# BIOLOGICAL AND BEHAVIORAL SURVEY AMONG MEN WHO HAVE SEX WITH MEN IN UKRAINE (2021)

STUDY PROTOCOL

**Version: 1.8: July 14, 2021**

**Kyiv, Ukraine**

# Contents

# 1. SURVEY OVERVIEW

## 1.1 Protocol summary/Abstract

This protocol describes an HIV biobehavioral survey (BBS) among men who have sex with men (MSM) in Ukraine. The BBS will estimate the burden of HIV and other sexually transmitted infections (STIs), related risk behaviors, service utilization, and population size and inform progress towards reaching UNAIDS {95-95-95} targets. The BBS will utilize respondent-driven sampling (RDS) to recruit participants. App-based, social network-based ("Telefunken"), service multiplier, and successive sampling methods will be used to calculate population size estimates (PSE) in BBS regions; service multiplier method to calculate PSE in oblasts where BBS will not be conducted. The target sample size is 6,900 respondents. The survey is planned to be implemented in 16 cities: Vinnytsia, Dnipro, Mariupol (Donetsk oblast), Zhytomyr, Zaporizhzhia, Ivano-Frankivsk, Kyiv, Kropyvnytskiy, Lviv, Mykolaiv, Odesa, Rivne, Kharkiv, Kherson, Cherkasy, Chernihiv. Persons who are 14 years or older, male, have had one oral or anal sexual contact with a male within the last 6 months, and had been living/working/studying in the survey area for a period of at least 3 months. 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 bacterial STIs. Formative assessment will be conducted as part of this protocol. This will include In-depth interviews (IDIs) 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 programmes among target group.

## 1.2 Investigators and institutional affiliation


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CDC 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.

### 1.3 Funding source

The survey "Biological and Behavioral Surveillance among Men who have Sex with Men in Ukraine (2021)" will be conducted as a component of a SILab Project "Support for the Ministry of Health of Ukraine in HIV epidemiological surveillance and laboratory QM/QI, improvement of strategic information use and public health capacity building within the framework of the US President's Emergency Plan for AIDS Relief (PEPFAR)",

being implemented by the State Institution “Public Health Center of the Ministry of Health of Ukraine” (PHC) with support from the US Centers for Disease Control and Prevention (CDC) (Cooperative agreement number - NU2GGH002168).

The survey is implemented in accordance with the Strategic Plan to ensure sustainability of bio-behavioral surveys in Ukraine (2018-2021).

## 1.4 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

FSW - female sex worker

GAM – UNAIDS Global AIDS Monitoring

HCV – Hepatitis C – an infectious disease caused by the Hepatitis C virus that primarily affects the liver

HIV – human immunodeficiency virus infection

HTS – HIV testing services – medical and psychological counseling of a person in regards to HIV/AIDS and counseling-associated voluntary medical testing of this person for the presence of HIV antibodies

BBS – Integrated Biological and Behavioral Surveillance – cross-sectional behavioral and biological survey connected in time and location with the same respondent

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 intercourses 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)

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

RITA – The Recent Infection Testing Algorithm – a generic name for a number of tests to distinguish recent HIV infections from HIV infections which have been present for some time

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 as a whole.

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

UNAIDS — Joint United Nations Program on HIV/AIDS

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

# 2. BACKGROUND AND JUSTIFICATION

The HIV epidemic is ongoing in the countries of Eastern Europe and Central Asia region (EECA). According to the results of BBS conducted in Ukraine in 2017–2018 among key populations, HIV prevalence among PWID is 22.6%, MSM 7.5%, FSW 5.2% [1]. Additionally, the armed conflict in the East of Ukraine (Donetsk and Luhansk oblasts) affected the territory with the high HIV and TB burden [2].

According to the last population size estimation, there are 179,400 MSM in Ukraine (2018) [3], but other authors estimated the minimum number of MSM to be 242,670 [4].

**HIV prevalence** among MSM in Ukraine is 7.5% (95% CI: 6.8-8.2%), which does not differ statistically from the prevalence in 2016 — 8.5% (95% CI: 7.7-9.4%). The highest prevalence of HIV among MSM was in Donetsk (22.8%), Cherkasy (14.3%), Odesa (13%), Mykolaiv (7.3%) and Kyiv (7.1%). Knowledge of HIV positive status is 59%/ 46% of HIV positive MSM, who know their status, receive ART [5]. HIV prevalence has been increased among MSM under 24 y. o. — from 5% (95% CI: 3.8-6.0%) in 2016 to 6.7% (95% CI: 5.7-7.8%) in 2018. However, comparing older and younger MSM, HIV prevalence is higher among MSM above 25 y. o. — 8% (95% CI: 7.1-8.9%) in 2018 [6].

**Prevalence of anti HCV antibody and STIs.** According to self-reporting during BBS 2017, Hepatitis C — 1.5% [7]. According to the data of BBS 2015, when MSM were tested, 4.2% had anti-Hepatitis C antibodies, and 3% syphilis [8]. Data from the European MSM Internet Survey (EMIS 2017, self-reporting) revealed, that 2% of respondents in Ukraine had cases of syphilis, 2% — gonorrhea, 2% — chlamydia and 4% — human papillomavirus during last year [9].

The previous BBS among MSM was conducted in 2018. Data collected through BBS such as trends in STI, 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 the epidemic tendencies and intensity, as well as cause the spread of HIV among general population, surveillance among the MSM is an important tool for obtaining a realistic assessment of the HIV spread, HIV knowledge, key risk behavioral characteristics of MSM. It also allows to generate data for construction of outcome and impact indicators of the on-going National AIDS Program and for population size estimation. For today, the most recommended approach for obtaining such strategic data is carrying out bio-behavioral survey (BBS). For national HIV program, BBS among MSM will allow both to

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 2021.

# 3. SURVEY GOALS AND OBJECTIVES

The overall goal of the BBS among MSM in Ukraine is to estimate the burden of HIV-related disease, service utilization, population size and assess progress towards reaching 95-95-95 UNAIDS targets.

The objectives of the BBS are:

*Primary objectives:*

(1) To estimate the prevalence of HIV among MSM

(2) To estimate the proportion of viral load suppression (viral load <1000 copies/mL) among MSM HIV-infected.

(3) To estimate the MSM population size

*Secondary objectives:*

(4) To estimate the prevalence of STIs and anti-HCV antibodies

(5) To identify risk factors associated with HIV infection.

(6) To examine HIV service uptake (prevention, treatment) and serostatus knowledge

# 4. SURVEY METHODS

## 4.1. Survey Locations

The survey will be conducted in 16 cities of Ukraine. Please see below for descriptions and rationale for selecting these 16 cities.

