INTEGRATED BIOLOGICAL AND BEHAVIORAL SURVEILLANCE AMONG PEOPLE WHO INJECT DRUGS IN UKRAINE (2023)

STUDY PROTOCOL

Version: 1.1: July 09, 2023

Kyiv, Ukraine

CONTENTS

LIST OF ACRONYMS AND DEFINITIONS

AIDS	acquired immunodeficiency syndrome - a chronic, potentially life-threatening condition caused by the human immunodeficiency virus
ART	antiretroviral therapy - the use of HIV medicines to treat HIV infection
Behavioral component	survey of behavioral factors by means of a face-to-face interview method - direct communication between the interviewer and the respondent
Biological component	testing of respondents for HIV infection, hepatitis C and syphilis, as well as pre-test and post-test counseling
CDC	Centers for Disease Control and Prevention
DBS	dry blood spot
GAM	UNAIDS Global AIDS Monitoring
HCV	hepatitis C - an infectious disease caused by the hepatitis C virus that primarily affects the liver
HIV	human immunodeficiency virus infection
HTS	HIV testing services - voluntary medical testing of this person for the presence of HIV antibodies
IBBS	Integrated Biological and Behavioral Surveillance – a methodology using cross-sectional surveys with behavioral and biological components that are linked at the respondent level
KI	key informants - representatives of NGOs or private persons with expert knowledge of the survey target group
MOH	Ministry of health of Ukraine
MSM	men who have sex with men
NGO	non-governmental organization - legalized or registered according to the legislation of Ukraine
PLHIV	people living with HIV
PrEP	pre-exposure prophylaxis - an HIV prevention strategy when HIV negative individuals take anti-HIV medications before coming into contact with HIV to reduce their risk of becoming infected
Primary respondents (seeds)	survey participants, recruited by the NGOs according to the criteria set, being the beginning of other responders' recruitment chain
PSE	population size estimation
PWID	people who inject drugs
RDS	respondent-driven sampling
Recruiter	survey participant recruiting other potential responders among the representatives of the survey target group
RITA	The Recent Infection Testing Algorithm - a generic name for a sequence of laboratory methods to distinguish recent HIV infections from HIV infections which have been present for some time
RT	rapid testing
Secondary respondents	survey participants invited by other PWID who have participated in all components of the survey
SOP	Standard Operating Procedures
SW	Sex workers

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1.0 SUMMARY

Conceived as a part of second-generation HIV surveillance[1], integrated biological and behavioral surveillance (IBBS), has become a critical element of HIV response in Ukraine. The primary purpose of IBBS is to estimate the burden of HIV disease and HIV-related risk factors, and estimate the coverage of prevention and treatment services for populations at increased risk for HIV. When conducted repeatedly, IBBS allows to evaluate trends in HIV prevalence and other key indicators over time. These data are essential for program planning, implementation, and evaluation.

This protocol describes the methodology of 2023 round of IBBS among people who inject drugs (PWID) in Ukraine. The study is designed as a cross-sectional survey with biological and behavioral components. The survey sample will be recruited using respondent-driven sampling (RDS) approach and will include 5000 participants in 10 cities across Ukraine. Behavioral data will be collected using individual, structured self/interviewer-administered questionnaire. Biological data will be collected using rapid testing algorithms for HIV, hepatitis C and syphilis. Participants with confirmed new positive test results will be referred to health care institutions for follow-up and care. Dry blood spot (DBS) samples will be collected to assess recency of HIV infection and viral load.

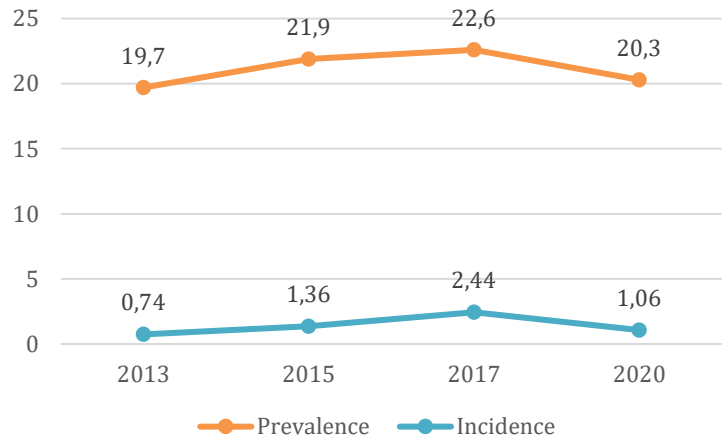
The survey "Integrated Biological and Behavioral Survey among People Who Inject Drugs" will be conducted in 2023, as a component of a SILTP "Strengthening HIV Treatment, Laboratory Services, Medication Assisted Therapy, and Program Monitoring in Ukraine under the President's Emergency Plan for AIDS Relief (PEPFAR)" implemented by the State Institution "Public Health Center of the Ministry of Health of Ukraine" (the PHC) with the support from the US Centers for Disease Control and Prevention (CDC). (Cooperative agreement number - NU2GGH002375).

[1] https://data.unaids.org/publications/irc-pub01/jc370-2ndgeneration_en.pdf

2.0 BACKGROUND AND RATIONALE

Ukraine has one of the highest burdens of HIV among European countries. In 2011, WHO and UNAIDS estimated that there were 230,000 (95% CI 180,000–310,000) people living with HIV (PLWH) in Ukraine[2]. By 2020, this number increased to a total of 257,000 HIV cases[3].

Figure 1. HIV incidence and prevalence among PWID based on 2013-2020 IBBS data



The epidemic continues to be driven by people who inject drugs (PWID). According to the previous IBBS round in 2020, HIV prevalence among PWID was 20.3% (in sampled cities), which was highest among all key populations subgroups (men who have sex with men, Transgender people, sex workers, people who inject drugs, people in prison and detention) [4], and more than 20 times higher than HIV prevalence in general population (0.9%)[5]. The trend in HIV prevalence and incidence among PWID is shown in Figure 1. Given the estimated size of PWID population of 350,500 in 2017, this translates into a total of around 71000 of PWID who are HIV-positive[3].

The official HIV case registration data confirm the increasing importance of PWID in HIV transmission. While heterosexual mode of transmission has been predominant since 2009, with the absolute number of newly registered cases attributed to injecting drug use (IDU) decreasing from 7105 in 2009 to 3773 in 2018, in 2019 and 2020 there was an increase in new IDU-related cases once again, with 4214 and 5960 cases, respectively. Of all cases officially registered in 2020, sexual transmission

[2] UNAIDS, Global AIDS Update 2020: Seizing the moment Tackling entrenched inequalities to end epidemics. 2020.

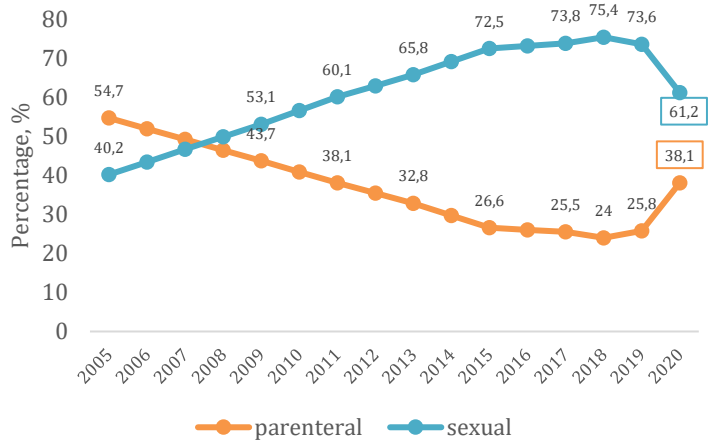
[3] Public Health Center of the MoH of Ukraine. HIV infection in Ukraine Informational Bulletin #52 Kyiv2021 [Available from: https://phc.org.ua/kontrol-zakhvoryuvan/vilsnid/monitoring-i-ocinka/informaciyni-byuleteni-vilsnid].

[4] https://www.theglobalfund.org/en/key-populations/#:~:text=In%20the%20context%20of%20HIV,Transgender%20people%2C%20especially%20transgender%20women

[5] Тітар І, Сальніков С, Огороднік С, et al. Звіт за результатами Інтегрованого біоповедінкового дослідження 2020 року серед людей, які вживають наркотики ін'єкційним шляхом. Київ: Центр громадського здоров'я МОЗ України, 2021.

accounted for 61.2% and parenteral for 38.1% (Figure 2). At the same time, the proportion of cases acquired through IDU is underestimated due to wide-spread stigma. In a survey of persons recently diagnosed with HIV, the true proportion of IDU-related cases was underestimated by 1.5 times, with true proportion ranging from 44.0% (according to self-report) to 59.7% (taking into account the presence of antibodies to HCV as a proxy indicator for IDU)[6].

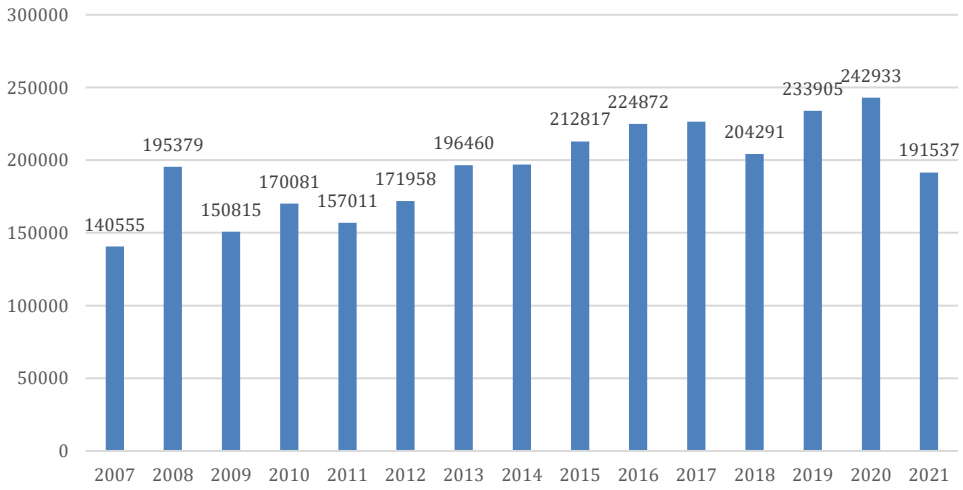
Figure 2. Modes of HIV transmission in Ukraine, HIV case registration data 2005-2020



Harm reduction programs such as needle and syringe exchanges (NSP) are a key HIV prevention strategy among PWID, and Ukraine has achieved the recommended coverage rate[7] of 60% by 2015 and has been maintaining it since then through a national network of non-government and community-based organizations (Figure 3).

Coverage of another key intervention, Medications for Opioid Use Disorder (MOUD) remains low, with about 18,000 patients receiving it in mid-2022, which is about 7% of the estimated number of people who inject opioids in Ukraine.

Figure 3. Coverage of PWID with NSP programmes in Ukraine



IBBS is one of the key components of HIV monitoring and evaluation. It has been conducted in Ukraine since 2003, and on a national scale since 2007. It allows for public health officials to monitor trends in key prevalence indicators, assess coverage with key services, and estimate the population size of key populations.

[6] Dumchev, K., Kornilova, M., Kulchynska, R., Azarskova, M., & Vitek, C., Improved ascertainment of modes of HIV transmission in Ukraine indicates importance of drug injecting and homosexual risk. BMC Public Health, 2020. 20 (1)(1288).

[7] WHO, UNODC, UNAIDS technical guide for countries to set targets for universal access to HIV prevention, treatment and care for injecting drug users – 2012 revision (p.43) Available from: https://www.who.int/publications/i/item/978924150437

3.0 OBJECTIVES

The IBBS among PWID in 2023 is designed to:

- assess HIV, anti-HCV, and syphilis prevalence;
- assess prevalence of HIV-related risk behaviors;
- estimate HIV incidence rate;
- assess HIV viral suppression;
- estimate coverage with HIV prevention, care and treatment services, in particular, HTS;
- assess the level of knowledge about routes of HIV transmission and prevention measures;
- estimate PWID population size;
- assess HIV treatment cascade;
- provide data for modelling, and national/international reporting (for example, UNAIDS Global AIDS Monitoring (GAM));
- develop recommendations for HIV prevention, care and treatment programs and identify future research needed to monitor and respond to the HIV/AIDS epidemic among PWID.

4.0 METHODOLOGY OVERVIEW

4.1 Sampling

The sample will be recruited using Respondent-driven Sampling (RDS) methodology. RDS is a variant of a chain referral sampling method, which was specifically designed to reach "hidden" populations[8]. RDS recruitment starts with some purposefully selected members of the study population referred to as "seeds". Emphasis is placed on selecting seeds with large social networks and who know people from diverse backgrounds. After enrolling and completing the survey process, each seed is given a specified number of uniquely coded coupons, with which to recruit their peers (i.e., eligible PWID). Recruited peers who agree to enroll and complete the survey steps make up the first wave of participants and are also given uniquely coded coupons with which to recruit their peers. The use of this recruitment strategy produces successive waves of recruitment, ideally long recruitment chains of respondents, and continues until the desired sample size is reached.

The number of involved representatives of the target group allowed to be recruited by each participant is limited to three (persons), allowing for the recruitment to be conducted in various social networks. RDS coupons contain the Study ID of a respondent and are registered in a special programmatic software to track who recruited whom (Annex 9. Survey participant's coupon). Encrypted QR-codes (electronic coupons) contain information about who and by whom is recruited to participate in the survey. The primary compensation is paid at the first survey visit for the participation in the survey. Secondary compensation is paid at the second survey visit for each person the participant recruits who participates in the survey.

Analysis of RDS data relies on each participant providing their social network size and active monitoring of who recruited whom using the information from the uniquely coded coupons. Use of the unique coupon codes eliminates the need to collect personal identifying information, such as names and addresses, maintaining the anonymity and confidentiality of survey respondents. When conducted and analyzed properly, RDS eliminates biases commonly associated with other chain referral sampling methods, which yields findings representative of the network from which the sample was taken.

4.2 Inclusion and exclusion criteria

Selection criteria and verification methods are described in the table below.

