MLV0504M

Some respondents were indifferent and would accept either medical professional or social workers in this role.

"I don't think it makes any difference. That is, if the person is open to this job, and they see the sense in it, then I think a social worker will be fine for helping, and a healthcare professional will communicate the information adequately". MVI0696M

Difference in approaches. Clients' views on whether to apply different approaches to assisted HIV testing using the Mylan HIVST kit varied. Some respondents pointed out that dividing people

into groups, like “consumers of psychoactive substances,” “men having sex with men,” etc., either by age or sex, was not acceptable and was similar to the division of society into “upper class,” “lower class” in contrast to the opinion of service providers’ views about approaches to assisted testing.

> ***“Everybody has the same blood. And it is drawn from the same place (laughing). The same way. So... there is nothing. As for having separate rooms for blood draws, everyone should be well aware of how these diseases are transmitted and that there is no risk for other people if high-risk individuals or ordinary people enter those rooms.” TLB3188M***

> ***“Because the population that takes the tests is roughly the same. Any person won’t just come in to do a blood test because they think they are ok.” TOV0583F***

Other respondents noted the personalized nature of this approach, taking into account the peculiarities of their age and lifestyle. At the same time, clients emphasized the importance of anonymity and confidentiality.

The stigma is also worth mentioning here (e.g., seeking health care in another city; avoiding communication with certain KP) or, at times, the stigma that discriminates against certain KP or KPs among themselves.

> ***“Of course, all people have equal rights. But when I test myself, I want to be with people like me. An employed person has an average income. They are self-sufficient, etc.” TGS1482M***

> ***“Actually, the testing should take place in a separate facility with bars, the glass is needed too. This is to prevent the client from leaving in case of a positive result and treating them forcibly.” ANI1285M***

Client perceptions of how HIV testing should be provided varied. Some respondents believed that the HIV testing service should be separate. Other respondents believed it should be combined, for example, with testing for viral hepatitis C and sexually transmitted infections. At the same time, another part was sure that it should be provided as an option as part of the “package” of services, e.g., in the framework of baseline medical examination and, preferably, it should not be a priority service.

> ***“There’s still this stigmatization of HIV. That’s why, perhaps, I do support the fact that a separate service should be provided. It may be included in the package of other services, but if the person requests to do it separately, well, it is necessary to do it separately.” TLB3188M***

FURTHER SUPPORT AFTER SELF-TESTING USING THE MYLAN TEST KIT

Respondents agreed that social workers should have information about the HCF or a doctor for referral in case of a reactive self-test result but in no case should they disclose the result.

In case of reactive self-test result, respondents expect that the assistant should maintain contact with the client, repeat the HIVST, accompany them to the HCF, if possible, and provide ongoing psychological support until the client receives confirmatory information about their HIV status and begins ART treatment and.

If the HIV test result is negative, respondents believe that the assistant should first provide affirmation to the client and note the importance of maintaining health and negative HIV status. Respondents indicated that social worker must advise on HIV prevention including PrEP, offer index and network testing, recommend coming back for repeated testing after six months, and maintain contact periodically, reminding the client about approaches to HIV prevention and recurrent testing.

WILLINGNESS TO RECOMMEND MYLAN TEST KIT TO FRIENDS

Respondents appreciated their experience with the Mylan HIVST kit. Despite the previously announced minor technical difficulties during the demonstration, respondents reported confidence in using the test kit by themselves and would recommend the kits to their friends since it is clear and easy to use.

Clients of the involved KP in this project consider it appropriate to use the Mylan HIVST kit in their community since it is clear, easy to use and has a full set of necessary components in one system.

Regarding the assistant's support, several clients noted that it would not be convenient for everyone to meet with the assistant because of different work schedules and jobs. Therefore, it would be more convenient for such people to perform ST — a personalized approach.

> ***"Possibly, but I'd still advise seeing a doctor because that's... Well, I would definitely see a doctor because there are some doubts because it's a device, maybe there's something wrong. This is not because I do not have trust..." ARN0681M***

> ***"I repeat once again, it's simple and easy. No further concerns, no worries, or extra time... I went to NGO, requested or asked if I could get tested, or if I could get tested or self-tested, and I was handed this test, and you can do it anytime. After work, before work, during lunch... and get the result. It's simple and easy." PGA0186M***

Some participants had a proactive stance and actively involved their acquaintances and friends in testing using the Mylan HIVST kit. The motivation to come to HIV testing for some respondents was the financial component, and they supported the view that involving KP in testing was the most productive through financial or other material motivation, for example, "If you bring a friend along, you can get a chocolate or some kit..." (ITG1789F), creative approaches with encouragement — "Test for HIV and get a certificate." This certificate could be exchanged for a cup of coffee in a coffee shop... it's very, very popular. They can make some 50 cups of coffee every day for free in exchange for these certificates. (MLV0504M).

In general, the authoritative opinion about HIV testing, especially in the context of reducing stigma and discrimination on HIV infection among participants, could be provided by "peer-to-peer" consultants, for others these could be doctors or influential, or the media to add "more authority" (VSO2995M) to the message, well-known physicians, representatives of the Ministry of Health of Ukraine, relevant posts on social networks. There was one view about the need to work more on debunking myths, which would help change thinking and perceptions of HIV.

The variability of opinions about approaches to the organization of testing, fears and phobias gives the understanding of the variability of approaches to be applied to attracting clients without excluding one another. Due to some technical difficulties experienced by clients, more attention should be paid to the characteristics of its application in non-assisted ST, as well as to the possible response to the reactive test result.

The overall impression of respondents about the Mylan HIVST kit was reactive, except for two participants who were uncomfortable with HIV testing in the presence of another person. Clients were willing to re-test and recommend it to friends.

10.5. To determine the possibilities of HIVST using the Mylan HIVST kit — in-depth interviews with service providers and other NGO representatives.

From August 19 to August 24, 2023, experienced independent interviewers conducted 12 semi-structured qualitative surveys with providers of assisted HIVST using Mylan HIVST kits: 3 employees from each NGO (1 manager, 2 service providers) from Kyiv, Poltava, Chernihiv,

Zaporizhzhia — all who were involved in the project and agreed to participate in the qualitative component of the project. Most interviews were conducted remotely (n=11) via telephone or Internet, and 1 interview was conducted in person. There were no breaks during remote interviews. The average length of the interview was 30 minutes (Table 8). The work experience of most respondent service providers at these NGOs (n=10) was more than one year, two respondents had experience of 1 year or less. The age of respondents ranged from 20 to 52 of them 4 were men and 8 were women.

Table 8 Socio-demographic and other characteristics of interviewees among service providers of assisted ST and other NGO employees (n=12)

Indicator	Quantity
Age, years (min. — 20, max. — 52)	37.9
male	4
female	8
Position at the NGO	
ST service provider	8
manager	4
Work experience, years	
1 year or less	2
1 to 5 years	3
5 to 10 years	4
10 to 20 years	3

Assisted ST services using the Mylan HIVST kit were delivered as part of this project at NGOs by employees of these organizations. Respondents demonstrated awareness of the variety of HIV testing options and testing approaches and their accessibility to clients.

TESTING AT NGOs AND HEALTHCARE ENTITIES — ADVANTAGES AND DISADVANTAGES

NGO-based testing is relevant according to respondents, as it is a low threshold, client-oriented, convenient, accessible and comfortable service for clients. It is important to maintain the confidentiality of information received from clients who are tested or engaged in other NGO services, thus allowing for reaching clients from hard-to-reach or closed groups.

NGOs, with a focus on HIV testing and referring clients to ART, implement different approaches to client engagement and HIV testing, which is an advantage over HCF. At the same time, when visiting a non-specialized healthcare facility, HIV testing is offered either rarely or not offered at all.

> ***"We are focused on HIV, and for them, the [e.g., public health facilities] HIV is part of the mechanism. They don't put that kind of emphasis on HIV, so I think that... they're looking at it just the other way." OUS3194M***

> ***"Our outreach routes aren't written in the way that we go around the same field and gather these people... We know exactly that we're going to a certain area, we have a pickup point, and we're installing a testing tent there to keep it confidential... We always write down all routes and try to motivate people to self-testing." LLO2879F***

"Healthcare professionals who are currently assigned this function, especially family doctors, fail to do it and do not offer HIV testing or offer it rarely. Speaking about Kyiv, the situation is quite normal, while in Kyiv Oblast, none of the healthcare professionals test for HIV infection, and family doctors do not offer this service". OLM1781F.

The next advantage of NGO-based testing is flexibility. Flexibility in the hours and week days when the social worker is available, as well as territorial flexibility. Respondents note that they are willing to arrange meetings with clients in a place convenient for them and ready to adjust for the client's convenience, only to have the meeting take place.

"The NGO may hold meetings both on its own and on someone else's premises. It can be performed in mobile testing points or at the client's home... it is convenient to bring the service closer to a person. The counselor may also give advice and bring the client to the healthcare entity, which registers HIV-positive people for further diagnostics, if tested positive, and help the client get treatment. Also, representatives may provide psychological support, refer to care and support programs, and generally help a person find additional resources, help them to get access to additional resources that they need." ALV0877F.

"We have relevant websites, any person may leave a request even at 3 in the morning. This person will be contacted in the morning, and they will answer if they agree to be tested, whereafter they may be immediately sending test kit for them." MNO1997M

Obtaining services at the HCF for some clients looks more ***"serious and scary" [VNI2498F].*** Providers point out an important fact that was observed during the work with clients — the trust in the social worker. Having a positive impression of communicating with social workers when receiving NGO-based services (including HIV testing), clients are more eager to involve their acquaintances in such services and ask for tests for their partners.

"Certainly, key groups are unlikely to go to health care entities because... they feel... discrimination, stigma there..". YNM2483F

"The advantage is that we get into these groups were. For example, the doctor will not come to a place with a bunch of drug addicts using one syringe and so on... And I can access this group, I can come, and I'm pretty sure I'll be safe. Doctors will not do that — it's the advantage." LLO2879F

Some motivational bonuses that NGOs can provide, but HCF cannot, may be important for KP clients. For example, free condoms and lubricants, payment for or of transport services for the client to compensate for their travel to the HCF, food certificates, distribution of food kits, raising awareness about the client's health, and accompanying to ART, etc.

Thus, the role of NGOs is invaluable in engaging clients in HIV testing and following up if they test reactive for HIV or in raising the awareness of clients when they test negative for HIV.

Both HCF- and NGO-based services may have human (low competence; low tolerance towards KP among health-care providers) and organizational factors that may serve as disadvantages when receiving the services at the HCF or NGO (availability of tests, improper storage of tests, incorrect working schedules, lack of separate rooms, etc.). The benefits of NGO-based confidential HIV testing are sometimes lost because of the requirements of certain projects. The service provider notes:

"If you do a "DataCheck", it's not very convenient for NGOs like us. We work with the PACT project, which is not very convenient because the person who comes does not know the result, but the first thing you need to do is fill out their first name, last name, and phone number to enter them into the database. Not every person is willing to give correct information. I mean, it's more of a...paperwork thing, it's not very thought-through. For example, there are some questions in the PACT project about sexual relations and risky relationships... when a person does not know anything and is not yet ready to tell anything, they are asked to tell some intimate details about their life to a stranger." ILI0377F

The work of NGOs on detecting and confirming HIV is somewhat limited by law compared to HCF. Therefore, some clients are limited in their ability to get tested for HIV at the NGO using blood tests. This is because, in the absence of a healthcare professional, blood tests are not allowed to be done at the NGO, so these clients have to contact HCF or get tested using oral tests, if available. In addition, with a reactive result, clients must refer to the HCF to confirm the diagnosis, which is a weak spot in the whole cascade in terms of leading clients to treatment.

"First, a non-governmental organization and its social worker are not allowed to test the client directly if the social worker does not have a degree in medicine, that is, the client must use self-testing or assisted testing. Clients are sometimes afraid of puncturing their finger, so these inconveniences may occur. Certainly, it is most convenient for these clients to use the oral test, which does not require puncturing the finger.

Speaking about healthcare entities, their disadvantage is that the risk group, which is the most affected by HIV, probably attends healthcare entities rarely, and they do not have access to this group." OLM1781F

CONDUCTING HIV TESTING USING NGO RESOURCES

HIV testing service providers who have participated in the qualitative part of the project generally agree that HIV testing may be conducted at a place where there is a social worker, a room and confidentiality. Several respondents noted that ST at home, although has some advantages for the client, also features shortcomings in case of a reactive result since the person's reaction may be unpredictable and, therefore, the presence of an assistant is still desirable during testing.

"At a mobile clinic and, of course, somewhere with social workers or psychologists. No matter what happens, we don't want the client to come home, in case of positive test result, and shrink into themselves, not knowing what to do because of panic and hysteria in case of a positive result. And there, people will explain what to do next and subsequent steps". VLH1171F

"My imagination about this test machine is great because they can get them anytime. So... they had my contact information, as a social worker, they had my cell phone number they could use to contact me and discuss it." VNI2498F

The arrangement of assisted testing using Mylan HIVST kits, according to the providers, can also be a flexible process, which ensures confidentiality. That is, it does not necessarily need to take place at the NGO. Providers admitted the possibility of testing both at the NGO office, in a separate room, and at the client's home, as well as at the mobile clinic. It is worth noting that clients were of the same opinion.

"If it is assisted self-testing using Mylan tests at the office, it should be anonymous, confidential and again — the person should feel safe, in any case Thus, when the person comes, they should realize that their identity, last name, first name, patronymic, and personal data will never be revealed. Coding is a code, that is, we make it with assisted self-testing using Mylan HIVST kits." OVO0903M

Assisted HIV testing services, according to providers, should be included in the overall scope of services the organization can provide. Some providers noted that HIV testing should not be part of basic service, but rather belong to other services, explaining this opinion by the existence of stereotypes about the "plague of the 20th century," fears, and stigma. Clients had different opinions on this – separately from other services and together with other services, but not as the top service.

As for the time of day, approaches to the involvement in the services for different groups and clients should be different because their hours of activity and work may differ and their situations vary, that is, it should be as flexible and client oriented as possible.

> ***"Basically, the same with other preventive services... it depends on the category and the key population. If these are people who inject drugs — we need syringes and alcohol wipes; if these are MSM or SW — then condoms, and lubricants; that is, depending on the key population". VNI2498F***

> ***"Thanks to such additional options we have more opportunities as the organization to reach such people when, besides testing, we have a choice of certain other services. A person should have an additional choice. Sometimes a person who comes for one service hears about the opportunity to test and may think, "Why not." Sometimes, these people have never been tested, or they were tested a long time ago, and then we have either a positive reactive test result, or the person agrees to additional services in the form of PrEP and so on." MNO1997M***

Service providers and customers hold the view that special conditions are not required for the introduction of assisted testing using the Mylan HIVST kit, as the HIVST kit is thought out in detail. Thus, providers consider that NGOs where they work are ready for such work in the future. Availability of trained staff, tests, space and access to target groups are the main factors for NGOs to introduce assisted testing using the Mylan HIVST kit.

Acceptability of the Mylan HIVST kit use in assisted testing

All respondents noted the acceptability of using the Mylan HIVST kit for assisted testing for both KP and other populations. According to providers, any person who has completed the training or tested themselves using this HIVST kit may serve as an assistant. Participants expressed the same opinion. Respondents believe that the client who got tested using the Mylan HIVST kit with the help of an assistant may serve as an assistant for their partner.

> ***"There is no barrier here. This can be any person with relevant or related education, a social worker, a doctor, possibly a psychologist, or the one who can give necessary advice on the test result. That is, a person should have relevant experience, expertise or education and be able to handle it." MNO1997M***

> ***"I think that a social worker or a person who has already been tested with the help of the social worker could see how the procedure takes place and realize that it is not scary and is convenient, that it is fast especially using the instructions. We already had a lot of such people when they were tested. I'm talking about me, let's say. They were tested with me, and everything was clear, so they could take tests for their partner and assist them without a problem." GNV1973F***

Many providers saw the possibility of testing using the Mylan system by clients at home after the initial testing with the assistant. It is important to note that clients consider themselves capable of performing ST using Mylan for the second time.

Some providers suggested that even for the first time, it would be acceptable for clients to test themselves, without any assistance because the instructions are simple, step-by-step and clear. As for the system itself, mostly no technical issues arose, but some clients were nervous and somewhat lost.

MYLAN ASSISTED TESTING APPROACH FOR DIFFERENT KPs

The approach to testing among different KP has its own peculiarities and differences. Participants, depending on their age and sex, responded differently to the entire assisted testing process using Mylan.

MSM, according to the respondents who work with them and have experience in communicating during assisted HIV testing with Mylan, are more likely to perceive information faster, and they understand almost everything. It is important to focus on how to engage and consult this group. This group is considered closed according to respondents. However, if the communication of the MSM group representative with a social worker seems pleasant to the client, they may bring their acquaintances, and so on. Typically, this group refers to NGOs in the afternoon or in the evening after a standard working day. Some MSM agree to come directly to the NGO office, but a significant share of MSM is sensitive to this issue.

> ***"MSM group requires information and communication with a social worker. They are open to contact, they're happy to test, and then bring their partners. They tell others about us, about this organization... that people can get tested..". HNV1973F***

The SW group is also closed and refers to NGOs or social workers in the afternoon or in the evening, or mostly, social workers need to go to the SW collection points.

Providers noted that SWs take into account the opinions of their colleagues. Therefore, if there is good and comfortable contact with the SW, their colleagues will also start contacting the NGO or social worker.

> ***"The category of sex workers... a way to approach them should be developed. I can't tell you how to approach them now, because we've tried different approaches and they haven't worked. It is in the stage of development..." HNV1973F***

> ***"Sex workers are more informed now. We have routes, we go to the highways and provide services: testing, condoms, lubricants, wet wipes for women and we provide our contact information. They understand that we are no threat to them at all... And when we give contact information, there are girls who call and say: "Listen, and we have a girl who said... when will you come again?" That is, they might not come to the office, and they won't say — I'm a sex worker, but when... you go on the same route every Thursday or every 10 days, then they gather there and have no fear, we come up to them as friends" LLO2879F***

As for PWID, providers noted greater courage of this group and willingness to contact NGOs for testing. However, financial motivation is important for this group, as most of them do not have a permanent job and yet have a regular need to use psychoactive substances to function during the day. Thus, it is for this group that financial motivation, humanitarian and food aid, seems like the most attractive recruitment and motivation method.

> ***"PWID representatives need more information on why it is needed. They need to know about HIV and AIDS, because they may not know what it is. This is information for PWIDs, and this is some assistance because this category may not have permanent jobs, and they need humanitarian aid... For example, ready meals... yes, they ask. That's what they can be interested in." GNV1973F***

Thus, a flexible, personalized approach is essential to attracting participants to HIV testing. Sex, age, and peculiarities of activities during the day should also be taken into account.

> ***"I would like to tell you from experience that men need more moral preparation for a finger puncture. Men are statistically more afraid of puncturing the finger than women. Even if this is a person who injects drugs and does not have any veins, they may be afraid of puncturing the finger. That is, it takes more time to prepare such a person". OUS3194M***

"I think it should be different, because... depending on how vulnerable the group is... both by age and gender. There are people who get the result at the age of 50 and say, "I have already lived my life, why do I need it? Young people should get it." Or, for example, they may say, "Listen, if I take it, someone young might not get it..."" LLO2879F

IMPRESSIONS OF USING MYLAN HIVST KITS

Providers have positively assessed the experience with the Mylan HIVST kit. Positive feedback on both the test's design and functionality indicate that it is a convenient hybrid that has everything you need for testing. The instructions are understandable, clear, step by step. Providers could place such tests in the safe box and give out them for ST.