## 4.2. Study design

We will collect data using the cross-sectional design. Respondent-driven sampling will be used to recruit MSM in these 16 cities. Behavioral data will be collected using the individual structured interviews. The biological data will be collected using rapid tests for HIV, anti HCV antibody and syphilis and DBS preparation. 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 [10]. 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.

Based on pre-existing contact and in consultation with local NGOs providing services to key population members, survey staff will recruit a handful of diverse and well-networked members of the target population who will serve as seeds (initial study participants) from the MSM population. Seeds receive an incentive for completing all of survey components (primary incentive) and another incentive for recruiting their peers in case, when peers participate in the survey (secondary incentive). Participants are provided with up to three RDS coupons to use in recruiting peers (Annex 9: Survey participant's coupon). RDS coupons contain the Study ID of a respondent and are registered in a special programmatic software to track who recruited whom. Encrypted QR-codes (electronic coupons) contain information about who and by whom is recruited to participate in the survey.

Recruited peers who decide to use their coupon will go to a fixed site to enroll in the survey. The coupons provide non-stigmatizing information about the survey location hours of enrolment and contacts for additional information (Annex 9: Survey participant's coupon). Seeds and subsequent recruited peers who enroll at a fixed location (survey site), complete a screening for eligibility, undergo consent (a detailed explanation of the survey's purpose, possible risks and benefits from participation and anonymity and confidentiality), a behavioral interview, and biological testing with pre-test counselling. Once these steps are completed, each participant (except for those at the very end of the survey) will receive up to three coupons to use in recruiting peers.

The seeds create the first wave of recruitment, and the participants (seeds) of the first wave create the second wave of recruitment, and so on. Ideally, there should be numerous waves of recruitment (>10) in at least one recruitment chain (i. e., the seeds and his or her recruits).

Recruitment progresses until both the sample size is reached and convergence (i. e., stability with respect to the composition of the sample) is achieved. Data collection will be performed using tablets and monitored on daily basis, which will allow making decisions on successful recruitment in real time.

### 4.2.2. Seeds

If a network becomes stuck in one sub-group, then the estimators may become unstable. To overcome this, seeds should have large social networks and know diverse people in order to overcome potential bottlenecks in the population network. 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 BBS MSM in Ukraine 2021 are described below.

| Inclusion criteria | Verification methods |
|---|---|
| Male sex | Visual confirmation by coupon-manager, self-declaration, |
| At least one oral or anal sexual contact with a male within the last 6 month | Self-declaration |
| 14 years old and older as of the survey period | Self-declaration, visual confirmation by coupon-manager |
| Not less than 3 months of residence/work/study in the area where survey is conducted | Self-declaration |

| | |
|---|---|
| Informed consent to participate in all survey components, namely:<br>1) behavioral component: interview;<br>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 | Signed informed consent to participate in the survey |

| **Exclusion criteria*** | **Verification methods** |
|---|---|
| Age under 14 | Self-declaration, visual identification by coupon-manager and/or interviewer |
| Repeated participation in one survey round | Self-declaration, visual identification by coupon-manager and/or interviewer |
| 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 | Visual confirmation by coupon-manager and/or interviewer |

** If recruit meets at least one of thecriterion, 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 three coupons each to use in recruiting other participants (Annex 9: Survey participant's coupon). 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 the survey participants will receive primary incentives of 250 UAH (9$) for enrolment into the study.

Regional teams are responsible for preventing the same participant from participating twice (more than once). Visual inspection will be used for this purpose, as well as the involvement of a representative(s) of the MSM community in the regional data collection team.

Participants who recruit their peers who enroll and complete the survey will receive a secondary incentive 120 UAH (4$) for one 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

According to the “Strategic plan to ensure sustainability of BBS in Ukraine (2018-2021)”[11], the general approach to building the MSM sampling size has been changed from previous BBS MSM data collection.

In connection with the envisaged Measures 1.4.1. “Calculation of the sample size based on the "viral load" variable” and 1.4.2. “Increasing the sample population size within each region to assess the viral load” of the Strategic plan, steps were taken to switch to the calculation of the BBS MSM 2021 sample size based on the Viral Load Suppression. The 2021 sample size was calculated using CDC Sample Size Calculator for Survey-based Viral Load Suppression [12].

Due to the increase in the regional sample size and according to Objective 1.2. “Prioritization of the regions for the BBS conduction in Ukraine” and Measure 1.2.1. “BBS conduction for specified key groups (PWID, SW, MSM, others) in a smaller number of settlements, where it is possible to reach the estimated sample size of 500 persons (according to CDC recommendations)” of the Strategic plan, the number of cities included in this BBS MSM round had to be reduced in order to optimize financial resources.

Since calculations for individual cities (oblast centers and cities with the largest general population) based on the Viral Load Suppression resulted in too big sample size, it was decided to select several clusters of regions (oblasts of Ukraine), for the most important of which to calculate the aggregated sample based on the Viral Load Suppression and to do the same for the aggregated overall sample.

### 4.3.2. Clusters and Geography

The places where BBS 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 a sufficient number of representatives of the target group. Donetsk oblast is represented by Mariupol as the biggest city under the government control and the seat of oblast state administrations. The administrative centers - Donetsk and Luhansk, as well as Simferopol and Sevastopol in Crimea, are excluded from the list of survey cities due to location on the territory not controlled by the government of Ukraine.

There were three main reasons to classify cities between clusters (Table 1):

- HIV prevalence among MSM population according to the last BBS MSM (2017);
- general population size of the cities (with additional considerations as to whether the city is a significant economic and/or cultural center and/or is a point of attraction for internally displaced persons);
- city's proportion of national MSM population according to the last PSE (2017).

HIV prevalence trend (between 2009, 2011, 2013, 2015 and 2017) and broader representation of macro-regions have been considered as additional reasons for the selection between the cities within a cluster.