Inclusion criteria	Verification methods
Drug injection within the last 30 days	Self-declaration AND confirmation by healthcare worker (presence of punctures on the participant's body from injection drug use)
14 years old and older as of the survey period	Self-declaration AND visual control by coupon-manager
Not less than 1 month of residence/work/surveying in the area where	Self-declaration

[8] Lisa G. Johnston (Tulane University), Keith M. Sabin (UNAIDS), "Sampling hard-to-reach populations with respondent driven sampling", Methodological Innovations Online (2010), 5(2) 38-48

survey is conducted	
Informed consent to participate in all survey components, namely: (1) questionnaire completion; (2) capillary blood collection with EDTA K3 blood micro containers (microtainers) for further rapid testing for HIV, hepatitis C and syphilis; second HIV diagnostic rapid testing in case of positive results; dry blood spot (DBS) for further testing to detect recent HIV infection and viral load level	Signed informed consent to participate in the survey

Exclusion criteria	**Verification methods**
Repeated participation in one survey round	Self-declaration OR visual identification of a repeated attempt by coupon-manager
Refusal to participate in one or several survey components	Absence of signed informed consent to participate in the survey
Alcohol or drugs intoxication, which does not allow to understand and answer questions of the questionnaire, and the respondent's behavior threatens his own safety or the safety of others	Visual control by coupon-manager

4.3 Selection of sites

Available recommendations suggest to perform sample size calculation based on indicators with lowest effective sample size (e.g., viral suppression, where effective sample is limited to the HIV positive fraction). However, with the desired level of precision (e.g. less than +/-10%) at the city level, this yields sample sizes which are not feasible, especially in the cities with low HIV prevalence (e.g. Kharkiv). Therefore, it was recommended to consider clustering of cities based on analyses of trends/similarities to ensure a larger sample size.[9]

Prior to 2020, the IBBS in Ukraine were conducted in each administrative unit (N=27), presumably generating a nationally-representative sample, enabling direct comparison of indicators across rounds and analysis of trends.[10] After the resources for surveillance became more limited, the number of participating cities was decreased to 12 in 2020. The selection of cities was made by the national working group, based on epidemiologic and programmatic priorities. Nevertheless, a direct comparison between 2020 and previous rounds is not possible due to the difference in geography and varying sample sizes in cities that participated in each round.

Considering that accurate monitoring of trends in key indicators in IBBS series is at least as important as point estimates, and also following the CDC recommendation (to cluster cities), it is proposed that *a single cluster of cities will be selected for this round and will remain stable* in the next rounds of IBBS. This strategic approach also corresponds to the concept of sentinel surveillance, in which a consistent sample of sites continues to generate data over an extended period of time. As the sentinel

[9] CDC/DGHT Key Population Surveillance Team and CDC Ukraine Joint Evaluation of IBBS in Ukraine – Nov. 2017

[10] Dumchev, K., Sazonova, Y., Salyuk, T., & Varetska, O. (2018). Trends in HIV prevalence among people injecting drugs, men having sex with men, and female sex workers in Ukraine. Int J STD AIDS, 29(13), 1337-1344. doi:10.1177/0956462418784096

approach implies, selected sites should represent geographically and epidemiologically diverse areas and be most likely to detect emerging behavioral and epidemiologic trends. Given that, the following cities were selected by the national IBBS working group as **sentinel** sites for the 2023 and future rounds of PWID IBBS in Ukraine:

- **Kyiv (fast track city, capital, northern sub-region, largest PWID population)**
- **Dnipro (fast track city, eastern sub-region, high IDU prevalence)**
- **Odesa (fast track city, southern port city, sensitive to new drug use trends)**
- **Kharkiv (north-eastern sub-region, on drug trafficking route from neighboring country, low HIV prevalence)**
- **Cherkasy (central sub-region, high HIV prevalence)**
- **Lviv (western sub-region, on drug trafficking route to/from EU, sensitive to European trends)**

Key characteristics of the selected cities are presented in the Annex. Selection of cities for the 2023 PWID IBBS **on page 55**.

Given the budget allocation for the 2023 IBBS, additional cities will be selected for participation by the national IBBS working group. Similarly to the 2020 round, the selection will be done by a working group based on programmatic and epidemiologic considerations. Possible reasons for selection include not being included in the recent IBBS rounds, assessment of impact of city-level interventions, evidence of outbreaks or unusual behaviors based on other data sources (e.g. SEM, other studies). For the 2023 round, an important priority will be to assess the situation in cities most affected by the war (previously occupied and/or severely damaged). The following cities will be considered as **additional** sites:

- Vinnitsa. (center, less affected by war, significant inbound migration, not included in the 2020 round). *At a meeting of the IBBS working group (June 16, 2023), Vinnytsia was chosen instead of Kherson (by a vote of IBBS working group members). After the Kakhovka dam on the Dnieper River was damaged by Russians, there're some difficulty to conduct IBBS in Kherson (regional team and participant's safety, other difficulties).*
- Zaporizzhia (south, near the front line, significant out-migration, not included in the 2020 round)
- Chernihiv (north, heavily damaged, not included in the 2020 round)
- Rivne (west, less affected by war, significant inbound migration, not included in the 2020 round)

4.4 Sample size and power calculation

To calculate the sample size, a design effect was empirically estimated in the 2020 IBBS data set using the Gile's SS estimator based on the actual network size in "RDS" package in R v.4.0.5 (Table).

	HIV prevalence				Viral suppression			
	Est.	95% CI LL	95% CI UL	D.Eff.	Est.	95% CI LL	95% CI UL	D.Eff.
Bila Tserkva	16.1%	10.2%	21.9%	3.11	77.7%	66.6%	88.7%	2.39
Dnipro	26.5%	19.8%	33.2%	2.78	68.8%	54.8%	82.6%	3.56
Ivano-Frankivsk	9.3%	5.8%	12.9%	2.61	89.3%	82.8%	96.4%	1.44
Kirovohrad	10.2%	7.0%	13.4%	1.80	74.2%	61.4%	87.3%	2.70

Kryvyi Rih	21.9%	16.1%	27.7%	2.13	70.6%	59.9%	81.1%	1.72
Kyiv	18.2%	12.9%	23.5%	3.27	86.0%	77.0%	95.0%	2.96
Mariupil	30.5%	25.3%	35.6%	2.11	80.9%	72.7%	89.1%	2.21
Mykolaiv	33.2%	27.5%	38.9%	2.88	76.4%	68.3%	84.4%	2.49
Odessa	21.2%	15.3%	27.1%	2.50	80.7%	73.4%	87.9%	1.31
Kharkiv	7.5%	4.1%	11.0%	2.12	90.9%	91.0%	91.0%	-
Khmelnytskyi	29.7%	23.7%	35.7%	2.47	81.9%	74.3%	89.3%	1.91
Cherkasy	38.4%	31.4%	45.6%	2.43	86.5%	80.1%	93.0%	1.61

As shown, the design effect for HIV prevalence ranges from 1.8 to 3.3, and for viral suppression from 1.3 to 3.6. Therefore, a conservative value of 3.0 is used for the following sample size calculation.

The calculation was made for *the single sentinel cluster* sample, with expected HIV prevalence of 21% and 44% viral suppression (combined weighted estimate using 2020 round data for 5 cities and 2017 data for Lviv). Based on the simple asymptotic CI formula,[11] 0.05 probability of type I error, anticipated 5% of missing data, and 14% desired precision level for the viral suppression indicator (e.g. 44±7%), the resulting sample size should be 2914.

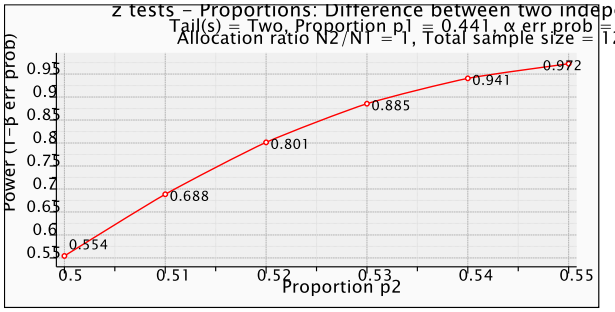
In order to simplify trend analysis across rounds, the total sample will be distributed evenly across participating cities, yielding a rounded target sample size of 500 in each city. This result corresponds to the standard universal sample size used in the US NHBS-IDU.[12] At the city level, assuming the design effect of 3.0 and 5% of missing data (e.g. incomplete data entry, entry errors), a sample size of 500 will provide ~16% precision for a maximally-conservative estimated prevalence for any indicator – 50% (i.e. 50±8%, the interval will be narrower for proportions closer to extremes, either 0 or 100%).

The same target sample size will be used for each additional city (outside the sentinel cluster).

For the trend analysis, assuming the HIV prevalence of 21%, the total sample (with N=629 living with HIV) will provide 80% power to detect a statistically significant increase in viral suppression from 44% (weighted average in sentinel cities in 2020) to 52% (and higher) in the next round, based on 0.05 probability of type I error (Figure).

[11] Appendix I-22: Sample Size Calculator for Survey-based Viral Load Suppression

[12] Centers for Disease Control and Prevention. National HIV Behavioral Surveillance System Round 5: Model Surveillance Protocol. December 11, 2018. Available from: www.cdc.gov/hiv/statistics/systems/nhbs/operations.html


z tests - Proportions: Difference between two independent proportions
Tail(s) = Two, Proportion p1 = 0.441, α err prob = 0.05,
Allocation ratio N2/N1 = 1, Total sample size = 1258
Power (1 - β err prob)
0.95
0.9
0.85
0.8
0.75
0.7
0.65
0.6
0.55
0.554
0.688
0.801
0.885
0.941
0.972
0.5
0.51
0.52
0.53
0.54
0.55
Proportion p2

5.0 PREPARATORY STAGE

5.1 National Working Group

The preparatory stage of the 2023 IBBS will begin with a formal meeting of the national IBBS working group, which includes representatives of governmental bodies, state agencies, non-governmental and international organizations, HIV laboratories, HIV clinics, PWID community representatives, and academic institutions. The composition of the National Working Group is approved by the decision of the Interdepartmental Task Force on Monitoring and Evaluation of Measures against HIV/AIDS, Tuberculosis and Other Socially Dangerous Diseases. The Group meetings will be open to interested parties to ensure the transparency and objectivity of survey. External advisers on specific issues are involved as appropriate.

The National Working Group is responsible for:

- ensuring coordination of planning, data collection, analysis, dissemination and use of the IBBS findings in Ukraine;
- technical assistance with the development of protocol, standard operating procedures and survey toolkit
- determining of geographic focus and selection of participating cities;
- monitoring and assurance of data quality at the stages of planning, data collection, analysis, dissemination and use of findings
- overseeing and conducting (for selected members) analysis for the population size estimation (see section 10.0).

5.2 Regional Working Groups

The Regional Working Groups will be established in each participating city. The groups will include: a regional IBBS coordinator; representative of NGOs working with PWID; representatives of HIV clinics (epidemiologist) and Oblast Centers for Disease Control; representatives of the PWID community.

Responsibilities of the members of Regional Working Groups are as follows:

Member	Responsibilities
Regional IBBS coordinator	Selection of team members involved in data collection; Overall responsibility for conducting all research procedures according to the Protocol at the city level; Development of the list of facilities and services for referral of subjects receiving positive test results
Representative of NGOs working with PWID	Establishment of cooperation with local representatives of PWID, facilitating the communication with the community; Participation in the formative assessment; Finalization of the list of services for referral
Representatives of HIV clinics and Oblast Centers for Disease Control	Selection of team members performing biological testing; Finalization of the list of services for referral; Participation in the formative assessment;
Representatives of PWID community	Participation in the formative assessment; Coordination of unique objects distribution

The Regional Working Groups will hold at least five meetings during the survey period: at the formative assessment stage; a week after the field stage begins; in 2-3 weeks after the field stage begins; upon the completion of field stage.

5.3 Regional data collection team

A regional data collection team (RDCT) is established in each participating city and is managed by the regional IBBS coordinator. In addition to the IBBS coordinator, the team includes: a coordinator for biological component; a coupon-manager; interviewers, a healthcare worker (HTS/ sample collection specialist); a social worker or psychologist.

Responsibilities of the members of the RDCTs are as follows:

Member	Responsibilities
Regional IBBS coordinator	Supervision over the daily work of the site, communication with the principal investigator, process reporting to the national coordinator
Biological component coordinator	Ensuring a biological component of the survey, communication with the HIV clinic, storage of DBS samples and shipment to the Reference-Laboratory for HIV/AIDS Testing
Coupon-manager	RDS coupon management and screening, informed consent
Interviewer	Administering the questionnaire to the participants
Healthcare worker	Pre- and post-test counseling, collection of capillary blood samples, rapid tests, preparation of DBS samples, referral to health care facilities and other services. Health care worker also can perform the duties biological component coordinator.
Social worker or psychologist	Selection and recruitment of seeds, control over the queue at the site and provision of social support

5.4 Research staff training

A series of training courses for each member of RDCT and other responsible staff will be conducted:

Personnel category	Training objective
Regional coordinator	Methodology and procedures of formative assessment; survey and biological component; compliance with the Standard Operating Procedures (SOPs); human subjects protection. Online event.
Medical or HTS specialists	IBBS procedures; HIV testing in accordance with the National HTS Protocol; rapid tests and DBS quality control; human subjects protection. In addition, external quality assessment will be carried out to check the specialists' qualifications in a form of practical exercises with real biological data collection and analysis, PWID Sensitization Training. Offline event
Monitoring consultants	Methodology of the IBBS; assessment of compliance with the Survey Protocol and SOPs by the regional groups; reporting on the site situation, including events that may affect the quality of collected data. Online event.
Laboratory personnel	Stages of the IBBS implementation; laboratory testing within the IBBS; analysis and use of the IBBS findings; laboratory quality control and assurance, recent infection and viral load of HIV infection.

	The personnel of Reference-Laboratory for HIV/AIDS Testing already trained on May 2020

All RDCT members of the regional groups will be cross-trained on the behavioral and biological components in order to ensure that the site and the survey are managed properly even in the absence of some specialists within a certain period of time.