"It was interesting because it was new. It is also interesting for my clients, because an interesting box, a beautiful box, the test itself is unusual, that is, where exactly this tube should be flipped, well, as such a thing, I call it, it was very interesting for them. Well, here is what comes first — it's interesting to them. Well, it's understandable, because of what the wave was about — because they were rewarded, they were tested, and they were rewarded for it, which is also a plus, a motivation for a person. I really enjoyed working with this." VLH1171F

There were some difficulties with the first interaction of participants with this HIVST kit and instructions. Participants had to note the need to read the instructions, not everyone was ready for it. Furthermore, from a technical perspective, some participants did not immediately understand the nuances of working with a scarifier or a test tube and a well. Providers noted that some participants might not have washed their hands before testing or looked at the expiration date.

"Flip this blood tube until it clicks — this is not written in the instructions, so people are afraid of doing it. They can flip it when it is not full because they're afraid something might break, for example. Or just like puncturing a finger with the scarifier — also, it should be done until the click is heard, whereafter the finger may be released. Because I have seen how people do it, and at these stages, they just pierce and hold because the instructions do not say, "When you hear a click, the finger is punctured." That is, you have already done everything correctly. That is, the instructions should be more detailed." ILI0377F

Several respondents noted that the test contained only one alcohol wipe, but this was not enough because participants had different blood density, and there were cases when the blood the blood flow freely, which was uncomfortable for all participants in the process.

Several respondents noted that the scarifier did not immediately puncture the finger because the participant's skin was thick. A few respondents noted that the use of tests for blood samples was restricted because of the fear of puncturing the finger and also because of the fear of blood. There was one case where the participant felt unwell. Certain participants had to be calmed down before puncturing their fingers.

The NGO's role in post-test counseling and support

All providers are unanimous in their opinion and approach to customer support in case of HIV-reactive results of the rapid test. NGOs and social workers have direct contact with infectious disease specialists and infectious disease hospitals and know how to work in cases of reactive HIV testing. Providers consider the approach to the client's support, referral and ART to be an important component of their HIV testing work. Clients also expressed opinions on the appropriateness of providing advice and support in case of reactive test results, but only with the consent of the client and without disclosing any confidential data, without notifying the HCF.

In case of a negative HIV test result, social workers provide counseling on HIV transmission routes, advice on the timing of repeated testing, pre-test and post-test prevention, and offer engagement in prevention services, provided by NGOs.

In general, most respondents' impressions of participating in this demo project and the experience of interacting with Mylan HIVST kits and assisted testing are positive. Respondents are willing to use this HIVST kit for their clients.

> ***"I wanted to express my gratitude for this opportunity to study Mylan tests, it was interesting. Our organization, our social workers and our clients liked the tests. We also liked the considerable job done with these tests coming to Ukraine — and they are convenient, yes... We can reach more of our population. Because these tests are very convenient and safe for people, they will gladly take tests for self-testing. Our key group will take tests, we asked them and surveyed them, asking if they were interested in testing. — Their answers were positive. They will take tests for themselves, as well as for their partners". GNV1973F***

11. Conclusions

1. The project program data, the results of assisted ST and semi-structured interviews demonstrated the feasibility and appropriateness of using the Mylan HIVST kit for assisted HIV self-testing at NGOs. During a limited period of 34 days (July 24 – August 29, 2023), 240 participants were involved in the project — representatives of KP and their partners, which corresponds to the planned number. All those who met the inclusion criteria gave verbal consent to participate in the project.
2. Introducing assisted HIVST using the selected HIVST kit made it possible to involve a wide range of participants based on socio-demographic characteristics and types of risky behavior. Thus, the average age of participants was 34.7±9.7, where the youngest participant was 19 and the oldest was 58; male participants predominated — 187 (77.9%). Almost two-thirds of the participants were single — 154 (64.2%) and quite a large number were widowers/widows — 63 (26.3%). The overwhelming majority of participants had upper secondary or higher education — 196 (81.7%). A significant number of participants had permanent jobs — 96 (40.0%), however, the number of unemployed and those having odd jobs was also high — 31 (12.9%) and 77 (32.1%), respectively. Personal monthly income averaged UAH 12,429.
3. Most out of 187 men reported only one type of risky behavior — 128 (68.4%). The MSM and PWID were two main and substantially separated KPs among men. Almost half of men had no other risks of HIV infection than sex with men — 89 (47.6%). 42 (22.5%) of men injected drugs, and 34 (18.2%) had sexual contacts with PWID, in addition to drug use (76 persons (40.6%)). The distribution of risky behavior combinations among women was more wide than among men. Five most common risky behavior combinations among women were: (1) injecting drug use + sexual contacts with PWID — 16 (30.2%); (2) paid sex + sexual contacts with PWID — 8 (15.1%); (3) sexual contacts with PWID — 8 (15.1%); (4) paid sex — 6 (11.3%); and (5) injecting drug use — 5 (9.4%).
4. The overwhelming majority of participants had a negative HIV status (a result obtained more than a year ago) — 194 (80.8%), and 46 (19.2%) participants had never been tested for HIV and did not know their own HIV status.
5. Out of 194 participants who reported a negative HIV test result, the majority obtained this result through ST – 120 (61.9%), that is, 50% of the total number of participants had ST experience. Most of participants were not NGO clients — 194 (80.8%). Most of them knew where to go for HIV testing — 153 (78.9%) and knew about rapid tests (RT) for ST —

135 (69.6%). The figures among 46 NGO clients were even higher: 41 (89.1%) of them knew where to go for HIV testing and 32 (82.6%) knew about RT for HIVST.

6. Most participants (141 (58.8%)) answered all questions of the structured interview correctly and, accordingly, demonstrated an understanding of the instructions for all ten ST stages.

7. That is one or more times, 99 (41.3%) participants gave incorrect answers or noted that they did not know the answer (132 times in total). Among them, the four largest groups by sex and risky behavior (64.6% in total)) were (1) men who inject drugs and have sexual contacts with PWID — 25 (25.3%); (2) men who reported oral or anal sex with men — 16 (16.2%); (3) men who injected drugs — 14 (14.1%); and (4) women who injected drugs — 9 (9.1%).

8. The smallest share of participants who understood individual stages of the instructions correctly (≤95%) was observed in relation to the following stages and questions: Stage 1 *"If a HIVST kit has expired, can this HIVST kit still be used for self-testing?"* — 216 (90%); Step 3 *"Can the test be used only if the green tip is turned and removed?"* — 226 (94.2%); Step 4 *"Can the test puncture a finger several times?"* — 223 (92.9%); and Stage 7 "Do I need to fill the test tube with blood by half?" – 198 (82.5%).

9. In the cascade of participants who understood all ST stages correctly, the largest decrease in the amount also occurred at Stage 1 *(wash and dry your hands, clean your finger with an alcohol wipe, check the expiration date)* — (-10%); Stage 3 *(gently turn and remove the green tip, then discard it)* — (-17%); Stage 4 *(press the gray button and puncture the finger)* — (-22%); and Stage 7 *(fill the tube with blood)* — (-36%). That is, at some stages, wrong or missing answers were given mostly by some participants and, at other stages, by others.

10. The success of assisted ST using the Mylan HIVST kit is evidenced by the following results: all 240 participants conducted ST successfully — they all received the test result (236 (98.3%) participants received a negative result, and 4 (1.7%) a reactive one); in all cases, test results reported by the participant and the assistant were identical. One negative result was obtained after repeated testing (the first test was invalid). Average ST duration was 24±6 minutes. All four test-reactive participants were referred to health care entities (HCF). 227 (96.2%) out of 236 participants who tested negative for HIV were referred to preventive care services.

11. More than half of the participants (122 (51%)) completed all stages of ST immediately or after receiving answers to questions. Ultimately, after the intervention of assistants, the remaining participants also completed all stages and substages of ST, which made further testing technically possible *(turn and remove the tip, press the gray button and puncture the finger, fill the tube with blood, flip the tube with blood and add four drops of solvent in the well to get the result).*

12. At the end of ST, one participant reported feeling unwell and attributed it to the puncture of the finger and the blood. He subsequently felt better, no medical care was needed Two participants used two HIVST kits because they pressed the gray button but did not pierce the finger at Stage 4; one participant added three drops of solvent instead of four at Stage 9, and the other one — six drops, in both cases, a stripe was recorded opposite the letter C.

13. The lowest level (≤95%) of ST immediately or after receiving answers to the question was recorded at Stage 1 *(wash and dry your hands, wipe your finger with an alcohol wipe, check the expiration date)* — 147 (61.3%); Stage 2 *(massage the finger for 5–10 seconds)* — 213 (88.8%); Stage 3 *(carefully turn and remove the green tip, then discard it)* — 223 (92.9%); and Stage 5 *(place the test on the instructions near the result's description)* — 223 (92.9%).

14. Simultaneously, a poor level of understanding and performance of ST was typical of Stage 1 *(wash and dry your hands; wipe your finger with an alcohol wipe; check the expiration date)* and Stage 3 *(gently turn and remove the green tip, then discard it).* The specific reasons for the poor level of understanding and performance of Stage 1 are the complexity of the

stage *(the need to perform three consecutive steps)*; often a lack of the need to wash and dry hands (if this was done before); not understanding the need to check the expiration date (according to the participants in the assisted ST, it should be done by the assistant). A fairly poor level of understanding and performance of Stage 3 is mainly related to the technical complexity of the stage (the need to turn the tip, turn in the right direction, turn to a sufficient angle, and then remove the tip).

15. Stage 2 *(massage the finger for 5–10 seconds)* and Stage 5 *(place the test on the instructions near the result's description)* were characterized by a relatively low poor level of performance without interference but a fairly high level of instruction comprehension. A significant number of participants massaged the finger only after being reminded about it, but some participants did not do this even after the reminder, explaining that the blood flow was good. Many participants did not immediately place the test on the instructions near the result's description but most did it after the assistant's reminder.
16. The cascade of participants completed the steps of all stages immediately or after receiving answers to questions, which demonstrates that the largest decrease in the share of persons who completed all stages correctly was observed only at Stage 1 *(wash and dry your hands; wipe your finger with an alcohol wipe; check the expiration date)* — (-39%). At subsequent stages, this decline was 0–3%. A subgroup of participants, most of whom did not immediately complete the next steps, was formed at Stage 1
17. Out of 118 participants who failed to complete all stages immediately or after receiving answers to their questions, the four largest groups, depending on gender and risky behavior (a total of 83 (70.3%)) were (1) men who reported oral or anal sex with men — 31 (26.3%); (2) men who injected drugs and had sexual contacts with PWID — 26 (22.0%); (3) men who injected drugs — 17 (14.4%); and (4) women who injected drugs — 9 (7.6%).
18. A significant share of participants showed both an understanding of all ST stages based on the instructions and completed all ST stages (from the first time or after receiving answers to questions) — 94 of 240 (39.2%).
19. Based on the case study of in-depth interviews, the participants' overall impression of participating in the project and assisted HIV testing with the Mylan HIVST kit was positive. Participants were willing to re-test and recommend it to their friends. The attitude of respondents towards assisted testing using the Mylan HIVST kit has not deteriorated or improved since it was conducted.
20. Participants of the qualitative part of the project noted the convenience and compactness of the Mylan HIVST kit and the possibility of using it in any premises where confidentiality can be ensured and where it is comfortable and convenient for all participants in the HIV testing process. There are no special conditions for NGOs to arrange the testing process using Mylan; confidentiality, access to KP representatives, availability of tests and training of social workers must be ensured.
21. Participants complied with the instructions in Ukrainian step-by-step. Participants followed the pictures but did not always read the accompanying text; in this case, assistants noted the importance of reading the accompanying text for the correct performance and obtaining the correct result of the HIV test.
22. Some participants noted the difficulty using the Mylan HIVST kit due to a lack of experience and ignorance of technical nuances (ignorance of the force of finger pressing, manipulations with the test tube and a drop of blood).
23. Providers and participants noted the novelty and modernity of the Mylan HIVST kit and its ease of use. It was noted that some clients needed more support, so the presence of assistants when using this HIVST kit was helpful.

24. Several clients and providers noted that one alcohol wipe was insufficient, which was inconvenient because the blood could flow out, and there was no additional wipe to clean it.
25. Communication with assistants during assisted ST was pleasant, which contributed to the openness of clients and calming down in the process of waiting for results. At the same time, only several clients experienced discomfort and inconvenience because of another person being present during testing. According to clients, the assistant should be a person with knowledge of HIV and experience working with the Mylan HIVST kit. At the same time, they did not care about the assistants' education. Non-disclosure of information, observance of anonymity and confidentiality requirements are the most important criteria of trust.
26. Some participants had fears about the process of testing for HIV, in particular, assisted ST using the Mylan HIVST kit: fear of knowing the result, fear of puncturing the finger, fear of blood, fear of the new thing they had no previous experience with. In addition to the mentioned fears, the following were also noted: fear of losing privacy, fear of stigma, fear of not finding out about the HIV infection on time, and the fear of bringing up the topic of HIV in general. The variability of different fears and phobias of potential HIV testing clients is worth considering in terms of selecting approaches to the involvement, dissemination of information about testing capabilities, and organization of the HIV testing process.
27. Providers positively assessed the experience using the Mylan HIVST kit. Positive feedback on both the test's design and functionality indicates that it is a convenient hybrid which has everything you need for testing. The instructions are understandable, clear, step by step.
28. Participants were committed to NGO-based testing, which was also confirmed by assistants. Clients were more open and had more confidence in social workers, as part of peer-to-peer interaction, than in healthcare professionals. Some clients expressed some degree of mistrust in HCF surveys in terms of confidentiality, with testing done at the HCF being taken more seriously than that performed at the NGO. Yet this is also a factor of reluctance to contact HCF compared to the NGO.
29. The flexibility in providing services is the advantage of NGOs over HCF, as is knowledge of KP features. Providers are aware of the peculiarities of KPs they work with and therefore have sufficient knowledge to engage with KP and provide services, including HIV testing.

12. Recommendations

1. Considering the positive results of the demonstration project, continue implementing assisted HIVST using the NGO-based Mylan HIVST kit.
2. During the stage of attracting people for HIV testing, pay attention to the correct delivery of information to potential clients concerning the entire testing process, the way it is performed (in private, with an assistant, the possibility to come with a partner, etc.) to avoid misunderstandings and for better comfort of clients.
3. Involve representatives of communities in the dissemination of information about HIV testing using the Mylan HIVST kit. It needed, provide a system of remuneration and motivation for involvement for recruiters and recruits, if possible, depending on the KP characteristics.
4. When organizing the provision of assisted testing services, if it is possible - to test clients in private in a separate room at the NGO after the assistant's instructions. In this case, clients who are uncomfortable doing ST in the presence of an assistant could feel comfortable being able to ask a question, if needed.

5. Develop a step-by-step algorithm for repeated communication with clients who do self-testing. Provide for communication between the social worker and the client to clarify the success of ST and, if necessary, arrange an escort to a HCF.
6. Develop restrictive policy recommendations concerning ST for persons who have a phobia of medical procedures using needles, fear of blood, perception of the test result, physical limitations for ST (absence of upper limbs, fingers) and poor eyesight.
7. While implementing assisted HIVST using the Mylan HIVST kit, NGOs should ensure the training of social workers (assistants), considering the specifics of this HIVST kit.
8. Pay attention to training and regularly upgrading the competencies of the assistant providing HIV counseling, testing, and support before starting ART. Training should include not only HIV knowledge, HIV testing, and ART testing but also communication training, communication skills, and trusting relationships development.
9. Add to the standard set of the HIVST kit another alcohol wipe for use in the "field," off-premise, at the mobile clinic, etc., where there is no access to additional wipes and water in case of excess blood.
10. If needed, indicate in the instructions whether the first drop of blood should be wiped away.
11. If possible, update items 3 and 4 of the instructions. Item 3 should read as follows: "Gently turn the green tip counterclockwise until you hear a distinctive sound, remove the green tip, then discard it." Item 4 should read as follows: "Firmly press the gray button to puncture your finger."
12. Make the text describing the image of the invalid result appropriate (repeated testing following an invalid result): "This is a preliminary test. Contact the health-care facility for further examination," and the text of the instruction "What to do if my result is invalid. The test will show no result if it is performed incorrectly. You will need to repeat the test using a new test device. If you are unsure if you have performed the test correctly, please speak to your doctor."
13. Publish the text of the instructions as follows:

    "Not suitable for people who are afraid of blood and finger puncturing using a needle."

    "The Mylan HIV Self-Test has also correctly identified 99.6% (904/908) of HIV positive samples in the laboratory setting (this is known as the test's sensitivity ~~specificity~~)".

    The text of the description of Stage 8: "~~Place the test on the table.~~ Now flip the blood tube into the well." (Stage 5: "Place the test on the instructions next to the result description." The instructions do not further specify that the test should be picked up).

13. Limitations

1. KP representatives and their partners were conveniently involved in the demo project in the selected territories, so the findings cannot be extrapolated to the entire KP population and their partners.
2. The HIV test was conducted in the form of assisted ST, therefore, its results in terms of the ability to use the Mylan HIVST kit in the unassisted ST format can be used only partially.
3. The activities using the Mylan HIVST kits were carried out in the premises of NGO's during the summer of 2022. The Mylan HIVST kits were not used in outdoor environments (e.g., outreach routes) or other environments other than NGO premises.