**Table 1. Distribution of cities by clusters before sample calculation**

| City* | HIV prevalence among MSM, % (2017) | Proportion of the MSM population, % (2017) | Cities with general population over 700,000 of inhabitants | Macro-region | Cluster |
|---|---|---|---|---|---|
| Donetsk | 23 | 4.4 | yes | east | 1 |
| **Cherkasy** | 14 | 2.2 | no | south | 1 |
| **Odesa** | 13 | 7 | yes | south | 1 |
| **Mariupol** | 9 | 1.7 | no | east | 1 |
| **Kyiv** | 7 | 37 | yes | north | 2 |
| **Mykolaiv** | 7 | 3.1 | no | south | 3 |
| **Zaporizhzhia** | 6 | 4.3 | yes | south | 2 |
| **Lviv** | 6 | 5.7 | yes | west | 2 |
| **Kherson** | 6 | 1.6 | no | south | 3 |
| **Vinnitsya** | 5 | 2.4 | no | center | 3 |
| **Dnipro** | 5 | 5.2 | yes | center | 2 |
| **Zhytomyr** | 5 | 0.9 | no | north | 3 |
| **Ivano-Frankivsk** | 4 | 1.5 | no | west | 3 |
| **Kropyvnytskyi** | 4 | 1.2 | no | center | 3 |
| Lutsk | 3 | 0.7 | no | west | 3 |
| Rivne | 3 | 1.7 | no | west | 3 |
| **Poltava** | 2 | 2.7 | no | center | 3 |
| **Kharkiv** | 2 | 9.2 | yes | east | 2 |
| Chernivtsi | 2 | 2 | no | west | 3 |
| Ternopil | 1 | 0.9 | no | west | 3 |
| Uzhhorod | 1 | 0.7 | no | west | 3 |
| Khmelnitskyi | 1 | 1.5 | no | west | 3 |
| **Chernihiv** | 1 | 1 | no | north | 3 |
| Sumy | 0 | 1.2 | no | north | 3 |

*Cities selected for BBS MSM 2021 are in bold.*

This reasoning resulted in the following distribution of the cities, chosen for BBS MSM 2021:

| Cluster | Explanation | Cities, included in the BBS MSM 2021 |
|---|---|---|
| **1** | Cities with the highest HIV prevalence in the previous rounds of BBS MSM | Cherkasy, Odesa, Mariupol)[1] |
| **2** | Cities with the largest general population (over 700.000 of inhabitants) and a large proportion of the MSM population, large economic and cultural centers, and areas of attraction for internally displaced persons | Kyiv, Kharkiv, Dnipro, Lviv, Zaporizhzhia |
| **3** | Cities with the medium HIV-prevalence and smaller proportion of the MSM population | Vinnitsya, Zhytomyr, Ivano-Frankivsk, Kropyvnytskyi, Mykolaiv, Kherson, Poltava, Chernihiv |

So, as opposed to the previous BBS rounds, BBS MSM 2021 will be conducted in only 16 cities of Ukraine.

### 4.3.3. Sample size

The overall aggregated sample size calculated on the basis of the viral suppression is 6,900 participants (Table 2). This sample allows to measure HIV prevalence for each of the city and Viral Load at the level of clusters (Target Confidence Interval 1/2 Width (%) for VLS = 10) and sample in general (Target Confidence Interval 1/2 Width (%) for VLS = 5).

Given that for individual cities (primarily in Cluster 1 and Cluster 3) the recommended sample size represents a significant proportion of the total group size, special measures will be taken to increase the involvement of representatives of the MSM group in the study.

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.

[1] The city of Donetsk was excluded because it is located in an area not controlled by the government of Ukraine.

## Table 2. Sample size calculation

| | HIV prevalence (%), 2017 | Proportion of HIV-pos with VLS (%), 2017 | 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 | Rounded city level sample* |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| All cities included | 7 | 36 | 31 | 41 | 5 | 1.34 | 5 | 95 | 356 | 502 | 6,877 | 6,900 |
| | | | | | | | | | | | | |
| Cluster 1 | 13 | 27 | 17 | 37 | 10 | 2.07 | 5 | 95 | 76 | 165 | 1,279 | 1,400 |
| Cherkasy | | | | | | | | | | | | 400 |
| Odesa | | | | | | | | | | | | 600 |
| Mariupol | | | | | | | | | | | | 400 |
| | | | | | | | | | | | | |
| Cluster 2 | 7 | 47 | 37 | 57 | 10 | 1.23 | 5 | 95 | 96 | 124 | 1,797 | 2,400 |
| Kyiv | | | | | | | | | | | | 600 |
| Kharkiv | | | | | | | | | | | | 450 |
| Dnipro | | | | | | | | | | | | 400 |
| Lviv | | | | | | | | | | | | 500 |
| Zaporizhzhya | | | | | | | | | | | | 450 |
| | | | | | | | | | | | | |
| Cluster 3 | 5 | 17 | 7 | 27 | 10 | 1.14 | 5 | 95 | 54 | 64 | 1,280 | 3,100 |
| Vinnytsya | | | | | | | | | | | | 350 |
| Zhytomyr | | | | | | | | | | | | 450 |
| Ivano-Frankivsk | | | | | | | | | | | | 350 |
| Kropyvnytskyi | | | | | | | | | | | | 400 |
| Mykolaiv | | | | | | | | | | | | 400 |
| Kherson | | | | | | | | | | | | 400 |
| Poltava | | | | | | | | | | | | 350 |
| Chernihiv | | | | | | | | | | | | 400 |

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

# 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, including representatives from:

- Public Health Center of the Ministry of Health
- US Centers for Disease Control and Prevention
- 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 to 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. 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, Regional AIDS clinics and M&E Centers (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.

4. 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;
- Identify the selection criteria for seeds;

- Identify the selection of study sites (locations) where the survey will be administered, and testing will occur.

The formative assessments will be performed by the Regional working groups using qualitative methods, including Key informant interviews.

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 UAH 150 (5$) for the time spent for their participationand related expenditures (for example, transportation costs) (Annex 3: Log of compensation to the key informants (formative assessment stage).

### 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;

- one of the seeds is 25-40 years old, all other seeds are younger than 25 years old and at least one of them younger than 19 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. 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”) [13, 14].

### 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 easily 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.

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 2017), 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. Mykolaiv and Ivano-Frankivsk). Selection will be done by the Regional working groups and will follow the same approach and criteria as selection of RDS seeds.

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 UAH 200 (7$) for the time spent for participation in the survey and related expenditures (for example, transportation costs) (Annex 5: Log of compensation for questionnaire piloting).

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 BBS 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 chosen 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 |
| 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 |
| Interviewer | Clarifying questionnaire items to the respondent, if and when needed |
| Medical specialist | Collection of capillary blood samples, rapid tests, preparation of DBS samples, referral to health care institutions providing medical care for HIV infection |
| Social worker, psychologist | Recruitment and selection of primary respondents, control over the queue at the site and provision of social support |

## 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 BBS 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 BBS.<br>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 dried tube specimens (DTS) described for the content of HIV serological markers.<br>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 BBS; 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 BBS implementation; laboratory testing within the BBS; analysis and use of the BBS findings; the survey quality as to determination of the serological markers, recent infection and viral load of HIV infection. |

Regional coordinator, coupon-manager; interviewer(s) should be trained using tablets and printed forms and materials identical to the ones to be used in the behavioural 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, and interviewer(s) 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 of time.

