BIOLOGICAL AND BEHAVIORAL SURVEY AMONG MEN WHO HAVE SEX WITH MEN IN UKRAINE (2024)

STUDY PROTOCOL

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Kyiv, Ukraine

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ACRONYMS AND ABBREVIATIONS

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
Bio-behavioral survey	linked biological and behavioral survey of the same respondent
Behavioral component (of Bio-behavioral survey)	survey of HIV infection-associated risk behavior by means of a face-to-face interview method – direct communication between the interviewer and the respondent
Biological component (of Bio-behavioral survey)	testing of respondents for HIV infection, anti HCV antibody 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
HCF	Health Care Facility
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	medical and psychological counseling of a person regarding HIV/AIDS and counseling-associated voluntary medical testing of this person for the presence of HIV antibodies
IBBS	Integrated Biological and Behavioral Surveillance – cross-sectional behavioral and biological survey connected in time and location with the same respondent
IRB	The Institutional Review Board
KI – key informants	representatives of non-governmental organizations or private persons who have expert knowledge about the surveyed target group, including representatives of this target group
MOH of Ukraine	Ministry of health of Ukraine
MSM	men who have sexual intercourse with male partners. In this study we are focusing on the men who are practicing male-to-male sexual relations in the last 6 months. The MSM who are practicing bisexual behavior also could be included in the sample
NGO	non-governmental organization – legalized or registered according to the legislation of Ukraine
PHC	Public Health Center of the MOH of Ukraine
PLHIV	people living with HIV
PrEP	pre-exposure prophylaxis – an HIV prevention strategy where HIV-negative individuals take anti-HIV medications before coming into contact with HIV to reduce their risk of becoming infected
Participants	– MSM who enroll in their own population survey (they completed consent, answered the questionnaire and gave biological sample)
PCR	Polymerase Chain Reaction
PEPFAR	President's Emergency Plan for AIDS Relief

Primary respondents (Seeds, in RDS)	survey participants, recruited according to the criteria set by survey staff, rather than a peer by the NGOs. Seeds are the initiators of the chain recruitment process of RDS
PSE	population size estimation
PWID	people who inject drugs
RDS	respondent-driven sampling – sampling, which is driven and implemented by the respondents themselves
Recruit	person, recruited by a recruiter, but has not yet enrolled in the survey (participant)
Recruiter	survey participant recruiting other potential responders among the representatives of the survey target group. A person who, after being interviewed, received coupons by which other respondents of the same target group can be recruited
RPR	rapid plasma reagin) – a screening test for syphilis
RT	rapid testing
Sampling population	part of a larger source population, entities of which act as main observed entities. This part of the source population is sampled using defined rules so that its properties reflect the properties of the source population and allow a representative understanding of the population
Secondary respondents (in RDS)	survey participants invited by their peers who have participated in all components of the survey
SOP	Standard Operating Procedures
STIs	Sexually Transmitted Infections
STD	Sexually Transmitted Disease
TP	Treponema pallidum
UNAIDS	Joint United Nations Program on HIV/AIDS
USAID	United States Agency for International Development
VL	Viral Load
Wave	Degree or distance from the seed in terms of recruitment. An MSM recruited directly by a seed are in wave one
WHO	World Health Organization

INVESTIGATORS

Principal investigator:

Ivan Titar, Chief specialist in research coordination
State Institution “Public Health Center of the Ministry of Health of Ukraine”, i.titar@phc.org.ua
Responsible for protocol, tools, budget development, submissions to Ethical Review Board (ERB), field stage coordination, regional working groups’ management, protocol observance, data management and quality control, data analysis, publication and dissemination.

Co-investigators:

Serhii Salnikov, Chief specialist in research coordination
State Institution “Public Health Center of the Ministry of Health of Ukraine, s.salnikov@phc.org.ua
Responsible for protocol development, data management and quality control, PSE, data analysis, publication and dissemination.

Olena Nesterova, Head of Departament for Scientific Research Coordination of the State Institution “Public Health Center of the Ministry of Health of Ukraine”, o.nesterova@phc.org.ua
Responsible for national IBBS team coordination.

Yana Redko, Scientific Research Specialist
State Institution “Public Health Center of the Ministry of Health of Ukraine”, y.redko@phc.org.ua
Responsible for procurement of supplies and development of the survey questionnaire

Oleksandra Sheiko, Immunologist of Reference-Laboratory for HIV/AIDS Testing
State Institution “Public Health Center of the Ministry of Health of Ukraine”, o.sheiko@phc.org.ua
Responsible for biological component of the survey, testing supervision and results analysis.

Iryna Andrianova, Immunologist of Reference-Laboratory for HIV/AIDS Diagnostic
State Institution “Public Health Center of the Ministry of Health of Ukraine”, i.andrianova@phc.org.ua
Responsible for biological component of the survey, testing supervision and results analysis.

Maksym Kasianczuk, Researcher at the Institute of Sociology of NAS of Ukraine, Strategic Information Advisor of the Eurasian Coalition on Rights, Gender and Sexual Diversity (ECOM), Estonia; Head of Interregional Center for LGBT-studies, Ukraine; Expert of the Expert Group on Health and the Rights of Gay and Other MSM in Ukraine, maxim@ecom.ngo
Responsible for protocol, annexes and questionnaire development.

Lyudmyla Dobrovolska, Strategic Information Advisor, CDC/DDPHSIS/DGHT/CGH, Ukraine, mty6@cdc.gov, SIQT 01/11/2027
Responsible for protocol development, data analysis, publication of results, national extended working group management

Avi Hakim, KP Surveillance Technical Lead
US Centers for Disease Control and Prevention, DGHT, hxv8@cdc.gov, SIQT 02/27/2026
Responsible for protocol development, data analysis and publication of findings.

Marianna Azarskova, Laboratory Research Advisor
US Centers for Disease Control and Prevention, DGHT Ukraine, vpy1@cdc.gov, SIQT 08/08/2026
Responsible for biological component of the survey, testing supervision, training in testing procedures of field and laboratory staff.

Ayayi Ayite, MPH, MBA, MT (ASCP), pvq4@cdc.gov, SIQT 8/4/2026
Subject matter expert responsible for technical support to project implementers on the budget and cost objective.

Madeleine Baker-Goering, PhD, wqf3@cdc.gov, SIQT 07/27/26
Subject matter expert responsible for technical support to project implementers on the budget and cost objective.

Hanna Blyumina, Strategic Information and Program Management Specialist, Office of Health USAID Ukraine,

hblyumina@usaid.gov

Subject matter expert providing input for protocol development.

Jessica Grignon, HIV/AIDS Advisor, Office of Health USAID/Ukraine, jgrignon@usaid.gov
Subject matter expert providing input for protocol development.

CDC and USAID investigators are non-engaged and will not have any direct contact with the study participants and will not have access to identifiable data or specimens.

1. 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 2024 round IBBS among men who have sex with men (MSM) in Ukraine. The study is designed as a cross-sectional survey with biological and behavioral components. The IBBS will estimate the burden of HIV/HCV and prevalence of syphilis, related risk behaviors, service utilization, and population size and inform progress towards reaching UNAIDS {95-95-95} targets[2]. The IBBS will utilize respondent-driven sampling (RDS) to recruit participants. App-based, privatized network sampling, service multiplier, and successive sampling methods will be used to calculate population size estimates (PSE) in IBBS regions; service multiplier method to calculate PSE in oblasts where IBBS will not be conducted. The survey is planned to be implemented in 10 cities. Persons who are 16 years or older, male, have had one oral or anal sexual contact with a male within the last 6 months are eligible to participate. Written informed consent will be obtained for all participants. Proposed procedures include administration of a structured questionnaire, rapid HIV and viral load testing and other tests (anti HCV antibody and syphilis), and counselling. Survey staff will provide referrals to treatment and support services for all those found to be HIV-positive but not in care. Survey staff will also facilitate linkage to treatment to those who test positive for syphilis testing. Dry blood spot (DBS) samples will be collected to assess recency of HIV infection and viral load. Formative assessment will be conducted as part of this protocol. This will include interviews using semi-structured questionnaire with key population(s) and others such as health service providers. Findings of the survey will be disseminated to national stakeholders to guide future prevention activities and health care planning and to monitor HIV prevention, care, and treatment programs among the target group.

[1] https://data.unaids.org/publications/irc-pub01/jc370-2ndgeneration_en.pdf
[2] https://www.unaids.org/en/resources/presscentre/pressreleaseandstatementarchive/2023/november/20231129_new-research-on-opt-out-hiv-testing-england

The survey “Biological and Behavioral Surveillance among Men who have Sex with Men (MSM) in Ukraine” will be conducted in 2024 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)" (Cooperative agreement number - NU2GGH002375)

2. BACKGROUND AND RATIONALE

The HIV epidemic is ongoing in the countries of Eastern Europe and Central Asia region (EECA). According to the results of IBBS conducted in Ukraine in 2019–2021 among key populations, HIV prevalence among MSM is 3.9% [1].

According to the last population size estimation, there were 202,200 MSM in Ukraine (2021) [2]. However, after the start of the full-scale Russian invasion on February 24, 2022, previous population size estimates became irrelevant due to substantial displacement of the Ukrainian population at large, including key populations such as MSM. As of July 2023, almost 5,9 million refugees from Ukraine have been recorded across Europe (over 8 million refugees at peak periods) and 0,4 million beyond Europe.[3] Although a significant number of refugees were women and children, there were also men among them. As of May 2023, 5,1 million Ukrainians were internally displaced[4] (7-8 millions at peak periods). This large-scale displacement, as well as the damage caused by the Russian invasion to the ability to collect quality programmatic and routine epidemiological statistics, increases the need for surveillance data collection.

HIV prevalence among MSM in Ukraine is 3.9% (95% CI: 3.8-4.1%), which differs statistically from the prevalence in 2018 — 7.5% (95% CI: 6.8-8.2%). The highest prevalence of HIV among MSM was in Cherkasy (10%), Dnipro (6%), Kharkiv (6%) and Vinnytsia (6%). HIV prevalence has been decreased among MSM under 24 y. o. — from 6.7% (95% CI: 5.7-7.8%) in 2018 to 2% in 2021. However, comparing older and younger MSM, HIV prevalence is higher among MSM above 25 y. o. — 5% in 2021 [1].

Prevalence of HCV antibody and STIs. According to rapid-testing during the 2021 IBBS, Hepatitis C — 1.8% (95% CI: 1.7-1.9%), syphilis — 3.2% (95% CI: 3.1-3.4%). According to the data of the 2018 IBBS, 1.5% had Hepatitis C antibodies.

The previous IBBS among MSM was conducted in 2021. Data collected through IBBS such as trends in STI prevalence, PrEP uptake, co-morbidities etc. provide the opportunity to assess program implementation and program performance in affected cities and regions and help guide resource allocation and program improvement.

Since the size of MSM and risky behaviors of their representatives affect epidemic trends, and contribute to the spread of HIV among general population, surveillance among MSM is an important tool for obtaining a realistic assessment of spread of HIV ,

[3] https://data2.unhcr.org/en/situations/ukraine
[4] https://reliefweb.int/report/ukraine/unhcr-europe-situations-data-and-trends-arrivals-and-displaced-populations-may-2023

HIV knowledge and, key risk behavioral characteristics of MSM. It also allows generation of data for construction of outcome and impact indicators of the on-going National AIDS Program and for population size estimation. Currently, the most recommended approach for obtaining such strategic data is carrying out bio-behavioral surveys. For national HIV program, IBBS among MSM will allow both assess the progress in cascade of care and help to identify key characteristics for facilitators and barriers at each step. We plan to implement the next round of HIV biological and behavioral surveillance among MSM in 2024.

3. OBJECTIVES

The overall goal of the IBBS among MSM in Ukraine is to estimate HIV prevalence, viral load suppression level and progress towards reaching 95-95-95 UNAIDS targets, assess service utilization, and gather information for population size estimation.