14. References

1. WHO Guidelines Approved by the Guidelines Review Committee. Guidelines on HIV Self-Testing and Partner Notification: Supplement to Consolidated Guidelines on HIV Testing Services. World Health Organization Copyright © World Health Organization 2016.; 2016.
2. World Health Organization. Technical Specifications Series for submission to WHO Prequalification–Diagnostic Assessment: Human immunodeficiency virus (HIV) rapid diagnostic tests for professional use and/or self- testing. Geneva: World Health Organization; 2017
3. Tonen-Wolyec S, Dupont R, Batina-Agasa S, Hayette MP, Belec L. Capillary whole-blood IgG-IgM COVID-19 self-test as a serological screening tool for SARS-CoV-2 infection adapted to the general public. PLoS One. 2020;15(10):e0240779. doi:10.1371/journal.pone.0240779
4. Fajardo E, Watson V, Kumwenda M, et al. Usability and acceptability of oral-based HCV self-testing among key populations: a mixed-methods evaluation in Tbilisi, Georgia. BMC Infect Dis. May 31 2022;22(1):510. doi:10.1186/s12879-022-07484-2
5. Braun V, Clarke V. Using thematic analysis in psychology. Qualitative Research in Psychology. 2006;3:77-101. doi:10.1191/1478088706qp063oa
6. World Health Organization. Public Report for Mylan HIV Self Test (PQDx 0320-090-00). August 2023, version 4.0. Accessed Oct. 25, 2023. https://extranet.who.int/prequal/sites/default/files/whopr_files/PQDx_0320-090_00_MylanHIVSelfTest_v4.0.pdf

Annexes

Table 9 Socio-demographic and behavioral characteristics and awareness of participants about ST (n=240)

N°	Indicator	Absolute value / mean value	% / Standard deviation	Comments
1.	**Age (min. — 19, max. — 58)**	34.7	9.7	
2.	**Age group**			
	18–24	54	22.5	
	25–34	57	23.8	
	35–44	93	38.8	
	45+	38	15.0	
3.	**Sex**			
	male	187	77.9	
	female	53	22.1	
4.	**Injecting drugs at least once during the last 30 days**			
	yes	111	46.3	
	no	129	53.8	
5.	**Sex for remuneration during the past 6 months**			
	yes	25	10.4	
	no	215	89.6	
6.	**Sexual contact with PWID in the past 6 months**			
	yes	94	39.2	
	no	146	60.8	
7.	**Sexual contact with SW in the past 6 months**			
	yes	24	10.0	
	no	216	90.0	
8.	**Oral or anal sexual contact with a man in the past 6 months**			**For men only (n=187)**
	yes	98	52.4	
	no	89	47.6	
9.	**Sexual contact with the man who had sex with men in the past 6 months**			**For women only (n=187)**
	yes	1	1.9	
	no	52	98.1	

№	Indicator	Absolute value / mean value	% / Standard deviation	Comments
10.	**Permanent residence in the project region during the war or forced displacement to project regions after February 24, 2022**			
	forced displacement	13	5.4	
	permanent residence	224	94.6	
11.	**Marital status**			
	I have never been married	154	64.2	
	married	18	7.5	
	divorced	63	26.3	
	widow/widower	5	2.1	
12.	**Cohabitation and maintaining a household**			
	with parents/relatives	57	23.8	
	with a female partner	26	10.8	
	with a male partner	38	15.8	
	alone (including with roommates in a shared dormitory room, in a rented apartment together with other lodgers, etc.)	112	46.7	
	other	7	2.9	
13.	**Education**			
	primary education (incomplete 9th grade)	5	2.1	
	basic (incomplete) secondary education (full 9 grades)	39	16.3	
	complete general secondary (or vocational) education (11 grades, etc.), incomplete higher education	100	41.7	
	basic higher education (higher education institution of I-II levels of accreditation, vocational school)	29	12.1	
	complete higher education (bachelor's, specialist's, master's degree) (higher education institution of III-IV levels of accreditation, university)	66	27.5	
	scientific degree (PhD, Doctor of Sciences)	1	0.4	

№	Indicator	Absolute value / mean value	% / Standard deviation	Comments
14.	**Primary occupation**			
	unemployed	31	12.9	
	maintaining a household	7	2.9	
	odd jobs	77	32.1	
	permanent job	96	40.0	
	no other occupation except sex work	11	4.6	
	disabled (person with a disability)	8	3.3	
	vocational school student	1	0.4	
	university student	7	2.9	
	other	2	0.8	
15.	**Personal income for the past 30 days (min. — UAH 0.0, max. — UAH 220,000)**	12,429	17,689	Median — UAH 8,000
16.	**HIV status**			
	unknown — never tested for HIV	46	19.2	
	negative — was tested for HIV and received a negative result more than a year ago	194	80.8	
17.	**Knows about RT for HIVST**			
	yes	173	72.1	
	no	67	27.9	
18.	**ST**			
	yes	120	61.9	Tested more than a year ago (among those who received a negative result) (n=194)
	no	74	38.1	

Table 10 Results of the structured interview on the ability to understand and interpret the instructions for using the Mylan test system (n=240)

№	Indicator	Absolute value	%	Comments
1.	**If a test system has expired, can this test system still be used for self-testing?**			
	yes	18	7.5	
	no	216	90.0	
	not sure	6	2.5	
2.	**Does massaging the finger before its puncturing increase blood circulation to get a sufficient amount of blood?**			
	yes	236	98.3	
	no	3	1.3	
	not sure	1	0.4	
3.	**Can the test be used only if the green tip is turned and removed?**			
	yes	226	94.2	
	no	11	4.6	
	not sure	3	1.3	
4.	**Can the test puncture a finger several times?**			
	yes	8	3.3	
	no	223	92.9	
	not sure	9	3.8	
5.	**After puncturing the finger, is it necessary to place the test on the instructions in the designated place?**			
	yes	229	95.4	
	no	5	2.1	
	not sure	6	2.5	
6.	**Do you need to squeeze your finger so that blood comes out after the puncture?**			
	yes	237	98.8	
	no	1	0.4	
	not sure	2	0.8	
7.	**Should the test tube be half full of blood?**			
	yes	38	15.8	
	no	198	82.5	
	not sure	4	1.7	

Nº	Indicator	Absolute value	%	Comments
8.	**Do you need to flip the test tube so that the blood gets to the well?**			
	yes	233	97.1	
	no	5	2.1	
	not sure	2	0.8	
9.	**Do you need to add one drop of solvent to the well?**			
	yes	9	3.8	
	no	230	95.8	
	not sure	1	0.4	
10.	**If a line appears opposite the strip opposite the letter C, and there is no strip opposite the strip with the letter T, is the test result “negative”?**			
	yes	230	96.8	
	no	2	0.8	
	not sure	8	3.3	
11.	**All answers correct**			
	yes	141	58.8	
	no	99	41.3	

Table 11 Results of ST observation (n=240)

Stage/ substage implementation	Absolute number	%	Notes/comments on the stage performance	Questions on the stage performance		Questions on the stage performance	Assistant's intervention in ST		Major interventions during the stage performance	General comments
				Absolute number	%		Absolute number	%		
STAGE 1. Substage 1 — Have you washed and dried your hands?				5	2.1	Where is the information about the expiration date? Can you puncture my finger? Where is a wipe? How can I open it? Do you have scissors?	49	20.4	Scissors have been given. Drew attention to the instructions. Reminded participants to wash and dry their hands. Reminded participants to wash and dry their hands and check the expiration date. Reminded participants to wash and dry their hands, use alcohol wipes and check the expiration date. Reminded participants to check the expiration date. Reminded participants to use alcohol wipes and check the expiration date. Reminded participants to use alcohol wipes. Prompted where to find the expiration date. Reminded about the sequence of actions	Foil packaging has no opening. To open the package, make an effort or use scissors. Assisted ST format was used, and the assistant checked the expiration date of the test system. There is one alcohol wipe in the kit. There are no gauze napkins in the kit. There is a recycling bag in the kit.
yes	200	83.3	Treated with disinfectant — 3. The participant said that they had already washed their hands — 1.							
no	40	16.7								
STAGE 1. Substage 2 — Did you wipe your finger with an alcohol wipe?										
yes	226	94.2	The participant said that their hands were clean because they had washed them — 2. The participant said that he would need an alcohol wipe later — 3.							
no	14	5.8								
STAGE 1. Substage 3 — Did the participant check the expiration date before opening the foil package?										
yes	162	67.5	Checked after opening the package — 1 The participant said that during assisted ST, the assistant was supposed to check the expiration date — 4							
no	78	32.5								
ACCOMPLISHED ALL SUBSTAGES										
yes	147	61.3%								
no	93	38.8%								

Stage/ substage implementation	Absolute number	%	Notes/comments on the stage performance	Questions on the stage performance		Questions on the stage performance	Assistant's intervention in ST		Major interventions during the stage performance	General comments
				Absolute number	%		Absolute number	%		
STAGE 2. Did the participant massage the finger for 5–10 seconds?										
yes	213	88.8	The participant said the blood was coming out anyway — 2.	2	0.8	I cleaned it with a wipe; then I rubbed my finger. Should I clean it all over again with the alcohol wipe? What finger should I draw the blood from?	12	5.0	Reminded to massage the finger. Reminded to massage the finger, but the participant said the blood was already too liquid. Prompted which finger blood should be drawn from.	
no	27	11.3								
STAGE 3. Did the participant carefully turn and remove the green tip and then discard it?										

Stage/ substage implementation	Absolute number	%	Notes/comments on the stage performance	Questions on the stage performance		Questions on the stage performance	Assistant's intervention in ST		Major interventions during the stage performance	General comments
				Absolute number	%		Absolute number	%		
yes	223	92.9	It was easy — 1. Failed to remove the tip at first — 8. Couldn't remove the tip by themselves — 1. It took me a while to get the tip off without turning — 1. It took me a while to figure out how to turn the tip — 1. It took me a while to figure out what side to turn the tip — 2. Turned the green tip carelessly — 1 I turned the tip, but I didn't remove it — 1. Was too careful because of fear to break a test — 1.	26	10.8	Which way should I turn the tip? Where should the blood be dripped? Is it possible to remove the tip without turning it? To what extent should I turn the tip? Does it hurt? What should I turn — a gray or green thing? How can I remove the tip? How can I turn the tip? How can I turn and remove the tip?	34	14.2	Showed the participant how to turn and remove the tip. Showed the participant how to turn and remove the tip (at first, the participant tried to puncture their finger with a green tip attached). Showed the participant how to turn and remove the tip (at first, the participant began to pull the tip without turning it). Showed the participant how to turn and remove the tip (at first, the participant was holding the gray part (button) and tried to turn it). Helped to remove the tip. Helped to turn and remove the tip. Prompted that the tip should be turned to the left at first. Prompted the way to remove the tip. Prompted that the tip should be turned 90 degrees. Confirmed the correctness of the participant's actions	Instructions do not specify that the tip should be turned until the distinctive sound is heard.
no	17	7.1								

Stage/ substage implementation	Absolute number	%	Notes/comments on the stage performance	Questions on the stage performance		Questions on the stage performance	Assistant's intervention in ST		Major interventions during the stage performance	General comments
				Absolute number	%		Absolute number	%		
STAGE 4. Did I push the gray button and puncture the finger?										
yes	238	99.2	It took some time for the participant because they were afraid to puncture the finger — 4. The participant mentioned that instructions should indicate the need to press until the distinctive sound is heard — 1. The button was not pressed hard enough — 1. The participant did not understand where to press at first — 1.	30	12.5	What is the best place to puncture? Should the blood be collected using the gray button? Where is the button? Should I press and hold? Does it work? Nothing happens? I did not feel anything. Did I actually puncture the finger? Should I just press it? How long should I hold the finger this way? The participant did not press the gray button hard enough and asked if they did it the right way. Is there a needle there? Does it hurt? Do you have an extra wipe? How do I puncture the finger? How do I use the gray button? How hard should I press the button?	28	11.7	Confirmed that the puncture was successful. Gave an alcohol wipe. Reassured the participant. Prompted the place to puncture the finger. Prompted to press hard. Prompted that the finger had already been punctured, and the test could be released. Showed how to press the finger. Explained how to puncture the finger. Told the participant to press until a distinctive sound was heard and then place the test on the table.	Instructions do not specify that the gray button should be pressed until the distinctive sound is heard. If the stage was completed incorrectly (the button was pressed, but the finger was not punctured), the participant had to use a new test system.
no	2	0.8								

Stage/ substage implementation	Absolute number	%	Notes/comments on the stage performance	Questions on the stage performance		Questions on the stage performance	Assistant's intervention in ST		Major interventions during the stage performance	General comments
				Absolute number	%		Absolute number	%		
STAGE 5. Did the participant place the test on the instructions next to the result's description?										
yes	223	92.9	The participant fidgeted the test in their hands — 1. The participant placed the instructions in a different place — 2. The participant placed the test next to the instructions on the table — 5.	2	0.8	Where is the pipette? Where should I put it?	16	6.7	Blood flowed down the finger, so the participant would find it inconvenient to press the finger against the test tube. He suggested turning the test for convenience. The participant was reminded where to put the test. The participant wanted to add the blood into the test tube while holding the test in their hands, and the assistant noted that it should be placed in the designated place on the instructions.	
no	17	7.1								

Stage/ substage implementation	Absolute number	%	Notes/comments on the stage performance	Questions on the stage performance		Questions on the stage performance	Assistant's intervention in ST		Major interventions during the stage performance	General comments
				Absolute number	%		Absolute number	%		
STAGE 6. Did the participant squeeze the finger firmly against the puncture site to get blood?										
yes	229	95.4	Blood flew from the finger intensively without squeezing — 4. The participant pressed with one finger so the blood did not come out — 1.	9	3.8	Is it enough blood? Why isn't it bleeding? How much blood do I have to squeeze? Do you have an extra wipe? How do I draw blood?	10	4.2	Gave an extra wipe. Reminded that the tube should be full. Prompted how to squeeze the finger to make it bleed. Prompted that blood could be squeezed into the test tube several times.	The instructions didn't say whether the first drop of blood should be wiped off.
no	11	4.6								
STAGE 7. Substage 1. Did you fill the tube with blood?				19	7.9	Where should the blood be added to? Where should the blood be added to? Is it necessary to squeeze it into the well? May I have an additional wipe? How much more blood do I need to add to the tube? Can I bring my finger to the test tube several times to fill it? Are you sure the tube is full? How can I fill the tube? How do I transfer the blood into the tube?	23	9.6	Gave a napkin. Replied that the tube was full. Reminded to squeeze the finger and get a good drop of blood. Reminded that it was necessary to squeeze the finger additionally to fill the tube completely. Showed an easier way to squeeze the finger and fill the test tube. Explained how to add blood. Explained where and how to add blood. Explained how much blood to add. Explained how to add blood. The participant asked to hold the test on the table because he was missing two fingers on his right hand, and the third one was injured. Hence, it was inconvenient to complete this stage for them.	
yes	182	75.8	Failed the first time — 7. The blood did not flow well — 3. Not enough blood — 5.							
no	58	24.2								
STAGE 7. Substage 2. If the blood tube was not full, did the participant squeeze the finger and add more blood?										
yes	57	23.8 / 98.3	Several times — 1. It took quite a long time to draw blood — 1.							
no	1	0.4 / 1.0	Blood came out poorly — 1.							
ACCOMPLISHED ALL SUBSTAGES										
yes	239	99.6%								
no	1	0.4%								

Stage/ substage implementation	Absolute number	%	Notes/comments on the stage performance	Questions on the stage performance		Questions on the stage performance	Assistant's intervention in ST		Major interventions during the stage performance	General comments
				Absolute number	%		Absolute number	%		
STAGE 8. Substage 1 — Did you place the test on the table?				20	8.3	What way should I turn the tube? At what point should the test tube be flipped? This way? The participant flipped the test tube halfway and asked if it was correct. Do you have an extra wipe? Could the blood sprinkle into the eyes? Is the blood flowing? Did it coagulate? How could I understand it? Will the blood get into the well or beyond it? How should the test tube be flipped?	24	10.0	Replied that the test tube should be flipped all the way. Replied that the blood would get into the test well. Gave an alcohol wipe. When the participant raised the test tube to flip it, they were stopped in time to flip the test tube correctly. Prompted that there was no need to cover the test tube with the finger when flipping the tube. Prompted to lower it until the blood started flowing into the well. Prompted how to flip the test tube. Confirmed the correctness of steps. Explained the mechanism and algorithm of adding blood and solvent. Told the participant to lower the tube more.	
yes	237	98.8	The participant placed the test next to the instructions, not on them — 1.							
no	3	1.3								
STAGE 8. Substage 2. — Did you flip the tube with blood into the well?										
yes	237	98.8	The participant succeeded in flipping the test tube after the second try — 1. The participant succeeded with help — 1. The participant mentioned that it was better to mention in the instructions to what extent to flip the test tube — 1. The participant did not immediately understand how to flip the test tube — 1. After prompting — 2. The participant did it after some time — 1.							
no	3	1.3								
ACCOMPLISHED ALL SUBSTAGES										
yes	234	97.5								
no	6	2.5								

Stage/ substage implementation	Absolute number	%	Notes/comments on the stage performance	Questions on the stage performance		Questions on the stage performance	Assistant's intervention in ST		Major interventions during the stage performance	General comments
				Absolute number	%		Absolute number	%		
STAGE 9. Did you add 4 drops into the well?										
yes	235	97.9	The participant added 3 drops, but one drop missed the well — 1. After reminding — 1. Requested the assistant's help because the participant had poor eyesight — 1. The participant added 6 drops of the solvent — 1.	7	2.9	Where should I add the solvent? How many drops should be added: 3 or 4? — 1 Why do I need to add exactly 4 drops?	12	5.0	Helped (a participant with poor eyesight) to add 4 drops. Reminded of the need to add the solvent. Prompted where the solvent should be added. Prompted how many drops to add. Prompted that it was better to hold the solvent perpendicular to the test.	Instructions do not specify why exactly 4 drops are needed
no	5	2.1								
STAGE 10. Did the participant wait 15 minutes before recording the result? Did the participant read the result after more than 20 minutes had passed?										
yes	239	99.6	Decided that 10 minutes were enough — 1. Carefully read the instructions regarding the test result — 1.	6	2.5	Are the results reliable? A strip appeared opposite the letter C; can I stop waiting? Why do I need to wait 15 minutes if the strip appeared opposite the letter C? Is it necessary to take the test again in three months? — 1 How often do I need to take the HIV test?	4	1.7	Reminded about the need to record the time.	
no	1	0.4								

<table>
<tr><th rowspan="2">Stage/ substage implementation</th><th rowspan="2">Absolute number</th><th rowspan="2">%</th><th rowspan="2">Notes/comments on the stage performance</th><th colspan="2">Questions on the stage performance</th><th rowspan="2">Questions on the stage performance</th><th colspan="2">Assistant's intervention in ST</th><th rowspan="2">Major interventions during the stage performance</th><th rowspan="2">General comments</th></tr>
<tr><th>Absolute number</th><th>%</th><th>Absolute number</th><th>%</th></tr>
<tr><td colspan="12">RESULT AND REFERRAL TO SERVICES DEPENDING ON THE ST RESULT</td></tr>
<tr><td rowspan="2">Recorded by the participant</td><td colspan="5">Recorded by the interviewer</td><td colspan="3" rowspan="2">Referred to preventive services (in case of a negative result) or to the health center in case of a positive result</td><td rowspan="5">Refusal — 3.
A participant is in the harm reduction program — 1.
Does not want — 4.
Does not need — 1.</td><td></td></tr>
<tr><td colspan="2">negative</td><td colspan="2">positive</td><td colspan="2">invalid</td><td></td></tr>
<tr><td>negative</td><td>235 / 236</td><td>97.9 / 98.3</td><td colspan="2"></td><td colspan="2"></td><td>yes</td><td>231</td><td>96.3</td><td></td></tr>
<tr><td>positive</td><td></td><td></td><td colspan="2">4</td><td colspan="2">1.7</td><td rowspan="2">no</td><td rowspan="2">9</td><td rowspan="2">3.8</td><td></td></tr>
<tr><td>invalid</td><td></td><td></td><td colspan="2"></td><td colspan="2">1 / 0</td><td>0.4 / 0</td><td></td></tr>
<tr><td colspan="6">COMPLETING ALL STAGES (ON THE FIRST TRY OR AFTER RECEIVING ANSWERS TO QUESTIONS)</td><td colspan="4">ST DURATION</td><td></td></tr>
<tr><td colspan="4">yes</td><td colspan="2">122</td><td>50.8</td><td colspan="3">Average duration
min. — 14 min
max. — 45 min</td><td>24 min</td><td></td></tr>
<tr><td colspan="4">no</td><td colspan="2">118</td><td>49.2</td><td colspan="3">Standard deviation</td><td>6 min</td><td></td></tr>
</table>

Annex 2.
General Report on the Implementation of Stage 3 of the Demonstration Project

Analytical report on the results of Mylan HIV Self-Test distribution among regional partners (NGOs) for targeted distribution to PWID, CSW, MSM and other key and priority populations to enhance self-testing capabilities among customers and their communities

1. Description of the approach to the targeted distribution of Mylan HIV Self-Tests among PWID, SW, MSM and other KP and PP

Mylan HIVST kits were distributed to regional partners (NGOs) to target key and vulnerable populations to whom HIV testing or index testing services or testing in social/risk networks are offered during Stage 3 of the demonstration project (July – October 2023).