# 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<br>Healthcare professional | Coupon-manager | Participant, involving coupon-manager | Interviewer |
| 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 health care institutions providing medical care for HIV infection (for HIV-positives) / Referral 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. Enrolment and screening

### 7.2.1. Recruitment and enrollment

Recruitment for MSM in various cities will commence with various seeds. Each MSM seed will receive 3 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 someone you know, and they know you who and he also represent target group".

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 receives 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 enrolment. 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 [15].

### 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

All participants will sign written informed consent to participate in the survey (Annex 10 and 11: Participant's Informed Consent (in Ukrainian and Russian respectively)). 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.

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 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. BBS Data Collection

## 8.1. Behavioral component (interview)

Face-to-face interview will be conducted with all participants, with the use of piloted questionnaire. Questionnaires and other tools will be administered in Ukrainian and Russian languages. 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, the Ukrainian and Russian versions will be adjusted accordingly.

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.

The questionnaire will be read out by the interviewer from the tablet. 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 antibodies and syphilis serological marker detection, two confirmatory rapid tests for HIV (if the result of the first test is positive), filling out 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).

### 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 (for HIV-negative and HIV-positive) is required. Additionally, 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 the sufficient quantity of blood necessary for all the subsequent stages of the survey, making testing algorithm less traumatic and prolonged for participants, and reducing the number of possible medical interventions and ensuring the required amount of capillary blood for all planned tests.

Samples of capillary blood 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, confirmatory second and third HIV rapid tests, filling the DBS cards for further laboratory detection of recent HIV infection and viral load.

**Diagram 1.**
**Graphic representation of HIV-testing algorithm**

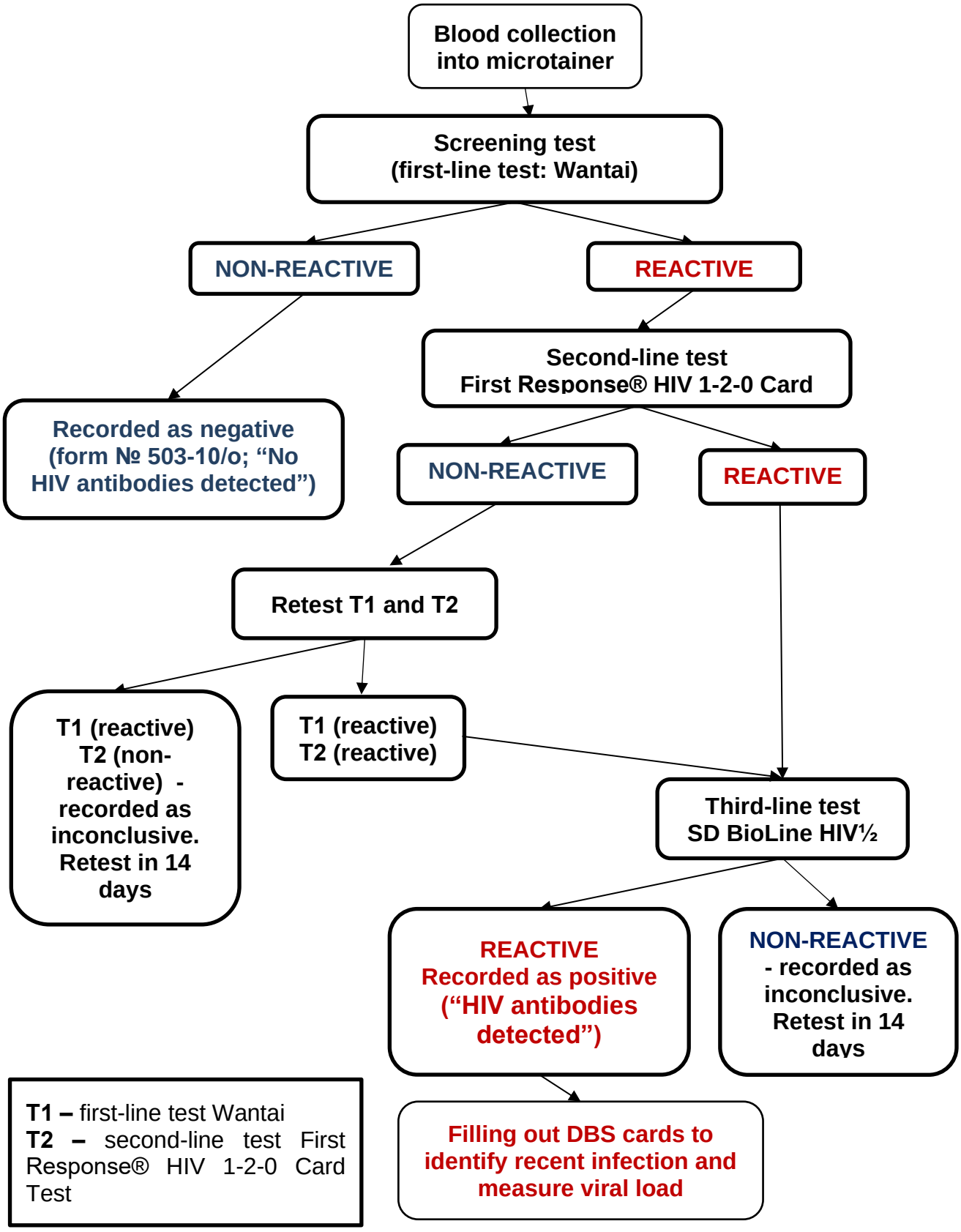
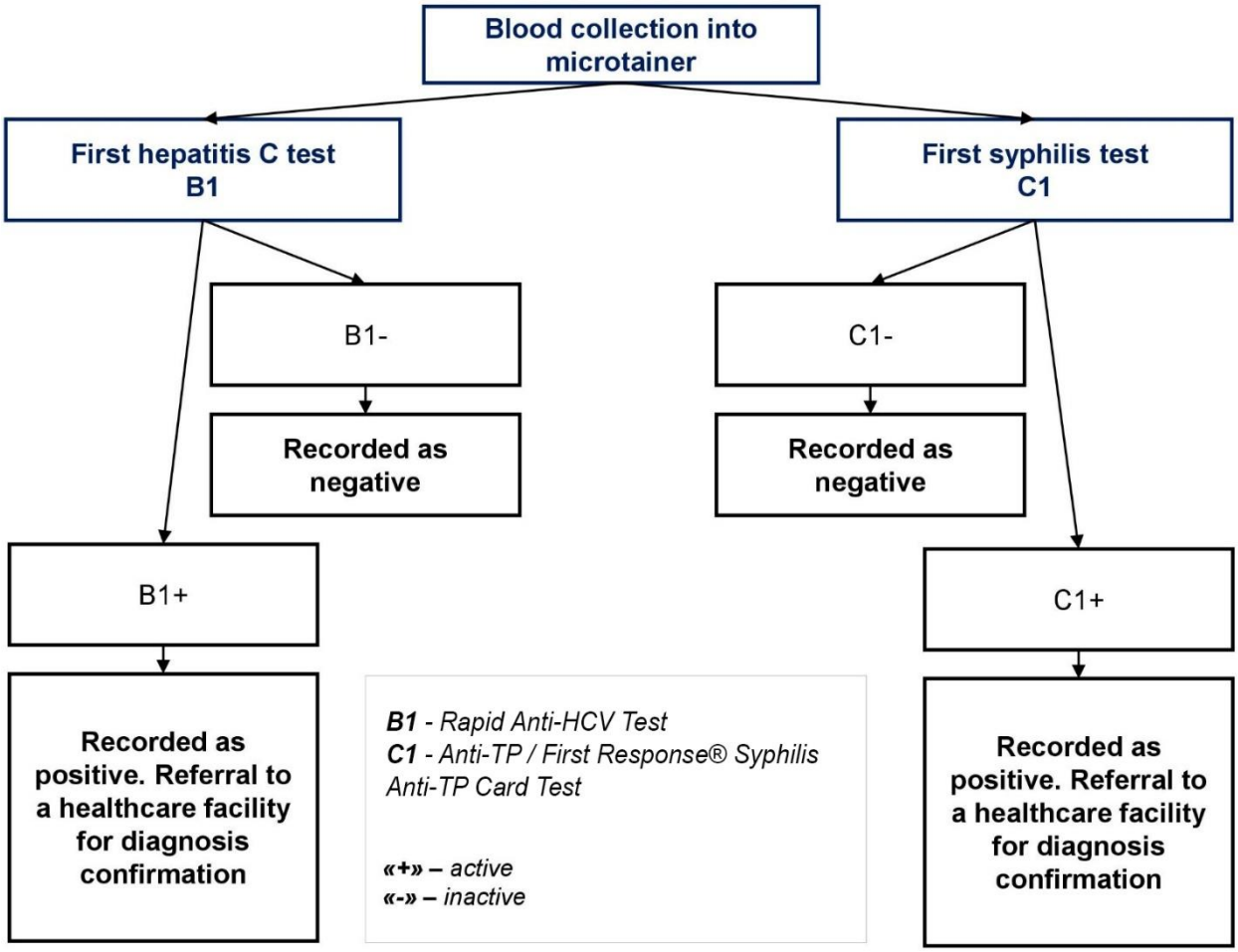