Within each training session, some time will be dedicated to the explanation of the requirements for protection of human subjects in research and corresponding procedures (see Chapter 12 "Ethical Considerations").

6.0 FORMATIVE ASSESSMENT

In each participating city, a formative assessment will be conducted prior to survey implementation. The purpose of the formative assessment is to guide local implementation of IBBS activities to ensure successful data collection. Particularly, formative assessment can help understand the context of the survey in each community, ensure that the desired sample size is achieved and that the resulting sample is reflective of the PWID population.

The formative assessment will be conducted by a designated member of the RDCT via in-depth interviews with key informants. During these interviews, the regional group learns about unique features of drug scene in the city, social environment and extent of personal networks, feasibility of achieving the target sampling size, possible attitude/actions of law enforcement agencies towards PWID, etc. The assessment also includes piloting of the questionnaire with the representatives of PWID community. **Considering the war context, the formative assessment in 2023 will additionally investigate the level of physical risk in the cities, and all possible precautions to ensure safety of participants and staff.**

If the results of formative assessment or toolkit piloting require significant changes, the amended Protocol and survey toolkit will be re-submitted for the ethical review and approval.

6.1 Key informant interviews

Fifty key informants will be recruited (at least 5 in each selected city, but no more 80) for the formative assessment. Based on the previous IBBS experience, this sample is sufficient to achieve all formative goals.

The key informants for the formative assessment will be recruited using purposive sampling method, to ensure participation of at least one representative of each of the following groups:

- active members of the PWID community
- staff of non-governmental organizations that provide HIV prevention services to PWID
- staff of healthcare facilities providing services to PWID
- social workers or outreach workers providing services to PWID
- law enforcement familiar with the drug scene and PWID context (optional).

Members of the Regional Working Group may participate as key informants in the interviews. If more than one specialized NGO works within the city, each will be involved in key informants' recruitment. Within the formative assessment framework, personal data of key informants' will not be collected, and no video recording will be done. The key informants will provide verbal informed consent (Annex 1: Verbal informed consent for formative assessment) and all key points from their responses will be written down by the interviewer.

Key informants will be compensated with monetary equivalent of $10 for the time spent for participation in the assessment and related expenditures (for example, transportation costs) (Annex 3. Log of compensation to the key informants).

The interviews will cover the following topics:

- specifics of the drug scene and social networks of PWID in the city;
- suggestions for seed selection;

- options for selection of the survey site;
- optimal working days and hours for the survey site and RDCT;
- options for referral of participants with positive rapid tests (list of facilities with addresses);
- appropriate amount of compensation for participants;
- sample size feasibility;
- safety in the study area, and at the proposed survey sites, measures to ensure safety of participants and staff.

Formal analysis of the interviews will not be done. Instead, the interview notes will be summarized by the interviewer and presented at the joint meeting of the Regional Working Group and RDCT. The group will discuss the results, prepare the Formative Assessment Report (Annex 2), and make final organizational decisions for the IBBS implementation. The Reports will be submitted to the National Coordinators and then will be used in the analysis stage.

6.2 Piloting of the survey instruments

The pilot will test the pre-final version of the questionnaire, data collection forms, and the online platform, to ensure that data collection platform is working properly, all questions are clearly understood by the participants, are sensitive enough and that the total interview duration is acceptable.

Fifteen representatives of the target population will be selected in Kyiv and two additional cities of research using purposive sampling. Screening, recruitment, and data collection for the pilot will follow the procedures to be used in the main phase, with the exception of the biological component. Since the signature on the informed consent may be the only record that links the participant with the survey, the interviewers obtain verbal informed consent (Annex 4. Verbal consent to questionnaire piloting). Each pilot participant will receive monetary compensation equivalent of $10 (Annex 5. Log of compensation for questionnaire piloting).

Participants will be additionally instructed to notify the interviewer about unclear or ambiguous wording, questions that may cause discomfort, questions that are unlikely to be answered truthfully, not working skip patterns, and any other concerns related to the instruments or procedures. The interviewer will record all comments and concerns of the respondents and will summarize them in a report to the National Working Group. The group will review all comments and make adjustments to the instruments. In case of significant modifications that will require changes to the protocol, the updated version will be re-submitted for the ethical review and approval.

6.3 Primary seeds selection

Using direct or indirect references from the key informants during the formative assessment, 4-6 primary seeds will be selected in each city. After making a contact by phone or personally, the potential seeds will be screened for eligibility and quotas (Annex 7. Screening questionnaire for primary respondents). Additional seeds may be added during the field stage as needed (if the recruiting rate is lower than expected, or a certain number of recruiting chains break off).

Primary seeds sampling is purposive and based a set of following criteria:

Criteria	At least 1 primary seed	At least 1 primary seed

Motivation to participate in the survey	Motivated to participate in the survey and distribute information about it among PWID in their social network	
Social network size	Social network of PWID contacts has at least 7 people	
Special characteristics of drugs use	Injection opioids	Injecting stimulants
Drug use experience	More than 2 years	Less than 2 years
Participation in prevention programs	Client	Not a client
Self-declared HIV-status	Positive	Negative
District of residency	District X	District Y
Age group	Under 19 years old	Age 20 and up
Sex	Female/male	Male/female
Self-declared social and economic status	Low	High

Additional criteria may be proposed by key informants or regional groups. Primary respondents (seeds) are involved into both research components - survey and laboratory testing.

6.4 Selection of survey sites

During the formative assessment, the survey data collection points (sites) are determined. Sites selection is carried out according to the following criteria:

- geographical accessibility and convenience for respondents (public transportation should be close by, a respondent can easily and quickly find a selected site, there are no obstacles to reach the site);
- enough rooms, specifically: waiting rooms, a room for conducting the survey – filling in questionnaires, a room for pre-test and post-test counseling, rapid testing and DBS sample collection with possibility to ensure adequate sanitary conditions;
- privacy and comfort (to ensure the confidentiality of information, convenience for the respondent and limitation of distractions);
- geographical remoteness from the places where HIV prevention and treatment services are provided;
- **relative safety in the war context, availability of a bomb shelter nearby.**

Survey sites may be located in rented premises; general hospitals; at the NGOs locations (except NGOs providing services to PWID). During the formative assessment the required number and selection of sites in each city will be specified.

7.0 PROCEDURES

7.1 Participant algorithm

Each participant will have to complete four stages of the survey; the approximate total duration to complete all steps is 82-195 minutes:

Completion of each stage has to be verified by the responsible staff in the Participants' Card (Annex 10. Participant`s Card).

Stage:	STAGE 1. SCREENING			STAGE 2. BEHAVIORAL COMPONENT
	Screening of potential participant	**Coupon validation**	**Informed consent signing**	**Survey**
Responsible staff:	Coupon-manager Healthcare professional	Coupon-manager	Participant, involving coupon-manager	Interviewer
Approximate duration:	5 minutes	1 minute	10-15 minutes	30-40 minutes

Stage:	STAGE 3. BIOLOGICAL COMPONENT							
	Pre-test counseling	**Capillary blood collection with EDTA k3 blood micro containers**	**Testing for HIV, hepatitis C, syphilis (rapid tests)**	**Second HIV rapid diagnostic test for those with first positive test**	**Third HIV rapid test for those, who are positive for first and second rapid tests**	**Blood collection for DBS to test the recent HIV-infection and viral load (for HIV-positives and those who stated that they are receiving ART)**	**Notifying participants of their testing results**	**Referral to HIV clinics (for HIV-positives) / Referral to HCF (for other)**
Responsible staff:	Healthcare professional	Healthcare professional	Healthcare professional	Healthcare professional	Healthcare professional	Healthcare professional	Healthcare professional	Healthcare professional
Approximate duration:	5-10 minutes	5 minutes	10-15 minutes	10-20 minutes	10-20 minutes	3 minutes	10-20 minutes	5 minutes

Stage:	STAGE 4. COMPENSATION AND PEER RECRUITMENT				
	Primary compensation (participant)	**Other PWID recruiting instruction**	**Other PWID recruitment**	**Other PWID participation in the survey**	**Secondary compensation (recruiter)**
Responsible staff:	Coupon-manager	Coupon-manager	Participant	Participant	Coupon-manager
Approximate duration:	1 minute	5 minutes	up to 20 days	82-195 minutes	1 minute

7.2 Participant recruitment

Recruitment starts with the initial respondents ("seeds") selection and then it is driven by the participants themselves. Upon the completion of both survey components, participants are offered to refer their peers and are instructed by the coupon-manager on the process of peer recruitment and respective compensation.

Recruitment is carried out on a voluntary basis for all participants. Each participant who completed the survey can recruit up to three PWID from their social network for further participation in the survey. There is a date on the participant's coupon beginning from which the PWID, who received the coupon, may come to the survey site for participation. The recruited PWID may not participate in the survey the same day the recruiting PWID participates. Accordingly, a potential respondent may participate in the survey the day after the recruiter's participation.

A feature of the RDS approach is that recruitment of participants is not evenly distributed in time and is more "wave-like", especially, at the data collection stage. At the last days of the site work, it may become quite crowded, as an increasing number of interested PWID may gather on the site, potentially causing problems in the neighborhood. In order to minimize this scenario, the coupon is only valid for one week. The coupon managers will emphasize that after the receipt of the coupons, potential recruiters have only a week to bring their peers to the site.

The coupon managers are responsible for performing all procedures related to RDS recruitment. They will explain the procedure of recruitment to seeds and subsequent participants (Annex 26. Instructions for Recruiters), handle the coupons, verify their validity, keep track of all coupons via compensation log, and manage secondary compensation for successful recruitment.

7.3 Screening

Each potential survey participant must present a coupon given to him by his/her recruiter. All coupons will be validated by a coupon manager via PHC software. To verify the network connection, the coupon manager will additionally ask about who has given the coupon to the potential participant, how many times during the last month they have seen his recruiter, and if coupon was exchanged for anything.

Screening involves a brief assessment of potential survey participants according to inclusion and exclusion criteria. If the coupon manager has doubts about the potential participant eligibility during screening, he will ask additional contextual questions (Annex 8: Screening Form for Participants). At the screening stage, the healthcare worker examines potential participants for visible signs of drug injecting.

If the potential participant is eligible and does not show visible signs of alcohol or drug intoxication, he is given the informed consent form for reading. Participants will be given either Ukrainian or Russian version based on their personal choice (Annexes 11-1 and 11-2 Participant's Informed Consent). After reading the form, the candidate may ask clarification questions to the coupon manager. After that, the coupon manager verifies understanding of the main points in the consent form by the participant, and if understanding is satisfactory, both sign the consent form (see details of the consent procedure in ETHICAL CONSIDERATIONS).

Only those PWID who agree to take part in both behavioral and in biological components are eligible

to participate in the study. If a candidate is willing to take part in the interview, but he does not want to be tested, they are not eligible to participate in this study. If a candidate is willing to be tested for HIV, hepatitis C and syphilis, but does not want to fill in the questionnaire, they are not eligible to participate in this study, however the research staff provides them with all the necessary information about specialized facilities.

Potential participants who do not have a valid coupon, do not meet eligibility criteria, are unable or refuse to sign the informed consent form are declined to participate in the survey), and the Refusal Form is completed by the coupon manager indicating the reason for non-participation (Annex 13. Registration form for refusals to participate in the survey). For those ineligible, the specific criterion which led to their exclusion is not disclosed.

After determining eligibility, the participant receives identification number, which is then used in the questionnaire and in the Form of test results (Annex 15. Test results form).

7.4 Data collection and instruments

Behavioral data will be collected using a structured questionnaire. The questionnaire collects information for HIV epidemic monitoring, national and international reporting, and population size estimates of PWID. The structure and the core content of the questionnaire are preserved from the previous rounds to enable estimation of trends in key indicators. However, some sections are revised to address emerging programmatic and epidemiologic priorities, and to improve wording that was deemed ambiguous after analyzing the previous round data. The prefinal and final versions of the questionnaire will be reviewed and approved by the National IBBS Working Group, which includes program specialists and community representatives.

The questionnaire will be administered in Russian or Ukrainian languages, per participant's choice. Translation of survey documentation into English is made for review purposes only.

The primary mode of data collection will be through the proprietary online platform of the Public Health Center (PHC_Research). Electronic survey tools on the planform are available for tablets or laptops. Each interviewer will get a unique login, which would allow individualized activity tracking.

The electronic form of the questionnaire provides significant advantages, namely:

- no need to enter data from paper forms into the database, eliminating the entry errors;
- unified approach to the survey administration to all respondents;
- convenient to fill out a questionnaire (for example, automatic skipping patterns, language selection) and availability of logical control of input data;
- no need for additional expenses (for example, copying of questionnaires);
- instant and easy data export for further analysis

As a backup option, paper-based questionnaire forms will be available at the sites in case of possible problems with the electronic platform (internet connectivity, application "freezing" during data entry, incorrect records of compensation). In case of the need to use the paper questionnaire, the interviewer will inform the regional coordinator and then fill the completed data from the paper form to the electronic questionary PHC_research.

The structured survey will be administered by a qualified interviewer, in a face-to-face format. The interview will take place at the survey site, in a room that will ensure the privacy of the study

participant and confidentiality of the data. Questions and response options will be read by the interviewer to the participants verbatim, with minor standard clarifications if needed. All responses will be entered directly in the online platform. The interviewers will interview no more than 10 participants per day.

In order to avoid queues and minimize the time of a potential participant's presence on the site, the system of preliminary registration of respondents will be introduced at the site and/or capillary blood collection will be conducted at the same time as informing a participant about peer recruitment. Appropriate optimization methods will be pre-agreed with the regional coordinators and the National Working Group to avoid misunderstandings.

The survey will be conducted in compliance with security measures established at the central and local levels according to the martial law. The survey will not be conducted: in the occupied territories; during the curfew set by the local military administration; during air raid alerts; during active hostilities in or near the cities participating in the study. In the event of an air raid alert happening during the survey, survey participants and data collectors will proceed to a designated shelter.