The objectives of the IBBS are:

Primary objectives:

(1) To estimate the prevalence of HIV among MSM
(2) To estimate progress toward UNAIDS 95-95-95 targets
(3) To estimate the proportion of viral load suppression (viral load <=1000 copies/mL) among HIV-infected MSM
(4) To estimate progress toward UNAIDS 10-10-10 targets
(5) To estimate MSM population size

Secondary objectives:

(6) To estimate HIV incidence
(7) To estimate the prevalence of syphilis and anti-HCV antibodies
(8) To identify risk factors associated with HIV infection among MSM
(9) To examine HIV service uptake (prevention, treatment) and HIV status knowledge
(10) To collect and assess the cost of key resources used in the formative assessment, biobehavioral survey, and population size estimation

4. SURVEY METHODS

4.1. Survey Locations

The number of cities was discussed at a meeting of the IBBS working group (May 12, 2023). The survey will be conducted in 10 cities of Ukraine (Dnipro, Kharkiv, Kyiv, Odesa, Zaporizhzhia, Cherkasy, Chernivtsi, Lviv, Poltava, Vinnytsia). Please see below for descriptions and rationale for selecting these cities.

4.2. Study design

We will collect data using the cross-sectional design. Respondent-driven sampling (RDS) will be used to recruit MSM in 10 cities. Behavioral data will be collected using structured questionnaire (interviewer-administered on a tablet). The biological data will be obtained using rapid tests for HIV, anti HCV antibody and syphilis and DBS preparation *(whole blood, after rapid tests, be used to create DBS cards for additional testing in laboratory for HIV in PHC).* We will confirm all HIV-positive rapid test results using second and third HIV rapid tests, according to the National HIV testing algorithm.

4.2. Sampling approach

4.2.1. Respondent-driving sampling (RDS)

Participants will be sampled using RDS. The theoretical background of RDS has been well established in published literature [3]. RDS reduces biases commonly found in other chain-referral methods by using a restricted peer to peer recruitment system (peers can recruit pre-defined number of peers thereby reducing overrepresentation of those with large social networks) that generates long recruitment chains of participants (thereby reducing bias of non-randomly selected initial participants and deeper penetration into the network of the target population). Furthermore, RDS assumes sampling from a network rather than from a population. Analysis involves weighting data by network sizes so that those with larger networks are given less weight and those with smaller networks are given more weight. Each participant will be asked to answer interviewer's questions (based on all criteria used in the eligibility) which will provide the size of participant's social network.

4.2.2. Seeds

Seeds should have large social networks and know diverse people in order to overcome potential bottlenecks in the population network. If the network is focused on a

single subgroup, the estimates can become unstable. Characteristics that are most prone to bottlenecks in a particular network must be assessed during a formative assessment. Ideally, the best approach is to find seeds who know and will recruit diverse types of people. The investigators can work with the seeds to identify diverse characteristics of people that the seed can recruit from their social network. Based on knowledge about the networks in Ukraine, potential bottlenecks include geographic location within the survey catchment area, age (young vs. old), socio-economic status, high or low risk, HIV status, beneficiaries and not beneficiaries of HIV prevention programs, etc. Seeds should be selected based on their ability to recruit these different types of people. For detailed criteria see subsection “6.2.2. Selection of seeds”.

4.2.3. Eligibility criteria

Selection criteria and verification methods for participation in the IBBS MSM in Ukraine 2024 are described below.

Inclusion criteria	Verification methods
Male sex	Self-declaration
At least one oral or anal sexual contact with a male within the last 6 months	Self-declaration
16 years old and older as of the survey period	Self-declaration
Informed consent to participate in all survey components, namely: 1) behavioral component: interview; 2) biological component: capillary blood collection with EDTA K3 blood micro containers (microtainers) for further rapid testing for HIV, anti HCV antibody and syphilis; second and third 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	Agree with informed consent to participate in the survey

Exclusion criteria*	Verification methods
Age under 16	Self-declaration
Repeated participation in one survey round	By exclusion of used number of e-coupon
Refusal to participate in one or several survey components	Absence of signed informed consent to participate in the survey
State of 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	Self-declaration

** If recruit meets at least one of the criterion, he should be excluded from the survey, his coupon should be taken away and recruiter does not receive a secondary incentive for this recruit.*

4.2.4. Coupons for recruitment distribution

After completing all the survey steps, participants (except at the very end of the survey), including seeds, will be provided with up to 3 RDS paper coupons to use in recruiting peers (Annex 9: Survey participant's coupon). Three paper coupons should be distributed among MSM in recruiter's city. Each coupon will have unique identification numbers to link behavioral and biological data and to link who recruited whom (essential information for data analysis).

4.2.5. Incentives

All survey participants will receive primary incentives of $12 for enrollment into the study (including blood tests). If participant filled in the questionnaire on site research offline, but not gave the blood tests, he will not receive the primary incentive. The total amount received by one participant is $33.

Participants who recruit their peers who enroll and complete the survey (including blood tests) will receive a secondary incentive $7 for each recruited participant.

We will confirm the local appropriateness of these compensations during formative assessment.

4.3. Geography and Sample Size

4.3.1. Rationale for the Approach to Sample Calculation and proposed Geography

- Russia's full-scale invasion of Ukraine, which began on February 24, 2022, has led to a significant displacement of the MSM population
- Accurate estimates of the population size of the MSM group in different regions and cities of the country are not yet available at the time of the development of this Protocol. There is a general understanding that as of the spring of 2023, there has been a significant displacement of the MSM population to the western and central regions of Ukraine (and to a certain extent – abroad)
- Even if such estimates were available, the full-scale war is ongoing, which poses the threat of new significant displacements of MSM groups.

This renders the sample calculations, based on assumptions about the generally unchanged composition of the MSM population in individual cities and the absence of significant dynamics of such epidemiological indicators as the prevalence of HIV infection and the level of viral suppression (as was done in previous rounds) meaningless.

After the consultations with CDC-Atlanta and the Expert Group on Health and the Rights of Gay and Other MSM in Ukraine (EGHR-Ukraine), the general approach to building the MSM sampling size has been changed from previous IBBS MSM data collection.

Given the low prevalence of HIV infection and the rather high level of viral suppression in the previous round of the biobehavioral study (IBBS MSM 2021), calculating the sample based on the viral suppression rate at the individual city level resulted in unrealistically high sample sizes.

In line with the approach first proposed for the IBBS among people who inject drugs (PWID) 2023, it was decided to identify a cluster of sentinel cities that would represent all major regions of Ukraine and cities with the largest MSM population, as well as a cluster of additional cities (which may vary depending on epidemiological or programmatic requests). It should be noted that the places where IBBS can be conducted are limited only to the oblast centers, Kyiv and the cities of oblast significance, due to the large population and possibility to recruit enough MSM.

Given that, for practical (financial and organizational) reasons, the total sample size of the 2024 round should not exceed 4000 people, two separate samples based on viral suppression were calculated for the cluster of sentinel cities (N=2350) and optional cities (N=1500). Details of the calculations are presented in Table 1. To unify the sampling approach with the approach first proposed for the IBBS PWID 2023, there is a sentinel cluster, but the list and number of cities differs, given the differences in the epidemiological situation and location of the MSM population. Also, unlike the sample of the IBBS PWID 2023, it was not possible to ensure the same sample size of 500 participants for all cities. This is dictated by practical considerations of the possibility of achieving such a sample size based on the size of the MSM population in each particular city. For example, before the full-scale Russian invasion, a sample size of 500 participants would have been feasible for Kharkiv (the second largest total population and MSM population), but after the invasion, there was a significant outflow of population from the city. Conversely, a sample of 450 participants in Lviv would have been difficult to implement, but after the full-scale Russian invasion it became more feasible, as Lviv experienced a significant influx of internally displaced persons, including MSM.

Table 1 Samples for clusters of sentinel and optional cities (the sample for WEB-component is not included)

	HIV prevalence (%), 2021	Proportion of HIV-pos with VLS (%), 2021	LB	UB	Target Confidence Interval 1/2 Width (%) for VLS	Design Effect calculated*	Non-response NR/ Missing Data (%)	*Confidence Level*	Calculated HIV-unadjusted pos sample	Calculated HIV pos sample adjusted for DE & NR	Calculated total sample	City level sample*
All cities	4%	55%	43%	67%	12%	2	5%	95%	67	140	3500	
I. Cluster 1 (sentinel)	4%	55%	40%	70%	**15%**	2	5%	95%	43	89	2225	**2350**
Dnipro												450
Kharkiv												400
Kyiv												550
Odesa												500
Lviv												450
II. Cluster 2 (optional)	4%	55%	36%	74%	**19%**	2	5%	95%	27	56	1400	**1500**
Cherkasy												300
Chernivtsi												300
Zaporizhzhia												300
Poltava												300
Vinnitsya												300
										Total	3625	3850

**** Final sample size was calculated with enough power to calculate VL for cluster level and HIV prevalence for each city level***

Both the sentinel and optional clusters were selected to represent cities with large MSM populations, as well as different macro-regions of Ukraine. The considerations of the LGBT community (represented by EGHR-Ukraine) regarding the feasibility of sample in the context of war and massive population displacement were also taken into account.

The sample sizes for individual cities were calculated (eq. 1) to be sufficiently large to capture HIV prevalence and PrEP use (Table 2).

$$N = D \cdot Z \cdot \frac{P(100-P)}{d^2} \qquad \text{Equation 1}$$

Where N — calculated sample size, D — design effect (2 for each city), Z — normalized standard deviation (1.96 for 95% CI), P — % of the given parameter in total MSM IBBS 2021 sample (3.9% for HIV prevalence or 55% of PrEP use).

The total sample will be 3850 MSM (2350 or 61% in the sentinel cluster and 1500 MSM or 39% in the optional cluster).

Table 2 Cities and samples

	HIV prevalence (2021)					PrEP use (2021)					Recomended sample size	
	2	**2**		**5**		**2**	**1,96**		**5**			
	D	**Z**	**P, %**	**d**	**n**	**D**	**Z**	**P, %**	**d**	**n**	**Cluster 1 (sentinel)**	**Cluster 2 (optional)**
All	2	2	3,9	5	115	2	1,96	11	5	301	2350	1500
Vinnitsya	2	2	6	5	173	2	1,96	10	5	277		300
Dnipro	2	2	6	5	173	2	1,96	3,7	5	110	450	
Zaporizhzhia	2	2	4	5	118	2	1,96	4,2	5	124		300 (!)
Kyiv	2	2	2	5	60	2	1,96	32,8	5	677	550 (!)	
Lviv	2	2	2	5	60	2	1,96	6,3	5	181	450	
Odesa	2	2	5	5	146	2	1,96	16,3	5	419	500 (!)	
Poltava	2	2	0	5	0	2	1,96	1,3	5	39		300
Kharkiv	2	2	6	5	173	2	1,96	13,3	5	354	400 (!)	
Cherkasy	2	2	10	5	277	2	1,96	3,6	5	107		300
Chernivtsi*	2	2	2	5	60	2	1,96	0	5	0		300
										Total	3850	

*Data from IBBS MSM 2017-18

***(!) denotes cities, where it is recommended to open two sites because of big city's size*

In case the planned sample size by oblast/city is unable to be reached, the national coordinator of the research, upon agreement with the National Work Group, will reapportion the sample across all regions, while keeping the total size of the sample.

5. PREPARATORY STAGE

5.1. Working groups

5.1.1. National working group

The preparatory stage will begin with establishment of the National working group (is an advisory board established to plan and coordinate the implementation of the IBBS in Ukraine, the results of which will be used to make a decisions in the field of public health and to promote the improvement of the quality of prevention and treatment services on the way to overcoming the HIV epidemic in Ukraine), including representatives from:

- Public Health Center of the Ministry of Health
- US Centers for Disease Control and Prevention
- USAID
- PEPFAR
- Alliance for Public Health
- National experts in research and data analysis
- Representatives of the National expert group on LGBT rights and health in Ukraine and other experts on MSM.

Meetings of the working group will be open to participation for other stakeholders and M&E group members in accordance with the principle of transparency. If necessary, additional involvement of other consultants on specific issues is possible.

The main responsibilities of the national working group are:

- Selection of the regional study coordinators;
- Review and approval of SOPs;
- Review of data quality control approach;
- Revisions of the study protocols and survey instruments, if needed;
- Development and approval of the training plan and oversight of training activities;
- Selection of contractor(s) for and oversight of data quality control activities;
- General oversight of all study activities performed by the implementing agency.