**Diagram 2.**
**Graphic representation of the testing algorithm for anti HCV antibody and syphilis**




### 8.2.3. Rapid anti HCV antibody and Syphilis Testing

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

- Rapid Anti-HCV Test (InTec PRODUCTS);

Anti-TP / First Response® Syphilis Anti-TP Card Test (Premier Medical Corporation).

Healthcare professionals 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 and

syphilis serological markers, the results are recorded as positive and notified to the participant. The participant will be redirected to the healthcare facility for the confirmatory diagnosis;

- 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

Establishment and 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.

### 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 in their questionnaires (Annex 23: DBS registration form).

All stages of the DBS preparation will be conducted in compliance with the SOP (IBSS-05.01, page 19).

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

## 8.3. Laboratory testing

Specimens will be stored in the PHC Reference Laboratory for HIV / AIDS Diagnostics. They will be used to identify recent infection, viral load, and for quality control (to confirm rapid tests results). In addition, the specimens can be used to verify the validation of rapid testing algorithms.

All DBS samples will be tested for recent infection and viral load (VL) in the Reference Laboratory for HIV / AIDS Diagnostics (hereinafter - RLHIV) in accordance with approved procedures in the laboratory (Annex 24: Form of routine forwarding of the DBS samples to the Reference Laboratory).

Results of confirmed recency test along with VL will be returned by the lab to each site coordinator, who in turn will hand them over to local health care institutions providing medical care for HIV infection to which participants will be redirected. A medical specialist informs participants about the possibility of obtaining their results after they have been processed by the laboratory and received by the relevant institutions.

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

## 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 -and third rapid diagnostic test are informed by healthcare workers about the final result (Annex 17: Certificate of HIV test results) and referred on the same day to the nearest 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 (AIDS Center)). 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 groups is linked to care. The reluctance of HIV-positive participants to be registered with a HCF may be an obstacle to starting treatment the same day. Therefore, 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, are involved for their participation in social care and support projects (Annex 19: Social support referral form for the survey participant).

In order to increase the level of linkage to care of HIV-positive participants, it is expected that healthcare workers record contact information from MSM, providing 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.

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

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***

According to the national guidelines on Hepatitis C, diagnosis is made based on the results of laboratory testing. In case of a positive screening rapid test result for anti-HCV antibodies, the participant is consulted on possible viral infections and the need for follow-up examination (Annex 18: Certificate of test results for hepatitis C , syphilis; Annex 21: Registration log of referrals to healthcare facilities). Participants with positive result will be referred to:

- health care institutions providing medical care for HIV infection, (in case of HIV/viral hepatitis co-infection),
- family doctor,
- infectious diseases physician at a clinical diagnostic center at the place of their residence,
- infectious diseases physician at a specialized department of clinical hospital at the place of their residence.

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

Social worker will be accompanying participants who on the rapid tests tested positive with anti-HCV antibodies, to the medical facilities that will be providing free treatment. Due to the fact that diagnosis of hepatitis is expensive for the participant, the research team is looking for additional funding from the partner organizations and donor organizations to pay for confirmatory diagnostics. Two weeks after the end of the field stage, the Regional Coordinator will provide follow-up information on the number of people who got diagnosed and who have refused to be diagnosed; number of people who received treatment, and those, who refused treatment; number of people awaiting treatment and who have started the treatment. All participants will be given informational and promotional materials about the prevention and treatment of the hepatitis C by a coupon manager.

***Syphilis***

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

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

At the stage of formative assessment, the Regional Working Group members, in particular, a regional coordinator and the representatives of health care institutions providing medical care for HIV infection, will prepare a list of facilities for referral.

## 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 (BBS REGIONS)

## 9.1. Methods of calculating the estimated number of MSM

In 2021, the number of MSM will be locally calculated for 16 cities, in which BBS among MSM will be conducted. In the previous rounds of MMS-BBS in Ukraine the main methods to estimate the number of MSM in Ukraine were the multiplier method, capture-recapture and the successive sampling method [16].

Due to the high cost of three-source capture-recapture method using unique objects, which became apparent during the BBS PWID 2020, in BBS MSM 2021, four other methods will be used to estimate the number of MSM in BBS regions, namely: app-based, social network-based (so called “Telefunken” method), service multiplier, and successive sampling methods.