7.5 Participants compensation

The survey participants may receive two types of compensation: primary (for the time spent and transportation costs associated with the participation in the survey) and secondary (for each recruited eligible respondent) (Annex 25. Compensation Log). The primary compensation is paid in monetary equivalent of $11. During the formative assessment, the appropriateness of the amount will be examined, and, if needed, the amont may be revised in a particular city. In addition to monetary compensation, the survey participants will be offered informational materials on the prevention of HIV, HCV and syphilis, as well as condoms and syringes (provided by the available HIV prevention and harm reduction programs in the area).

The secondary compensation will be provided for recruiting each eligible participant who completed the survey. The status of coupons and eligibility of referrals will be recorded in the Compensation Log (Annex 25.). The amount of secondary compensation will be fixed as a monetary equivalent of $7 for each successful referral.

In order to receive the secondary compensation, the participant will need to come to the site and fill in a short form about PWID who were invited for participation but refused a coupon (Annex 14. Form of refusal to participate in the survey for recruiters).

8.0 BIOLOGICAL COMPONENT

The biological component includes capillary blood collection with EDTA K3 blood micro containers for the purposes of rapid diagnostic tests for HIV, HCV, syphilis, the second HIV rapid diagnostic test, the third rapid HIV test, preparing DBS cards for detection of HIV recent infection and viral load (see Diagram 1).

This protocol involves the use of a diagnostic test labeled as research use only (RUO) in a way that is not in compliance with the manufacturer's certification or requirements. The Public health center will ensure that all applicable country laws/regulatory approvals related to investigational diagnostic tests, such as the one being used, have been obtained. CDC is not directly purchasing the tests, specifying the manufacturer, or in any way directing or requesting the off-label use of this assay during the implementation of this protocol.

8.1 Pre-test counseling

After completing the survey and before capillary blood collection, all participants undergo a pre-test counseling on HIV in accordance with the National Protocol on HIV testing services. Pre-test counseling includes clarification of the ways of contraction and transmission of HIV infection, HCV and syphilis, the significance of test results, the risks associated with injection drug use and risky sexual behavior, as well as prevention and treatment of HIV and sexually transmitted infections.

8.2 Capillary blood collection

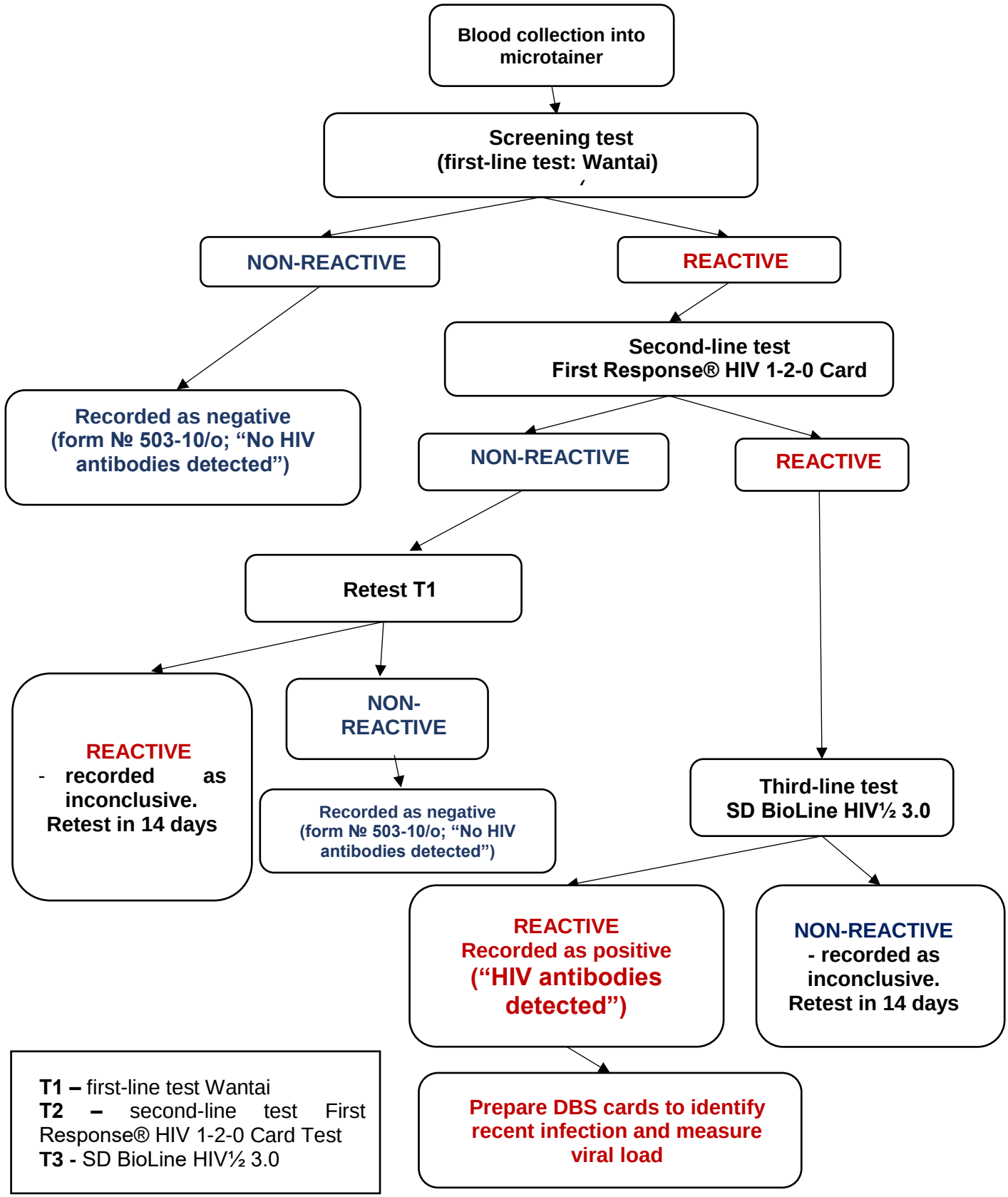
In order to carry out all planned assays within the biocomponent, the collection of a total of 600 µl of blood (for HIV-negative and HIV-positive) is required. Additionally, 5 rapid tests and capillary blood collection from a finger means having up to four punctures, which may be too much for participants and result in their refusal to participate in the survey.

Capillary blood collection with EDTA K3 blood micro containers (microtainers) will ensure the sufficient quantity of blood necessary for all the subsequent stages of the survey, making testing algorithm less traumatic and prolonged for participants, and reducing the number of possible medical interventions and ensuring the required amount of capillary blood for all planned tests.

Samples of capillary blood will be obtained using EDTA K3 blood micro containers.

Capillary blood sample will be used to conduct the first HIV screening test, rapid tests for hepatitis C, syphilis, the second HIV rapid diagnostic test, third HIV test, and preparing the DBS cards for further laboratory detection of recent HIV infection and viral load.

Diagram 1. Graphic representation of HIV-testing algorithm



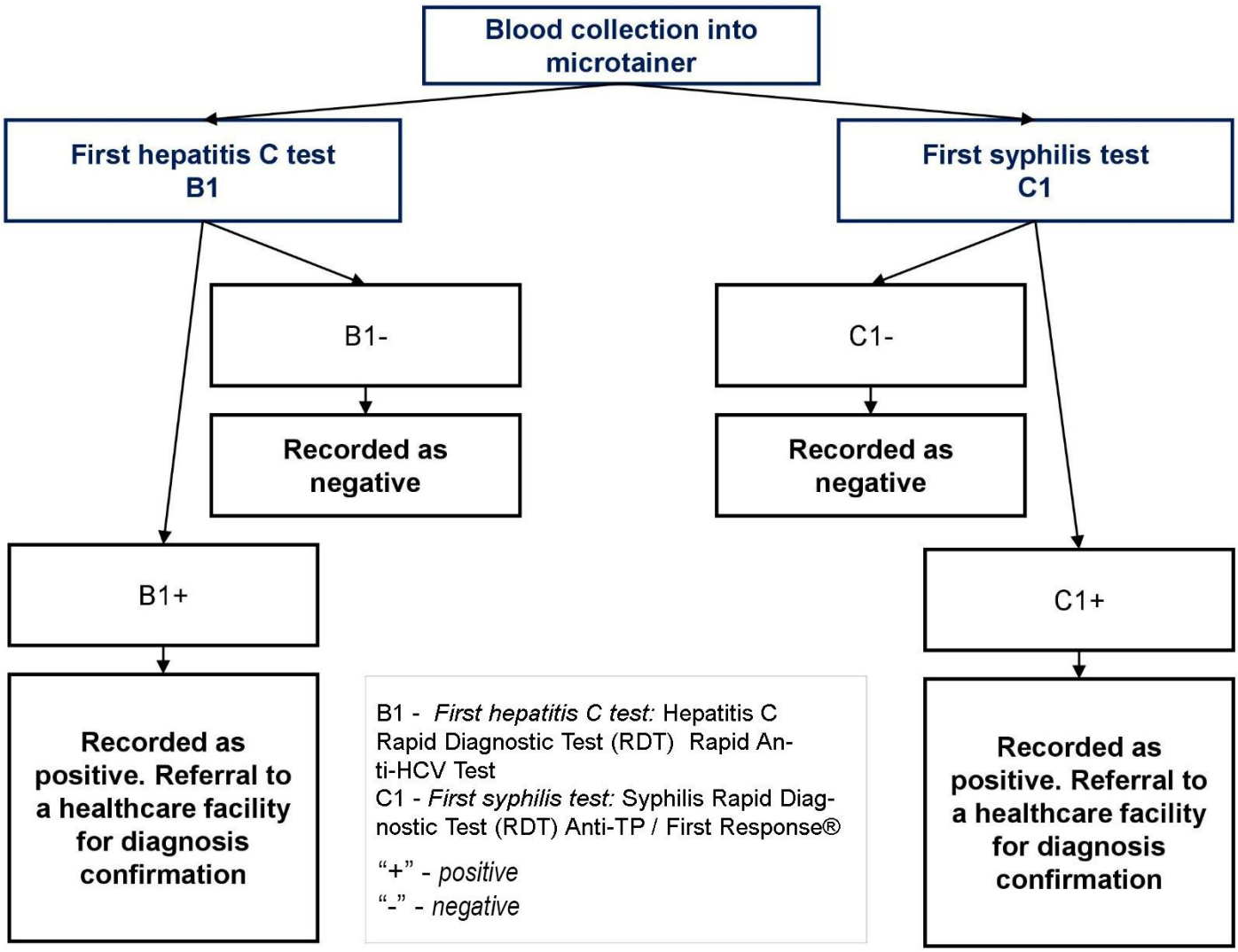


Diagram 2. Graphic representation of the testing algorithm for hepatitis C and syphilis

8.3 Rapid testing

For screening testing, rapid diagnostic tests (RDTs) will be used to detect serological markers of HIV, hepatitis C and syphilis, namely:

- HIV-1/2, Rapid Test for Antibody to HIV, Colloidal Gold Device, Beijing Wantai Biological Pharmacy Enterprise Co., Ltd., China;
- Hepatitis C Rapid Diagnostic Test (RDT) Rapid Anti-HCV Test, (Set №40), InTec PRODUCTS, INC, China;
- Syphilis Rapid Diagnostic Test (RDT) Anti-TP / First Response® Syphilis Anti-TP Card Test, Premier Madical Corporation Private Limited, India. Healthcare professionals will carry out testing according to the manufacturer's instructions and the SOPs of the survey.

When using rapid tests, it is possible to receive negative, positive or invalid results:

- in case of negative result of the first rapid test to detect HIV serological markers, the results are notified as negative to the participant according to the standard form No. 503-10/o of the results of rapid HIV test (Order of the MOH of Ukraine No. 794 of 2019) and information on

the local NGOs providing preventive services to PWID is given;
- in case of a positive result of the first rapid test to detect HIV serological markers, the second rapid test is conducted;
- in case of invalid results on the first rapid test to detect HIV serological markers (absence of control mark), the testing procedure is repeated using the same test.

8.4 Second rapid HIV test

HIV-1/2.0, First Response v.3.0 Cards Kit, Premier Madical Corporation Private Limited, India, will be used to confirm the HIV-positive result of the first screening rapid test.

When using the second rapid diagnostic test, two results are possible: positive or negative results:

- in case of two positive test results to detect HIV serological markers, the third rapid test is conducted;
- in case of non-matching (discordant) results of two rapid tests (the first test is positive result, the second test is negative result), the repeated testing is carried out using the first rapid tests. If a negative result is obtained when test 1 is repeated, the participant is given a certificate of negative HIV test result (standard form No. 503-10/o of the results of rapid HIV test (Order of the MOH of Ukraine No. 794 of 2019); If a positive result is obtained when repeating Test 1, the test result is considered indeterminate and a certificate 503-10/o is given.

8.5 Third rapid HIV test

The third rapid test HIV-1/2, Bioline 3.0, Abbott Diagnostics Korea Inc, is used in the case of two positive test results with the tests HIV-1/2, Rapid Test for Antibody to HIV, Colloidal Gold Device, and HIV-1/2.0, First Response v.3.0 Cards Kit.

When using the third rapid HIV test, it is possible to receive positive and negative results:

- in case of the first test positive result and the second test positive result and the third test positive result to detect HIV serological markers, the result is recorded as "positive";
- in case of the first test positive result, second test positive result and third test negative result to detect HIV serological markers, the result is recorded as "indeterminate" and the participant is proposed to undergo re-testing in 14 days;

The test`s result is given to the participant according to the standard form No. 503-10/o of the results of rapid HIV test (Order of the MOH of Ukraine No. 794 of 2019).

It's planned to provide the EQA HIV program 1 time and 3 times – for the internal QA program (1 time per month)

8.6 Blood collection and DBS preparation

DBS samples are produced from EDTA capillary blood samples for each survey participant with positive results of the third HIV rapid test, and for 10% participants with HIV-negative result of the first rapid test, selected randomly in each city of survey, as well as for those participants who stated they are receiving ART in their questionnaires (Annex 23. DBS registration form).