5.1.2. Regional working groups

In each participating city, a Regional working group (RWG) will be established. The RWG will meet once per two weeks during pilot and data collection stages. At the first meeting, representatives of the RWG should consider and agree on the safety and

feasibility of conducting the IBBS among MSM in their city, as well as the possibility of fulfilling the sampling frame. The following representatives will be included:

1. Regional data collection team supervisor is responsible for
    i. selection of the team that will work on the survey implementation;
    ii. conducting the formative assessments (incl. confirming feasibility of recruitment of the proposed sample size by analyzing available data sources (number of prevention program clients etc.) and finalizing the list of services for referrals);
    iii. pilot testing of the standard operational procedures;
    iv. pilot testing of the survey questionnaire.
2. Representatives of NGOs working with the target group are responsible for
    i. setting up the cooperation with local representatives of the target group who serve as community liaisons to assist project implementation;
    ii. conducting the formative assessments;
    iii. finalizing the list of services for referrals.
3. Representatives of Public health centers, HIV clinics and Oblast Centers for Disease Control
4. (2 people: regional epidemiologist and regional M&E center representative) are responsible for
    i. selection of the team that will work on the survey implementation;
    ii. conducting the formative assessments;
    iii. confirming feasibility of recruitment of the proposed sample size by analyzing available data sources;
    iv. finalizing the list of services for referrals;
    v. pilot testing of the standard operational procedures.
5. Representatives of the communities (up to 5 persons), who take part in conducting the formative assessments.

5.2. Formative assessment

5.2.1. Objectives and key informants of formative assessment

Prior to the implementation of the survey a brief formative assessment will be conducted in each of the participating cities. If findings from the formative assessment or

pilot testing of the questionnaire identify the need to make changes, the amended protocol and survey toolkit will be re-submitted for the ethical review and approval.

Objectives of the formative assessment are to:

- understand the unique features of the MSM population in the city, the social environment (including places where potential participants meet), personal networks and the possibility of achieving the target sample size, attitudes/actions of social groups and stakeholders in the city towards MSM;
- assess the risks and barriers to participation in the study, including the impact of mobilization and air raids (and possible strikes and shelling) on participants' perceptions of their safety and ability to move around the city;
- identify the selection criteria for seeds;
- identify the selection of study sites (locations) where the survey will be administered, and testing will occur;
- assess the feasibility of implementing privatized network sampling.

The formative assessments will be performed by the Regional working groups using qualitative methods, including Key informant interviews. All information will be collected in paper and pencil format.

Three to four key informants will be selected in each city. The regional working group will identify, select and invite the key informants based on the following:

- at least one community representative, a recognized activist from the target group, or a leader of community organization or self-support group;
- at least one health care worker serving the target group;
- at least two social or outreach workers serving the target group;
- at least five years of experience serving (for health care, social or outreach workers) or being a member of the community.

Key informants will be interviewed by the Regional working group members who have been trained in qualitative methods previously or will be trained for the purpose of the study.

The key informants will be invited from the NGOs working with the target population in the city. If there is more than one NGO and community organization in the area, key informants will have to be selected from different ones. Within the formative assessment framework, personal data on key informants will not be collected, and neither audio nor video interviews are conducted. The key informants will provide verbal informed consent (Annex 1: Verbal informed consent to be interviewed (formative assessment stage) and all the given answers are written down by the interviewer.

Key informants are remunerated in the amount of nor less than $5 for the time spent for their participation and related expenditures (for example, transportation costs) (Annex 3: Log of compensation to the key informants (formative assessment stage).

During formative assessment research team try to assess the feasibility of implementing privatized network sampling among MSM in Ukraine. Questions asked during the formative assessment will include:

Do MSM have multiple phone numbers? Do they change phone numbers often? Are they able and willing to list their peers' phone numbers?

5.2.2. Selection of seeds

Formative assessment will identify approximately 4-6 seeds per study site through direct or indirect referrals by key informants (Annex 6: Screening questionnaire for primary respondents). Additional seeds may be added during the field phase if recruitment speed is slower than anticipated or too many recruitment chains die out.

Seeds selection will be based on the following criteria:

- motivated to participate in the study and share information among their network;
- represent different city districts;
- two of the seeds are older than 30 years old, at least one younger than 19 years old, one seed 25-30 years old, all other seeds are younger than 25 years old
- at least one prevention program client, at least one non-client;
- at least one bisexual male;
- at least one with high socio-economic status.

Additional criteria may be suggested by the key informants or the regional working groups. Any participant identified as being a sexually exploited minor (younger than 18 y.o., exchanging sex for money or goods) will not serve as a seed. Seeds will participate in the survey and testing under the same conditions as all participants (as described in the sections “Behavioral component” and “Biological component”).

5.2.3. Selection of locations

Survey site in each city will be selected according to the following criteria:

- geographically separated from the HIV-treatment or KP prevention service provision places
- geographical convenience for participants (quickly and easy to find the place, there should be no obstacles for the participants to get to the place);

- comfort (to provide confidentiality of information as well as respondents' comfort and limit respondents' distraction);
- enough space to interview participants, pre-test and post-test counseling, blood collections;
- only one survey (risk group) can take place at one site at the same time;

The following facilities are usually be used for study implementation:

- rented apartments/offices;
- general health clinics;
- NGOs which aren't specialized on the service provision to MSM;
- availability of a bomb shelter/bunker in the building or nearby in case of air raid alarm.

Each Regional working group discusses results of the formative assessment, selection of seeds and selection of survey locations and approves them at a specially convened meeting (Annex 2: Formative assessment results form).

5.3. Questionnaire Piloting

Even though the questionnaire will be based on the previous round's version (IBBS MSM 2021), to ensure understanding of questions, appropriate level of sensitivity, and acceptable duration of interview, it will be piloted. Five representatives will be selected in Kyiv region and another 10 in other cities (e. g. Vinnitsya and Lviv). Selection will be done by the Regional working groups and will follow the same approach and criteria as selection of RDS seeds.

All gathered information will be collected in paper format only. No personally identifiable information will be collected during the pilot. Only a verbal informed consent procedure will be administered (Annex 4: Verbal consent to questionnaire piloting). Participants are remunerated in the amount of $10 for the time spent for participation in the questionnaire piloting and related expenditures (for example, transportation costs) (Annex 5: Log of compensation for questionnaire piloting). These participants will not be considered as seeds/participants of the main survey (but they can still later participate in it if eligible and recruited).

Based on the pilot results, the interviewers will report any issues to the National working group and suggest modifications, if needed. This approach was used for piloting the questionnaires in previous rounds of IBBS in Ukraine.

In case of any significant changes in the questionnaire, a revised version will be resubmitted to the local IRB and to the CDC for approval.

6. REGIONAL DATA COLLECTION TEAM FORMATION AND PERSONNEL TRAINING

6.1. Regional data collection team formation

A regional team for data collection is formed in each city. It is led by the regional research coordinator. The team also includes coordinator of biological component; coupon-manager; at least one interviewer (but preferably several), medical specialist(s); social worker or psychologist.

Functional roles and responsibilities of the members of the regional data collection team are as follows:

Member	Responsibilities
Regional coordinator	Supervision of the daily work at the site, communication with the principal investigator, submitting region reporting, clarifying questionnaire items to the respondent, when needed
Biological component coordinator	Ensure the biological component of the survey, communication with the health care institutions providing medical care for HIV infection
Coupon-manager	Ensuring management and screening of recruitment
Medical specialist	Collection of capillary blood samples, rapid tests, preparation of DBS samples, referral to health care institutions providing medical care for HIV infection/ linkage of HCV/syphilis
Social worker, psychologist	Recruitment and selection of primary respondents, control over the queue at the site and provision of social support, linkage for HIV/HCV/syphilis services

In other cities we'll have blood testing sites only, whose team will consist of medical specialist and social worker/psychologist.

6.2. Training

In order to collect reliable data and ensure understanding of and adherence to SOPs, we plan the following activities:

- conduct a two-day training for medical specialists who will participate in the biological component of the study;
- conduct a two-day training for regional coordinators;
- conduct a training for all data collection team members;
- conduct the webinar for monitoring specialist who will be conduct sites monitoring visits during data collection stage;

- all study personnel will be trained on human subject issues and ethical conduct of the studies (each member of the Regional data collection team is required to complete a training in the ethical standards of the survey and receive a confirmatory certificate; see more details in the “Ethical Considerations”);
- all personnel dealing with participant information will have to sign the Data Use and Confidentiality Agreement (Annex 27: Data Use and Confidentiality Agreement for personnel).

Within the framework of preparation for a qualitative implementation of the IIBBS MSM a series of training courses for each category of personnel will be conducted:

Personnel category	Training objective
Regional groups	Methodology and procedures of formative assessment; behavioral and biological components; compliance with the Standard Operating Procedures (SOPs); communication skills and peculiarities of work with MSM; safety and professional ethics during the survey.
Medical specialists	Proper blood collection techniques, HIV testing services in accordance with the National HTS Protocol; DBS preparation; safety and observance of ethical principles during the survey, procedures of IBBS. In addition, all the health workers will receive practical training with further assessment of their competence in blood collection techniques, preparation of dried blood spot samples, HIV testing procedures and its quality control, using dry tube samples (DTS) described for the content of HIV serological markers. During the field stage of the study all the medical workers will participate in an external assessment of the quality of HIV testing. This will allow additional evaluation of their competencies. An external quality assessment will be organized by the PHC Reference Laboratory for HIV / AIDS Diagnostics and, in the event of unsatisfactory results, the healthcare professional will be advised to investigate and implement corrective action.
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.
Laboratory personnel	Stages of the IBBS implementation; laboratory testing within the IBBS; analysis and use of the IBBS findings; the survey quality as to determination of the serological markers, recent infection, and viral load of HIV infection.

Regional coordinator, coupon-manager should be trained using tablets and printed forms and materials identical to the ones to be used in the behavioral component, and

the medical specialist(s) should be trained using tests and equipment to be used in the biological component of the study.

Regional coordinator, coupon-manager will be cross-trained on the behavioral component in order to ensure that the survey is managed properly even in the absence of some specialists within a certain period.

7. SURVEY PARTICIPANT PROCEDURES

7.1. Participant's algorithm

The participant will take part in 4 stages of the survey (Annex 10. Participant`s Card); the approximate total duration to complete all steps is 55-115 minutes:

Stage:	STAGE 1. SCREENING			STAGE 2. BEHAVIORAL COMPONENT
	Screening of potential participant	**Coupon validation**	**Informed consent signing**	**Survey**
Responsible person:	Coupon-manager	Coupon-manager	Participant, involving coupon-manager	Self-administered interview
Approximate duration:	5 minutes	1 minute	5-10 minutes	25-35 minutes

Stage:	STAGE 3. BIOLOGICAL COMPONENT						
	Pre-test counseling	**Capillary blood collection with *EDTA* k3 blood *micro containers***	**Testing for HIV, anti-HCV antibodies, syphilis (rapid tests)**	**Second and third HIV rapid test (for HIV-positives)**	**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 and post-test counseling**	**Referral to HCF providing medical care for HIV infection (for HIV-positives) / Referral to private laboratory for active infection testing and to HCF (for other)**
Responsible person:	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	3 minutes	5-10 minutes	5-10 minutes

Stage:	STAGE 4. COMPENSATION AND PEER RECRUITMENT				
	Primary compensation (participant)	**Other MSM recruiting instruction**	**Other social network participants' recruitment**	**Other MSM participation in the survey**	**Secondary compensation (recruiter)**
Responsible person:	Coupon-manager	Coupon-manager	Participant	Participant	Coupon-manager
Approximate duration:	1 minute	5 minutes	up to 20 days	55-115 minutes	1 minute

7.2. Enrollment and screening

7.2.1. Recruitment and enrolment

Recruitment for MSM in various cities will commence with various seeds. Each MSM seed will receive 3 paper coupons from a staff member (Annex 9: Survey participant's coupon). The coupon will specify the date, time and location of the appointment for the interview. The coupon will also have an expiration date, after which it will be invalid. When an appointment becomes invalid, this is an indication to staff that a new seed should be found.