### 9.1.1. App-based (census) method

According to BBS MSM 2017, 72.4% of respondents over the past 6 months have used mobile applications or Internet sites to find male partners. In Ukraine, this is the most popular way to find sexual partners among MSM.

It is planned that PHC will contact (through partner NGOs) the owners of the mobile application "Hornet" (which is the most popular partner search application among MSM in Ukraine) or other similar applications and request the number of unique profiles of the participants active for the last 30 days with geolocation within the territory (radius) around the cities of the BBS MSM.

If the social app administrators are willing to collaborate, we would require them to share the total aggregate, unduplicated, non-identified number of app users in that city over a period of one month. Since the BBS 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. It is tentatively planned to use the method in 5 cities out of 16. The list of cities will be submitted for consideration and approval by the BBS 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. Social network-based (“Telefunken”) method

Estimation of the number of MSM by network-based capture-recapture method will be conducted for the first time in Ukraine. The method was proposed by K. Dombrowski [

17] in 2012, and within it the study participants will be asked to provide information about themselves and their acquaintances (height, weight, hair color and gender) and "telefunken code" (encoded the last three digits of their mobile phone number).

The principle of data encoding and creation of a unique anonymous participant code is as follows:

| Characteristics | Value | Code element |
|---|---|---|
| Three last digits of the phone number | 0, 1, 2, 3, 4 – S (little) | L |
| | 5, 6, 7, 8, 9 – B (big) | B |
| Three last digits of the phone number | 0, 2, 4, 6, 8 – E (even) | E |
| | 1, 3, 5, 7, 9 – O (odd) | O |
| Height | Short | S |
| | Middle | M |
| | High | H |
| Weight | Thin | T |
| | Normal | N |
| | Obese | O |
| Hair | Dark | D |
| | Ginger / red | G |
| | Light | L |
| | White | W |
| | No hair | N |
| Gender | Male | 1 |
| | Female | 2 |

For example, if an MSM is a man of middle height with normal weight and dark hair, and his phone number ends 912, his code will be BLLOEE-MND1.

After completing the survey with each participant (capture), the interviewer asks them the information needed to generate a unique code. The interviewer then asks the participant to randomly

select in their phone the contacts of 5 acquaintances of the MSM aged 14 and older who live in the locality of the study (recapture). If the respondent has less than 5 acquaintances of the MSM who meet the criteria and the number of which is saved in their phone, they name all available contacts. For each of these acquaintances, the respondent generates unique codes following the same pattern.

If the participant does not have a phone number and does not know the phone numbers of his acquaintances, or refuses to provide such data – the interviewer records this information on a general form. The failure rate and the absence of telephones will be taken into account during the final data calculation.

The advantages of this method, compared to others, are: no need for additional resources (the ability to obtain the necessary information to generate codes immediately after the survey) and the anonymity of the participants. To facilitate coding, all interviewers will be trained, and to minimize possible subjectivity while describing characteristics of their acquaintances, reference cards will be provided to participants.

The MSM population size assessment based on network-based capture-recapture method will be calculated using the Lincoln-Peterson formula:

$$O_5 = \frac{(S_1 * S_2)}{R}$$

where:

$O_5$ – MSM population size estimate;

$S_1$ – number of MSM covered by the study with valid telefunken code;

$S_2$ – number of valid telefunken codes indicated by the MSM within the study;

$R$ – number of MSM with telefunken code indicated by other MSM, except for erroneous coincidences.

The variance will be calculated by using the following formula:

$$Var(O_1) = \frac{(S_1 * S_2 * (S_1 - R) * (S_2 - R))}{R^3}$$

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

$$95\%\ CI: O_2 \pm 1.96 * \sqrt{Var}(O_2)$$

### 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 BBS;

$S$ – sample size of MSM within BBS.

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 2021 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, 2020 and June 30, 2021. | SYREX database, ICF "Alliance for Public Health" |
| 2 | Estimation based on the indicator called | 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 |

| | | | | |
|---|---|---|---|---|
| | «Condoms distribution» | | | 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 2020?<br>Were you tested with a rapid test for HIV in non-governmental organization in 2021? | Number of MSM who have been tested with the HIV rapid tests for 2020 and 2021 (separately for each year). | SYREX database, ICF “Alliance for Public Health” |

### 9.1.4. The successive sampling method

This method is based on the Bayesian approach to population estimation using data collected using the RDS method [18].The method evaluates population size using only RDS survey data that are ordered by network size and does not take into account the network structure in the RDS recruiting sequence. It is based on the assumption 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 fourteen? 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. [19].

## 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:

- The coverage of MSM representatives by prevention services provided by NGO is used as a limiting minimum;
- The size of male population of a city aged 15-59 as of January 1, 2021 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 particular methods and to define the most probable range at a regional level. The final estimate of the group size is determined by intersection of the maximum number of separate assessment ranges and by averaging. A method of anchored multiplier, that allows synthesizing several estimates of a group number into a single consensus estimate, is also planned to be approbated. Anchored Multiplier calculator [20], created by the researchers from University of California, San Francisco (UCSF) led by Paul Wesson, uses a Bayesian simulation model to combine empirical estimates. The calculator is suitable for entering data into beta distribution, which reflects data "strength". “Stronger” data (with narrower confidence interval) will have greater impact on the final estimate than “weaker” data (with wider confidence interval).

### 9.2.3. Estimates extrapolation

In 2021, the estimated number of MSM in each BBS city can be determined using the calculation methods stated above. Estimates extrapolation will be conducted to obtain regional estimates. Within extrapolation, populated localities are assumed to have similar characteristics to those cities where BBS has been conducted and where the estimates calculated, therefore they have similar estimated number of a key group members. Consultations with the National Working Group and regional stakeholders will determine whether populated localities comply with a number of criteria, such as: total population, population density, availability of recreational areas, etc. Information on the presence of populated localities with the MSM concentration within oblast where BBS is performed will be obtained from a participants’ survey.

Data of PSE obtained for BBS regions will be later also extrapolated to non-BBS regions based on criteria of similar characteristics (male population, HIV prevalence, economic characteristics etc). The methodology for extrapolation to non-participating regions will be developed in cooperation with Alliance for Public Health and with requested technical assistance from CDC Atlanta HQ. Amendment to the protocol describing detailed approach to extrapolation will be submitted.

# 10. 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 a number of components, namely: data documentation, data dictionary, unique participant's ID, data access, data security.

All BBS 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).