One Whatman 903 Protein Saver Card (EU) DBS card should be filled with at least with 75 µl of blood

per circle. Sterile disposable pipettes with appropriate calibration are used to transfer a blood sample from a container with EDTA capillary blood to DBS card. It's necessary to turn the EDTA container 20 times before sample transfer. All other stages of DBS preparation must be carried out in accordance with the procedure specified in the relevant SOPs. The survey site healthcare worker will be trained in accordance with the CDC's instructions for this procedure; his/her competence will be checked by the national coordinator. The DBS cards are identified by a survey identification number and dried on a grid at room temperature at the testing sites. After drying, the cards are packed into hermetically sealed packages, along with the humidity indicator and the dryer, and forwarded to the Reference Laboratory for HIV/AIDS diagnostic (each new batch is forwarded in 10 days) by a transport service that guarantees the appropriate temperature conditions.

All test results are entered into the Test Results Form (Annex 15. Test Results Form).

8.7 Laboratory testing

All DBS samples are tested for recent infection and viral load (VL) in the Reference Laboratory for HIV/AIDS diagnostic in accordance with the testing algorithm and SOPs (Annex 24. Form of routine forwarding of the DBS samples to the Reference Laboratory).

Results of confirmed recency test will not be returned to patients. Results of VL will be returned by the lab to each site coordinator, who in turn will hand them over to local HIV clinics to which participants will be redirected. A medical specialist informs participants about the possibility of obtaining their results after they have been processed by the laboratory and received by the HIV clinics.

The quality of DBS cards is checked before testing (Annex 22. Form of rejected DBS registration). The cards are not tested if: there is a blood clot on a paper; blood is applied on both paper sides; insufficient amount of blood to cover the circles with 15 mm diameter; blood from different circles merged into one spot; serum separated from thrombocytes on a paper and created light circles around them; blood spots are blurred and not-colored; samples were not dried completely before transportation (intensive red spots); there are signs of rotting and mycotic DBS damage.

All HIV-positive DBS samples are tested as to recent infection (Maxim HIV-1 EIA Lag-Avidity EIA for Dried Blood Spots) and viral load (Abbott Real Time HIV-1 Test). Samples with VL ≥ 1000 copies/ml are considered to be the confirmed cases of recent HIV-1 infection. Samples with VL ≤ 1000 copies/ml are classified as long-term infection.

If the test is not performed correctly, an additional test is performed using the already collected sample (in a tube with anticoagulant). Additional blood is not collected. All residual samples are disposed of as corresponding category B in accordance with the order of the Ministry of Health of Ukraine dated June 9, 2022 No. 1602 On approval of changes to the State Sanitary and Epidemiological Rules and Norms for the Management of Medical Waste (https://zakon.rada.gov.ua/laws/show/z1387-22#Text)

All samples are destroyed and not used for future testing.

As of December 2020, RTRI (i.e., HIV recency tests) have not been pre-qualified by the World Health Organization or approved by the U.S. Food and Drug Administration (FDA) for clinical use and are being used primarily for surveillance."

8.8 Post-test counseling and referral to services

HIV: All respondents undergo post-test counseling in accordance with the National Protocol of the HTS. The participants with HIV-positive result under the second and the third rapid diagnostic tests are informed by healthcare workers about the final result (Annex 17. Certificate of HIV test results) and referred on the same day to the nearest HIV clinic or ART site for ART initiation (Annex 16. Referral form for the survey participant; Annex 20. Registration log for referrals to HIV Clinics). During the data collection phase, representatives of local NGOs providing HIV testing and linkage services to PWID will be present at survey sites, and will enroll newly detected HIV positive participants in their projects, which provide active referral (accompanying) to HIV clinics and extended follow-up. The regional coordinator ensures the presence of social workers from a specialized NGO on the study site to accompany participants. If one social worker will not be enough, the regional coordinator will attract the necessary number of specialists to the site. Additionally, information on the referral to medical institutions, including the HIV clinic, is indicated in the informed consent that is provided to participant when he/she arrives at the site.

In accordance with the national procedure of ART prescription (Order of the Ministry of Health of Ukraine No. 551 of 2010), ART can be initiated immediately after an HIV-positive representative of a key groups is linked to care. The reluctance of HIV-positive participants to be registered with a HCF may be an obstacle to starting treatment the same day. Therefore, the specialized projects provide extended follow-up to ensure linkage to care when participant is ready for this.

If present in the city, additional referrals will be provided to social care and support projects (Annex 19. Social support referral form for the survey participant).

In case of HIV negative result all PWID who tested negative will be informed about PrEP options, which are available for free at the nearest HIV clinic/ART site. They will be offered to be accompanied by the social worker for PrEP initiation.

In case of a positive result of an HIV test, a medical specialist will also provide information on recent/long-term HIV infection, consequences for the health of participants, preventive activities for participants and their family members and social environment (Appendix 35 Fact sheet on understanding recent and long-term HIV infection). Also, a medical specialist will inform the participants that they will be able to obtain their results after processing by the Reference Laboratory for HIV / AIDS diagnostic by contacting the AIDS Centre in their city and giving the ID number that is indicated in the referral (Annex 16 Referral for the participant of the study).

Tracking of HIV clinic referral outcome will be done by the social worker of the specialized NGO using the Referral Log (Annex 20). Two weeks after the end of the field stage, the Regional Coordinator will aggregate and submit the information on the number of participants who have visited the HIV clinic and who have started the ARV-treatment or PrEP to the central study team.

Hepatitis C: According to the national guidelines on Hepatitis C, diagnosis is made based on the results of laboratory testing. In case of a positive screening rapid test result for anti-HCV, the participant is consulted on possible viral infections and the need for follow-up examination. Participants with positive result will be referred to:

- HIV clinic (in case of HIV/viral hepatitis co-infection),
- family doctor,

- infectious diseases physician at a clinical diagnostic center at the place of their residence,
- infectious diseases physician at a specialized department of clinical hospital at the place of their residence.

At the stage of formative assessment, the Regional Working Group members, in particular, regional coordinator and the representatives of HIV clinics, will make up an up-to-date list of facilities that provide HCV diagnostic and treatment referral, as well as available projects that may cover the diagnostic costs. Participants who test positive for HCV antibodies and do not self-report having been treated for HCV will be referred to the identified clinics and projects using the Referral Form (Annex 16), accompanied by the Test Result Form (Annex 18).

To track the referral outcomes, the participants will be asked to provide their phone number. The study team social worker will call these participants two weeks after referral and record the results in the Referral Log (Annex 21). Two weeks after the end of the field stage, the Regional Coordinator will aggregate the data from the Log, and submit the information on the number of people who were successfully linked to a treatment facility. According to the data from the Log, we receive two indicators: 1. the number of PWID, who visited HCF (for consulting and confirmatory testing); 2. the number of PWID who started treatment after HCV PCR testing. Only the second indicator we can consider a successful linkage. All participants will be given informational and promotional materials about the prevention and treatment of the hepatitis C by a coupon manager.

Syphilis: According to the national guidelines on syphilis, diagnosis needs to be confirmed by laboratory testing. In case of a positive rapid screening test result for syphilis, the participant is consulted on possible bacterial infection and the need for diagnostic testing. Participants with positive result will be referred to:

- dermatovenerological dispensary;
- dermatovenerological hospital;
- dermatovenerologist at a clinical diagnostic center at the place of their residence.

At the stage of formative assessment, the Regional Working Group members, in particular, a regional coordinator and the representatives of HIV clinics, will prepare a list of facilities for referral.

Referral will be made using the Referral Form (Annex 16). To track the referral outcomes, the participants will be asked to provide their phone number. The study team social worker will call these participants two weeks after referral and record the results in the Referral Log (Annex 21). Two weeks after the end of the field stage, the Regional Coordinator will aggregate the data from the Log and submit the information on the number of people who were successfully linked to a treatment facility.

9.0 DATA MANAGEMENT AND ANALYSIS

The questionnaire data were exported from PHC_Research to a SPSS datafile, with attached variable and value labels. The questionnaire dataset will be cleaned, recoded, and re-labeled as necessary. The coupon management and biological testing data will be cross-checked, cleaned, and merged with the main survey dataset.

9.1 RDS weighting and diagnostics

To verify RDS assumptions, data will be imported to specialized RDS software ("RDS" package for R or RDS-Analyst). Convergence plots will be constructed to assess whether equilibrium was achieved in each city. Additionally, bottleneck plots and recruitment homophily for key variables of interest will be assessed. Recruitment chain graphics will be constructed to visualize the process of recruitment in each city. This will be done during data collection to inform recruitment (i.e. terminating and adding new chains), as well as during the analysis phase to verify assumptions.

In order to minimize biases inherent to RDS, all descriptive analyses will apply individual RDS network weights calculated using a sampling estimator selected based on the recruitment and sampling characteristics (e.g. the Gile's successive estimator). The first set of weights will be based on the network size variable (the number of PWID representatives older than 14 years old that the respondent has seen over the past 30 days) as reported by the participants, and an alternative set will be calculated using the imputed visibility produced by the RDS package (to be used in sensitivity analyses).

9.2 Descriptive statistics

Descriptive statistics for all key variables (prevalence of infections, drug use, behaviors, service use, HIV treatment cascade, etc) will include category size (n), population proportions with 95% confidence intervals, means with standard errors or medians with interquartile range. All descriptive statistics including confidence intervals will be calculated using the RDS weights. The total sample estimates will use the RDS weights but will not be additionally weighted due to the equal sample size in each city. When the population size calculation becomes available (see below), additional weighting by population size in each city will be done to obtain estimates for the entire city sample for key variables. Descriptive tables will be disaggregated by city and key demographic characteristics (age group and gender). Visualizations for selected variables and disaggregations will be provided in bar or line charts. The design of tables and charts will take into account the structure of the previous reports on the IBBS findings in Ukraine.

9.3 Inferential statistics

Bivariable associations between key outcomes of interest (HIV/HCV/syphilis prevalence, HIV recent infection, HIV treatment cascade indicators, HIV knowledge, etc.) and predictors of interest may be analyzed using Pearson's chi-square test for categorical variables (or Fischer's test for variables with low counts), Student's t-test for normally distributed continuous variables, and non-parametric tests for non-normally distributed variables (Kruskal-Wallis or Wilcoxon).

Multivariable analysis may be used to test the associations of key outcomes with independent variables that were significant in bivariable analysis. Logistic regression may be used for categorical

outcomes and linear regression for continuous outcomes.

9.4 Trend analysis

To analyze the changes in key outcomes of interest across rounds, the final dataset may be merged with datasets from previous rounds. Only cities that participated in each analyzed round will be included. Combined weights (a product of RDS weight and city sample size weight OR the city population size, when becomes available) will be calculated and applied in the trend analyses. The significance of trend will be tested using two methods: (a) Mantel-Haenszel test of trend, used in the previous studies[13], and (b) regression models with the survey round as an ordinal independent variable. Additionally, comparison between two consecutive rounds using Pearson's chi-square tests.

9.5 Estimation of HIV incidence

The biological component of the IBBS will provide estimates of recent HIV infection and viral load, to be used for calculation of HIV incidence among PWID.
A new method for calculating annual incidence[14] will be used. The corresponding method was implemented in the package "inctools" (version 1.0.15) for R. This approach has been previously reviewed and approved by international experts and statistics specialists.

The report on the IBBS findings will include a median incidence estimation and interquartile range observed in different cities among PWID, allowing for understanding the variability across the different regions of the country.

9.6 Treatment cascade indicators among PWID living with HIV

HIV treatment cascade calculation will include the following indicators:

Cascade indicator	Calculation
PWID living with HIV	The latest available PWID population size estimate will be multiplied by the prevalence of HIV among PWID according to the IBBS 2023 data
Know about their HIV-positive status	The proportion of PWID who self-reported their HIV-positive status during survey (among those who received HIV-positive rapid test result upon survey and agreed to answer questions about their experience of previous HIV-testing). This calculation will be cross-checked with the healthcare worker's forms.
Registered in the HIV clinic	The proportion of PWID who self-reported to be officially registered in the HIV clinic as HIV-positive (among those who received HIV-positive rapid test result upon survey and agreed to answer questions about their experience of previous HIV-testing). This calculation will be checked through the healthcare worker's form.
Receive ART	The proportion of PWID who self-reported receiving ART (among those who received HIV-positive rapid test result upon survey and agreed to answer questions about their experience of previous HIV-

[13] Dumchev, K., Sazonova, Y., Salyuk, T., & Varetska, O. (2018). Trends in HIV prevalence among people injecting drugs, men having sex with men, and female sex workers in Ukraine. Int J STD AIDS, 29(13), 1337-1344. doi:10.1177/0956462418784096

[14] Kassanjee R, McWalter TA, Bärnighausen T, Welte A. A new general biomarker-based incidence estimator. *Epidemiology*. 2012 Sep;23(5):721-8. doi: 10.1097/EDE.0b013e3182576c07.

	testing). This calculation will be checked through the healthcare worker's form.
HIV viral suppression	Results of viral load testing carried out at the stage of laboratory analysis.

10.0 POPULATION SIZE ESTIMATION

Three methods will be used population size estimation (PSE) of PWID in selected cities using the IBBS 2023 data: multiplier, "capture-recapture" and successive sampling methods.

10.1 Multiplier method

The multiplier method is based on availability of at least two overlapping data sources specific to the population of interest, one being a count or registry of unique individuals belonging to the population, and another one being a representative survey that assessed whether the participants are present in the first data source. The data sources have to be independent of each other; define the target group in the same way; present the same time period, age and target group geography; be of sufficient data quality.

The formula to calculate the population size using the multiplier method is: N= M/P, Where:

N = Estimated Size

P = Proportion of survey participants who reported belonging to the registry (receiving the service, the object, or participating in the survey).

M = Number of individuals in the registry.

The 95% confidence intervals for proportions calculated for descriptive statistics using bootstrapping method with RDS weights will be used to calculate the lower- and upper limits for the population estimates.