The first wave of participants will be recruited by seeds. Thereafter, each person recruited and enrolled in the survey will receive up to three recruitment coupons, if they agree to be recruiters, with which to recruit their peers into the survey. Being a recruiter is voluntary and if participants choose not to be recruiters, they will still be paid the incentive for completing the survey. The recruiter will be asked, for instance, "Please give the blue coupon to other MSM you know who also know you".

All the participants, including seeds, will be provided with three coupons to use in recruiting other participants and will be instructed about eligibility criteria for inviting potential study participants (Annex 26. Instruction for peer recruitment). After the desired sample size will be reached, the distribution of coupons will be stopped. A recruit will present the coupon he received to the interview site. The first RDS staff member a recruit will encounter is the coupon manager, to whom a recruit will give his referral coupon. The coupon manager will check the coupon validity and after the validation, will assess the recruit's eligibility. If a recruit is eligible, the coupon manager will fill in the appropriate form, to which the coupon will be attached. Then the screener will explain in detail the activities conducted within the framework of the survey (interview, collecting blood sample for HIV testing, etc.). If a recruit agrees to participate in the survey, he signs informed consent. Then the screener will escort the participant to the interviewer.

7.2.2. Coupon management

Issuance and receipt of coupons will be monitored both electronically and manually/visually. While the participants initially receive three coupons this number will be reduced to two and later one as sampling progresses. Once the sample size approaches the target, no coupons will be handed out to remaining participants. The goal is to start with as few seeds as possible and to create long recruitment chains with >10 waves.

Coupons will have the following elements (Annex 9: Survey participant's coupon):

- coupon number (printed as QR-code-sticker and attached to the coupon);
- survey name (the target group and exact purpose will not be mentioned);
- interview site address;
- contact details of survey office;
- days and hours of operation;
- activation date: a date before which the coupon may not be used for enrollment. This date may vary. Initially the activation date will be two days after the coupon's issuance date. At the discretion of the project manager or the principal investigator, participants presenting coupons before the activation date may be accepted;
- expiration date: a date after which coupon should not be used. Initially, coupons will be valid for two weeks. This time period may be extended or shortened if coupon return rates are below or above expectation and as the sample size approaches the target. At the discretion of the project manager or principal investigator, participants with coupons that are within a set period of days past the expiration date may still be accepted;
- proposed date and time for 1st visit;
- date of collection (returned and retained by coupon manager): added once redeemed;
- information about its use and validity.

A coupon may be invalid if expired, tampered with, unreadable, or already used. Invalid coupons will be retained and marked accordingly. Valid coupons of participants undergoing screening for eligibility will be retained and may be marked "USED". Participants who are re-scheduled for a future visit have their coupons returned to them. Re-scheduled visit dates may be past the coupon expiration date without rendering the coupon invalid.

IDs will be necessary to link behavioral to biological tests without the need to collect personal information. For the coupons, the numbering system will be systematic allowing the field team to monitor the waves and chains of each seed.

7.2.3. Coupon verification and eligibility assessment

The coupon manager will examine the coupon (dates, originality) presented by the potential recruit. Where doubts about eligibility remain, staff or key population volunteers may pose additional (non-standardized) questions to confirm true eligibility. The checklist

(Annex 8: Checklist for screening) will be used to indicate if the recruit has a valid coupon (attached to checklist) and meets the inclusion criteria (as per screening interview). The coupon manager will be used for reading QR codes and confirm their validity.

7.2.4. Communication with participants

Prior to each procedure of the survey, staff will offer to answer any remaining questions and re-iterate the main points.

7.2.5. Informed consent

This study satisfies the requirements for using only verbal consent to participate in research. However, since legislation of Ukraine requires to obtain written consent, this study will use written consent for participants. All participants will sign written informed consent to participate in the survey (Annex 10 and 11: Participant's Informed Consent (in Ukrainian)). A member of the team (coupon manager) should propose to each eligible recruit to read informed consent by themselves, or it may also be read by the team member aloud. Prior to obtaining informed consent, the coupon manager will probe and confirm the recruit's understanding and discuss any remaining questions the recruit may have after reading or having listened to the information sheet. Participants should be provided with answers and clarifications on all issues that may arise. More details can be found in the "Obtaining informed consent" section of "Ethical Considerations". Written informed consent will be anonymous to maximize confidentiality and participation. Informed consent will cover procedures at both visits.

The specifics of obtaining informed consent to participate from participants under the age of 18 are described in subsection 14.11.

If the eligible participant agrees to participate in the survey, he signs 2 copies of the informed consent, one is passed to the representative of the regional group, and another one remains with the respondent. Survey staff will document on the checklist whether written informed consent was obtained.

Coupon-manager issues the participant participant's card (Annex 10: Participant`s Card) and signs it is confirming that participant's coupon is valid, he is eligible for the survey, and he also signed a written informed consent. The participant's card is subsequently signed by each team member after the participant has successfully passed each subsequent stage of the survey.

If a participant ceases to participate in any of the stages of the survey, appropriate information about the reasons is collected (Annex 13: Registration form for refusal to participate in the survey (non-response form)).

8. IBBS DATA COLLECTION

8.1. Behavioral component (interview)

Online self-administered interview will be conducted with all participants, with the use of piloted questionnaire. Questionnaires and other tools will be administered in Ukrainian. Questionnaires and other tools were originally designed in Ukrainian and were translated into English by qualified project staff only for review purposes, if any modifications would be suggested by reviewers.

Every questionnaire used during RDS will include a unique surveillance identification number (ID). ID numbers will be also used to label containers of biological specimens.

On sites participants will be interviewed by interviewers with tablets. However, the survey location will also have backup paper copies of the questionnaire (in case of a tablet malfunction, survey software or internet problems).

The questionnaires contain questions, covering all the basic indicators including social and demographic characteristics, risk behaviors, HIV testing and being covered by prevention programs, size estimations etc. It should take approximately 25–35 minutes to complete a questionnaire.

8.2. Biological component

The biological component includes capillary blood collection with EDTA blood microtainers for the purposes of rapid tests for HIV, anti-HCV antibody, and syphilis anti-TP antibody serological marker detection, two confirmatory rapid tests for HIV (if the result of the first test is positive), preparing DBS cards to identify recent infection and measure viral load among the respondents who received three consecutive positive rapid test results, and those who reported receiving ART (Diagram 1, Diagram 2). Participants who test positive for antibodies to HCV and syphilis will be additionally referred to a private laboratory for testing for active infection.

Although testing for hepatitis B is important for MSM, the corresponding pre-qualified tests cannot be imported into Ukraine at the time of preparation of the study. Therefore, testing for viral hepatitis B will not be carried out as part of this study.

8.2.1. 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 sexual behavior, as well as prevention and treatment of HIV and sexually transmitted infections.

8.2.2. Capillary blood collection

In order to carry out all planned assays within the biocomponent, the collection of a total of 600 µl of blood (from all participants) is required. Additionally, up to 5 rapid tests and capillary blood collection from a finger means having up to five 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 microtainers will ensure enough blood necessary for all the subsequent stages of the survey, making the 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.

Diagram 1.
Graphic representation of HIV-testing algorithm

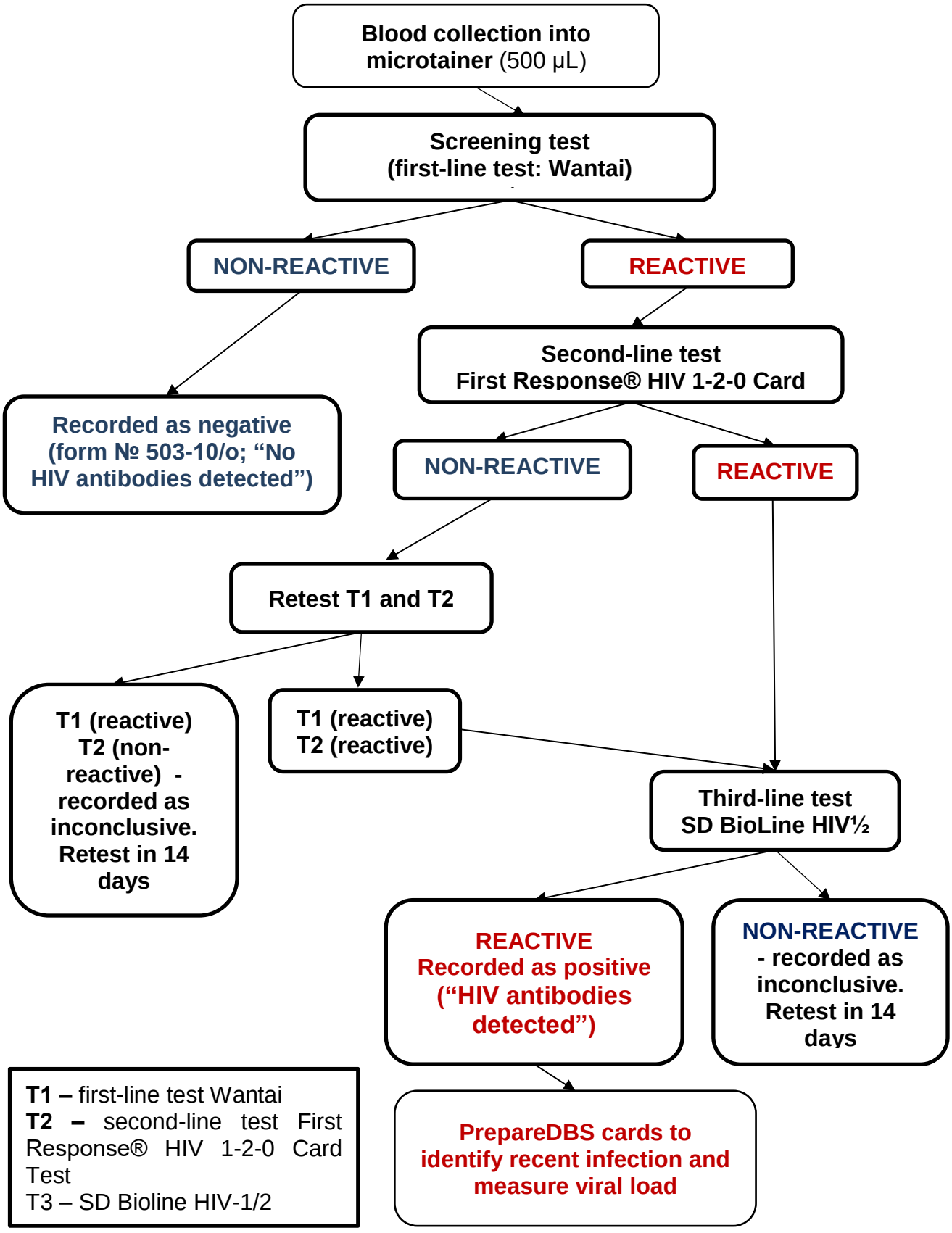
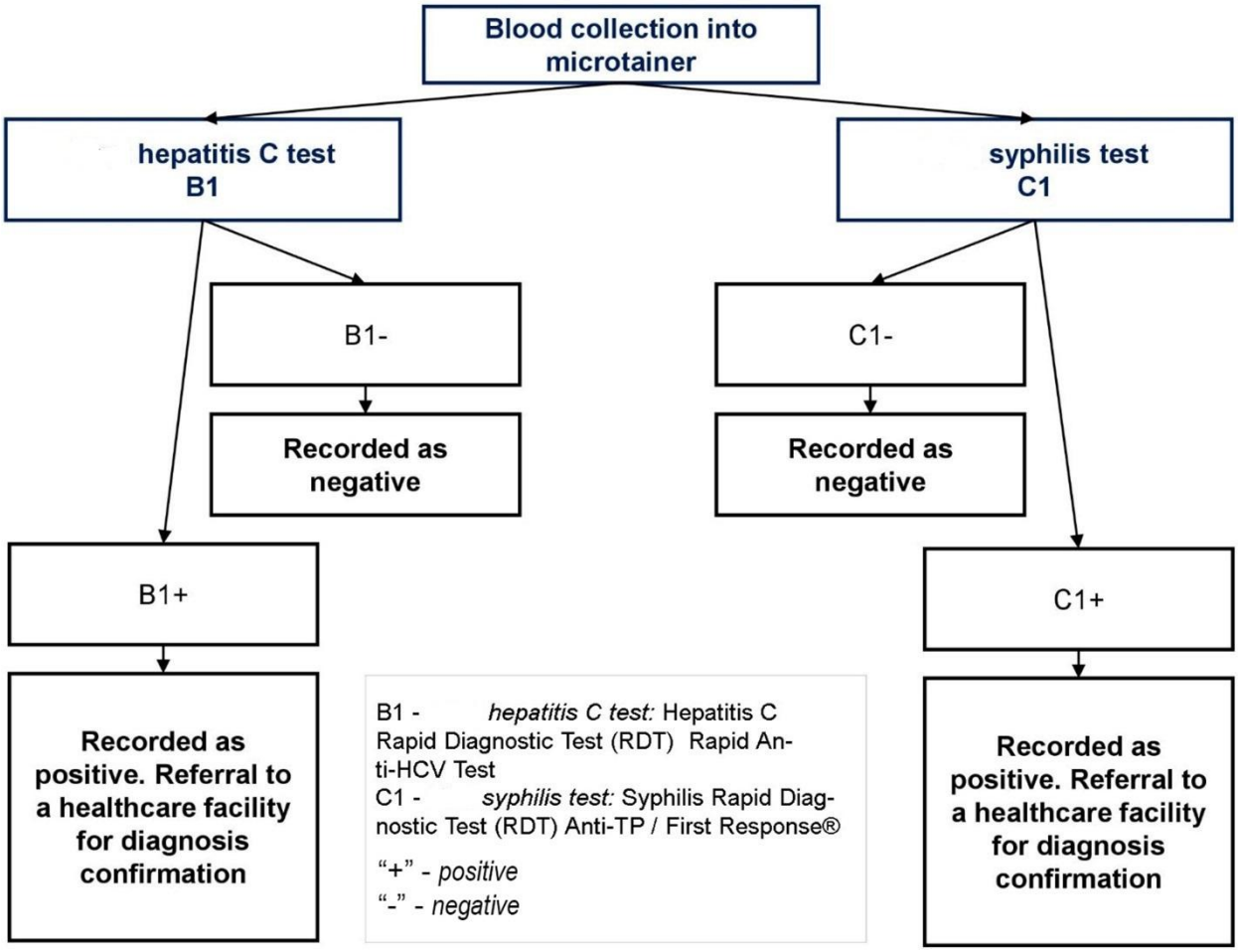