## 10.1. Data documentation

The BBS team uses the following forms and tools:

1. Verbal 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. Participant's Informed Consent (in Russian language)
13. Registration form for refusal to participate in the survey (Non-response form)
14. Questionnaire of refusal to participate in the survey for recruiters
15. Test Results Form
16. Referral form for the survey participant
17. Certificate of HIV test results
18. Certificate of test results for hepatitis C, syphilis

19. Social support referral form for the survey participant
20. Registration log for referrals to health care institution providing medical care for HIV infection (AIDS Center)
21. Registration log of referrals to healthcare facilities
22. Form of rejected DBS samples
23. DBS registration form
24. Form of routine forwarding of the DBS samples to the Reference Laboratory
25. Compensation Log
26. Instructions for a recruiter
27. Data Use and Confidentiality Agreement for personnel
28. Unforeseen circumstances notification form
29. Reporting form on serious adverse events
30. Form of the Protocol deviations
31. Weekly reporting form of the national coordinator
32. Weekly reporting form of the regional coordinator
33. Report of the regional team on the survey findings
34. Report on the monitoring visit to the survey site
35. Fact sheet on understanding recent and long-term HIV infection
36. Information regarding PrEP
37. 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.

## 10.2. 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 |
|---|---|---|---|---|---|---|
| | | | | | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| | | | | | | |

## 10.3. Unique participant's ID

Each participant in BBS has two codes, which helps to ensure data confidentiality and minimize the risk of information disclosure about him.

Each participant on the research site will receive a unique QR-code, which is affixed to the participant's coupon. By scanning in the «PHC_Research», QR-code is entered into blocks: screening, questionnaire, medical testing, test results, primary compensation, coupon dissemination, secondary compensation. QR-code is generated using the sequential generation of letters and numbers for each BBS city, and does not contain any identifying information about the participants.

ID-code is assigned to each participant by coupon manager and is recorded in all documents of BBS. ID-code is generated using the sequential generation of letters and numbers for each BBS city. Using ID-code, it is impossible to identify the participant and his answers to the questionnaire and test results in BBS.

## 10.4. Data access

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

Roles are assigned to selected individuals to create analysis data sets to minimize redundancy. To ensure secure access to data, one-factor authentication for each role and a horizontal hierarchy of access to information are used. Each regional team member only has access to their block in «PHC_Research» software: screening, questionnaire, medical testing, test results, primary compensation, coupon dissemination, secondary compensation. Each block is accessed through verification with the help of a personal login and password, which each representative of the research team has.

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

«Questionnaire» is filled out by the interviewer during the face-to-face interview. Changes to the Questionnaire block are possible after filling in. Changes are made if the respondent decides to

change his / her answer to the questionnaire and informs the interviewer after the interview is completed.

«Medical testing» is completed by a healthcare worker, recording the fact of providing consultation and testing to each BBS 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.

## 10.5. 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 located in his office. During the field stage, the regional coordinator will report on recruiting and the main results of the sampling every week, which will quickly receive information (if any of the documents are lost, it will be possible to restore files inclusively until the current week). The regional coordinator

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

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

# 11. DATA ANALYSIS

The main data analysis will be carried out taking into account the structure of the previous reports on the BBS findings in Ukraine, prepared by the ICF "Alliance of Public Health". Examples of tables to be used in the reports are presented below.

## Prevalence of HIV, anti HCV antibody and syphilis among MSM

| Characteristic | Prevalence… | | |
|---|---|---|---|
| | HIV N (%) | Anti-Hepatitis C N (%) | Syphilis N (%) |
| **Among all** | | | |
| **Age** | | | |
| 14-19 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 | | | |

## 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** | | |
| 14-19 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 | | |
| | | |

## 11.1. 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 14 years old that the respondent has seen over the past 30 days. The indicators obtained in each city will be aggregated into the national wide HIV prevalence indicator. Analysis of HIV prevalence among test participants will include stratification by age, sexual orientation, education, income, LGBTQ NGO client, etc.

## 11.2. 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 BBS 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 (in particular 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%).

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 taken into account using the available software.

## 11.3. Estimation of HIV incidence

The biological component of the BBS provides for receiving the DBS results for recent infection and viral load, to be used for calculation of HIV incidence among MSM. The approaches to the calculation may be additionally agreed with the international experts and statistics specialists. As of now, it's planned to use the approach presented below.

Incidence at the level of each city will be calculated as annual risk (Ia) using the WHO recommended formula according to the 2011 Guidelines "When and how to use assays for recent infection to estimate HIV incidence at a population level":

$$I_a = 1 - \exp\left(-\frac{R - \varepsilon P}{(1-\varepsilon)\omega N}\right)$$

where indicators calculated during the survey:

$N$ – number of HIV-negative survey participants,

$P$ – number of HIV-positive survey participants,

$R$ – number of people classified as RITA (recent infection testing algorithm) positive and calibration parameters are specified as follows:

$\omega$ – is the mean RITA duration specified in units of years (130 days or 0.36 years),

$\varepsilon$ – false rejection rate (FRR) of the RITA (2%).

Confident intervals will be calculated using approximation by the direct derivative search method, which may include an error that is normally distributed and associated with the calibration parameters. The coefficient of variation (Cv) will be calculated according to the formula:

$$C_v = 1 - \exp\left(-\sqrt{\frac{1}{P}\left(\frac{N+P}{N} + \frac{(P-R)\,R\,[1+\varepsilon/(1-\varepsilon)]^2}{[R-\varepsilon/(1-\varepsilon)(P-R)]^2}\right) + \frac{\sigma_\omega^2}{\omega^2} + \frac{\sigma_\varepsilon^2 (P-R)^2}{(1-\varepsilon)^4[R-\varepsilon/(1-\varepsilon)(P-R)]^2}}\right)$$

where:

$\sigma_\omega$ – standard deviation of the mean RITA duration, if normal distribution 0.36 is assumed

$\sigma_\varepsilon$ – standard deviation FRR, if normal distribution 0.41% is assumed.

Confident interval (CI) 95% for $I_a$ is calculated as follows:

$$I_a \pm 1.96 \times I_a C_v$$

The formulas given are not designed for complex BBS data. Therefore, during the calculation of the HIV incidence based on the BBS sample it's necessary to use the sampling scales to the calculated weighted sums of $N'$, $P'$, $R'$ instead of $N$, $P$, $R$ in the calculation of the WHO estimated incidence. It is in line with the objective – at simple random sampling, values used for the estimation equation ($N$, $P$, $R$) are taken from the trinomial distribution, based on the number of HIV-negative respondents ($N$), number of recent infection cases according to the testing data ($R$) and number of HIV-positive old cases ($P - R$). If for the purposes of calculation of $N'$, $R'$ and $P' - R'$ the standard scales are used and divided by total sample size, it's possible to receive valid estimates of shares $\rho N$, $\rho R$ and $\rho P - R$ for trinomial distribution based on the standard sample theory. These indicators will be valid for calculation of estimated incidence, adjusted with consideration of the survey peculiarities.