This stage involved an enhanced approach to secondary distribution of Mylan HIVST kits by key and vulnerable population representatives among their sexual partners (distribution by clients with newly diagnosed HIV infection in index testing), as well as among social networks characterized by risk of HIV transmission. Representatives of key and priority populations were asked to recruit their partners and social network members and to promote self-testing with Mylan HIVST kits with social and psychological assistance (NGO-based) delivery system and medical (on the basis of specialized health care entities). In selected partner NGOs, social workers skilled in HIV-assisted testing and treatment linkages served as mentors for clients who agree to become recruiters.

Recruiters played a dual role of disseminating information about the availability and importance of HIV self-testing using Mylan HIVST kits to their social environment and assisting during the testing procedure for others who would agree to self-test.

The main tasks of recruiters were:

1. Distributing Mylan HIVST kits among sexual partners and/or their social environment practicing risky behavior.
2. Distributing information and other accompanying materials on HIV self-testing using Mylan HIVST kits.
3. Motivating sexual partners and/or the social environment to HIV self-testing using Mylan HIVST kits.
4. Assisting in HIV self-testing by sexual partners and/or social environment if necessary.
5. Follow-up or redirecting to HIV service NGOs for inclusion in the continuum of HIV testing and treatment services in case of feedback from partners and/or the social environment on reactive testing results
6. Supporting the two-way communication with mentors regarding success in motivating partners and/or the social environment to HIV self-testing, as well as testing results (providing only anonymous information about self-testing results known to recruiters).

Mentors from selected and separately trained NGO-based HIV assisted testing services will serve as mentors and coordinators for recruiters.

The main tasks of mentors were:

1. Offering clients to be recruiters, explaining their roles, tasks, expectations, and benefits.
2. Training clients selected as recruiters in the procedure of HIV self-testing using Mylan HIVST kits, as well as basic skills and scenarios of motivational counseling for self-testing and compiling final recruitment lists.
3. Agreeing on the schedule and manner of consultations to provide moral and advisory support to the recruiter for successfully completing tasks.
4. Forming and granting a personalized “recruiter package” consisting of:
    - Mylan HIVST kits (in the quantity agreed with the recruiter).
    - Instructions and related information materials.
    - Algorithms of actions, scenarios of motivational interviews (for target groups agreed with the recruiter).
    - Feedback forms on the experience of using HIVST kits and self-assessment of the recruiter role.
    - Instructions on communication with mentors.
5. Mentoring the recruiter (moral and advisory support).
6. Collecting and summarizing results of the recruitment process for HIV self-testing of partners and/or the social environment of recruiters.
7. Ensuring a continuous referral process for diagnosis and treatment services for clients who have received a reactive self-testing result and were directed by the recruiter.

Support from the Project:

The project team provided the main resource and coordination support for implementing the proposed intervention.

Major tasks of the Project team included:

1. Forming standard “recruiter packages” consisting of:
    - Mylan HIVST kits.
    - Instructions and related information materials.
    - Algorithms of actions, scenarios of motivational interviews for recruiters.
    - Feedback forms on the experience of using HIVST kits.
    - Recruiter instructions for communication with the mentor.
2. Forming standard “mentor packages” consisting of:
    - Snstructions and related information materials on the use of Mylan HIVST kits for HIV self-testing.
    - Algorithms and rules for attracting recruiters from among clients, algorithms for providing mentoring support.
    - Algorithms of actions, scenarios of motivational interviews for recruiters.
    - Forms, tools to collect information on the process of involving recruiters for HIV self-testing of their partners and/or the social environment of recruiters.
3. Distributing packages to selected partner NGOs.
4. Training mentors to use Mylan HIV Self-Tests.

5. Training mentors to provide moral and advisory support to recruiters.
6. Providing resource, methodological and coordination support to partner NGOs based on which the proposed intervention will be implemented.
7. Analytical support of work results of mentors and recruiters.

Regional partners and geographical coverage:

The implementation of the proposed intervention carried out with the participation of existing regional partners of the Project NGOs, in particular

- Charitable Organization 100% Life Network. Zaporizhzhia (Zaporizhzhia Oblast).
- Chernihiv Branch of Charitable Organization All-Ukrainian Network of People Living with HIV/AIDS (Chernihiv Oblast).
- Charitable Organization 100% Life Network Dnipro (Dnipropetrovsk Oblast).
- Charitable Organization "Svitlo Nadii" (Light of Hope) (Poltava Oblast).
- Charitable Organization "Free Zone" (Cherkasy Oblast).

2. Analysis of the Mylan HIV Self-Test distribution based on socio-demographic indicators among KP and PP representatives:

2.1. Analysis of the Mylan HIVST kit distribution among NGOs participating in the project

Charitable Organization "100% Life Network. Zaporizhzhia"

The Organization introduced the secondary dissemination of Mylan testing systems through key and vulnerable populations and for their sexual partners and social environment that practiced HIV risk behaviors during the reporting period.

Two social workers acting as mentors involved 5 recruiters from key populations.

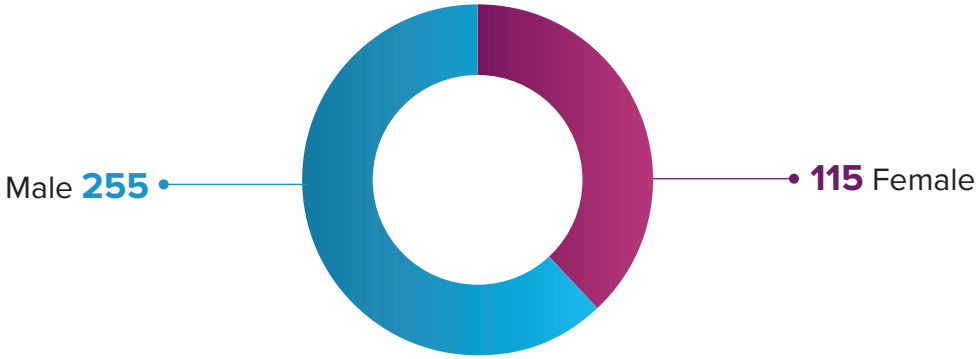
Overall, the organization's recruiters distributed 375 Mylan HIVST kits to the following KP representatives: PWID — 267, MSM — 100, SW — 4, and other KP — 4, representing 100% of the planned figure for the reporting period (see Fig. 1)

Fig. 1 — Analysis of the Mylan test system distribution to the following KP representatives (Charitable Organization "100% Life Network. Zaporizhzhia")



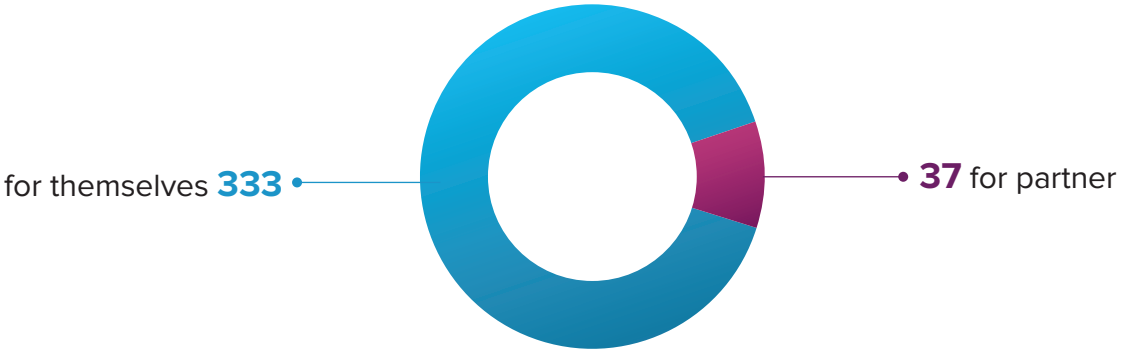
255 males (68.00%) and 115 females (32.00%) of 375 KP representatives received Mylan HIVST kits (see Fig. 2)

Fig. 2 — Gender distribution of KP representatives who received the service (Charitable Organization "100% Life Network. Zaporizhzhia")



Of 375 KP representatives who received Mylan HIVST kits, 333 persons received HIVST kits for themselves, and 37 received them for their sexual and/or injecting partners (see Fig. 3)

Fig. 3 — Distribution of test systems received for HIVTS (Charitable Organization "100% Life Network. Zaporizhzhia")

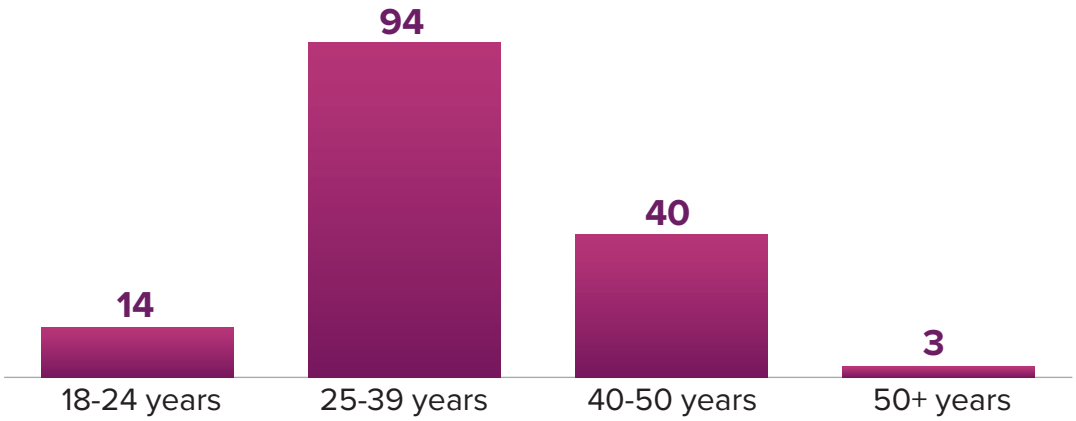


People who inject drugs (PWID):

The organization served 151 men and 116 women of 267 PWID.

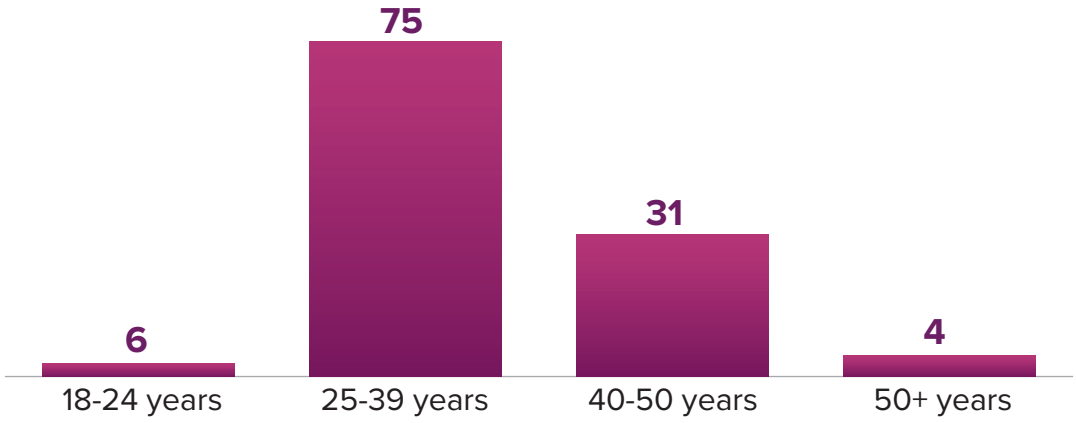
14 persons of 151 male PWID were aged 18–24, 94 persons — 25–39, 40 people — 40–50 and 3 people — were 50+ (see Fig. 4.1)

Fig. 4.1 — Age disaggregation of male PWID who received Mylan test systems (Charitable Organization "100% Life Network. Zaporizhzhia")



6 persons out of 116 female PWID were aged 18–24, 75 persons — 25–39, 31 people — 40–50 and 4 people were 50+ (see Fig. 4.2)

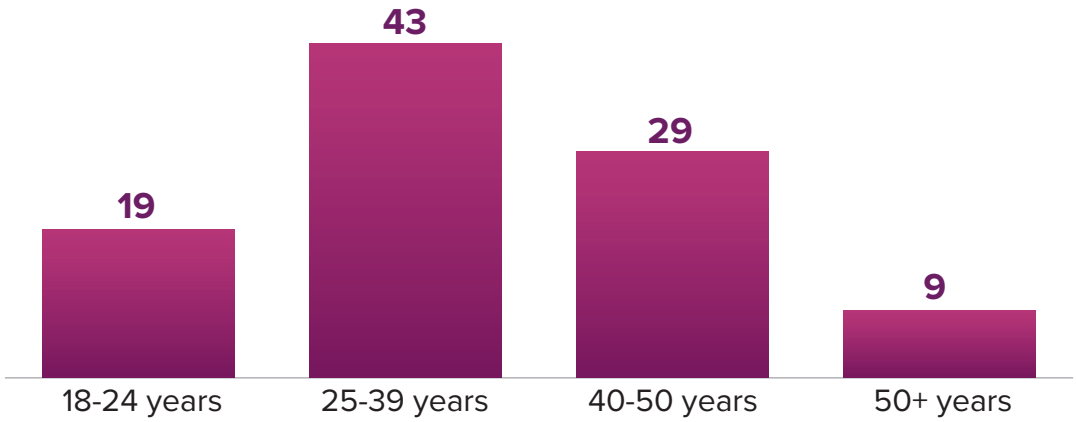
Fig. 4.2 — Age disaggregation of female PWID who received Mylan test systems (Charitable Organization "100% Life Network. Zaporizhzhia")



Men who have sex with men (MSM):

19 persons of 100 MSM were aged 18–24, 43 persons — 25–39, 29 people — 40–50 and 9 people were 50+ (see Fig. 5)

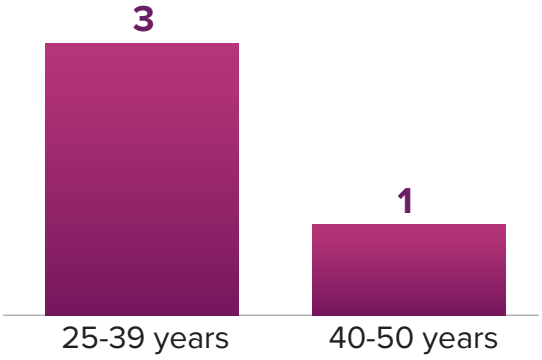
Fig. 5 — Age disaggregation of MSM who received Mylan test systems (Charitable Organization "100% Life Network. Zaporizhzhia")



Sex workers (SW):

3 persons of female SW belonged were aged 25–39, and one person was in the age category of 40–50 (see Fig. 6)

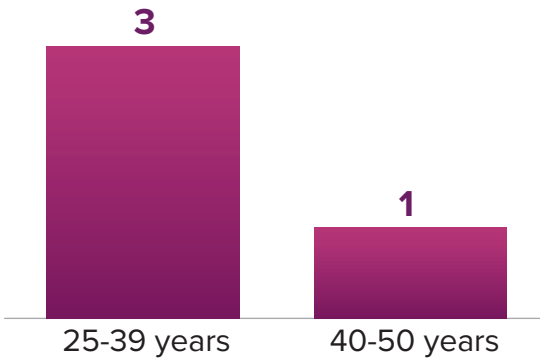
Fig. 6 — Age disaggregation of female SW who received Mylan test systems (Charitable Organization "100% Life Network. Zaporizhzhia")



Other key populations:

3 persons of male KP were aged 25–39, and one person belonged to the age category of 50+ (see Fig. 7)

Fig. 7 — Age disaggregation of other male KPs who received Mylan test systems (Charitable Organization "100% Life Network. Zaporizhzhia")



Two reactive test results were obtained during the activity, one of which was confirmed at the screening, verification, and identification stages of the examination. That person was registered for medical supervision and started receiving ART. The second person belongs to a key group of PWID and a subgroup of homeless, communication with the client is lost, work is underway to find the client through risk networks to begin treatment.

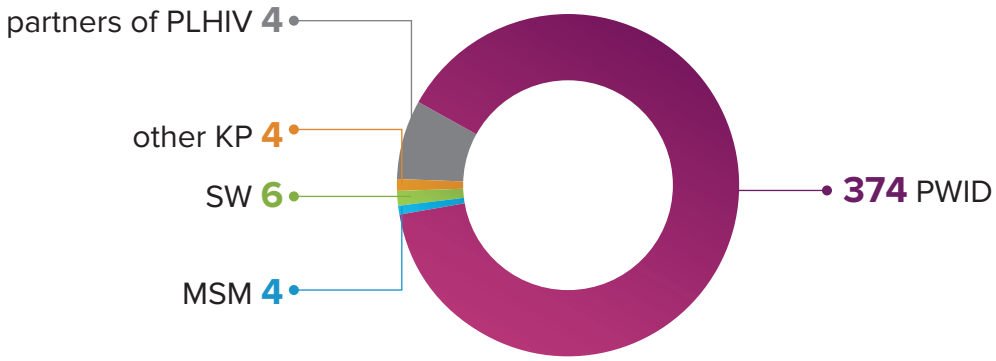
Charitable Organization 100% Life Network Dnipro

The Organization introduced the secondary dissemination of Mylan testing systems through key and vulnerable populations and for their sexual partners and social environment that practiced HIV risk behaviors during the reporting period.

Two social workers acting as mentors involved 7 recruiters from key populations.