Diagram 2.
Graphic representation of the testing algorithm for anti HCV antibody and syphilis



** All participants with positive results of rapid tests for antibodies to HCV and syphilis will have the opportunity to undergo free testing for active infection in a private laboratory.*

Samples of capillary blood (approximately 500μL) from all participants will be obtained using EDTA k3 blood microtainers. Capillary blood sample will be used to conduct the first HIV screening test, rapid tests for anti-HCV antibodies, syphilis, and confirmatory second and third HIV rapid tests, and preparing the DBS cards for further laboratory detection of recent HIV infection and viral load.

8.2.3. Rapid anti HCV antibody and Syphilis Testing, referral for testing for active infection

Testing for the viral hepatitis C or syphilis infection will be carried out in two stages: 1) directly at the study site using rapid tests, 2) in a private laboratory to detect active infection.

For screening anti-HCV antibody and syphilis testing, rapid tests will be used to detect serological markers of anti-HCV antibody and syphilis, namely:

- Rapid Anti-HCV Test; ITPW01153-TC40. InTec PRODUCTS, INC, China

Anti-TP / First Response® Syphilis Anti-TP Card Test. PI08FRC25, Premier Medical 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 non-reactive, reactive, or invalid results:

- in case of non-reactive result of the rapid tests to detect anti HCV antibody and syphilis serological markers, the results are recorded as negative and notified to the participant. The participant will also receive information on the local NGOs providing preventive services to MSM;
- in case of a reactive result of the rapid tests to detect anti-HCV antibody or syphilis serological markers, the respective results are recorded as positive and notified to the participant. Since such rapid testing does not establish the presence of active infection, participant with positive rapid test results will be issued voucher (valid for two weeks) with unique participant's ID that will allow him to receive free testing for active infection in a private certified laboratory (belonging to one of the major Ukrainian laboratory networks) in accordance with the national diagnostic algorithm. Laboratory testing for active hepatitis C will be done by the PCR method, and for active syphilis – by the RPR method. If participant agrees to be tested for active infection, he can visit the private laboratory specified in the voucher, get tested, and then will be able to receive the results of such testing by e-mail or telephone. At the same time, his results (in anonymized form, with only the participant's ID) will be sent to the principal investigator. In turn, the principal investigator will send participant's test result to the regional data collection team in the respective city so that they can support the participant's referral for treatment (if necessary). In accordance with national standards of medical care, all persons with positive rapid test results will be recommended to visit a health care facility (family doctor or specialized medical institution) for diagnosis. The addresses and contact information of the relevant institutions will be provided to participants. If the results of testing in a private laboratory for the presence of active hepatitis C are positive, in accordance with national treatment standards, the participant will be able to start free treatment after contacting a family doctor or specialized medical institution. If active syphilis is detected, in accordance with national treatment standards, the participant must undergo an additional clinical examination to

establish the diagnosis. Syphilis treatment in Ukraine is paid. Referral of participants who test positive for antibodies to HCV and/or syphilis is explained in more details in subsection "8.4. Post-test counseling and referral to services";

- in case of invalid results on the rapid tests to detect anti HCV antibody and syphilis serological markers (absence of control mark), the testing procedure is repeated using the same test.

8.2.4. Rapid HIV Testing

The confirmation of HIV status with the use of rapid tests within the research will be carried out in accordance with the Order of the MOH of Ukraine No. 794 of 2019, by identifying and confirming the presence of HIV serological markers (HIV antibodies 1/2) in two stages — screening stage (identification of HIV serological markers) and verification stage to confirm the presence of HIV serological markers (confirmation stage).

The HIV status of the participant will be determined through the consistent use of a combination of three immunochromatographic tests:

- first-line test – Wantai Rapid test for antibodies to human immunodeficiency virus (HIV) (colloidal gold), Beijing Wantai Biological Pharmacy Enterprise Co., Ltd, China;
- second-line test – First Response® HIV 1-2-0 Card Test, Premier Medical Corporation Limited, India;
- third-line test – SD BioLine HIV½ 3.0, Standard Diagnostics Inc., ABBOTT, USA.

Rapid tests will be carried out in accordance with the instructions for using the specific rapid test and SOP of the study.

In order to identify recent infection and determine HIV-1 viral load levels, the study procedure requires preparation of DBS for respondents with positive results from all three tests, as well as for those who reported taking antiretroviral drugs and for 10% participants with HIV-negative result of the first rapid test as quality assurance.

Referral of participants who test positive for HIV is explained in subsection "8.4. Post-test counseling and referral to services".

8.2.5. Blood collection and DBS preparation

DBS samples are produced from EDTA capillary blood samples for each survey participant with positive results of the three HIV rapid tests, 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 (despite the result of the HIV test) in their questionnaires (Annex 23: DBS registration form).

In this study we use DBS cards: 903 Perforated 5 Circle Card CE Mkd 100/PK (Lasec), EASTERN BUSINESS FORMS, INC. 530 Old Sulphur Springs Rd Greenville, SC 29607 USA. One card per participant will be used. In each card will be filled 5 spots.

All stages of the DBS preparation will be conducted in compliance with the SOP.

All test results will be entered on the test results forms (Annex 15. Test Results Form).

All DBS samples received by the laboratory are recorded in a log. The condition of moisture indicators is checked. DBS samples are checked for quality.

The health care worker at the research site will be trained according to CDC guidelines for this procedure and his/her competence will be verified by the national coordinator. During the training, competence is assessed using blind samples. During the field stage, HIV laboratory staff assesses the competence of regional teams using such DTS samples.

The national lab staff also undergoes training from the CDC (2023) with further competency assessment.

8.3. Laboratory testing

Specimens will be stored in the PHC Reference Laboratory for HIV / AIDS Diagnostics. (The collected DBS cards are placed on a drying rack and left there for at least 2 days at room temperature. The maximum drying time for the card at the research site is up to 7 days. DBS cannot be stored and/or transported at ambient temperature for more than 14 days. DBS are transported at ambient temperature by a transportation service. Samples are sent no later than 7 days from the date of collection of the first sample in the batch to be sent and no earlier than 2 days from the date of collection of the last sample in the batch.) They will be used to identify recent infection, viral load, and for quality control (to confirm rapid tests results). In addition, the remnant specimens can be used to verify the rapid testing algorithms and remnant specimens with detectable viral load (VL) may be used for HIV 1 genotyping molecular testing for the molecular surveillance purpose.

All DBS samples after receiving from regional sites will be tested for recent infection and VL in the Reference Laboratory for HIV / AIDS Diagnostics (RLHIV) in accordance with approved procedures in the laboratory (Annex 24: Form of routine forwarding of the DBS samples to the Reference Laboratory). In the laboratory, the cards

are stored in a refrigerator at a temperature of -70 Celsius. The collected blood samples will be destroyed within 5 years from the date of completion of the study.

The quality of DBS cards is checked in compliance with the SOP before testing (Annex 22. Form of registration of rejected DBS samples).

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 the confirmed cases of recent HIV-1 infection. Samples with VL ≤ 1000 copies/ml are classified as long-term infection.

Results of confirmed recency test will not be returned to patients. The results of VL testing will be returned to participants, if they agree to leave their phone number.

8.4. 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 or third rapid diagnostic test will be informed by healthcare workers about the result (Annex 17: Certificate of HIV test results) and referred on the same day to the nearest health care institution providing medical care for HIV infection, or ART site for ART initiation (Annex 16: Referral form for the survey participant; Annex 20. Registration log for referrals to health care institution providing medical care for HIV infection). In each city, we plan to involve social workers who will accompany all HIV-positive participants and ensure their access to the health care institutions providing medical care for HIV infection. 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 be not enough, the regional coordinator will attract the necessary number of specialists to the site. Information on the referral to medical institutions, including health care institutions providing medical care for HIV infection, is indicated in the informed consent that is provided to participant when he arrives at the site.

In accordance with the national procedure of ART prescription (Order of the Ministry of Health of Ukraine No. 1292 of 2019), ART can be initiated immediately after an HIV-positive representative of a key group 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, a healthcare worker should ensure linkage to care when participant is ready for this.

At all stages of the survey, experts from local NGOs, that provide services to MSM, will be involved for their participation in social care and support projects (Annex 19: Social support referral form for the survey participant).

To increase the level of linkage to care of HIV-positive participants, it is expected that healthcare workers record contact information from MSM, provided participant's voluntary consent. In case of HIV negative result all MSM who tested negative will be informed about PrEP options, which are available for free at the nearest health care institution providing medical care for HIV infection / ART site (Annex 36: Information regarding PrEP). They will be offered to be accompanied by the social worker for PrEP initiation.

Two weeks after the end of the field stage, the Regional Coordinator will provide follow-up information on the number of participants who have visited the health care institution providing medical care for HIV infection, and who have started the ARV-treatment or PrEP.

Anti-Hepatitis C

Participants who test positive with rapid HCV antibody tests (Annex 18: Certificate of test results for hepatitis C, syphilis; Annex 21: Registration log of referrals to healthcare facilities) will receive vouchers that allow them to be tested free of charge in a private laboratory. The voucher will contain a unique participant ID, will not contain the name of the study (and references to the fact that the participant belongs to the MSM group), and will contain information that the testing must be completed within two weeks. The participant will also be asked to leave his phone number so that the regional team can contact him to verify that he has been tested and/or started treatment.

The laboratory will send the results of the test for active HCV to the participant by mail or notify him by phone.

At the same time, the laboratory will send the results (but without personal data, only with the ID) to the principal investigator, and he/she will send them to the regional coordinators to record the results of the participant's testing for active HCV. After that, the regional data collection team will contact the participant (if he left his phone number or when he comes to collect the secondary reward) to find out if he has received his test results for active infection and have gone to the healthcare facility for treatment.

Along with the voucher, participants will be provided with addresses and contact details of HCV treatment facilities. After receiving a confirmatory diagnosis based on HCV RNA testing, treatment in Ukraine is free of charge.