The following data sources and indicators will be used for the multiplier method:

#	PSE indicator	Questionnaire item	Existing registry	Data provider
1	Registration in drug treatment clinics	Are you registered with the state narcological clinic in connection with drugs abuse or addiction?	Currently undetermined. Previously: Reporting form No.11 “Report on the morbidity of individuals with mental and behavioral disorders due to psychoactive substance use”, annual. Table 2120 “Number of individuals with mental disorders due to intravenous drug use”. Indicator: “among people under the supervision at the end of the reporting period”.	Regional and city state drug treatment clinics.
2	Substance use treatment	Were you getting treatment in the state narcological clinic in 2022? (in-patient treatment / out-patient treatment) Have you been getting treatment in the state narcological clinic in 2023 (January-March)? (in-patient treatment / out-patient treatment)	Currently undetermined. Previously: Reporting form No.11 “Report on morbidity of individuals with mental and behavioral disorders due to psychoactive substance use”, annual. Table 2300 “Composition of individuals in a drug treatment in-patient clinic”. Indicator: “Mental and behavioral disorders due to the use of opioids, cannabinoids, cocaine, hallucinogens, combinations of several drugs and other psychoactive substances, total” Currently undetermined. Previously: Form No.11 “Report on the morbidity of individuals with mental and behavioral disorders due to psychoactive substance use”, annual. Table 2100 “Contingent and treatment of individuals with mental disorders due to psychoactive substance use”. Indicator: “Mental and behavioral disorders due to opioid use – covered with in-patient/out-patient treatment”. Includes data on the number of people registered with a substance abuse clinic, who have already completed in-patient treatment at the end of the reporting period, including those, who have been treated at day drug treatment in-patient clinics.	Regional and city state drug treatment clinics.
3	Criminal	Have you been detained by the police in 2022?	Number of people notified of suspicion under articles	Statistical data

	prosecution	Have you been detained by the police in 2023?	307 and/or 309 during 2019 and 2023. Identified people who committed criminal offences under articles 307 and/or 309 during 2022 and 2023. Committed criminal offences under the influence of drugs, toxic and psychotropic substances under articles 307 and/or 309 during 2022 and 2023.	of the city police and the prosecutor's office.
4	Medications for opioid use disorder (MOUD) coverage	Have you received methadone or buprenorphine within the MOUD program in 2022? Are you taking methadone or buprenorphine within the MOUD program (January-March 2023)?	Number of people who were receiving MOUD in all city medical facilities during 2022. Number of people who were receiving MOUD in all city medical facilities during January-March 2023.	Public Health Center
5	Harm reduction coverage	Are you a client of any NGO working with people who inject drugs (have a client's card or an individual code)? Have you received free sterile needles/syringes from a non-governmental organization within the last 12 months (March 2022-March 2023)? Have you received free condoms from a non-governmental organization within the last 12 months (March 2022-March 2023)? Have you received HIV testing services from a non-governmental organization within the last 12 months (March 2022-March 2023)?	Number of PWID who received any harm reduction services in March 2022-March 2023.	SYREX database
6	Needle and syringe program coverage	Have you received sterile needles/syringes from a non-governmental organization within the last 3 months (January-March 2023)?	Number of PWID who have received syringes/needles within NGO network (average indicator for 3 moths).	SYREX database
7	Condom programming coverage	Have you received condoms from a non-governmental organization within the last 3 months (January-March 2023)?	Number of PWID who have received condoms within NGO network (average indicator for 3 months).	SYREX database
8	HIV testing coverage	Were you tested with a rapid test for HIV in non- governmental organization in 2022? Were you tested with a rapid test for HIV in non- governmental organization in 2023 (January-March)?	Number of PWID who have been tested with the HIV rapid tests for 2022 and 2023 (separately for each year).	SYREX database
9	HCV testing	Did you get a rapid test for hepatitis C at NGO	Number of PWID who have been tested with the HCV	SYREX

	coverage	in 2022? Did you get a rapid test for hepatitis C at NGO in 2023 (January-March)?	rapid tests for 2022 and 2023 (separately for each year).	database
10	HBV testing coverage	Did you get a rapid test for hepatitis B at NGO in 2022? Did you get a rapid test for hepatitis B at NGO in 2023 (January-March)?	Number of PWID who have been tested with the HBV rapid tests for 2022 and 2023 (separately for each year).	SYREX database
11	Syphilis testing coverage	Did you get a rapid test for syphilis at NGO in 2022? Did you get a rapid test for syphilis at NGO in 2023 (January-March)?	Number of PWID who have been tested with the syphilis rapid tests for 2022 and 2023 (separately for each year).	SYREX database

These data will be collected for both IBBS and non-IBBS regions, to enable extrapolation of estimates.

* Considering the continued process of transition of harm reduction funding from international sources to the government, and potential changes in client counting approach, all service coverage indicators will be carefully examined for consistency of trends at the city level. In case of any rapid changes (particularly increases), additional data verification will be done, which will include cross-checking of reports and source documentation, and in-depth interviews with service providers. If any evidence of double counting will be identified, a correction coefficient will be proposed for these indicators.

10.2 Modified capture-recapture methods

Capture-recapture (CRC) methods were originally developed in biology for estimating animal populations by sampling and marking the members of a population at a given time and then re-sampling the population at a subsequent time. The population size is then estimated by using the sample sizes and the number of members common to both samples. This methodology was later adapted and recommended to use for PSE of key populations by UNAIDS.

The CRC models have four assumptions. First, the population is closed. Second, the individuals in the first sample can be identified in the second sample. Third, the two samples are independent—the probability of being selected in one sample does not affect the probability of being selected in the other sample. Fourth, all individuals have equal probability of inclusion in each of the samples.

Separate CRC studies of national scale were not feasible in Ukraine, therefore modified approaches were used in conjunction with IBBS rounds since 2015.

One modification uses participation in IBBS as a first "capture". Each subsequent round asks the participants about participation in the previous survey, providing a "recapture". The 2023 IBBS round will also include the questions about prior participation in the IBBS in 2017 and 2020 to produce two population size estimates that will be included in aggregated analysis.

In another modification, unique objects are distributed in the population, and the number of people receiving the objects serves as a first "capture". The type of unique object is determined according to the following criteria: acceptable and have intrinsic value (utility); useful to keep, but do not have commercial value that may facilitate the sale or trade for other things. The objects are distributed to individuals meeting the definition of the target population, in as many locations within the study area as possible. Starting one or two weeks after the distribution of the object, the survey asks whether the participants received the objects, serving as a "recapture".

The total population size is calculated using the Lincoln–Peterson formula:

$$N = \frac{(S_1 * S_2)}{R}$$

where:

N – estimate of total population size

S_1 – number of persons captured by the first "capture"

S_2 – number of persons captured by the second "capture" (the survey sample size)

R – number of survey participants reporting captured in the first "capture"

Variance will be calculated by using the following formula:

$$Var(N) = \frac{(S_1 * S_2 * (S_1 - R) * (S_2 - R))}{R^3}$$

95% confidence interval will be calculated by using the following formula:

$$95\%\ CI: N \pm 1.96 * \sqrt{Var}(N)$$

For the 2023 PSE round will use two different unique objects to improve accuracy of the method. During the formative assessment, the Regional Working Group, will prepare a list – as exhaustive as possible – of the venues where PWID can be found. On a specified date, approximately two weeks prior to the start of IBBS data collection, designated representatives of the regional working groups will visit **all** venues and distribute the first unique object to the PWID present at the venue and who meet eligibility criteria (same as for IBBS, Annex 8). Results of distribution will be recorded in the Form (Annex 36. Unique Object Distribution Form). One week after that, a second visit to **all** venues will be done to distribute the second object, results will also be recorded in the Form. If it will not be feasible to visit all locations within the limited time frame, the venues for each visit will be selected randomly and independently (no overlap is required), to ensure that samples are independent. According to the guidelines[15], the number of unique objects should be at least twice that of the target sample size. Since the sample size in each city will be equal to 500, the number of unique objects of each type to be distributed is 1000, total 2000 per city, or 4,000 in two cities. The cities will be selected by the National Working Group.

The following log-linear regression model will be used to estimate population size based on three 'captures'[16].

$$\log E(Zijk) = u + u1I(i = 1) + u2I(j = 1) + u3I(k = 1) + u12I(i = j = 1)$$

The model estimates the log expected count of the population size for a 3-list capture-recapture analysis and adjusts for a positive (or negative) dependency between lists i and j. This model allows to relax the assumption of independency between captures by controlling for list dependencies through interaction terms.

10.3 Successive sampling method

Successive sampling PSE method (SS-PSE) is based on data collected by the RDS methodology[17]. This method estimates the group size accounting for each participant's social network size, time and sequence of enrollment, number of people recruited by each participant. The underlying assumption is that the bigger network the respondent has, the earlier s/he will be recruited to the study. The recommended approach is to use the social network questions to impute a new degree (the number of people they know and have seen in the past two weeks who fulfill the study eligibility criteria) for each participant to reduce the recall bias. Prior knowledge about the population size, the imputed degree and other sampling data are used in a Bayesian framework (i.e., to quantify uncertainty about unknown quantities by relating them to known quantities) to quantify a population estimate with probability bounds. The SS-PSE will be conducted in "sspse" package for R or RDS-Analyst.

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[15] Blue Book

[16] Wesson P, Lechtenberg R, Reingold A, McFarland W, Murgai N. Evaluating the Completeness of HIV Surveillance Using Capture-Recapture Models, Alameda County, California. AIDS and Behavior. 2018 Jul;22(7):2248-2257. DOI: 10.1007/s10461-017-1883-6.

[17] Handcock MS, Gile KJ, Mar CM. Estimating the size of populations at high risk for HIV using respondent-driven sampling data. Biometrics. 2015;71(1):258–266

10.4 Calculation of the aggregated city-level estimates

10.4.1 Estimates validation

In order to validate the estimates obtained by all methods, the most probable range of PWID number in each IBBS city of survey will be determined:

- The coverage of PWID by prevention services provided by NGO (with a correction coefficient [see section 10.1] if applicable) will be used as a limiting minimum.
- Four percent of the total adult (age 15-59) general population as of January 1, 2023 (with appropriate correction for migration, if available) will be used as a limiting maximum. Previous rounds of estimations demonstrated that 3-4% threshold it is adequate for the PWID group.

Estimates that are outside of the probable range will be excluded from further analysis.

10.4.2 Estimates triangulation

Several estimates, calculated at a local level, will represent an estimation range for the number of PWID. This allows to compare the validity of individual methods and to define the most probable range at a city level. The final estimate of the group size is determined by intersection of the maximum number of separate assessment ranges and by averaging. A PSE method called anchored multiplier, that allows synthesizing several population size estimates into a single consensus estimate, is also planned. Anchored Multiplier calculator[18], uses a Bayesian simulation model to combine empirical estimates. The calculator is suitable for entering data into beta distribution, which reflects data "strength". “Stronger” data (with narrower confidence interval) will have greater impact on the final estimate than “weaker” data (with wider confidence interval). The single city-level consensus estimates will be considered final and will be used for further calculations.

[18] https://globalhealthsciences.ucsf.edu/resources/tools

11.0 DATA MANAGEMENT PLAN

Data Management Plan identifies the resources and tools needed for data collection, storage, and usage, providing for effective planning of data input, clearing and analyzing, control the data quality, managing data usage and exchange, ongoing management and data documentation. The plan covers three databases - survey data, laboratory data, RDS-coupons management base.

The Data Management Plan provides a number of components, namely: data documentation, data dictionary, unique participant's ID, data access, data security.

All IBBS personnel will be trained on the procedures of protecting confidentiality of participants within the training framework and will sign the Data Use and Confidentiality Agreement which explains the procedures for dealing with confidential data and liability for violations (Annex 27. Data Use and Confidentiality Agreement for personnel).

11.1 Data documentation

The following forms and tools will be used:

1. Verbal informed consent to be interviewed;
2. Formative Assessment Protocol;
3. Log of compensation to the key informants;
4. Verbal consent to questionnaire piloting;
5. Log of compensation to the respondents for questionnaire piloting;
6. Introduction for the potential participants of the survey;
7. Screening questionnaire for primary respondents;
8. Screening Form for PWID;
9. Survey participant's coupon;
10. Participant`s Checklist;
11. Participant's Informed Consent (Ukrainian version);
12. Participant's Informed Consent (Russian version);
13. Registration form for refusal to participate in the survey;
14. Questionnaire of refusal to participate in the survey for recruiters;
15. Test Results Form;
16. Referral form for the survey participant;
17. Certificate of HIV test results;
18. Certificate of test results for anti-hepatitis C, syphilis;
19. Social support referral form for the survey participant;
20. Registration log for referrals to HIV clinic;
21. Registration log of referrals to healthcare facilities;
22. Form of rejected DBS registration;
23. DBS registration form;
24. Form of routine forwarding of the DBS samples to the Reference Laboratory;
25. Compensation Log;
26. Instructions for a recruiter;
27. Data Use and Confidentiality Agreement for personnel;
28. Unforeseen circumstances notification form;

29. Reporting form on serious adverse events;
30. Form of the Protocol deviations;
31. Weekly reporting form of the national coordinator;
32. Weekly reporting form of the regional coordinator;
33. Report of the regional team on the survey findings;
34. Report on the monitoring visit to the survey site;
35. Fact sheet on understanding recent and long-term HIV infection
36. Survey Participant`s Questionnaire.
37. Verbal consent to Unique object

All forms are linked with the participant's ID and do not contain the participants' identifying information. The regional coordinator collects all completed forms from the responsible RDCT member (coupon manager, interviewer, healthcare worker). The regional coordinator checks the completeness and correctness of forms data, cross-checks the number of records between forms. On a monthly basis, a regional coordinator sends paper copies of the forms in a sealed envelope by a courier service to the national coordinator. Before that, the form copies are stored in his/her office in a locked cabinet.

11.2 Unique participant ID

Each participant in IBBS has two codes, which helps to link the data and ensure data confidentiality. The codes do not contain personally identifiable information and cannot be used to identify an individual.

ID-code is assigned to each participant by coupon manager and is recorded in all source documents in IBBS. The ID-code consists of two-letter city code, and three-digit sequential number (0001-0010 for seeds, and 0011-0999 for other participants).