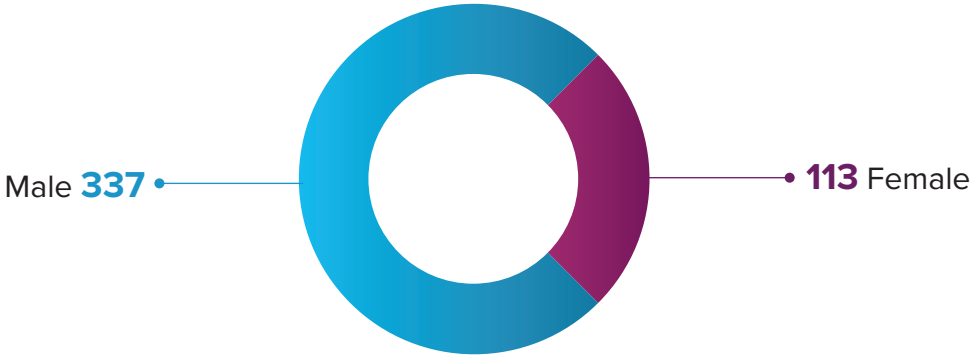
In general, the Organization recruiters distributed 450 Mylan HIVST kits for the following KP representatives: PWID — 374, MSM — 4, SW — 6, other KP — 435, sexual partners of PLHIV — 31, which made 100% of the planned figure for the reporting period (see Fig. 8)

Fig. 8 — Analysis of the Mylan test system distribution to the following KP representatives (Charitable Organization 100% Life Network Dnipro)



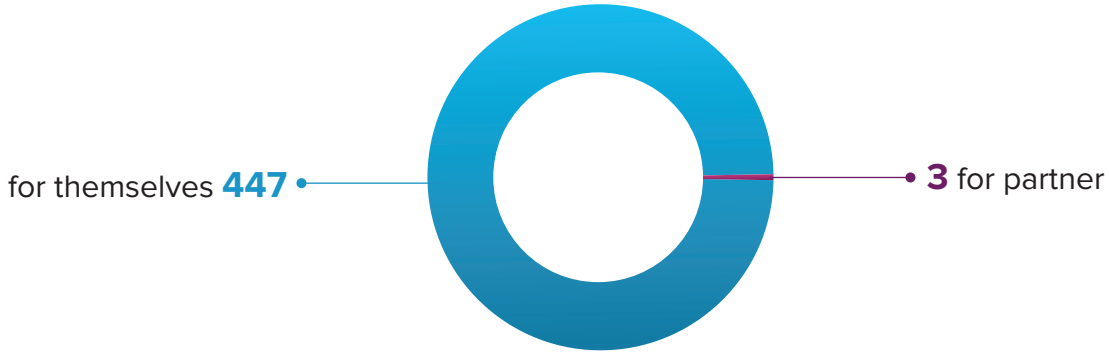
337 males (74.80%) and 113 females (25.20%) of 450 KP representatives received Mylan HIVST kits (see Fig. 9)

Fig. 9 — Gender distribution of KP representatives who received service (Charitable Organization 100% Life Network Dnipro)



Of 450 KP representatives who received Mylan HIVST kits, 447 persons received HIVST kits for themselves, and 3 received them for their sexual and/or injecting partners (see Fig. 10)

Fig. 10 — Distribution of test systems received for HIVTS (Charitable Organization 100% Life Network Dnipro)

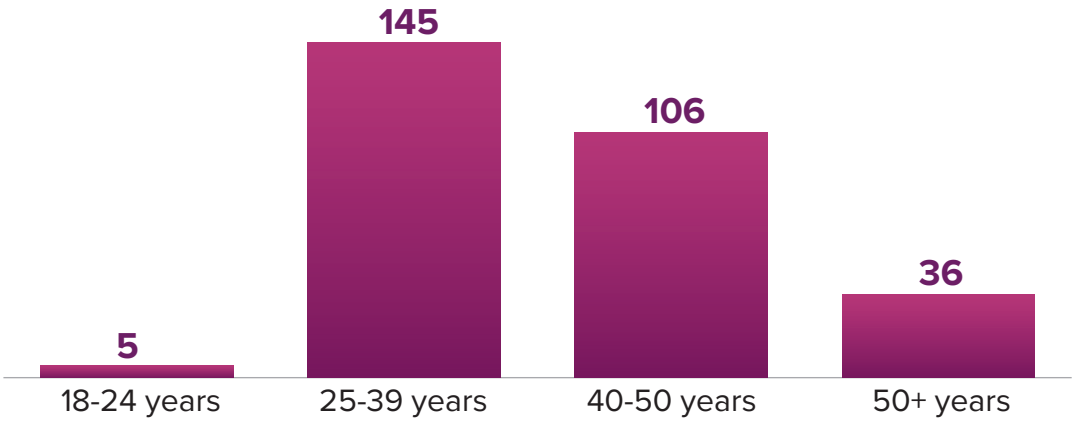


People who inject drugs (PWID):

292 men and 82 women out of 374 PWID representatives were served by the organization.

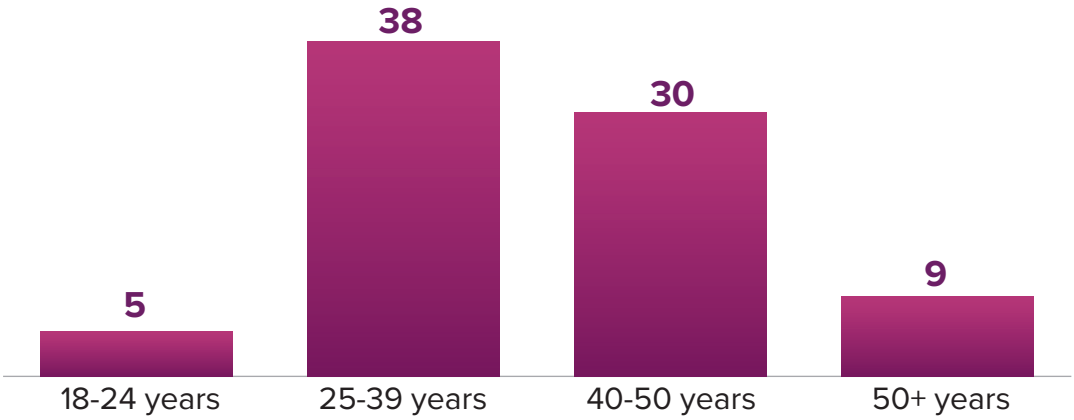
5 persons of 151 male PWID were aged 18–24, 145 persons — 25–39, 106 people — 40–50 and 36 people belonged to the age category of 50+ (see Fig. 11.1)

Fig. 11.1 — Age disaggregation of male PWID who received Mylan test systems (Charitable Organization 100% Life Network Dnipro)



5 persons of 82 female PWID were aged 18–24, 38 persons — 25–39, 30 people — 40–50 and 9 people belonged to the age category of 50+ (see Fig. 11.2)

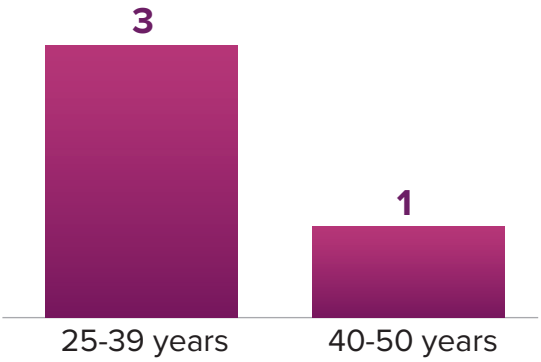
Fig. 11.2 — Age disaggregation of female PWID who received Mylan test systems (Charitable Organization 100% Life Network Dnipro)



Men who have sex with men (MSM):

3 persons of 4 MSM were aged 25–39, and 1 person belonged to the age category of 40–50 (see Fig. 12)

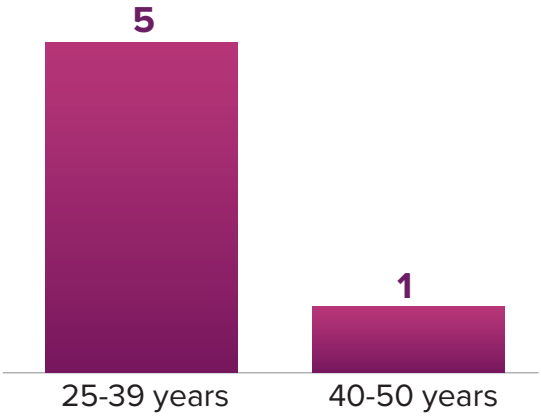
Fig. 12 — Age disaggregation of MSM who received Mylan test systems (Charitable Organization 100% Life Network Dnipro)



Sex workers (SW):

5 persons of 6 female SWs belonged to the age category of 25–39, and one person — 40–50 (see Fig. 13)

Fig. 13 — Age disaggregation of female SW who received Mylan test systems (Charitable Organization 100% Life Network Dnipro)

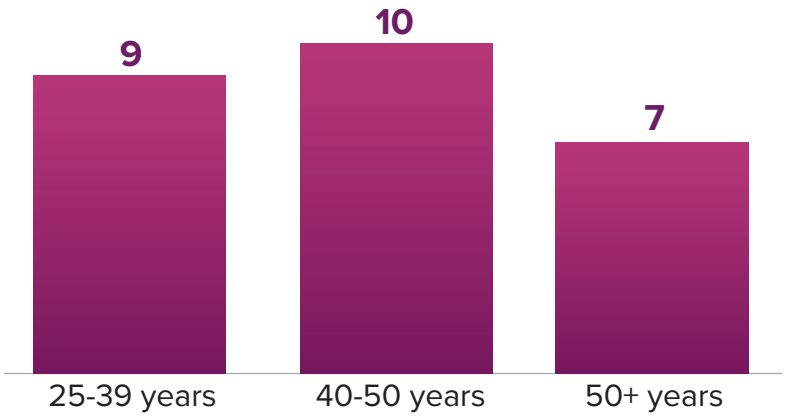


Other key populations:

26 men and 9 women out of 35 other KP representatives were covered by the Organization's services.

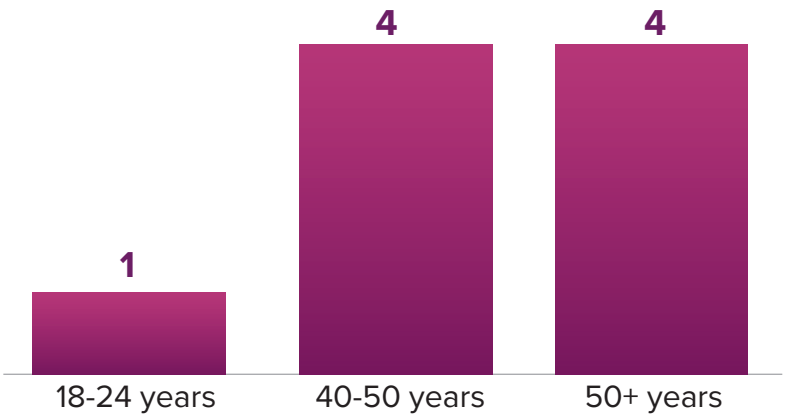
10 persons of the other KP male representatives were aged 25–39, 10 persons — 40–50, and 7 people belonged to the age category of 50+ (see Fig. 14.1)

Fig. 14.1 — Age disaggregation of other male KPs who received Mylan test systems (Charitable Organization 100% Life Network Dnipro)



One person of the other KP female representatives was aged 18–24, 4 persons — 40–50 and 4 people belonged to the age category of 50+ (see Fig. 14.2)

Fig. 14.2 — Age disaggregation of other female KPs who received Mylan test systems (Charitable Organization 100% Life Network Dnipro)

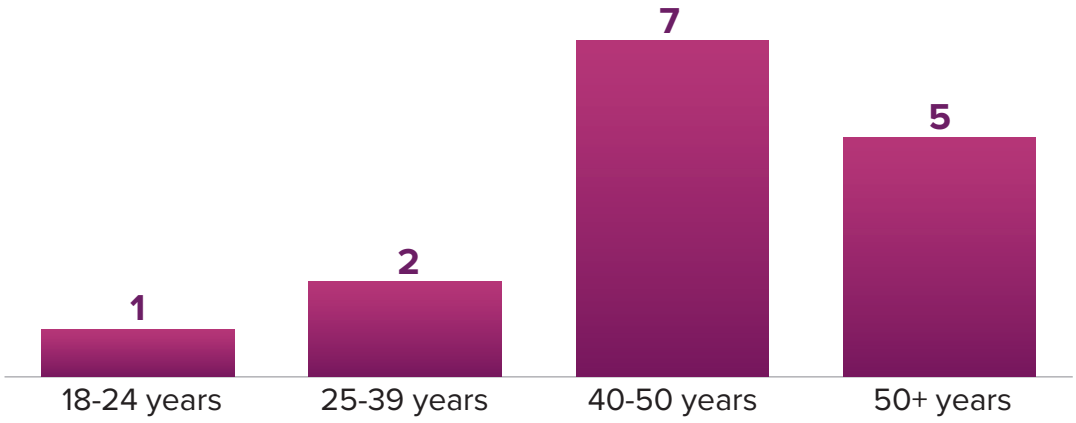


Sexual partners of PLHIV:

15 men and 16 women out of 31 sexual partners of PLHIV were covered by the Organization's services.

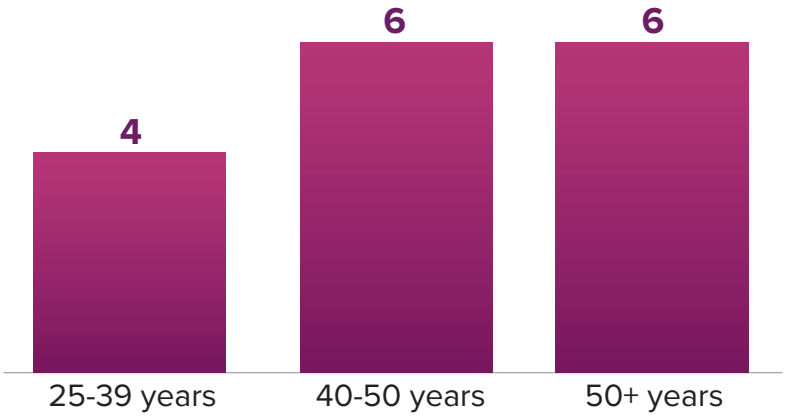
1 person of male sexual partners of PLHIV was aged 18–24, 2 persons — 25–39, 7 people — 40–50 and 5 people belonged to the age category of 50+ (see Fig. 15.1)

Fig. 15.1 — Age disaggregation of male sexual partners of PLHIV who received Mylan test systems (Charitable Organization 100% Life Network Dnipro)



4 persons of female sexual partners of PLHIV were aged 25–39, 6 persons — 40–50, and 6 people belonged to the age category of 50+ (see Fig. 15.2)

Fig. 15.2 — Age disaggregation of female sexual partners of PLHIV who received Mylan test systems (Charitable Organization 100% Life Network Dnipro)



Two reactive test results were obtained during the implementation of the activity, and they were confirmed at the screening, verification, and identification stages of the examination. Those persons were registered for medical supervision and started receiving ART.

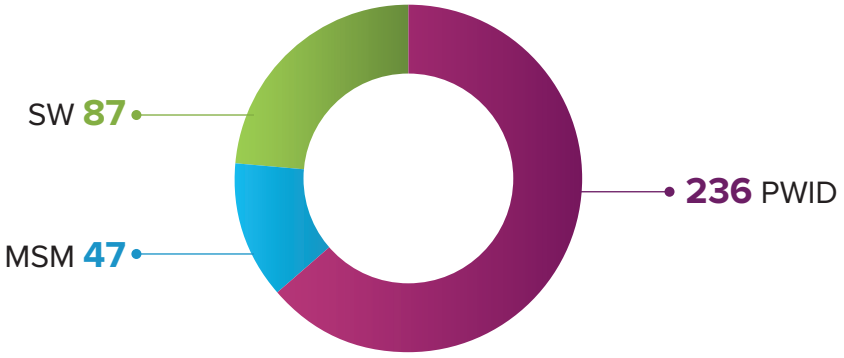
Svitlo Nadii (Light of Hope) Charitable Organization

The Organization introduced the secondary dissemination of Mylan testing systems through key and vulnerable populations and for thir sexual partners and social environment that practiced HIV risk behaviors during the reporting period.

Two social workers acting as mentors involved 4 recruiters from key population groups.

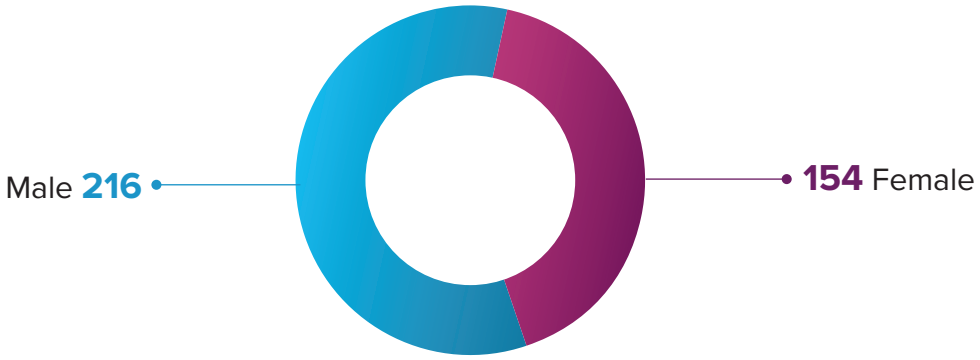
Overall, the Organization's recruiters distributed 370 Mylan HIVST kits to the following KP representatives: PWID — 236, MSM — 47, SW — 87, representing 100% of the planned figure for the reporting period (see Fig. 16)

Fig. 16 — Analysis of the Mylan test system distribution to the following KP representatives (Svitlo Nadii (Light of Hope) Charitable Organization)



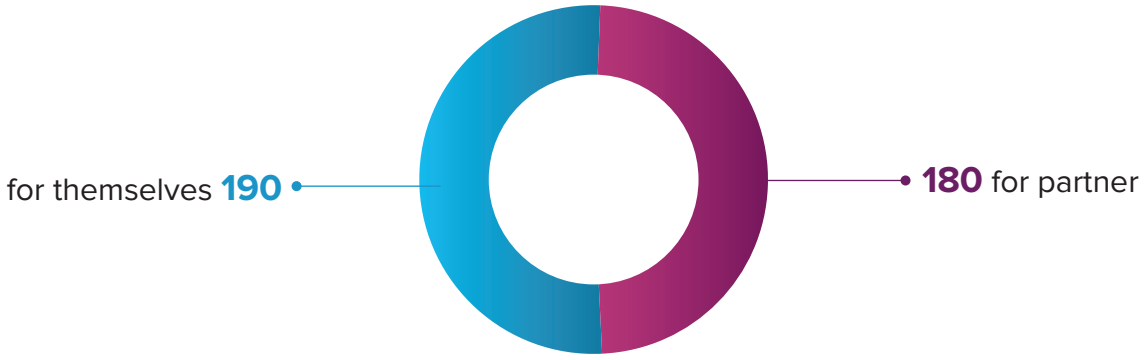
216 males (58.40%) and 154 females (41.60%) of 370 KP representatives received Mylan HIVST kits (see Fig. 17).

Fig. 17 — Gender distribution of KP representatives who received service (Svitlo Nadii (Light of Hope) Charitable Organization)



Of 370 KP representatives who received Mylan HIVST kits, 190 persons received HIVST kits for themselves, and 180 received HIVST kits for their sexual and/or injecting partners (see Fig. 18).

Fig. 18 — Distribution of test systems received for HIVTS (Svitlo Nadii (Light of Hope) Charitable Organization)

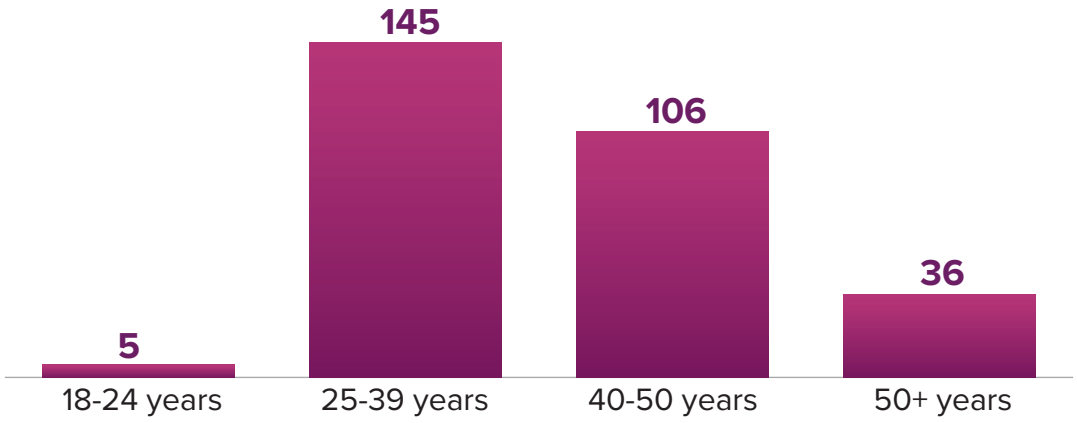


People who inject drugs (PWID):

169 men and 67 women out of 236 PWID representatives were covered by the Organization's services.