At the stage of formative assessment, the Regional Working Group members regional coordinator and the representatives of health care institutions providing medical care for HIV infection, will make up an up-to-date list of facilities for treatment referral.

Syphilis

Participants who test positive with rapid syphilis tests (Annex 18: Certificate of test results for hepatitis C, syphilis; Annex 21: Registration log of referrals to healthcare facilities) will receive vouchers that allow them to be tested free of charge in a private laboratory. The voucher will contain a unique participant ID, will not contain the name of the study (and references to the fact that the participant belongs to the MSM group), and will contain information that the testing must be completed within two weeks. The participant will also be asked to leave his phone number so that the regional team can contact him to verify that he has been tested and/or started treatment.

The laboratory will send the results of the test for active syphilis to the participant by mail or notify him by phone.

The laboratory will send the results (but without personal data, only with the ID) to the principal investigator, and he/she will send them to the regional coordinators to record the results of the participant's testing for active syphilis. After that, the regional data collection team will contact the participant (if he left his phone number or when he comes to collect the secondary reward) to find out if he has received his test results for active infection and have gone to the healthcare facility for treatment.

Along with the voucher, participants will be provided with counseling for syphilis treatment. According to the national standards, a confirmatory diagnosis requires additional clinical examination. Treatment for syphilis in Ukraine is paid.

8.5. Compensation and peer recruitment

Upon completing biological component, coupons will be collected and filed by coupon-manager. Coupon-manager checks complete list of signatures in the participant’s card (Annex 10: Participant`s Card) and signs it confirming that participant has successfully passed each subsequent stage of the survey. The participant’s card is taken by coupon-manager for storage After the check the participant will receive primary

incentives (Annex 25: Compensation Log), coupons and instructions for recruiting new peers.

Secondary incentives will be provided for every new recruited peer. The coupon manager will ask the participant how many eligible potential participants he approached and how many referral coupons he handed out.

Using a non-response form (Annex 14: Questionnaire of refusal to participate in the survey for recruiters), basic information will be collected on those who refused coupons or for potential participants who accepted the coupon but had not visited the survey office by the time the coupon expired.

9. ESTIMATES OF THE NUMBER OF MSM (IBBS REGIONS)

9.1. Methods of calculating the estimated number of MSM

In 2024, the number of MSM will be locally calculated for 10 cities, in which IBBS among MSM will be conducted. As in the previous round of MMS-IBBS in Ukraine the main methods to estimate the number of MSM in Ukraine will be the app-based (census/enumeration) method, privatized network sampling method, capture-recapture, and the successive sampling method.

9.1.1. App-based method

According to IBBS MSM 2021, 54% of MSM used special mobile applications to meet other men, and 39% used special online dating sites for this. The leader in terms of coverage among such virtual platforms is the mobile application “Hornet” (profiles on which 57% of participants have), the site “Bluesystem” (23%) and the mobile application “Badoo” (20%). In Ukraine, this is the most popular way to find sexual partners among MSM.

It is planned that PHC will contract (through partner NGOs) the local consultants, who will have to collect the data on Hornet and Grindr profiles in own cities and other online dating tools within the territory (radius) around the cities of the IBBS MSM.

Since the IBBS participants will be asked about the use of the two social apps (Hornet and Grindr) in the last 30 days (month), these two sets of PSE data can be matched. Depending on the success of negotiations and the requested charge of the service, as well as possible technical limitations, the number of cities in which this method will be used can be specified. The list of cities will be submitted for consideration and approval by the IBBS National Working Group and stakeholders.

In addition, the questions about the use of the two social apps (Hornet and Grindr) we also ask about the use of a fake social app “4-Guyder” and fake site “RainbowCupid”. This is a trap question to identify inattentive survey respondents.

The questionnaires for the cities which will not participate in the App-based (census) method, will be the same. The derived information on the use of particular social app combined with data provided by social app service will be used as the additional multiplier for PSE in the participating cities.

9.1.2. Privatized network sampling method

If feasible, for each survey participant, using a cryptographic hash function, a hashed (anonymized) ID will be created using the first initial of the participant's first name and the first initial of the participant's last name along with the last four digits of their cell phone number (in Ukraine, the full phone number is usually 10 numbers). This information will be put into a secure identity coder, which will generate a random, non-identifiable code. This code will always be the same for each person based on the information they have provided [28]. However, it will be impossible to trace back to an individual person. The hashed ID cannot be used to reconstruct the respondent's identity.

Similarly, a hashed ID will be created for up to 5 peers in the participant's personal network (aged 16 years old or older). If the participant states they know 5 or fewer peers, a hashed ID will be created for all of them. If the participant knows more than 5 peers, then 5 peers will be selected. Participants will also be asked how many telephone numbers they have.

As sampling progresses, it will be observed whether survey participants had been named as a peer or not. The rate at which participants' networks contain other sampled participants is related to population size. These data facilitate two new estimators informing population size using an R package on github (https://github.com/fellstat/pnspop):

1. Cross Sample Estimator: Similar to the One-Step estimator but does not assume a small sample fraction or long chains.
2. Cross Network Estimator: Uses both the number of cross-alter and cross-sample matches to estimate population size.

9.1.3. Service multiplier method

This method is applied when there are two independent data sources, for example, data on the number of representatives of the group, who received a specific type of service, and calculations of the study (proportions of study participants who share this characteristic). Calculations will be made by the formula:

$$O_1 = \frac{M}{P}$$

where:

O_1 – estimated MSM number;

M – quantitative statistical indicator of registered MSM group representatives in a particular data source;

P – proportion of MSM group representatives, who confirmed their registration in a certain data source within IBBS;

S – sample size of MSM within IBBS.

The variance will be calculated by using the following formula:

$$Var(O_1) = \frac{(M * S * (M - P) * (S - P))}{P^3}$$

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

$$95\%\ CI: O1\ \pm 1.96 * \sqrt{Var}(O_1)$$

In order to identify the estimated number of MSM by a multiplier method, 3 indicators with the following outgoing data source will be used:

No.	Indicator	Data source (question) in 2024 survey	Source of statistical information	
1	Estimation based on the indicator called «rate of registration within the NGO network implementing prevention activities»	Are you a client of an organization that provides HIV prevention services? TB? Do you go there, know anyone who works there? Received any type of care	Number of MSM-clients registered within NGO network as of December 31, 2023 and May 30, 2024.	SYREX database, ICF "Alliance for Public Health"
2	Estimation based on the indicator called «Condoms distribution»	Have you received FREE condoms from NGOs within the last 3 months?	Number of MSM who have received condoms within NGO network (average indicator for 3 months).	SYREX database, ICF "Alliance for Public Health"
3	Estimation based on the indicator called «Rate of HIV rapid tests use within NGO»	Were you tested with a rapid test for HIV in non-governmental organization in 2023? Were you tested with a rapid test for HIV in non-governmental organization in 2024?	Number of MSM who have been tested with the HIV rapid tests for 2023 and 2024 (separately for each year).	SYREX database, ICF "Alliance for Public Health"

Since previous rounds of study (after 2019) revealed the problem of insufficient quality of statistical data, primarily in terms of coverage of preventive services (due to the presence of non-duplicated individuals), all the data obtained from the service multiplier method and further calculations will be discussed (separately for each city) at the meeting of the National Working Group on the implementation of the IBBS in Ukraine to understand how reliable the data is and whether it can be used.

9.1.4. The capture-recapture method

Capture-recapture 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.

The capture-recapture 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.

The participation in IBBS will be considered 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.

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:

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

The capture-recapture method assumes that the population is closed and that participants from the first sample can be identified in the second. However, given that in the period between the previous and current wave of the study, a full-scale russian invasion of Ukraine began, which led to massive population displacement within the country and abroad, the first assumption will not hold true for a significant number of cities included in the study. Nevertheless, attempts will be made to obtain at least some estimates based on this method, as well as to adjust the estimates to take into account data on migration of participants between regions (or abroad).

9.1.5. The successive sampling method

This method is based on the Bayesian approach to population estimation using data collected using the RDS method. The method evaluates population size using only RDS survey data that are ordered by network size and does not consider the network structure in the RDS recruiting sequence. It assumes that a respondent with a high degree of network would have a better chance of being hired earlier in the survey sample than a respondent with a low degree of network. Respondent's answers to the following question cascade during survey are then used to calculate his/her network level:

- Can you recall your acquaintances (you know their names and they know yours) that who have had oral or anal sex with another man in the last 6 months? What is the number of these people?
- How many of them have you seen for the past 30 days?
- Have they all reached the age of sixteen? Are they older?
- How many of them live or spend most of their time in the city of survey?

The estimated number of MSM will be calculated using this method within the RDS-Analyst statistical package, which has specific features to make calculations using this method.

9.2. Stages of calculating the estimated number of MSM

9.2.1. Estimates validation

In order to validate the estimates obtained, the most probable range of MSM number in each city of survey will be determined:

- 1% of city's male population aged 15-59 as of January 1, 2023 is used as a limiting minimum according to UNAIDS' recommendation;
- The size of male population of a city aged 15-59 as of January 1, 2023 is used as a limiting maximum.

9.2.2. Estimates triangulation

Several estimates, calculated at a local level, form a certain estimation range of the number of MSM. This allows to compare the validity of methods and to define the most probable range at a regional level. The method of anchored multiplier, that allows synthesizing several estimates of a group number into a single consensus estimate, is planned to be used. Anchored Multiplier calculator [29], created by the researchers from University of California, San Francisco (UCSF) led by Paul Wesson.

9.2.3. Estimates extrapolation

Within extrapolation, it will be used the same approach as in 2021 PSE.

In the regions where the IBBS MSM 2024 will be conducted, extrapolation of local population size estimates will be carried out as follows: local population size estimate (in a city that is or can be equated to the oblast center) will be summed up with the estimate in the oblast excluding the respective city (in turn, this estimate will be obtained by summing up estimates in rural settlements of the oblast (will be equated to 1% of the male population of these settlements aged 15-59 years) and estimates in the remaining urban settlements of the oblast (will be equated to the percentage of the lower boundary of the confidence interval obtained in the calculation of local population estimates in the city that is or can be equated to the oblast center, applied to the male population aged 15-59 years in these settlements)).

In the regions where the IBBS MSM 2024 was not conducted, the extrapolation of population size estimates will be conducted as follows:

A) for the regions whose territories are not controlled by the Government of Ukraine in whole or in part as a result of the full-scale russian invasion (as of August 2023: The Autonomous Republic

of Crimea, the city of Sevastopol, almost the entire Luhansk oblast, significant parts of Donetsk, Zaporizhzhia and Kherson oblasts), the latest available estimates will be used,

B) for the rest of the regions, there will be used the latest available estimate adjusted for changes in the size of the male population aged 15-59 will be used.

10. COST ANALYSIS

Having accurate and timely information on HIV dynamics among KP provided by BBS/PSE is crucial to inform programs and policies which is important to help countries reach and sustain epidemic control. The new PEPFAR Five-year Strategy will prepare partner countries to implement key components of the HIV response, including surveys and surveillance activities. KP are faced with stigma, discrimination, and health inequities which lead to gaps in HIV care. Conducting BBS/PSE is essential to identify these gaps; however, countries and programs may be faced with resource limitations. In this context, it will be crucial to understand the required resources for program planning as activities shift from PEPFAR to partner countries. This requires understanding the resources used to implement activities and their costs.

Data on the types, amounts, and prices of resources (personnel, training, equipment, supplies, buildings and utilities, transport, travel, etc.) used can help assess minimum requirements to conduct BBS/PSE, not just what was procured for one specific survey. It can also account for resources that were provided in-kind or procured for other activities but used for survey (e.g., tablets, test kits and reagents). We plan to collect cost data to identify financial information essential to understand resources used for BBS/PSE and inform HQ and country teams for future surveys' budgeting and planning.

Understanding that partners who implement BBS/PSE may not have the necessary expertise in cost analysis, CDC HQ (HEFT and KPST) staff will collaborate on the design of the data collection tool with the partner, and independently complete the analyses to minimize the burden on the partners. This will require consultation with the partners, which will be completed in multiple steps over time. The first step will be to understand survey activities, budgets, and identify the phases of activities and types of resources needed. This project intends to understand resource use from initial preparatory activities required for BBS/PSE (e.g., protocol development) through the dissemination of the survey report. If BBS/PSE activities extend past the initial timeline, cost data collection will also continue until the results from the project are disseminated.