An additional QR code is used to link electronic forms in the PHC_research app. It has the same elements as the ID-code, with additional letters "PW" between the city code and sequential number. The QR-code is printed on the participant's coupon, and after scanning it with the PHC_research app, it is populated into linked forms: screening, questionnaire, medical testing, test results, primary compensation, coupon dissemination, secondary compensation.

Only the coupon manager is responsible for storing, maintaining, and assigning QR codes to participants. Access to the ID code link-log has a principal investigator, co-investigator, and national coordinator. ID code link-log will be stored on the "PHC-research" software server.

11.3 Data access

Only the Principal investigator and co-investigators will have access to the data and documents, the division of responsibilities between the personnel (primary data and coding, data entry, analysis, report preparation) will be ensured. Documents and computers will be password protected (at least one small letter, one capital letter, one digit and one character).

Roles are assigned to selected individuals to create analysis data sets to minimize redundancy. To ensure secure access to data, one-factor authentication for each role and a horizontal hierarchy of access to information are used. Each regional team member only has access to their block in «PHC_Research» software: screening, questionnaire, medical testing, test results, primary

compensation, coupon dissemination, secondary compensation. Each block is accessed through verification with the help of a personal login and password, which each representative of the research team has.

«Screening» is completed by the coupon manager, and after filling becomes inactive for editing.

«Questionnaire» is filled out by the interviewer during the face-to-face interview. Changes to the Questionnaire block are possible after filling in. Changes are made if the respondent decides to change his / her answer to the questionnaire and informs the interviewer after the interview is completed.

«Medical testing» is completed by a healthcare worker, recording the fact of providing consultation and testing to each IBBS participant. The block after filling becomes inactive for editing.

«Test result» is completed by the healthcare worker at the end of each day. This block contains information from the Test Results Form that the healthcare worker fill throughout the day for each study participant.

«Primary compensation» is filled in by the coupon manager, which records confirmation that the respondent has been compensated for his participation. The block after filling becomes inactive for editing.

«Coupon dissemination» is filled in by the coupon manager, which to capture the codes of issued coupons to recruit other PWID if the participant has agreed to become a recruiter. The block after filling becomes inactive for editing.

«Secondary compensation» is filled in by the coupon manager, which records the fact of payment to the participant after recruiting others PWID.

Principal investigator will have direct access to the data on the server. To ensure secure access to data, double authentication is used for the principal investigator. The administrator of PHC Information Systems Support Division has access via RDP / SSH to the system and its settings, without access to the research data.

Researcher access to data is traceable and to prevent sharing of access credentials. A full audit will be performed through the web interface (user login identification). Email is not used to transfer data through software.

11.4 Data security

From paper forms, data will be transferred to electronic format by a team member who do not have access to participants and will be involved only at the stage of entering information into the dataset. Each of these specialists will sign the Data Use and Confidentiality Agreement, which minimizes the risk of incorrect use of information. All reporting forms of regional teams will be checked by the Principal investigator and aggregated by him.

The regional coordinator is responsible for storing documents in a safe or locked cabinet, which will be located in his office. During the field stage, the regional coordinator will report on recruiting and the main results of the sampling every week, which will quickly receive information (if any of the documents are lost, it will be possible to restore files inclusively until the current week). The regional coordinator will immediately inform the Principal investigator of any unplanned situation with paper

forms in order to receive information on further steps. If some paper documents are lost or something happens to them, the Principal investigator will have access to the data array and will be able to recover the information (the data array will be filled online through «PHC_Research»).

Data transfers done through secure methods, and data are encrypted before transfer. Data transfer protection guaranteed by SSL/TLS 1.3 with Advanced Encryption Standard 256. To protect data that is entered through «PHC_Research», a cryptographic library for mobile devices is used. To develop the application, the most protected Android SDK Java Development Technology tool will be used.

An array of survey data and accompanying documents will be stored on a cloud protected server of the PHC, unavailable through the common networks. Database security is controlled by a firewall on the PHC server, and all data is stored in encrypted form. The database will be protected against viruses and other malware. To do this, anti-virus software is used on the central database, server and user computers.

The PHC Information Systems Support Division will administer the server, which involves daily backups and emergency recovery in case of server failure. The backup system is based on the RAID 10 or 01 scheme. A full backup is planned once a day after midnight on a separate sector of the PHC server. All data is encrypted on both sectors - primary and backup.

As the main implementer and owner of the data, the PHC is responsible for data arrays storage for at least 10 years after the completion of the survey. Only the Principal investigator will have access to cross cutting shredders. As needed intermediate data will be securely destroyed. Such data will be deleted by the Principal investigator from his computer, access to which is ensured by a strong password (no other staff will have access to this computer).

All paper documents will be stored in a secure place, in a safe in the office of the Principal investigator. After the presentation of the final IBBS report, all documents will be transferred to the general PHC archive, access to which will be available only to the Principal investigator upon request. After 5 years after the completion of IBBS, paper forms will be destroyed by national team using a shredder in accordance with the general document management policy at the PHC.

The study does not involve the collection of interim data.

After the field stage has been completed all tablets will be formatted and reset to factory settings by a national team.

12.0 DATA QUALITY ASSURANCE

The implementer will employ a range of measures at all stages of survey to assure quality of data.

12.1 Preparatory stage

The Protocol and the SOPs will be reviewed and approved by the National IBBS Working Group. Standard operating procedures (SOPs) will be developed to provide a consistent algorithm for data collection at all sites of the IBBS. The SOPs will cover the following aspects of survey implementation:

- recruitment and screening;
- prevention of re-participation in the survey and exclusion of non-eligible participants;
- informed consent;
- confidentiality of participants;
- completion of the survey instruments;
- collection and testing of biological samples;
- pre- and post-test counseling, referrals to healthcare facilities;
- storage and transportation of dry blood spots;
- compensation to respondents for participation in the survey, recruiting of other participants;
- survey algorithm for participants;
- team work on the survey site, its activation and closure;
- confidentiality of the participants;
- securing survey site for participants and staff;
- arrangement of waiting room;
- data management on the survey site;
- weekly reporting;
- survey monitoring and data quality assurance.

The personnel training is carried out based on the Protocol and SOPs, and the availability and compliance with the documentation on the sites is checked during monitoring visits. The personnel (regional teams, healthcare workers, monitoring consultants) will undergo a specialized training.

12.2 Field stage

The PHC_Research app used for data collection minimizes possible data entry errors and allows for automatic tracking of RDS coupons and compensation of participants, checking recruiting rates and the quality of behavioral and biological components. On a daily basis, both regional and national study coordinators will monitor data recruitment process to check for potential bottlenecks and modify recruitment, if necessary. To control the quality of data entry, PHC_Research contains logical filters that help to avoid errors or skipping questions during filling out the questionnaires. In case online forms cannot be used, the interviewer uses a paper form and later enters the received data to the platform at the same day.

Each regional coordinator will report weekly to the National Working Group and a national coordinator on the progress of data collection (Annex 31. Weekly reporting form of the national coordinator, Annex 32. Weekly reporting form of the regional coordinator, Annex 33. Report of the regional team on the survey process). The report will provide information on recruitment rates, number of collected and shipped DBS samples, a list of adverse events, measures taken to overcome the problems.

12.3 Field monitoring

As study sponsor, the CDC may perform monitoring and audit of activities conducted within the survey framework in order to ensure scientific accuracy and participants' rights and freedoms protection. Monitoring and audit of activities may be carried out by:

- CDC personnel ("internal");
- CDC authorized representative (for example, the contracted party, considered as being "external").

The survey is also a subject to control by the international and national partner organizations, as well as Ethics Review Board to review the observance of ethical requirements. The Principal investigator and the national research team will be conducting monitoring visits to the sites of the study. The dates of visits will be agreed upon with all the partners that are involved in the visits in order to ensure that on one site only one team is present. Overall, two monitoring visits per site are planned to take place.

Monitoring and audit can be carried out by visiting the investigator's workplaces or by other means of communication (for example, telephone, written correspondence). The schedule of visits must be agreed between the two parties, but the frequency of visits remains at the discretion of the CDC, the PHC and national partners. During the visit, either survey material may be reviewed and the investigator together with the survey personnel is required to discuss all the findings.

At the data collection stage, at least two visits to each site will be conducted. Regional sites will be visited by the PHC representatives, the National Working Group, CDC and external consultants to monitor the compliance with the methodology. The National Working Group will appoint monitoring consultants who will be trained in IBBS procedures and data quality management under the CDC mechanisms. The monitoring consultants will assess the Protocol compliance by the RDCTs, in particular, with regard to informed consent, pre-test and post-test counseling, referral to services, rapid testing, collection and storage of DBS (Annex 34. Report on the monitoring visit to the survey site).

Additional visits may be made to the National Reference Laboratory, to monitor their compliance to the protocol and Good Laboratory Practice guidelines.

13.0 DATA USE AND RESULTS DISSEMINATION

Data use and results dissemination will be in line with the developed communication strategy of the IBBS support with the indication of the target audience at the regional, national and international levels as well as peculiarities of findings dissemination and communication channels.

13.1 IBBS data use areas

The IBBS is an important part of strategic information on HIV/AIDS in Ukraine, as it provides data on key indicators, allowing to evaluate the impact of HIV/AIDS programs at the national level. It is necessary for planning and budgeting the prevention and treatment programs among PWID. Additionally, IBBS data are essential for population size estimation and modeling of the HIV epidemic. It is also useful as an alternative data source for HIV treatment cascade indicators, including registration of HIV-positive participants in healthcare facilities, prescription of ART and effective treatment with the achievement of an undetectable viral load. Recent improvements in IBBS methodology enabled estimation of HIV incidence (through identification of recent cases of infection using the DBS samples).

The IBBS data may be used for planning of HIV/AIDS response programs and advocacy of changes, formulating further studies rationale, namely:

- provide PWID information for the HIV/AIDS response program by social and demographic characteristics, risky behavior and morbidity;
- assess access to prevention and treatment programs for PWID, their affordability and acceptability;
- assess changes in behavioral practices of injecting drug;
- assess the use of services in the context of a continuous process of HIV prevention, treatment and care;
- demonstrate the need to increase funding for expansion of program activities;
- highlight issues related to stigma, discrimination and violence.

Data obtained in IBBS are suitable for the calculation of indicators in accordance with services and treatment cascade among HIV-positive PWID, in particular for monitoring the progress of the UNAIDS “95-95-95” goals to overcome HIV/AIDS epidemic and identification of gaps in the existing preventive and treatment programs.

The dissemination of the IBBS among PWID findings will be carried out not only in the context of public health and the role of PWID in HIV epidemic, but also in a view of behavioral practices and social aspects of PWID life.

13.2 IBBS results reporting

The results of IBBS will be presented in two reports: a brief report with priority results including city specific and aggregated HIV indicators, anti-HCV and syphilis prevalence, risky behavior, etc. within two months of data collection; and summary report containing the main survey findings within six months of data collection. In addition to the reports, the findings of the survey may be presented in a form of interactive visualization and dashboards for triangulating analysis according to the "95-95-95" and prevention effectiveness indicators.

The results will also be used for Ukraine’s Global AIDS Reporting to the UNAIDS. The following

indicators will be calculated:

- HIV prevalence among PWID (proportion of PWID living with HIV);
- HIV testing among PWID (proportion of PWID who have been tested for HIV over the past 12 months and know about their status);
- coverage with antiretroviral therapy of HIV-positive PWID (proportion of HIV-positive PWID receiving ART during the last 12 months);
- use of condoms among the PWID (proportion of PWID reporting condom use during the last sexual intercourse);
- coverage with HIV prevention programs among PWID (proportion of PWID reporting receiving of a combined package of HIV prevention services in the past 12 months);
- safe injecting practices among PWID (proportion of PWID reported on using sterile injecting instruments during the last injection);
- avoiding healthcare services due to stigma and discrimination related to PWID (proportion of PWID reported on their avoidance of healthcare services due to stigmatization and discrimination related to PWID).

13.3 Data use and dissemination policy

Dissemination of the IBBS findings will be carried out in compliance with the established by the CDC procedures for data exchange and disclosure. All official presentations at conferences or publications in scientific journals will be made in accordance with the CDC procedures for publications and presentations.

13.4 Data sharing

The PHC plans to create the Ukrainian IBBS data repository on its website. The repository will consist of the Protocol and the tools, supporting documents, reports, publications based on the results of a particular survey round. Access to the materials in the repository will be provided to previously authorized users, allowing data use for monitoring.

Within 60 days after the preparation of the final reports, the PHC will publish it and will notify the stakeholders through its official website, emails and social networks.

The priority results will be made available within two months of the end of data collection (and shared among all stakeholders) and a public Final report will be made available within six months of the end of data collection. The preliminary and final analytical reports on the findings of the survey will be placed in free access on the official site of the PHC. Additional analyses will be published in peer-reviewed journals as the results become available. All scientific articles with the IBBS findings or other publications will be pre-agreed with the CDC and will meet the requirements for electronic publications.

Copies of data sets may be provided to external investigators and the PHC personnel upon reasonable request. The request should describe the intended use of the data, hypotheses, analytic aims, statistical methods, and dissemination plan (Annex 38. PHC data request form.).

The data sharing process is governed by the PHC standard public data sharing operating procedures, as well as formal data access agreements between PHC and the partners. The decision to transmit data is taken by the Principal investigator in collaboration with IRB according to the request form

received. The purpose of request consideration is to ensure that the planned use of the data is of scientific value, namely:

- purpose of the project is clearly described;
- requested data are used to develop scientific knowledge;
- requested data corresponds to the planned project and are appropriate;
- requester has a sufficient level of competence to data use and implement the planned project;
- outcomes of project using IBBS data has a public benefit.

Data sharing will be available for research or program monitoring purposes only and subject to the conditions under which the data were originally collected. Requests for non-scientific use (for example, for marketing purposes) are not considered. If the request is approved, the requester must sign a data access agreement with PHC. Data sharing is free of charge. The Principal investigator is responsible for supporting the data use and reconciling the results of dataset using. The Principal investigator keeps a record of external experts or survey personnel who receive a copy of the survey data set. Upon completion of the requested project, the data, including paper and electronic copies, have to be destroyed by the date agreed with PHC.