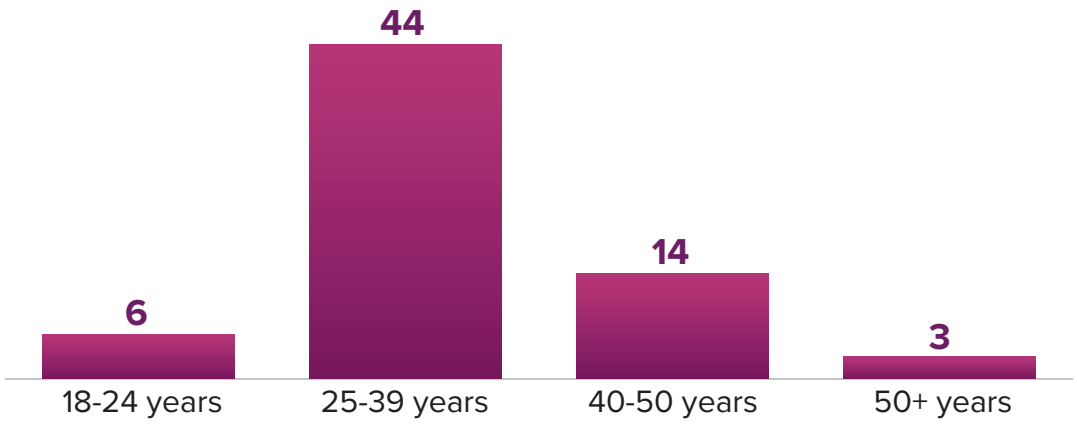
26 persons of 169 male PWID representatives were aged 18–24, 81 persons — 25–39, 54 people — 40–50 and 8 people belonged to the age category of 50+ (see Fig. 19.1).

Fig. 19.1 — Age disaggregation of male PWID who received Mylan test systems (Svitlo Nadii (Light of Hope) Charitable Organization)



6 persons out of 67 female PWID were aged 18–24 years, 44 persons — 25–39, 14 people — 40–50 and 3 people belonged to the age category of 50+ (see Fig. 19.2).

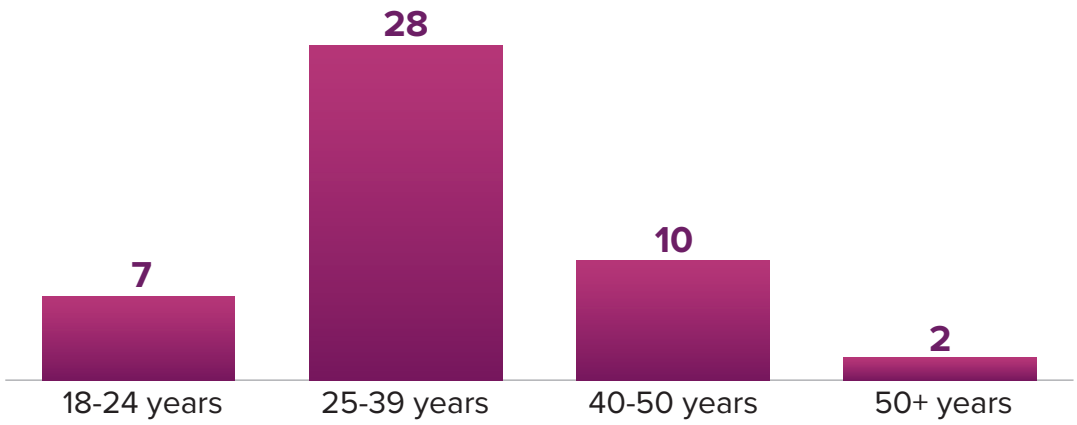
Fig. 19.2 — Age disaggregation of female PWID who received Mylan test systems (Svitlo Nadii (Light of Hope) Charitable Organization)



Men who have sex with men (MSM):

7 persons out of 47 MSM representatives were aged 18–24, 28 persons — 25–39, 10 people — 40–50 and 2 people belonged to the age category of 50+ (see Fig. 10.2) (see Fig. 20)

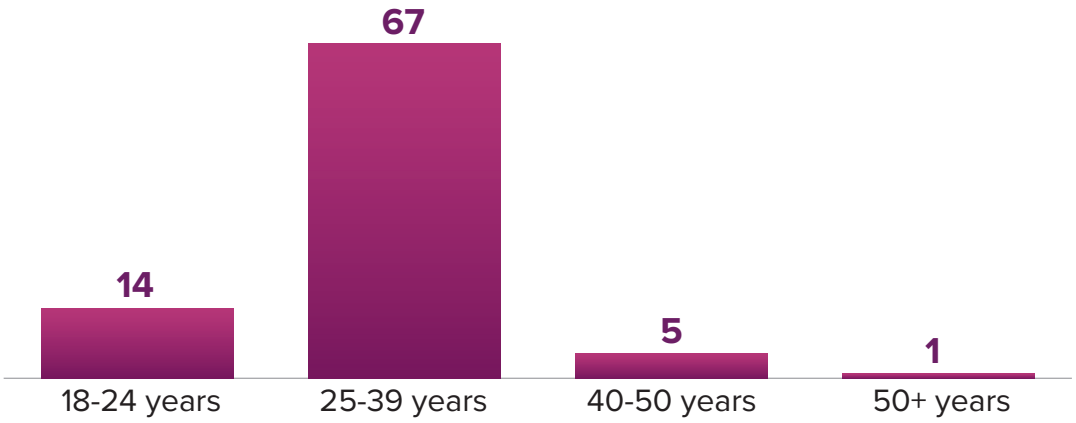
Fig. 20 — Age disaggregation of MSM who received Mylan test systems (Svitlo Nadii (Light of Hope) Charitable Organization)



Sex workers (SW):

14 persons of 87 female SW were aged 18–24, 67 persons — 25–39, 5 people — 40–50 and 1 person belonged to the age category of 50+ (see Fig. 21).

Fig. 21 — Age disaggregation of female SW who received Mylan test systems (Svitlo Nadii (Light of Hope) Charitable Organization)



No reactive test results were obtained during the activity implementation

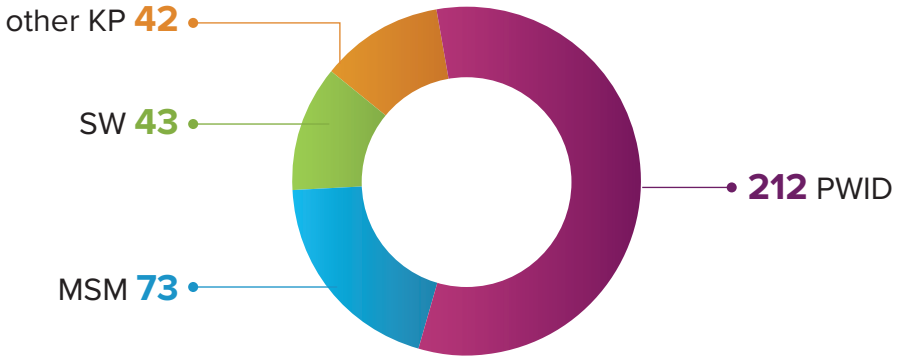
Chernihiv Branch of Charitable Organization All-Ukrainian Network of People Living with HIV/AIDS

The Organization introduced the secondary dissemination of Mylan testing systems through key and vulnerable populations and for them sexual partners and social environment that practiced HIV risk behaviors during the reporting period.

Two social workers acting as mentors involved 14 recruiters from key populations.

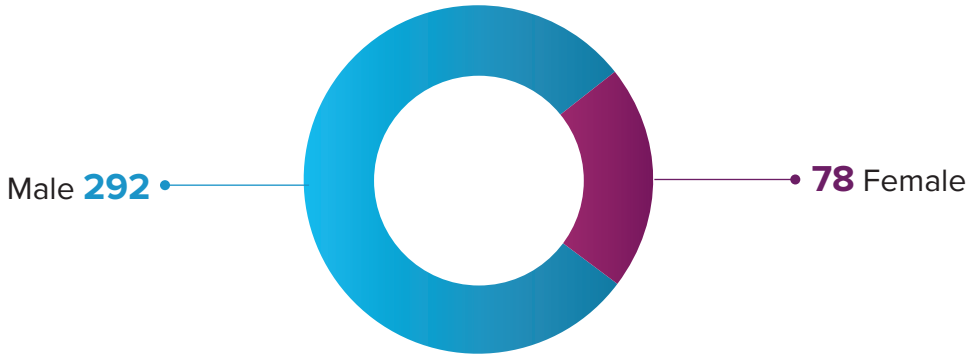
Overall, the organization's recruiters distributed 370 Mylan HIVST kits to the following KP representatives: PWID — 212, MSM — 73, SW — 43, other KP — 42, representing 100% of the planned figure for the reporting period (see Fig. 22)

Fig. 22 — Analysis of the Mylan test system distribution to the following KP representatives (Chernihiv Branch of Charitable Organization All-Ukrainian Network of People Living with HIV/AIDS)



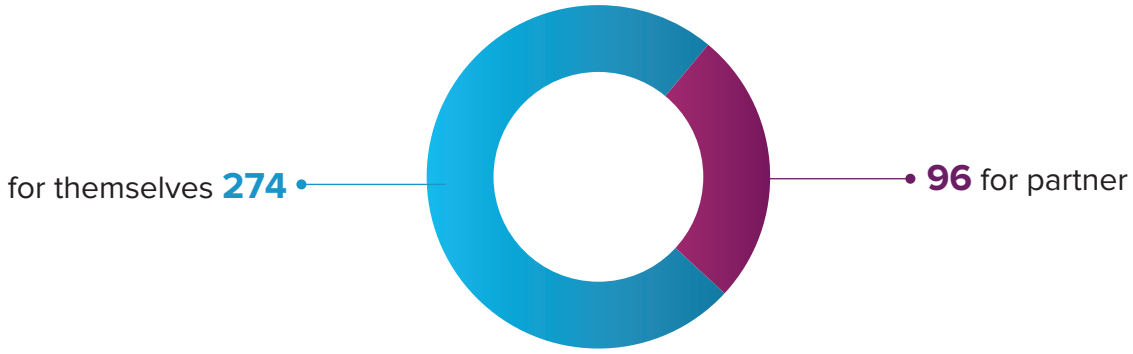
292 males (78.91%) and 78 females (21.09%) of 370 KP representatives received Mylan HIVST kits (see Fig. 23).

Fig. 23 — Gender distribution of KP representatives who received service (Chernihiv Branch of Charitable Organization All-Ukrainian Network of People Living with HIV/AIDS)



Of 370 KP representatives who received Mylan HIVST kits, 274 persons received HIVST kits for themselves, and 96 received them for their sexual and/or injecting partners (see Fig. 24).

Fig. 24 — Distribution of test systems received for HIVTS (Chernihiv Branch of Charitable Organization All-Ukrainian Network of People Living with HIV/AIDS)

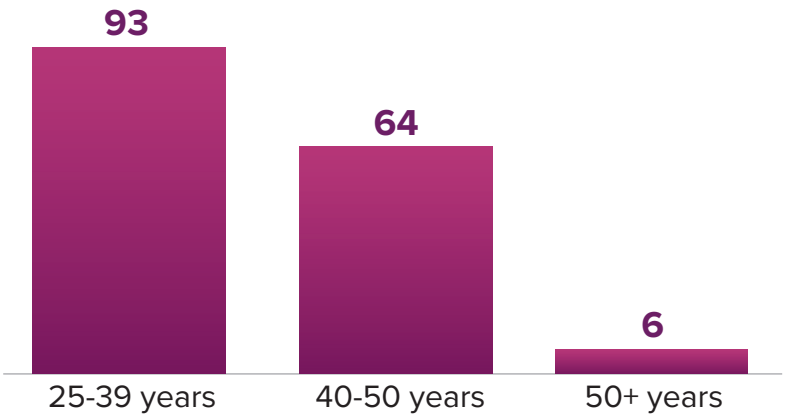


People who inject drugs (PWID):

163 men and 49 women out of 212 PWID representatives were covered by the Organization's services.

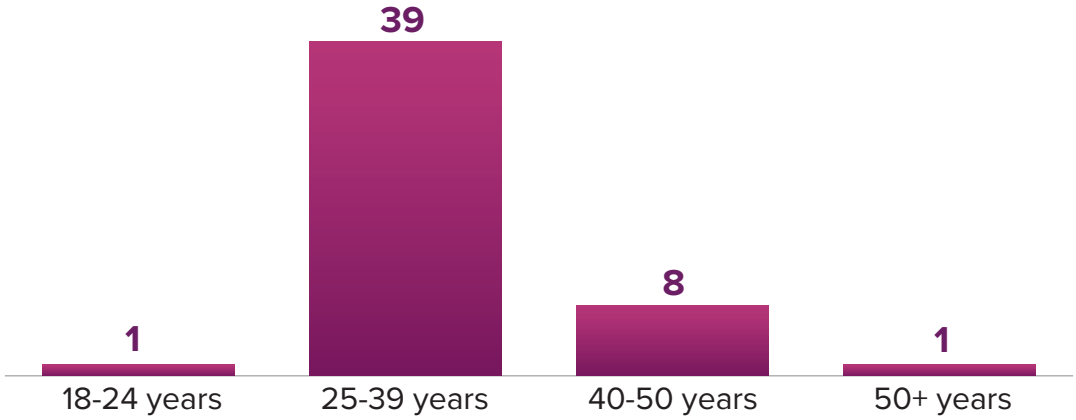
93 persons out of 163 male PWID representatives were aged 25–39, 64 people — 40–50, and 6 belonged to the age category of 50+ (see Fig. 25.1).

Fig. 25.1 — Age disaggregation of male PWID who received Mylan test systems (Chernihiv Branch of Charitable Organization All-Ukrainian Network of People Living with HIV/AIDS)



1 person out of 49 female PWID belonged to the age category 18–24 years, 39 persons — 25–39, 8 people — 40–50, and 1 person belonged to the age category of 50+ (see Fig. 25.2).

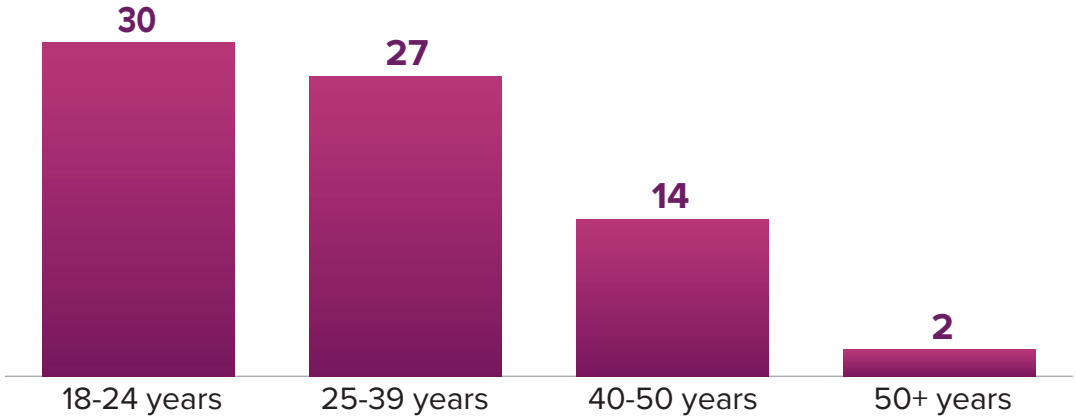
Fig. 25.2 — Age disaggregation of female PWID who received Mylan test systems (Chernihiv Branch of Charitable Organization All-Ukrainian Network of People Living with HIV/AIDS)



Men who have sex with men (MSM):

30 persons out of 73 MSM representatives were aged 18–24, 27 persons — 25–39, 14 people — 40–50 and 1 person belonged to the age category of 50+ (see Fig. 26).

Fig. 26 — Age disaggregation of MSM who received Mylan test systems (Chernihiv Branch of Charitable Organization All-Ukrainian Network of People Living with HIV/AIDS)

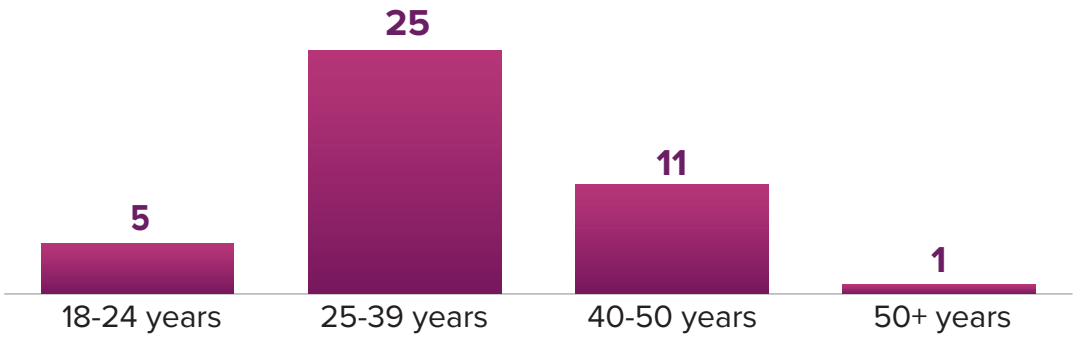


Sex workers (SW):

1 male of the age category 25–39 and 42 females out of 43 SW representatives were covered by the Organization's services.

5 persons out of 42 female SW were aged 18–24, 25 persons — 25–39, 11 people — 40–50 and 1 person belonged to the age category of 50+ (see Fig. 27).

Fig. 27 — Age disaggregation of female SW who received Mylan test systems (Chernihiv Branch of Charitable Organization All-Ukrainian Network of People Living with HIV/AIDS)

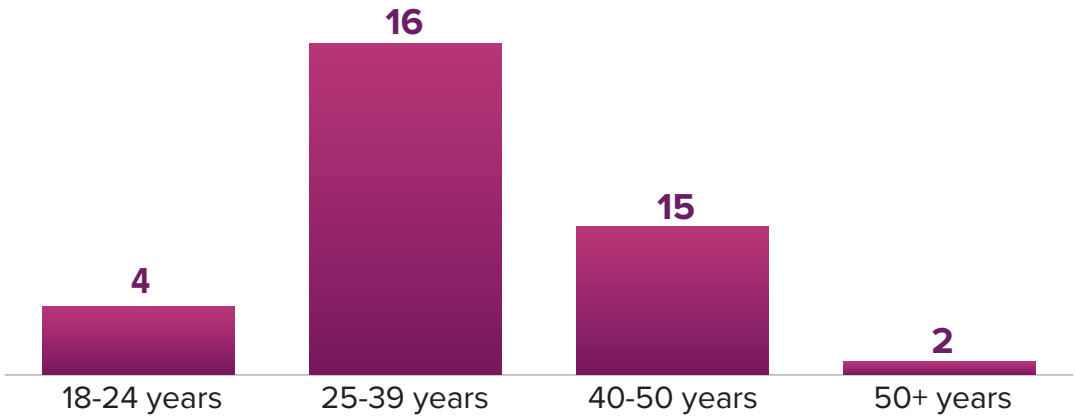


Other key populations:

27 men and 15 women out of 42 other KP representatives were covered by the Organization's services.