Once resources for BBS/PSE are identified, the second step will be to assess available records and systems such as budgets, invoices, other financial records. These will be examined to identify how those resources are measured and tracked. The third step will be to identify gaps where data are not available in existing systems, propose and agree upon what additional data collection will be needed, and whether they may need to be collected retrospectively or prospectively. For example,

records may be kept on personnel hours spent on BBS/PSE for a specific time, but not by activity or survey site. Additionally, different survey activities may occur at the same time. The approach to this project will be custom to the record keeping systems of implementing partners. As part of the third step, if there are any resources used but not paid for such as volunteers or donations, data on them may be collected, if feasible.

After completing these steps for the consultation process, the data collection approach will be finalized and implemented. Costs will be collected from the payer perspective using micro-costing. Both top-down and bottom-up cost methods will be used to capture and allocate resources to BBS/PSE. We expect that data will be collected and categorized by:

- Cost component
  - Personnel
  - Training
  - Equipment
  - Supplies
  - Contracted services
  - Travel
  - Buildings and utilities
  - Transport
- Phase of the survey
  - Survey preparation
  - Implementation
  - Post survey activities, including dissemination
- Level
  - Central support
  - BBS/PSE site

Cost categories, phases and levels may be adjusted as needed. Details on the quantities and prices of specific inputs unique to BBS/PSE will also be captured, such as unique objects distributed in PSE captures and tests performed in this BBS/PSE. Where specific data are not available for resources used in BBS/PSE, alternative sources will be identified and documented (e.g., national medical store price lists, PEPFAR, etc.). Both financial and economic costs of key resources will be estimated where possible (see Table 1 for illustrative examples). All costs will be collected in the local currency, as well as in US dollars. Data will be analyzed in Microsoft Excel.

Table 1. Key resources for BBS/PSE cost analysis

Illustrative BBS/PSE resources	Types of input data needed	Types of cost and price data needed	Result reported
BBS site	Length of site operations, urban/peri-urban	Rent, utilities, etc.	Operation costs per site
Tests	Tests and quantities (consultation might include questions on quality control, wastage/excess supply)	Cost per test, other costs such as transport, reagents storage cost, etc.	Cost per test and cost per participant tested
Personnel	Staff types, activities, survey phases	Salaries and benefits per staff	Personnel costs for BBS/PSE by survey phase
Training	Number of participants, number of trainers	Materials, space, refreshments, per diem, etc.	Training costs for BBS/PSE
PrEP and ART initiation	Number of eligible HIV negative people identified and linked to PrEP, Number HIV positive people identified and linked to ART	Cost related to onsite treatment, cost to link to offsite treatment	Cost per HIV positive person identified, cost per person linked to ART, cost per person referred to PrEP services
For PSE, unique objects	Number of objects purchased (sample size) and distributed per capture	Cost per object	Cost for unique object distribution

The country level results of the budget and cost analysis will be shared with the implementing partner and country office supporting the BBS/PSE and CDC HQ. Any aggregated analysis will be shared with CDC HQ, CDC country offices, and GHSD, as appropriate. Results will be summarized in the proposed summary budget and cost tables with accompanying text to support interpretation, contextualize the table output and note limitations on the data collection, analysis, results, and interpretation.

Use of the cost analysis results will be based on the output. The Budget Summary may be used to inform country-specific decisions in preparation for Country Operational Plan. The Cost Summary maybe used to inform various decisions on tradeoffs within a given allotment of funding for specific surveys.

11. DATA MANAGEMENT PLAN

Data Management Plan identifies the resources and tools needed for data collection, storage, analysis 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 several 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 IBBS team uses the following forms and tools:

1. Informed consent to be interviewed (formative assessment stage)
2. Formative assessment results form
3. Log of compensation to the key informants (formative assessment stage)
4. Verbal consent to questionnaire piloting
5. Log of compensation to the respondents for questionnaire piloting
6. Screening questionnaire for primary respondents
7. Introduction for the potential participants of the survey
8. Checklist for screening
9. Survey participant's coupon
10. Participant's Card
11. Participant's Informed Consent (in Ukrainian language)
12. Registration form for refusal to participate in the survey (Non-response form)
13. Questionnaire of refusal to participate in the survey for recruiters
14. Test Results Form
15. Referral form for the survey participant
16. Certificate of HIV test results
17. Certificate of test results for hepatitis C, syphilis
18. Social support referral form for the survey participant

19. Registration log for referrals to health care institution providing medical care for HIV infection (AIDS Center)
20. Registration log of referrals to healthcare facilities
21. Form of rejected DBS samples
22. DBS registration form
23. Form of routine forwarding of the DBS samples to the Reference Laboratory
24. Compensation Log
25. Instructions for a recruiter
26. Data Use and Confidentiality Agreement for personnel
27. Unforeseen circumstances notification form
28. Reporting form on serious adverse events
29. Form of the Protocol deviations
30. Weekly reporting form of the national coordinator
31. Weekly reporting form of the regional coordinator
32. Report of the regional team on the survey findings
33. Report on the monitoring visit to the survey site
34. Information regarding PrEP
35. Survey Participant`s Questionnaire.

All forms are linked with the participant's ID and do not contain the participant's identifying information. The regional coordinator collects all filled-in forms from the data collection team member (recruiter, coupon manager, interviewer, healthcare worker). The regional coordinator checks the completeness and correctness of forms filling-in, 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. Data dictionary

Data Dictionary includes: number of variables; questions; name of variables; values; massing values; type of variables; filter.

Number	Question	Name of variables	Values	Missing values	Type of variables	Filter

11.3. Unique participant's 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 SurveyMonkey app. It has the same elements as the ID-code, with additional letter "M" between the city code and sequential number. The QR-code is printed on the participant's coupon, and after scanning it with the SurveyMonkey 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 " SurveyMonkey " software server.

11.4. Data access

Data will be owned by PHC. 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 «SurveyMonkey» 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 MSM 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 MSM.

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, geolocation indication). Email is not used to transfer data through software.

11.5. Data security

From paper forms, data will be transferred to electronic format by specialists 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 (Annex 27: Data Use and Confidentiality Agreement for personnel), which minimizes the risk of incorrect use of information. All reporting forms of regional teams will be checked by the Principal investigator and systematized by him.

The regional coordinator is responsible for storing documents in a safe, which will be 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 «SurveyMonkey»).

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 «SurveyMonkey», a cryptographic library for mobile devices is 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 executor 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 deleted in accordance with the general document management policy at the PHC.

12. DATA ANALYSIS

Data will be analyzed in Respondent-Driven Sampling-Analyst (RDS-A) or R and appropriate weights will be applied based on the characteristics of the sample. The main data analysis will be carried out considering the structure of the previous reports on the IBBS findings in Ukraine. Examples of tables to be used in the reports are presented below.

Prevalence of HIV, anti-HCV antibody and anti-TP antibody, active HCV and active syphilis among MSM

Characteristic	Prevalence…				
	HIV N (%)	Anti-HCV antibody N (%)	HCV RNA result N (%*)	Anti-TP antibody N (%)	Active syphilis N (%**)
Among all					
Age					
16-19 years					
20-24 years					
25-34 years					
35 years and older					
Actual family status (with whom runs household)					
with parents / relatives					
one					
with a male partner					
with a female partner					
Education					
elementary or basic					
full general secondary or vocational (11 classes, school) or unfinished higher)					
basic higher					
higher					
Sexual orientation					
homosexual					
bisexual					
Income					
low					
medium					
high					
NGO clients					
clients					
non- clients					

***** *Among those reactive for anti-HCV who were tested. ** Among those reactive for anti-TP who were tested.*

Prevalence of risky practices among MSM

Characteristic	Had sex in the state of influence of non-injectable drugs (within month)	Had sex in the state of influence of injectable drugs (within month)
Among all		
Age		
16-19 years		
20-24 years		
25-34 years		
35 years and older		
Actual family status (with whom runs household)		
with parents / relatives		
one		
with a male partner		
with a female partner		
Education		
elementary or basic		
full general secondary or vocational (11 classes, school) or unfinished higher)		
basic higher		
higher		
Sexual orientation		
homosexual		
bisexual		
Income		
low		
medium		
high		
NGO clients		
clients		
non- clients		

12.1. Estimation of HIV infection prevalence

HIV prevalence will be assessed by weighing the sampling of HIV prevalence data received during the survey per size of the respondents' personal social network, namely: the number of MSM representatives older than 16 years old that the respondent has seen over the past 30 days. Analysis

of HIV prevalence will include stratification by age, sexual orientation, education, income, LGBTQ NGO client, etc.

RDS Analyst software version 0.72 will be used for RDS analysis[5].

12.2. Determination of the prevalence of behavioral practices related to HIV infection, hepatitis C and syphilis and the use of preventive and treatment services

The survey questionnaire contains questions about HIV-related risk behavior, the characteristics of sexual behavior, and the use of preventive and medical services. Independent variables on these issues will be used to analyze the link with HIV infection. Analysis with two or more variables will be used to identify the factors associated with the prevalence of infections. Cross-section survey design does not allow to draw conclusions about the causal relationships between dependent and independent variables, therefore the proper interpretation of the term “prognostic factor” is used. In the analysis of prognostic factors, the scales of RDS-Analyst using the "imputed visibility" function for each of the primary results will be applied.

The database of the IBBS will contain data on HIV-related risk behaviors, use of preventive and medical services without any identifying data. These variables will be individually verified for a link with the dependent variable — the recent infection — using the chi-square for categorical variables and the Student t-test for continuous variables. Non-parametric tests of Wilcoxon or Kruskal-Wallis will be used for continuous variables with skewed distribution.

Key social and demographic characteristics of participants (age), knowledge about HIV, HIV-related risk behaviors, use of preventive and medical services will be included in the logistic regression model. The automatic method of variables selection (inverse, direct, in both directions) will be chosen depending on the number of eligible variables, and the results will be compared to the full model. Final model with the optimal number of parameters will include age, region and variables with a value of p = 0.05 in models with many variables. The statistical parameters specifically designed for the relevant models (for example, the probability -2 Log, AIC, BIC) will be investigated in order to select the best models. In addition, a share of missing data will be reviewed. Before analysis with many variables, the method of multiple recovery of missed data will be used if their share is high (> 5%).

[5] https://rds-analysis-tool.software.informer.com/7.1/

Using the obtained model, one can estimate the contribution of each independent variable into prediction of seroconversion with simultaneous control over age, gender and oblast parameters. Interclass correlation within one city will be considered using the available software.

12.3. Estimation of HIV incidence

A method implemented in the package "inctools" (version 1.0.15) for R will be used as a primary method for calculating annual incidence. For this purpose, estimates of recent HIV infection and viral load will be used, which will be obtained by the Reference-Laboratory for HIV/AIDS Testing after testing of DBS samples (Abbott m2000sp and Abbott Real-time m2000rt compatible reagents and supplies will be used). This approach has been previously reviewed and approved by international experts and statistics specialists.

The possibility of using the testing history method will also be considered.

12.4. Treatment cascade indicators among MSM living with HIV

Data of the IBBS among MSM in 2024 will be used for treatment cascade calculation for MSM living with HIV.

Cascade indicator	Calculation
MSM living with HIV	Estimated number of MSM 2017 will be multiplied by the prevalence of HIV among MSM according to the IBBS 2021 data
Know about their HIV-positive status	Rate of MSM self-declared 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 checked by means of healthcare worker's form.
Registered in the health care institutions providing medical care for HIV infection	Rate of MSM self-declared their official registration in the health care institution providing medical care for HIV infection 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. OR Confirmation from health care institution providing medical care for HIV infection about official registration of participants as HIV-positive. This calculation will be checked through the healthcare worker's form and MSM self-declaration
Receive ART	Rate of MSM receiving ART (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.

	OR Confirmation from health care institution providing medical care for HIV infection about ART taking. This calculation will be checked through the healthcare worker's form and MSM self-declaration
Suppression of viral load	Results of viral load testing carried out at the stage of laboratory analysis.