Calculation of standard error for the estimated value is more complicated, that is two approaches to receive reliable data are planned to be used. For the first approach, the final formula will be used based on the WHO formula with changes made by Anindya De from the CDC/DGHA statistic expert group for the purposes of calculation of the standard errors of estimated incidence in the surveys with complex sampling. This method of application requires standard software for survey data processing to calculate the standard errors for trinomial proportions observed, $\rho N$, ρ$R$ and $\rho P - R$ and connected with them calculations of $N^{'}$, $R^{'}$ and $P^{'} - R^{'}$. Taking this into account, the adjusted formula gives relevant values of the standard error corrected for survey peculiarities which may be used for the calculation of confident interval 95% for annual incidence.

The second approach involves receiving of confident intervals resulted from empirical incidence values distribution based on Monte-Carlo sample method, containing a set of 100 000 or more values of $N^{'}$, $R^{'}$ and $P^{'} - R^{'}$ from relevant trinomial and connected standard errors, corrected for survey peculiarities, as well as values of $\varepsilon$ and $\omega$ samples, with assumption that they were taken from normal distribution with standard deviation $\sigma_{\varepsilon}$ and $\sigma_{\omega}$, accordingly. The limits will be set as the lower 2.5%-tile and the higher 2.5%-tile of the estimated incidence values. It is expected that the limits derived from these two approaches - Anindya De formulas and Monte Carlo sampling - will be very similar to each other. If the similarity is low, the reasons for the discrepancy will be studied, and the subsequent decision on setting the most appropriate limits will be taken.

The report on the BBS findings will include a median incidence estimation and interquartile range observed in different cities among MSM. The median value will be considered as national incidence estimation, and the interquartile range will allow for understanding the variability across the different regions of the country.

## 11.4. Treatment cascade indicators among MSM living with HIV

Data of the BBS among MSM in 2021 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 BBS 2020 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 | 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 |

| | |
|---|---|
| institutions providing medical care for HIV infection | 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.<br>OR<br>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.<br>OR<br>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.

# 12. DATA QUALITY ASSURANCE

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

## 12.1. Preparatory stage

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

## 12.2. Field stage

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

Each regional coordinator 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.

## 12.3. 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 BBS 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, in particular, with regard to 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).

## 12.4. Data processing and analysis stage

Data management at the processing and analysis stage, is carried out in accordance with the BBS 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 BBS findings.

# 13. ETHICAL CONSIDERATIONS

## 13.1. 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; FWA00026980, Expiry date: 20.06.2023 ) 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.

## 13.2. 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).

## 13.3. 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 BBS, 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.

## 13.4. 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 for the organization of re-referral and treatment, which will only be accessible to the healthcare worker of the site.

## 13.5. Survey sites preparation

The survey premises will be selected taking into account the potential risks for participants or survey teams (for example, so that visitors cannot hear answers to questions from the questionnaire or test results of another participant). The team does not disclose the list of sites until the data is collected.

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 BBS in future planning.

## 13.6. 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.

## 13.7. 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.

## 13.8. 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.

## 13.9. Potential benefits

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

## 13.10. Participants' compensation

The participants of the survey receive monetary compensation for the time spent and travel in the amount of UAH 250 (9$) (the amount may be changed based on the results of the formative assessment). Compensation for respondents is not a mandatory requirement for participation in the survey, but it often makes easier to attract hidden and hard-to-reach groups such as MSM. Compensation is paid by a coupon manager after the questionnaire completion, rapid testing and collection of DBS (if necessary). Secondary compensation participants can get for recruiting of eligible MSM from their social network. The amount of secondary compensation will not be less than ½ of the size of the initial one for participation in the survey, and will amount to UAH 120 (4$).

## 13.11. Age of respondents

Target survey group - persons aged 14 years and older. According to the Ukrainian legislation (the Law of Ukraine "On the Protection of Childhood") a child is considered a person under the age of 18 if, according to the applicable legislation, s/he does not acquire adult rights earlier. Provision 2.18 of the Code of professional ethics of a sociologist indicates that "*If a 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)"*

[21]. Code of professional ethics of a sociologist was approved by the Fifth Congress of Sociological Association of Ukraine on 20 May 2004. The detailed analysis of children's involvement as research objects is given in the UNICEF report [22]. Given the minimal risk of research and the fact that it is virtually impossible to conduct research in the case of attempts to obtain parental consent for the participation in the survey of respondents aged 14-17 years during the BBS, the team will obtain consent to participation in the survey from the potential participants.

As to biological component, the legislation of Ukraine guarantees the access to HIV testing without parental consent to all teenagers aged 14 years and older: "*Testing of people aged 14 and older is voluntary, subject to individual informed consent, obtained after previous consultation as to specifics of testing and its results as well as possible consequences, observing the personal data confidentiality, including data on health status*" [23].

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 BBS the PHC will assess the partnership in a sphere of HIV/AIDS at the national and regional levels among national and local authorities, state enterprises, NGOs, international organizations and projects, healthcare facilities with laboratories providing services on HIV infection diagnostic and those providing HIV-related medical care, key communities' leaders, academic institutions and research organizations. The majority of regional NGOs, providing services on harm reduction to key groups, may be the initial services providers to 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.

# 14.DISSEMINATION, NOTIFICATION AND REPORTING OF RESULTS

## 14.1 Reporting of results

### 14.1.1. 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: BBS MSM 2020 Ukraine Priority results table).

### 14.1.2. Summary sheet

Within two months of the end of data collection and testing of key biomarkers, we will release a brief summary (2-4 pages) of the main survey findings for each survey population and city that describes:

- Survey objectives
- Survey methods
- Key results including at least:
    - HIV prevalence
    - 95-95-95 achievements
    - Viral load suppression
    - STI prevalence

    - Population size estimate
- Key programmatic recommendations

### 14.1.3. 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 Programme}. 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.

## 14.2. Public access

The PHC plans to create the Ukrainian BBS 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 BBS among MSM 2020 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 BBS findings will be published in peer-reviewed journals with full access to the texts in 12 months after publication. All scientific articles with the BBS findings or other publications will be pre-agreed with the CDC and will meet the requirements for electronic publications.

## 14.3. Data use and dissemination policy

Dissemination of the BBS 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 take into account 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 BBS 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, have to be destroyed by the date agreed with PHC.

# 15. TIMELINE

| Activity | 2020 | | | | | 2021 | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | August | September | October | November | December | 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 BBS findings reports | | | | | | | | | | | | | | | | | |
| Development of informational materials following survey findings | | | | | | | | | | | | | | | | | |
| Survey findings demonstration | | | | | | | | | | | | | | | | | |

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