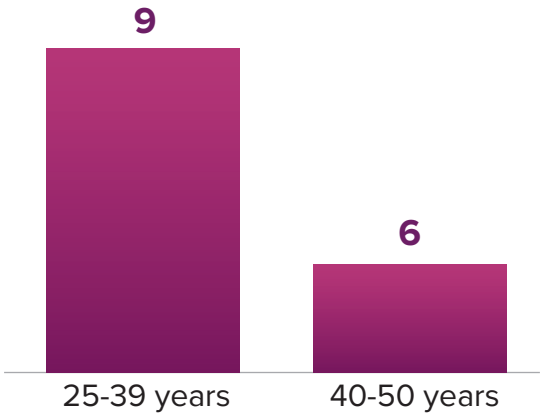
4 persons out of other male key populations belonged to the age category of 18–24, 16 persons — 25–39, 5 people — 40–50, and 2 persons belonged to the age category of 50+ (see Fig. 28.1).

Fig. 28.1 — Age disaggregation of other male KPs who received Mylan test systems (Chernihiv Branch of Charitable Organization All-Ukrainian Network of People Living with HIV/AIDS)



9 persons out of other female key populations belonged to the age category of 25–39, and 6 people — 40–50 (see Fig. 28.2).

Fig. 28.2 — Age disaggregation of other female KPs who received Mylan test systems (Chernihiv Branch of Charitable Organization All-Ukrainian Network of People Living with HIV/AIDS)



One reactive test result was obtained during the activity, according to the recruiter, the client is not yet mentally ready to consult the social worker and to use medical services.

Free Zone Charitable Organization

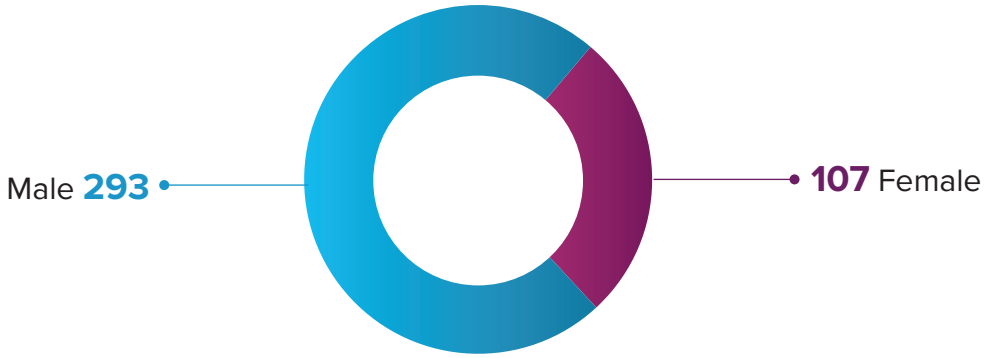
The Organization introduced the secondary dissemination of Mylan testing systems through key and vulnerable populations and for their sexual partners and social environment that practiced HIV risk behaviors during the reporting period.

The social worker, acting as a mentor, involved 3 recruiters from key groups.

Overall, the Organization's recruiters distributed 400 Mylan HIVST kits for PWID, representing 88.8% of the target for the reporting period (450 HIVST kits).

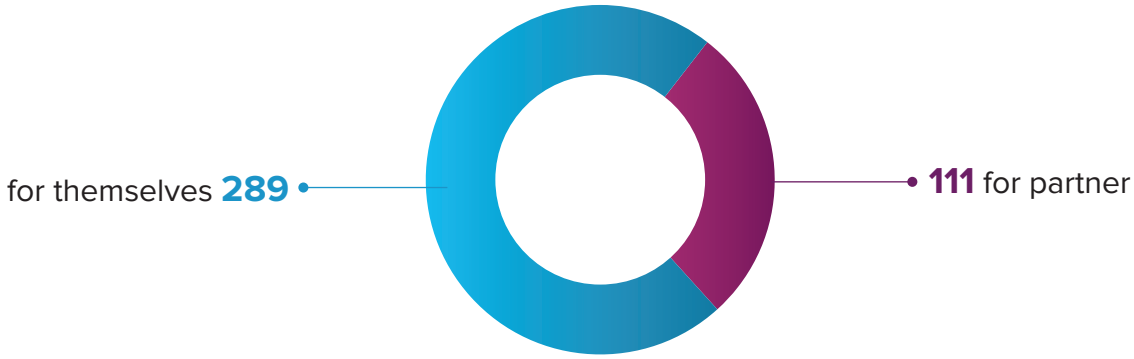
293 males (78.91%) and 107 females (21.09%) of 400 KP representatives received Mylan HIVST kits (see Fig. 29).

Fig. 29 — Gender distribution of KP representatives who received the service (Free Zone Charitable Organization)



Of 400 KP representatives who received Mylan HIVST kits, 289 persons received HIVST kits for themselves, and 111 received them for their sexual and/or injecting partners (see Fig. 30).

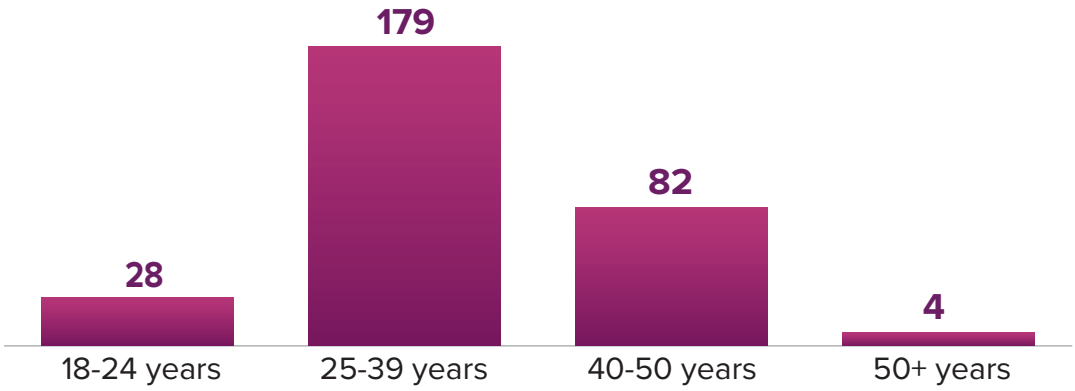
Fig. 30 — Distribution of test systems received by KP (Free Zone Charitable Organization)



People who inject drugs (PWID):

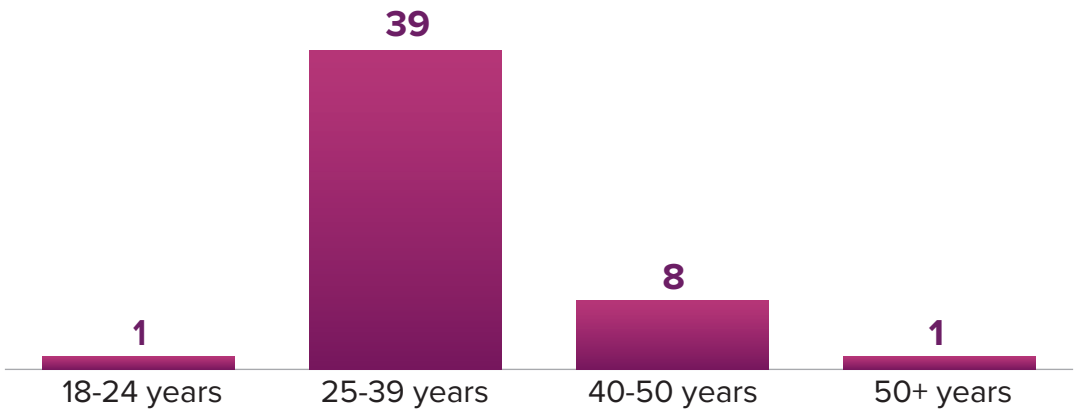
23 persons out of 293 male PWID were aged 18–24 years, 179 persons — 25–39, 82 people — 40–50 and 4 people belonged to the age category of 50+ (see Fig. 31.1).

Fig. 31.1 — Age disaggregation of male PWID who received Mylan test systems (Free Zone Charitable Organization)



8 persons out of 107 female PWID were aged 18–24, 85 persons — 25–39, 12 people — 40–50 and 2 people belonged to the age category of 50+ (see Fig. 31.2).

Fig. 31.2 — Age disaggregation of female PWID who received Mylan test systems (Free Zone Charitable Organization)



One reactive test result was obtained during the activities and was not confirmed at the screening and verification stages of examination at the HCF.

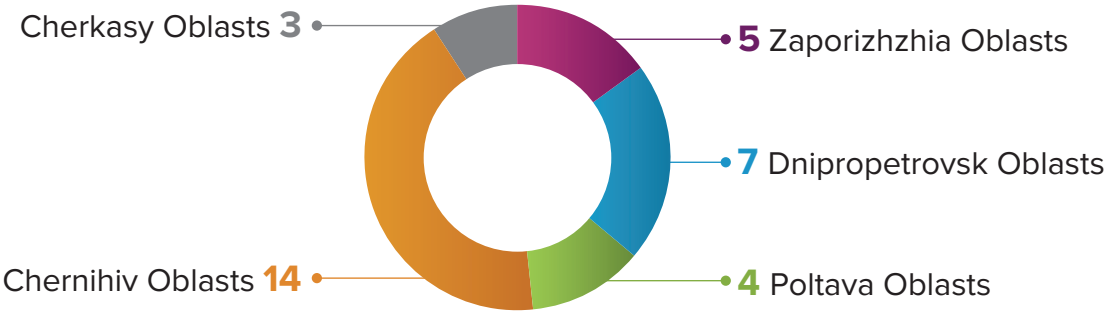
3. General analysis of the distribution of Mylan HIVST kits

Five Organizations introduced the secondary dissemination of Mylan testing systems through key and vulnerable populations and for their sexual partners and social environment that practiced HIV risk behaviors during the reporting period.

The demonstration project involved organizations from Zaporizhzhia, Dnipropetrovsk, Poltava, Chernihiv Oblasts, and the Cherkasy hub of the All-Ukrainian Organization.

Nine social workers acting as mentors recruited 33 recruiters from key populations (see Fig. 32).

Fig. 32 — Distribution of recruiters by regions of activity



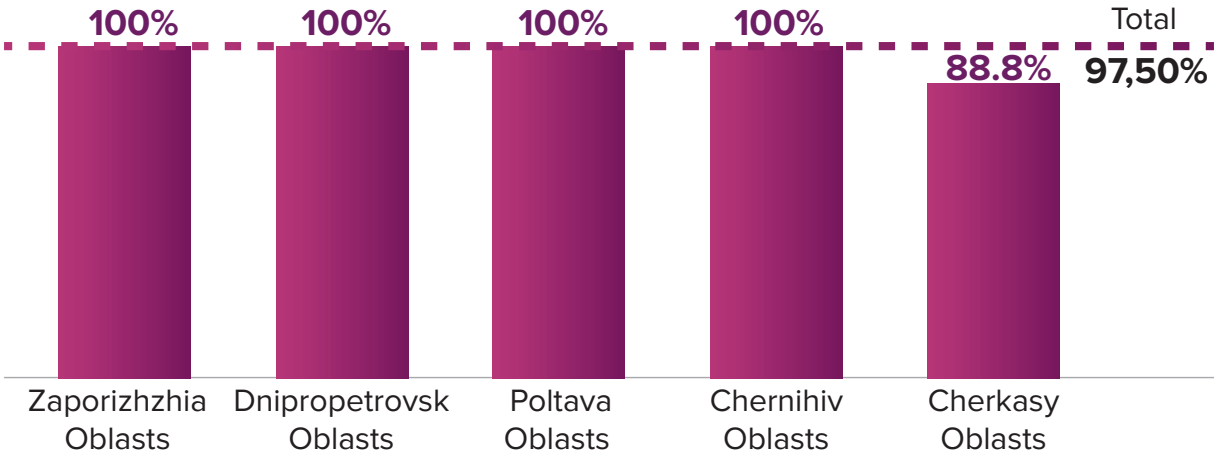
In accordance with the demonstration project plan, the targets for the distribution of HIVST kits were distributed as follows (see Fig. 33).

Fig. 33 — Distribution of planned indicators for distribution of test systems by regions of activity implementation



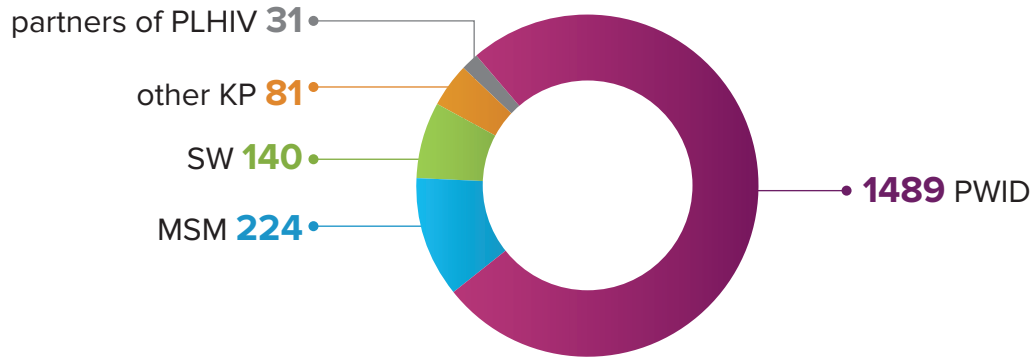
In general, during the activity implementation, 1,965 HIVST kits were distributed out of 2,015, which made 97.5% of the target (see Fig. 34).

Fig. 34 — Implementation of planned indicators by regions of activity



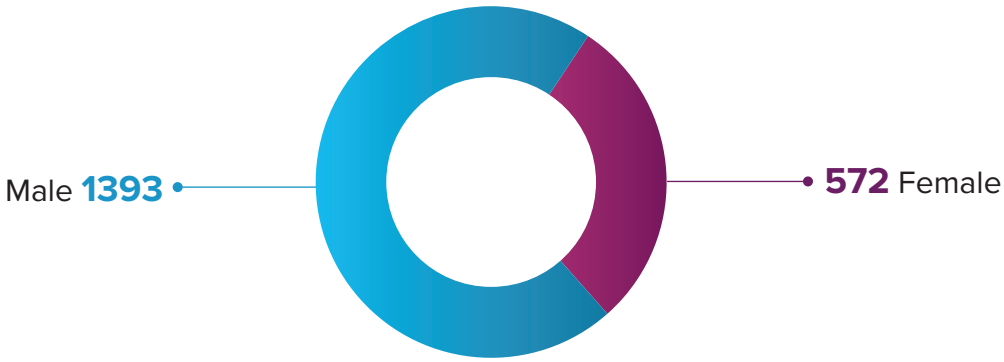
The following KP representatives received testing systems by region: PWID — 1,489, MSM — 224, SW — 140, other KP — 81, sexual partners of people living with HIV — 31 (see Fig. 35).

Fig. 35 — Analysis of the Mylan test system distribution to the following KP representatives



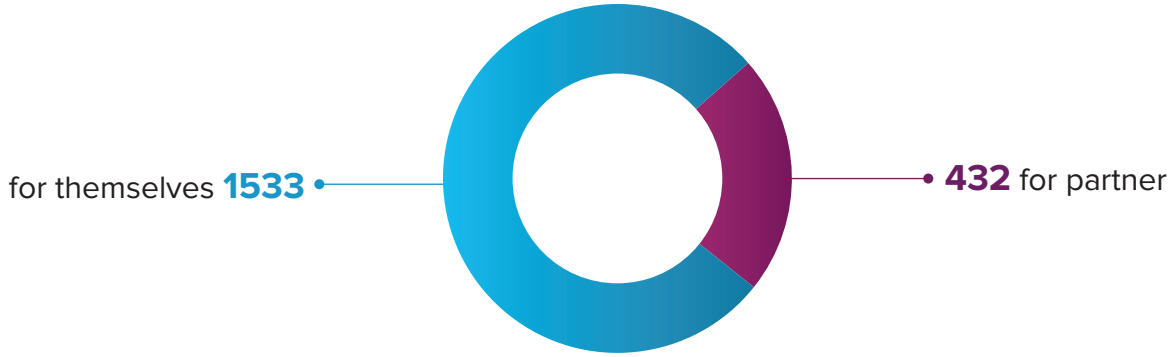
1,393 persons were male (70.89%) and 572 were female (29.11%) out of 1,965 KP representatives who received Mylan HIVST kits (see Fig. 36).

Fig. 36 — Gender distribution of KP representatives who received the service



Of the 1,965 KP representatives who received Mylan HIVST kits, 1,533 persons received HIVST kits for themselves, and 432 received them for their sexual and/or injecting partners (see Fig. 37).

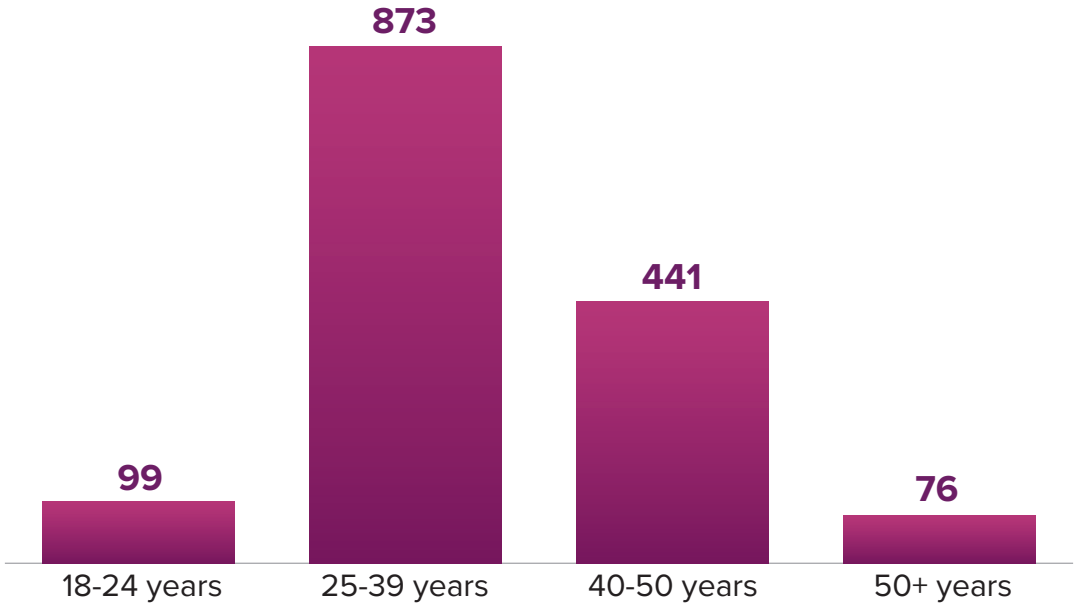
Fig. 37 — Distribution of test systems received for HIVTS



People who inject drugs (PWID):

99 persons out of 1,489 PWID were aged 18–24, 873 persons — 25–39, 441 people — 40–50 and 76 people belonged to the age category of 50+ (see Fig. 38).