14.0 ETHICAL CONSIDERATIONS

14.1 Ethical review

The survey report will be submitted to the Ethics Commission of the Public Health Center of the Ministry of Health of Ukraine (Kyiv, Ukraine) and to the Center for Disease Control and Prevention (Atlanta, USA) for ethical review to ensure compliance with human subject's protection laws and regulations. The decisions of the Ethics Commission will be in line with: the provisions on medical ethics of the Ministry of Health of Ukraine No. 218 of 01.11.2002; the provisions and principles of the Declaration of Helsinki adopted by the General Assembly of the World Medical Association (1964-2000); International Code of Medical Ethics (1983); The Council of Europe Convention on Human Rights and Biomedicine (1997); relevant provisions of the WHO and the International Council for Medical Scientific Societies.

14.2 Survey personnel training

Each investigator and member of the RDCTs is required to complete a training in the ethical standards of the research conduct and receive a confirmatory certificate. For the national group, it is required to complete the online course - Human Research - Group 2 Social & Behavioral Research Investigators from the CITI Program or Protecting Human Research Participants from the National Institute of Health (Ukrainian or Russian version of the course "Protecting Research Participants" on the online platform ProfiHealth). All medical or HTS specialists will receive "PWID Sensitization Training", including mental health motivational interviewing, from Alliance for Public Health.

14.3 Informed consent

During different stages of the study, written and verbal informed consent will be obtained. Verbal informed contest will be used for interview with key informants (see Section 6.1) and piloting the questionnaire (described in 6.2) during the formative assessment. Written informed contest will be used during the data collection (see Section 7.3).

The study team requests the waiver of written informed during the formative assessment and piloting of the instruments because in-depth interviews and instrument piloting will be confidential, present no more than minimal risk of harm to participants and involve no procedures for which written consent is normally required outside of the research context as per 45CFR46.117(c) 2.

For the data collection stage potential participants who pass screening and do not show the signs of intoxication, will be given the informed consent form for reading (Annex 11. Participant's Informed Consent or Annex 12. Participant's Informed Consent). After reading the form, the candidate may ask clarification questions to the coupon manager. Participants will be provided with answers and clarifications on all issues that may arise. Potential participants will be informed that participation in the survey is entirely voluntary and that at any time they can withdraw their informed consent and discontinue participation in the survey. The refusal to participate in the survey at any stage does not affect the access of the participant to medical services or treatment. It should be clearly explained to the participants, that all information received from them during the survey is confidential – any information that can be used for a personal identification will be deleted, and only general information will be included in the report. Participants will also be informed about the potential risks and benefits of participation in the survey.

After all questions are answered, the coupon manager verifies understanding of the main points in the consent form by the participant, and if understanding is satisfactory, both sign the consent form. Only those. PWID who gave voluntary informed consent and signed the consent form after screening and before an interview can participate in the survey. Participants will be offered a copy of the informed consent form.

14.4 Protection from risks

The survey provides participants with counseling and testing services for HIV, hepatitis C and syphilis, and they will be asked to provide information on the experience of drug use and sexual behavior. Questions about sensitive topics, such as the use of drugs, can cause participants' discomfort. Blood collection for rapid testing involves minor risks, including the possibility of local trauma and infection. For the participants who find out about their positive status for HIV, HCV or syphilis, there is a potential risk of emotional distress.

Participation in HIV infection prevention and treatment programs in Ukraine does not involve any social risk or the risk of punishment, apart from the possibility to experience stigma related to drug use. This survey does not increase the risk of stigmatization of such behavior.

The informed consent form contains names, contact information of organizations included into the survey and individual investigators, contact information of the Ethics Commission of the Public Health Center. Participants will be explained that they can appeal to anyone from the list in case they have questions or comments about the survey, if they believe their rights as a survey participant are violated or if their participation or inability to participate in the survey has caused damage. Participants will be informed that they may refuse to answer the sensitive questions, and the information received from them will not be disclosed to other participants.

To minimize the possibility of psychological discomfort, primary seeds will be recruited by the representatives of NGOs working with PWID, and participants will be recruited by their acquaintances. The interview will be conducted by a qualified interviewer. The interview will be conducted face-to-face in a private space in the presence of the interviewer and respondent only. The counseling and testing will be conducted by healthcare workers in specially designated private rooms in accordance with the national HIV counseling and testing recommendations. Participants with a positive test result will be informed that a final diagnosis is possible only after repeated testing at a HIV clinic. To minimize the stressful situations associated with obtaining positive test results, personnel trained in post-test counseling for people with first-time detected HIV will be involved. The survey personnel will also be able to refer participants who will need additional counseling services to non-governmental organizations, in particular, HIV treatment projects.

To protect confidentiality, any paper or electronic form will **not** contain names or other information that allows for participant's identification and will only be associated with the ID-code. Those who receive HIV-positive results will be asked to provide contact information for the organization of re-referral and treatment, which will only be accessible to the healthcare worker of the site.

14.5 Survey sites preparation

The survey premises will be selected taking into account the potential risks for participants or survey teams (for example, so that visitors cannot hear answers to questions from the questionnaire or test

results of another participant). The team does not disclose the list of sites until the data is collected.

14.6 Adverse events identification, management and reporting

All unexpected problems or adverse events (AEs) will be documented and reported to the national survey team, which in turn will inform the Public Health Center, the CDC office in Ukraine and the CDC in Atlanta (Annex 28. Unexpected events notification form). Serious AEs related to study participation will be discussed and a verbal and/or written plan will be developed and implemented within 24 hours from the first notification (Annex 29. Reporting form for serious adverse events). Unrelated serious AEs will be reported within 72 hours. The survey team will document the events, including the details of the action plan and the solution of the problem. The main investigators are responsible for reporting on unexpected problems and adverse events.

14.7 Emergency medical care

The respondents are not expected to have any harmful consequences of participation in the survey. However, if HIV-positive participant in the survey needs emergency medical care, the survey personnel is responsible for the arrangement of such care at the nearest healthcare facility.

14.8 Protocol deviations

Any deviation from the protocol, new or unpredictable results, and changes in the survey context will be documented and reported promptly to the national study team, which in turn informs the CDC in Ukraine, the Public Health Center and the CDC in Atlanta (Annex 30. Form of the Protocol deviations). If necessary, a formal report will be sent to the relevant Ethics Review Board, which is a responsibility of the Principal Investigator. An immediate response to any controversy, issue, or survey complaint will be provided to ensure a quick monitoring of the survey impact on participants. All necessary measures will be taken to settle down the situation properly.

14.9 Potential benefits

Participants do not receive any benefits in the treatment of HIV, hepatitis C, syphilis in any survey location. Anyone who does not meet survey criteria or has decided not to participate in it will have the same opportunities for receiving preventive or treatment services. However, participants with a positive test result will receive post-test counseling, consultation with a qualified specialist who will refer them to the appropriate facility and explain where to apply for treatment programs (for example, a local healthcare facility).

14.10 Compensation

The participants of the survey receive monetary compensation for the time spent and travel in the equivalent of $11 (the amount may be changed in any city based on the results of the formative assessment). Compensation for respondents is not a mandatory requirement for participation in the survey, but it often makes easier to attract hidden and hard-to-reach groups such as PWID. Compensation is paid by a coupon manager after the questionnaire completion, rapid testing and collection of DBS (if necessary). Secondary compensation participants may receive for recruiting of eligible PWID from their social network. The amount of secondary compensation will be equivalent to $7.

14.11 Age of respondents

Target survey group - persons aged 14 years and older. According to the Ukrainian legislation (the Law of Ukraine "On the Protection of Childhood") a child is considered a person under the age of 18 if, according to the applicable legislation, s/he does not acquire adult rights earlier. Provision 2.18 of the Code of professional ethics of a sociologist indicates that “If a study involves children, a sociologist obtains a consent from parents or current authorized caretaker. Sociologist may not ask the consent from parents or caretaker in the following cases: (1) the research results in minimal risks for its participants; (2) the research is almost impossible to be conducted in case of such consent obtaining; (3) a consent of parents or caretaker is not necessary action to protect a child (for example from parents deprived from parental rights)”19. Code of professional ethics of a sociologist was approved by the Fifth Congress of Sociological Association of Ukraine on 20 May 2004. The detailed analysis of children’s involvement as research objects is given in the UNICEF report20. Given the minimal risk of research and the fact that it is virtually impossible to conduct research in the case of attempts to obtain parental consent for the participation in the survey of respondents aged 14-17 years during the IBBS, the team will obtain consent to participation in the survey from the potential participants.

As to biological component, the legislation of Ukraine guarantees the access to HIV testing without parental consent to all teenagers aged 14 years and older: “Testing of people aged 14 and older is voluntary, subject to individual informed consent, obtained after previous consultation as to specifics of testing and its results as well as possible consequences, observing the personal data confidentiality, including data on health status”21.

For all participants under the age of 18 who during the survey will be found to be victims of violence, child trafficking or sexual exploitation, special measures will be taken to re-refer them to the specialized services that protect against harmful, violent or exploitative activities. Prior to the start of the data collection, the regional coordinator should contact the specialists in such services provision to confirm the social sensitivity and technical ability to provide such services, and to obtain an agreement to meet with such participants.

Before the IBBS the PHC will assess the partnership in a sphere of HIV/AIDS at the national and regional levels among national and local authorities, state enterprises, NGOs, international organizations and projects, healthcare facilities with laboratories providing services on HIV infection diagnostic and those providing HIV-related medical care, key communities’ leaders, academic institutions, and research organizations. The majority of regional NGOs, providing services on harm reduction to key groups, may be the initial services providers to PWID children with special needs, encountered during the survey. If needed, the PWID younger than 18 may be re-referred to:

- centers of social services for family, children and youth;
- departments and/or divisions of oblast administrations for work with children;
- representatives of regional organizations working with HIV/AIDS and tuberculosis;
- NGOs or charitable foundations;
- friendly to youth clinics;

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[19] http://www.sau.kiev.ua/codex.html

[20] https://www.unicef.org/ukraine/ukr/ethnic_principles.pdf

[21] https://zakon.rada.gov.ua/laws/show/2861-17#o2

- law enforcement agencies.

Documentation on the referral of adolescents to the proper services ensuring their protection and well-being will be kept at the PHC for three years. The relevant documentation will include: referral date, participant's age, referral type, name of organization to which the participant has been re-referred. The documentation will not contain identifying information about the participant. According to the Ukrainian legislation, Social Services Centers are responsible for collecting information about the facts of violence against the child. No mandatory reporting requirements have been established, but the consultant will explain to a child all the risks and benefits of providing such information and will ensure assistance regardless of a child's choice.

The Regional Working Group will develop an immediate response plan in case a person below the age of 18 is directly threatened and it will be used as a SOP for research teams.

For survey personnel who may potentially encounter children under the age of 18, who appear as victims of violence, child trafficking or sexual exploitation, the PHC will provide training in necessary counseling and referral skills.

15.0 STUDY TIMELINE

Activity	2022						2023												2024		
	July	August	September	October	November	December	January	February	March	April	May	June	July	August	September	October	November	December	January	February	March
Meetings of the IBBS working group	X																				
Protocol finalization	X	X	X																		
Ethics Committee review and approval				X	X	X	X														
TOR preparation for procurement of the research company						X	X	X													
Procurement of the research company									X	X	X										
Establishing of RDCT and Regional working groups											X	X									
Trainings for personnel													X	X							
Formative assessment												X	X								
Instrument piloting and finalization												X	X								
Sites activation														X							
Data collection													X	X	X	X					
Monitoring visits to the sites														X	X	X					
Data cleaning and processing														X	X	X	X				
Behavioral information statistical analysis																		X	X	X	
Laboratory analysis of collected biomaterials																	X	X	X	X	
Additional analyses																			X	X	X
Report writing																		X	X	X	X
Development of results dissemination materials																				X	X
Report presentation																					X

16.0 Annex. Selection of cities for the 2023 PWID IBBS

Region	City	PWID population 2017	HIV prevalence 2020	Viral suppression 2020	Number of IBBS rounds participated 2007-2020	Selection for the 2023 round
AR Crimea	Simferopol				6	
Vinnytsia	Vinnytsia	5400			5	
Volyn	Lutsk	1800			6	
Dnipropetrovsk	Dnipro	20100	23.0%	33.0%	8	sentinel
Dnipropetrovsk	Kryvyi Rih	13300	23.7%	14.1%	4	
Donetsk	Donetsk	11700			6	
Donetsk	Mariupil		29.4%	38.8%	2	
Zhytomyr	Zhytomyr	2600			5	
Zakarpattia	Uzhgorod	1400			5	
Zaporizzhia	Zaporizzhia	7900			5	additional
Zaporizzhia	Melitopol	3400			1	
Ivano-Frankivsk	Ivano-Frankivsk	2000	10.8%	61.5%	6	
Kyiv	Bila Tserkva	2700	15.9%	43.3%	5	
Kyiv	Vasylkiv	1300			3	
Kyiv	Fastiv	1200			3	
Kirovohrad	Kropyvnytskiy	5900	11.9%	28.4%	7	
Lugansk	Lugansk				5	
Lugansk	Sieverodonetsk	900			2	
Lviv	Lviv	6400			5	sentinel
Mykolaiv	Mykolaiv	8500	27.3%	56.4%	8	
Odesa	Odesa	21700	20.4%	42.1%	7	sentinel
Poltava	Poltava	4300			6	
Rivne	Rivne	3500			5	additional
Sumy	Sumy	7800			6	
Ternopil	Ternopil	3200			5	
Kharkiv	Kharkiv	9900	7.1%	20.0%	7	sentinel
Kherson	Kherson	4500			6	additional
Khmelnytskyi	Khmelnytskyi	5200	27.5%	53.2%	6	
Cherkasy	Cherkasy	4600	34.6%	62.1%	8	sentinel
Chernivtsi	Chernivtsi	3700			5	
Chernihiv	Chernihiv	4400			5	additional
Kyiv City	Kyiv City	33700	16.6%	39.6%	8	sentinel
Sevastopil	Sevastopil	6600			4	