All tables and approach to indicators calculation may be adjusted based on the survey findings.

13. DATA QUALITY ASSURANCE

Assurance of conduction of a qualitative survey at all stages of implementation is foreseen within the framework of IBBS among MSM.

13.1. Preparatory stage

The Protocol and the SOPs will be agreed with the National Working Group on the implementation of the IBBS in Ukraine. SOPs provide a consistent algorithm for data collection at all sites of the IBBS. The approximate SOP structure with a step-by-step algorithm of actions regarding a specific aspect of the IBBS implementation includes several sections, namely:

- introduction to respondents, recruiting and screening;
- prevention of re-participation in the survey and the exclusion of non-eligible participants;
- obtaining participant's informed consent;
- ensuring the confidentiality of participants;
- filling in the survey toolkit;
- data collection within the biological component;
- conduction of pre- and post-test counseling, referrals to healthcare facilities;
- preparation, storage and transportation of dry blood spots;
- compensation to respondents for participation in the survey, recruiting of other participants;
- survey algorithm for participants;
- organization of team work on the survey site, its activation and closure;
- ensuring the 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;
- development of unique participant's code.

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

13.2. Field stage

The data collection stage is scheduled to begin simultaneously in all cities of the IBBS in June 2024. A difference of 1-10 days is allowed due to the difference in the timing of the logistics of materials for the biological component, renting premises for the study sites and their preparation, etc. It is planned that the data collection for each study city will last no more than three months (see timeline, p.70).

The “Survey Monkey” 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. Daily 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, “Survey Monkey” 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 reports 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 findings). The report provides information on recruiting rates, the number of collected and forwarded DBS samples, a list of unforeseen circumstances and serious adverse events, measures taken to overcome the problems.

13.3. RDS recruitment monitoring

Recruitment data will be analyzed every 50 participants for the first 150 participants and every 100 participants thereafter. For each site and key population the following will be monitored:

Recruitment homophily: The ratio of number of recruits that have the same characteristic (e.g. HIV positive vs. HIV negative) as their recruiter to the number we would expect by chance, for that recruitment chain.

Recruitment plots: Stratified by HIV, the recruitment plots will show whether the average personal network size differs by wave, which can indicate when a substantial proportion of the population has been sampled. The plots will also indicate if recruitment chains are biased in terms of recruitment according to certain characteristics, such as HIV.

Convergence and bottleneck plots: these plots can indicate if the sample has reached convergence on HIV and other variables, and whether the population contains distinct sub-populations that could bias RDS estimates.

Additional analyses including coupon uptake will be conducted. Feedback from internal monitoring activities will be captured in a recruitment progress report and shared with survey investigators who will implement systematic recommendations so as to improve data quality and SOP adherence. For instance, if monitoring indicates that recruitment is slow, survey investigators will decide whether more coupons should be given out or if additional seeds are needed.

13.4. Field monitoring

As the study sponsor, the Centers for Disease Control (CDC) may conduct monitoring or auditing of study activities to ensure the scientific integrity of the study and to ensure the rights and protection of study participants. Monitoring and auditing activities may be conducted by:

- CDC staff (“internal”)
- authorized representatives of CDC (e.g., a contracted party considered to be “external”)
- both internal and external parties.

Monitoring or auditing may be performed by means of on-site visits to the Investigator’s facilities or through other communications such as telephone calls or written correspondence. The visits will be scheduled at mutually agreeable times, and the frequency of visits will be at the discretion of CDC. During the visit, any study-related materials may be reviewed and the Investigator along with study staff should be available for discussion of findings. The study may also be subject to inspection by regulatory authorities (national or foreign) as well as the IECs/IRBs to review compliance and regulatory requirements.

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, three 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, monitoring visits to survey sites, at least three visits to each site will be conducted. During the IBBS implementation, regional teams are visited by the PHC representatives, the National Working Group, CDC and external consultants to monitor the compliance with the methodology. The National Working Group appoints the monitoring consultants who will be trained in data collection and quality management under the CDC mechanisms. The monitoring consultants assess the compliance of the regional teams with the survey protocol and the SOPs regarding informed consent, pre-test and post-test counseling, questionnaires filling in, rapid tests, collection and storage of DBS (Annex 34: Report on the monitoring visit to the survey site).

13.5. Data processing and analysis stage

Data management at the processing and analysis stage, is carried out in accordance with the IBBS Data Management Plan. The Reference Laboratory for HIV/AIDS diagnostics will implement the data management system for effective registration, tracking of biomaterial samples and linking them with the survey data. The laboratory performance quality management (documentation of procedures and samples, re-testing of samples) is a key for obtaining reliable IBBS findings.

14. ETHICAL CONSIDERATIONS

14.1. Ethical expertise

The survey report will be submitted to the Ethics Commission of the Public Health Center of the Ministry of Health of Ukraine (Kyiv, Ukraine; FWA #: FWA00030968 Institution: Public Health Center of the MOH of Ukraine Expires: 02/02/2028) and to the Center for Disease Control and Prevention (Atlanta, GA, USA) for expert review as to observance of human rights. The conclusions 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 member of the survey team is required to complete a training in the ethical standards of the survey 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).

14.3. Obtaining informed consent

During formative assessment and piloting of the toolkit, oral informed consent will be used. To minimize the risk of a confidentiality breach, we request a waiver of the requirement of written informed consent as in-depth interviews 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.

Only those MSM who gave voluntary consent and signed an appropriate informed consent form after screening and before an interview can participate in the survey. A member of the team reads aloud the informed consent to each eligible participant. If they agree to participate in the IBBS, they sign 2 forms of the informed consent, one is passed to the representative of the regional group, and another one remains with the respondent.

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 disclosed, 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.

14.4. Participants' protection from the risks

The survey provides participants with counseling and testing services for HIV, anti HCV antibodies and syphilis, and they will be asked to provide information on the experience of risky behavior. Questions about sensitive topics, such as the sexual behavior or stigmatization, 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 HIV-positive status under the test results, there is a potential risk of stress.

Participation in HIV infection prevention and treatment programs in Ukraine does not involve any social risk or the risk of punishment, apart from the possible spread of stigma related to health issues and sexual behavior. This survey does not increase the risk of stigmatization of such behavior.

The form of the informed consent contains names and contact information of organizations included into the survey and individual investigators. 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 not answer the inconvenient questions, and the information received from them will not be disclosed to other participants.

To minimize the psychological discomfort, primary seeds will be recruited by the representatives of NGOs working with MSM, 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 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 the health care institution providing medical care for HIV infection. 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 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 leave personal data (telephone number) for the organization of re-referral and treatment, which will only be accessible to the healthcare worker of the site and principal investigator. If the participant agrees, this number will be used to return the results of laboratory testing for VL.

14.5. Survey sites preparation

The survey premises will be selected considering 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.

Each site should have "anonymous boxes" installed for the survey participants to receive feedback from them as to organization of the field survey and convenience of undergoing the participation algorithm in order to understand the situation on the sites and optimize the IBBS in future planning.

14.6. Adverse events identification, management and reporting

All unforeseen problems or adverse events (AEs) will be documented and reported to the national survey group, which in turn will inform the CDC in Ukraine, the Public Health Center and the CDC in Atlanta (Annex 28: Unforeseen circumstances notification form). Serious AEs 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 on serious adverse events). Other AEs will be reported within 72 hours. The survey team will document the events in writing, 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 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 survey group, 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

Potential benefits of participating in the study include receiving the results of rapid tests for HIV, antibodies to HCV and syphilis, as well as monetary renumeration for participation in the study.

Participants do not receive any benefits in the treatment of HIV, hepatitis C, or 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.

14.10. Participants' compensation

The participants of the survey receive monetary compensation for the time spent and travel in the amount of $12 (the amount may be changed 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 MSM. Compensation is paid by a coupon manager after the questionnaire completion, rapid testing and collection of DBS (if necessary). Secondary compensation participants can get for recruiting of eligible MSM from their social network. The amount of secondary compensation will not be less than ½ of the size of the initial one for participation in the survey and will amount to $7.

14.11. Violence or sexual exploitation of minors

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, he does not acquire adult rights earlier. Provision 2.18 of the Code of professional ethics of a sociologist indicates that "*If research 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".

Code of professional ethics of a sociologist was approved by the Fifth Congress of Sociological Association of Ukraine on 20 May 2004. 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 16-17 years during the IBBS, the team will obtain consent to participation in the survey only from the potential participants and not theirs parents.

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*".

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. Most regional NGOs, providing services on harm reduction to key groups, may be the initial services providers to MSM children with special needs, encountered during the survey. If needed the MSM children 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;
- law enforcement agencies.

Documentation on the referral of children 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, being victims of violence, child trafficking or sexual exploitation, the PHC will provide training in necessary counseling and referral skills.

15.DISSEMINATION, NOTIFICATION AND REPORTING OF RESULTS

15.1 Reporting of results

15.1.1. Priority results table

Within one month of the end of data collection and testing of key biomarkers, we will release a table of PEPFAR Priority Results (Annex 38: IBBS MSM 2020 Ukraine Priority results table).

15.1.2. Summary sheet

Within two months of the end of data collection and testing of key biomarkers, we will release a brief summary (6-8 pages) of the main survey findings for each survey population and city that describes:

- Survey objectives
- Survey methods
- Key results including at least:
    - Age
    - PSE
    - HIV prevalence
    - 95-95-95 achievements
    - Viral load suppression
    - STI prevalence
    - Anti-HCV prevalence
    - HCV RNA prevalence among those reactive for anti-HCV who were tested
    - Physical violence
    - Sexual violence
    - Stigma and discrimination
    - Outreach
    - PrEP
- Key programmatic recommendations

15.1.3. Survey report

Within 5 months of the end of data collection and biomarker testing, investigators will develop a comprehensive report inclusive of recommendations from key population members

and organizations. This draft report will be shared with stakeholders for feedback. Their comments will be addressed and integrated in the final report within 6 months of the end of data collection. The final report will be presented by the implementer to stakeholders including, but not limited to, Ministry of Health and other host country government institutions, CDC-Ukraine, key populations organizations and those working with them, CDC Atlanta, WHO, UNAIDS, Global Fund, United Nations Development Program. In collaboration with the implementing partners with whom authorship has been discussed, we will also present results at national and international scientific conferences and prepare scientific manuscripts for submission to peer-reviewed journals.

15.2. Public access

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 the previously authorized users, allowing data use for monitoring.

Within 60 days after the preparation of the final reports, the PHC will publish the data obtained following the conduction of IBBS among MSM 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 a report 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. Scientific articles on the IBBS findings will be published in peer-reviewed journals with full access to the texts in 12 months after publication. 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.

15.3. 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.

Copies of data arrays will be provided to external investigators and the PHC personnel if requested with description of the hypothesis, analysis purposes, and statistical processing. When disseminating data, the survey team will consider the minimum risk of causing damage to

participants, the data at the place of residence will be grouped into larger categories, and the variables that can be used for stigmatization will be removed from the array in public.

Data dissemination is regulated by the managed access model through a data request (Annex 37: Data Request Form).

The data submission process is governed by the PHC's standard data dissemination operating procedures, as well as a formal data access agreement between PHC and the requester. 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 access is for research 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 conclude a data access agreement with PHC, which is obliged to transmit the data under the contract within 10 days. Data transmission 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 array. Upon completion of the requested project, the data, including paper and electronic copies, must be destroyed by the date agreed with PHC.

16. TIMELINE

Activity	2023		2024											
	Q3	Q4	January	February	March	April	May	June	July	August	September	October	November	December
Formation of National Working Group														
Submission and approval of Protocol and toolkit to the Ethics Commission														
Formation of regional groups and personnel														
Meetings with regional groups														
Trainings for personnel														
Formative assessment in oblasts														
Toolkit piloting and finalization														
Survey sites preparation														
Field stage														
Monitoring visits to the sites														
Data clearing and processing														
Behavioral information statistical analysis														
Laboratory analysis of collected biomaterials														
Development of final databases														
Development of IBBS findings reports														
Development of informational materials following survey findings														
Survey findings demonstration														
Data dissemination	Two months after the field stage, the research team prepares preliminary key findings. Six months after the field phase, the research team presents the results to all stakeholders.													

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