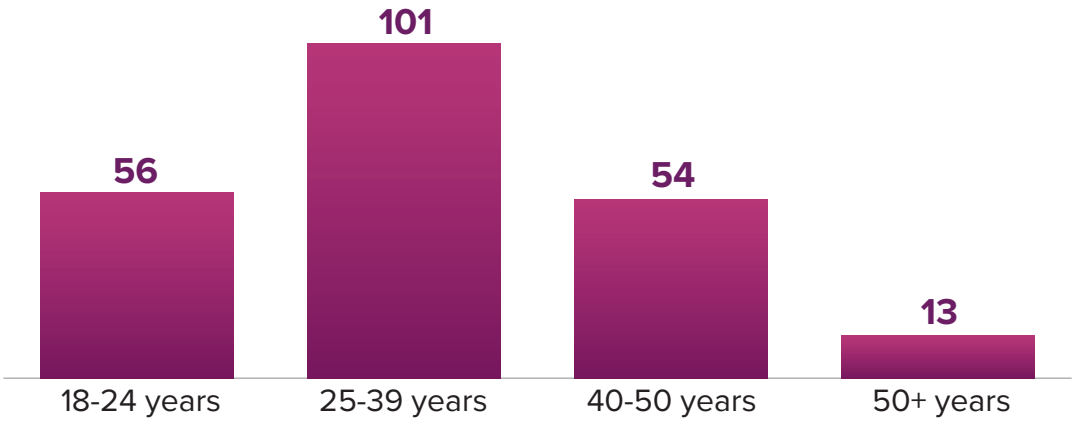
Fig. 38 — Age disaggregation of PWID who received Mylan test systems



Men who have sex with men (MSM):

56 persons of 224 MSM were aged 18–24 years, 101 persons — 25–39, 54 people — 40–50 and 13 people belonged to the age category of 50+ (see Fig. 39).

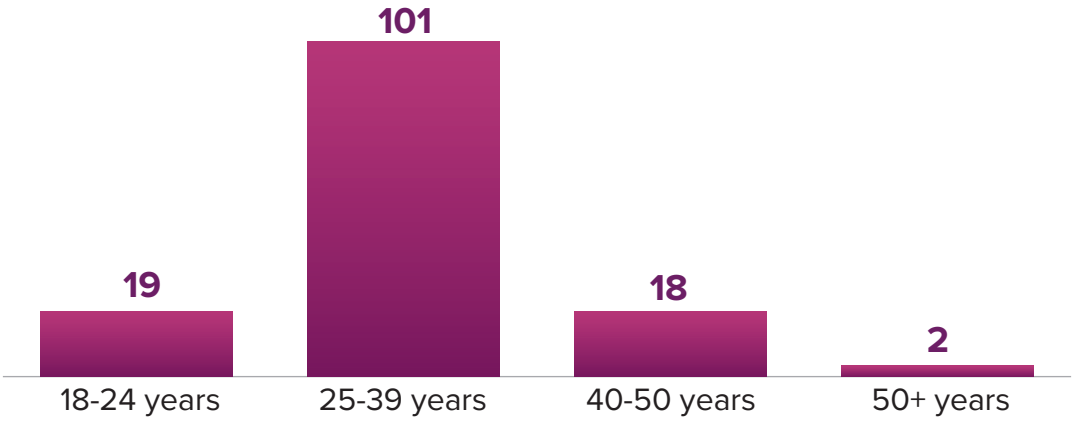
Fig. 39 — Age disaggregation of MSM who received Mylan test systems



Sex workers (SW):

119 persons out of 140 SW representatives were aged 18–24, 101 persons — 25–39, 18 people — 40–50 and 2 people belonged to the age category of 50+ (see Fig. 40).

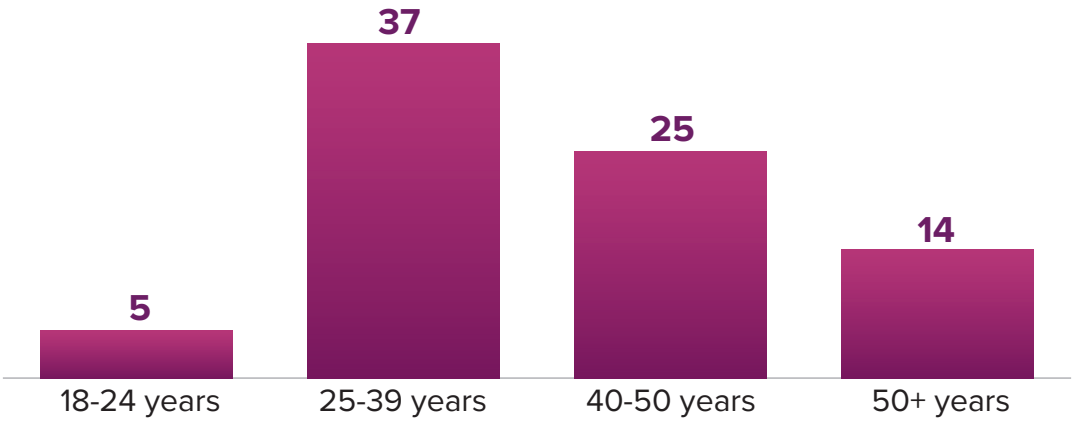
Fig. 40 — Age disaggregation of SW who received Mylan test systems



Other key populations:

5 persons out of 81other key populations were aged 18–24, 37 persons — 25–39, 25 people — 40–50 and 14 people belonged to the age category of 50+ (see Fig. 41).

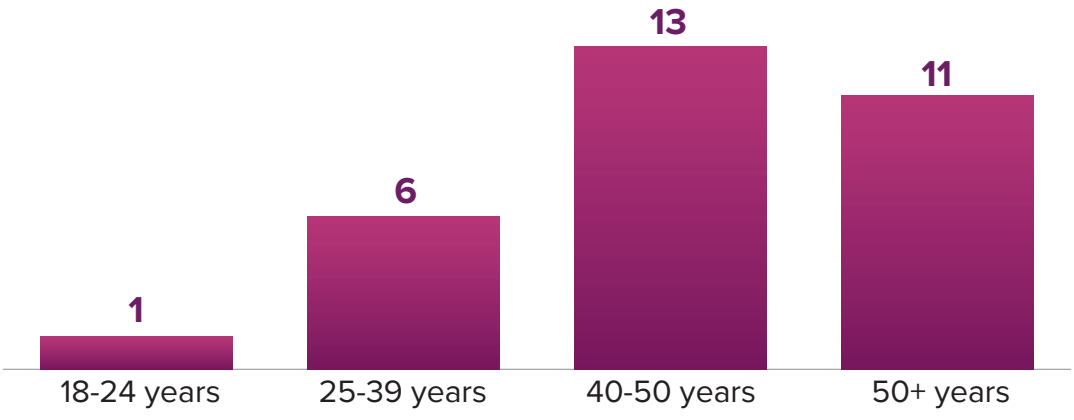
Fig. 41 — Age disaggregation of other KPs who received Mylan test systems



Sexual partners of PLHIV:

1 person out of 31 sexual partners of PLHIV were aged 18–24, 6 persons — 25–39, 13 people — 40–50 and 11 persons belonged to the age category of 50+ (see Fig. 42).

Fig. 42 — Age disaggregation of sexual partners of PLHIV who received Mylan test systems



Six reactive HIVST results were obtained during the implementation of the project, three of which were confirmed and registered for medical supervision and started receiving ART. Reasons for the other three not being confirmed include:

- Despite the reactive HIVST result, all follow-up testing at the HCF was negative.
- communication with the client was interrupted due to client's injection drug use and homelessness (work is underway to find the client through risk networks to begin treatment.)
- one client is not yet emotionally ready to consult a social worker to be brought to medical services

4. User feedback analysis based on the distribution of Mylan HIV Self-Tests

During the reporting period, mentors from NGO partners for recruiters implementing secondary distribution of HIVST kits proposed a survey to assess and evaluate the recruiter efficiency, as well as receiving feedback from recipients of testing services using Mylan HIVST kits that looked as follows:

No.	Issue	Recruiter's brief comment
1	What are the main successes in distributing self-tests this week?	
2	What were the difficulties you experienced while talking about self-testing and distributing rapid tests?	
3	Have you noted down the contacts of people I can invite for counseling and testing?	
4	Do you have any additional information about the results of pre-distributed tests of your acquaintances? Are there any reactive results?	
5	If you were informed of the reactive test result after self-testing, what did you offer to the person, and what was the person's response to your information?	
6	Do you inform your acquaintances about additional services that may be obtained from the organization? What are they interested in, and what are they afraid of?	
7	What is the customer feedback about your help and the information you provide?	
8	Feedback on self-testing from acquaintances:	
	• is it useful and valuable for them to learn their HIV status with your help?	
	• is it convenient, understandable, and comfortable to use HIV self-testing?	
9	Who else do you plan to offer self-testing? What ideas and plans do you have for the next week?	

No.	Issue	Recruiter's brief comment
10	Do we need additional training on your HIV self-testing conversations and questions from friends?	
11	What are your questions, requests, and suggestions to me regarding our cooperation?	

4.1. Advantages of using the HIVST kit

In general, positive feedback was received on its use as part of the secondary distribution of Mylan HIVST kits. Positive feedback was related to the ease and mobility of testing and the possibility of performing the test in an environment convenient for the client. Feedback from some clients regarding the "level of trust" in the HIVST kit turned out to be an interesting fact — they trust the results of testing using a blood sample rather than the oral fluid, and using this HIVST kit for self-testing is more acceptable than oral testing.

4.2. Shortcomings of using the HIVST kit

The secondary distribution of Mylan HIVST kits revealed the following shortcomings:

- The step-by-step instructions did not reference treatment of the puncture site with an alcohol wipe, although it is included in the test kit.
- Some PWID participants had difficulties pricking their fingertip due to rougher skin associated with their drug use (searching for "stash points"). In this case, recruiters suggested replacing the HIVST kit or providing an additional blood lancet.
- One test kit may have been faulty; the blood tube could not fill completely due to a blockage.
- Some participants had excess bleeding at the puncture site, and they suggested to include additional gauze and an alcohol wipe.
- Although assistants were instructed not to touch the test kit or physical assist the client, in a few cases due to vision problems or physical disability, assistants needed to help. For these cases, it was suggested by the clients that including rubber gloves with the test kit might be useful.
- Four test results were invalid (no stripes on the HIVST kit). These HIVST were repeated.
- The Ukrainian language instructions are separate from the HIVST kit.
- The tube for blood sampling broke during one test

5. Social worker feedback analysis based on the distribution of Mylan HIV Self-Tests

5.1. Arranging the interaction process with recruiters

The Project team arranged training for social workers who would be mentors on using Mylan HIVST kits as the first step in implementing activities during the preparatory stage.

The Project team developed a package of guidance materials for NGO mentors as part of the preparatory stage to ensure the process of interaction with recruiters, which included:

- The main messages when the recruiter talks to KP representatives about HIV testing using a quick test.
- Instructions for using Mylan rapid HIVST kit for HIV self-testing (step by step, for recruiters).

- Information about additional services at the NGO.
- Business card form for a social worker.
- Form of social services contract between the recruiter and social worker.
- Reporting documentation forms::
  - Recruiter survey.
  - List of inventory items given to the recruiter.
  - Recruiter's report on the distribution of HIVST kits.
  - Social worker's report on interaction with the recruiter.

At the start of the project implementation, the Project team held a founding meeting with the parties implementing the project, during which the features of its implementation were discussed:

- Features of project implementation and interaction with recruiters.
- Ways to involve recruiters from communities, including motivation systems.
- Planned indicators for the reporting period.
- Peculiarities of working with primary accounting documentation, in particular, filling algorithms and peculiarities of working with cloud storage.

To ensure continuous communication, the information and experience-sharing group was established on a messaging platform by the Project team. During the reporting period, the demonstration project coordinator made technical support visits to service delivery sites in Zaporizhzhia and Kremenchuk.

5.1.1. Selecting recruiters

When selecting recruiters, mentors from NGO social workers used the following selection criteria:

- Regular clients of the Organization from the KP with a good reputation with social workers.
- New clients of the Organization with KP members in their environment not involved in the cascade of prevention, testing and treatment services.
- Employees of the Organization from KP with access to closed KP (e.g., MSM or SW)
- Available volunteers of Organizations belonging to KP.

According to the feedback from mentors, there were no problems in selecting recruiters.

5.1.2. Peculiarities of communicating with recruiters

As part of the demonstration project implementation to ensure the effective implementation of Project team activities, a weekly meeting between the mentor and recruiter was proposed to consider widespread inventory items in the form of HIVST kits, gathering information from the recruiter on feedback from KP representatives regarding the use of HIVST kits and giving out motivational rewards.

In general, the system has been efficient. According to mentors, the weekly feedback from KP was efficient during the first weeks of distribution. In addition, according to mentors, some PWID recruiters came earlier than the appointment date to get motivational encouragement. Some recruiters tried to persuade mentors to provide advanced motivational incentives.

5.1.2. Activity scheduling and tracking of dissemination

According to the plan indicators, the demonstration project coordinator distributed indicators to NGO social workers and proposed weekly indicators of planned activities in accordance with the project timeline, which has been adapted in line with the current trend in the implementation of planned targets.

Social workers mentoring recruiters suggested the following methods of tracking the spread:

- Mapping of HIVST kit distribution activities during weekly meetings with recruiters (place and time of service)
  - Consequently, monitoring visits to service provision centers at the specified time.
- In one of the regions, as an innovative approach, the recruiter noted contact details (phone number) of persons who received the tests for one week. The social worker called clients from among these contacts to verify the provision of services.
- Clients who received HIVST kits independently contacted social workers on the phone number indicated on the business card to obtain additional information on the use of HIVST kits.

These tracking methods for the secondary distribution of HIVST kits may be effective at the major stage, but not limited to them.

5.1.4. Motivation system for recruiters

The coordinator and social workers introduced the motivation system for social workers and recruiters during the reporting period, which was as follows:

- Stimulating a reward of UAH 50 for the recruiter for one distributed test.
- Reimbursement for transport expenses of recruiters (UAH 600 for every social worker and his team of recruiters).
- Issuance of the recruiter's set consisting of a notebook, a pen, a shoulder bag ("banana-styled") and IEM.
- Reimbursement to the social worker in the amount of UAH 7,500.

Overall, the system has proven to be an effective model for encouraging both social workers and recruits. Considering the peculiarities indicated in the section "Peculiarities of Communicating with Recruiters," the recommendations are as follows:

- Implementing an indirect reward system, such as certificates for food or hygiene products
- Recruiting based on a civil contract with the payment according to the number of services provided in case of the organization's capacity.
- Based on the experience, the shoulder bag is not large enough to carry HIVST kits, so replacing it with a more convenient backpack or bag (e.g., a shopper) is recommended. You should also have small packages where you can put the HIVST kit and give them to the recruiter every time because they often come without any bag or backpack to take tests from the office for further distribution.
- To arrange the secondary distribution of HIVST kits, it is recommended to involve experienced social workers, including those from among equals, who understand the specifics of behavior, interests, and motives of KP and have enough experience for communication and arguments to encourage and involve people in cooperation, combining it at with the management of test distribution process and reporting.

5.1.5. Gathering feedback

Recruiters' feedback on their activities was collected using the feedback form given in the example in the section "User feedback analysis following the distribution of Mylan HIV Self-Tests."

When interacting with recruiters, social workers received positive feedback on using HIVST kits. Social workers identified the following development trends during the feedback:

- Need for enhanced mapping of recruiter sites.
- Need for enhanced training of recruiters, in the field of HIV infection, co-infection issues and lack of easy and convenient IEM.
- Need to train recruiters in basic counseling skills.

5.2. Benefits and shortcomings of using the HIVST kit from the point of view of social workers

Social workers acting as mentors for recruiters during the project highlighted the following benefits of using Mylan HIVST kits:

- HIVST kits are easy to use, especially for distribution and use on the outreach routes.
- Social workers evaluated the high sensitivity and specificity of HIVST kits (compared to WANTAI HIVST kits).
- Social workers also see the use of HIVST kits for secondary distribution as an opportunity to expand HIVTS and engage people who have never received them.

At the same time, social workers highlighted the following shortcomings in the use of HIVST kits in terms of the organizational nature of the process:

- The complexity of the deduplication process: the same client could theoretically use the services of several recruiters. As the documentation did not use direct and indirect identifiers, the tracking of HIVST kit service delivery became more complex.
- Concerns about misuse of HIVST kits by recruiters and clients who have received HIVST kits.

5.3. Peculiarities of working with the reporting documentation within the demonstration project

The team developed the following primary accounting documentation to monitor the quantitative and qualitative performance of the demonstration project:

- A recruiter survey is a form of receiving feedback on the interaction between the recruiter and KP representatives, the main successes and challenges in the work on secondary distribution of HIVST kits.
- A list of inventory items issued to the recruiter is a form of tracing provided goods and materials to the recruiter (HIVST kits, prevention materials, shoulder bags).
- Recruiter's report on the distribution of HIVST kits — the form of the quantitative report based on the number of distributed HIVST kits, preventive means for KP representatives.
- Social worker's report on interaction with the recruiter — social worker's report on the work with recruiters.

Document flow within the demonstration project was organized using cloud storage — every social worker had access to their document folder only. There were no personal identifiers in the records during the implementation of the demonstration project. Given the different

experiences of social workers in working with cloud storage, the project coordinator provided mentoring support to the process of data exchange between social workers and the project team, as required.

According to feedback from social workers, the documentation offered was user-friendly, easy to understand and contained sufficient data. The following statements were received among the recommendations made by social workers to optimize documentation forms:

- Using depersonalized identifiers (for example, SYREX or CASE++) for persons who received Mylan HIVST kits to avoid the cross-delivery of services by different recruiters.
- Completing the Recruiter Survey form every month or every two weeks.

6. Recommendations for adapting the approach to the distribution of Mylan HIV Self-Tests among regional partners (NGOs) for targeted distribution to PWID, SW, MSM and other key and priority populations to enhance self-testing capabilities among customers and their communities

Considering the above information on the demonstration project results, a SWOT analysis of activities is provided to give practical recommendations concerning the implementation of activities for the Mylan Self-Test distribution.

Strengths	Weaknesses
1. Existing experience in implementing the secondary distribution of Mylan HIVST kits. 2. NGOs have significant human and technical capabilities to carry out activities. 3. Existing client base and loyal clients that can serve as the base for implementing secondary distribution of Mylan HIVST kits.	1. Uneven service coverage of different KP representatives. 2. Insufficient monitoring of test results during the secondary distribution of HIVST kits. 3. The test package and the instructions contain some mismatches. 4. Insufficient qualification level of recruiter training on HIV issues.
Opportunities	**Threats**
1. Existing experience has been gained in prompt response to unusual cases during the secondary distribution of testing systems. 2. Developing partnerships and cooperation with KP community representatives.	1. Possibility of HIVST kits misuse by clients. 2. Possibility of HIVST kits misuse by recruiters.

Based on the results of the SWOT analysis, the following recommendations may be highlighted to optimize the activities for the targeted distribution of Mylan HIV Self-Tests among PWID, SW, MSM and other KP and PP representatives:

1. Introducing the mentoring support system for NGOs not involved in the distribution of Mylan HIVST kits, with the involvement of experienced social workers from the participating NGOs in the demonstration project through routine interactive meetings or other formats acceptable for participants.

2. Adapting the Recruiter Package according to the available feedback when implementing the demonstration project.
3. Providing recommendations for NGOs in the next project year on strengthening the mapping of recruiters' work in the regions.
4. The use of depersonalized identifiers (for example, SYREX or CASE++) for the beneficiaries to organize the system of deduplication of services.
5. Introduce a unified training system for recruiters using existing information and educational materials and/or those designed specifically for the area.
6. Ensure additional marking of HIVST kits with information about their free use ("Not for sale," etc.) to avoid misuse of HIVST kits by clients and recruiters.
7. Consider the possibility of distributing HIVST kits online through specialized social networks and marketplaces in the category FREE to expand the access of KP to HIVTS and avoid misuse of HIVST kits by clients and recruiters.

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