

Field implementation

TLS operations manual



UCSF GLOBAL HEALTH SCIENCES

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TLS operations manual

The TLS operations manual is designed to guide project staff during the implementation of behavioral surveillance surveys using time-location sampling. This manual can be adapted for use with other target populations.

This manual will cover

- Procedures for recruitment and enrollment
- Procedures for survey participation
- Roles and responsibilities of staff and survey communication
- Documentation and data management
- Forms for field work

Review the manual during staff training to ensure understanding of roles and responsibilities.

- It is helpful for each staff member to carry a copy of the operations manual with them while in the field.
- Any procedural changes should be documented in writing and attached to the operations manual
- Regular practice sessions and refresher courses help maintain quality of work
- The field staff should be regularly given the opportunity to request clarifications about the implementation of the operations manual

GSI provides technical assistance (TA) in implementing IBBS. Please [visit our website and contact us](#) for trainings and TA.



Men's Health Survey

Integrated biological behavioral survey using time location sampling among men who have sex with men

Operations manual

We would like to thank the San Francisco Department of Public Health's Time Location Sampling Resource Guide for much of the content of this operations manual. The Resource Guide can be accessed from globalhealthsciences.ucsf.edu/prevention-public-health-group/training-resources/hivaids-epidemiologic-surveillance-trainings



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Project overview

This project will measure HIV prevalence, related risk behaviors, and access to prevention and care services among MSM in [INSERT location]. The overall approach is based on standardized methods for IBBS used around the world with adaptations for the local context. A formative assessment phase and multiple methods to estimate the size of the MSM population are included within the survey protocol. Given that MSM are hard to reach, time location sampling (TLS) is proposed to enroll participants, since MSM are accessible at certain venues (e.g. depending on the country context and MSM specific venues). TLS is a sampling method that seeks to approximate probability sampling by mapping the universe of venues where the key population can be found, randomly selecting the day, time, and location for recruitment and systematically selecting participants from the venue. In accordance with ethical standards, informed consent will be required. Stringent safeguards will be implemented to restrict access to all survey forms and documentation. Further, for the protection of participants, staff will not ask for identification for those agreeing to be part of the survey.

Proposed procedures include

- Administration of a risk behavior questionnaire
- Rapid HIV testing with individual diagnosis and disclosure counseling
- Specimen collection and dried blood spot (DBS) preparation
- ELISA testing for HIV
- External quality assessment testing for HIV

The risk behavior questionnaire will be required for participation in the survey. Participants may consent to or decline all other parts of the survey (e.g. rapid HIV testing, sample collection for surveillance testing). Persons testing positive on rapid HIV tests will be referred to collaborating clinics for care and support services. Findings of the survey will be disseminated to stakeholders to advocate for needed services for MSM, develop appropriate prevention and care interventions, guide future research, and assess the impact of the response to the HIV epidemic over time.

Survey objectives

The purpose of the IBBS is to gather in-depth data that can be used to better understand characteristics and behaviors of MSM. The IBBS will provide important information on prevalence of HIV and risk behaviors in this population that will ultimately be used to develop appropriate prevention interventions. Specific objectives include

- Estimate the prevalence of HIV and associated risk behaviors among MSM
- Estimate the population size and distribution of MSM
- Identify and assess determinants of access and utilization of health and social welfare programs among MSM
- Enhance the national capacity to conduct IBBS for key populations as a key component of a strengthened second generation national HIV surveillance system

Survey population

Eligibility for the MSM IBBS includes the following reported criteria

- Biologically male
- Age \geq 18 years
- Able to speak one of the survey languages
- Had anal and/or oral sex with a biological male in the past six months with ability to answer screening questions to verify knowledge of MSM sexual behavior
- Approached by survey staff in designated venue/time
- Capable and willing to provide informed consent to participate

Exclusion criteria

- Previous participation in the survey
- Inability to provide informed consent (including persons incapable of providing consent do to the influence of alcohol or drugs)

Nationality and citizenship will not be inclusion or exclusion criteria under the rationale that foreigners may form part of the MSM population in the survey areas.



Survey sites and sample size

The MSM IBBS will take place in *[INSERT location]*. This was chosen a key location through formative assessment. During formative assessment, various key informants made reference to *[INSERT location]* being a key site for conducting the IBBS. It has a sizeable gay community, with numerous potential venues for TLS, including bars, taverns, restaurants, public parks where MSM are known to meet and socialize. The precise recruitment venue day time periods will be determined prior to IBBS implementation based on information from field work preparation activities.

A sample size of 400 MSM in the survey site is based on providing 80% power to detect a significant ($p < 0.05$) 15% absolute change in self reported condom use between the proposed survey and future rounds of IBBS among MSM using a chi-square test and assuming a design effect of 2.0.

Duration of survey

This surveillance project will start in YYYY with the expectation of all phases being complete within 14 months.

Background

Men who have sex with men (MSM) in sub-Saharan Africa are at high risk for acquiring and transmitting HIV. A recent meta-analysis found African MSM are nearly four times more likely to be HIV infected than the general population. Published studies of MSM from Botswana, Malawi, Namibia, Senegal, South Africa, and Uganda have noted high rates of unprotected anal intercourse (UAI) between men. In addition, the Senegal survey and VCT and vaccine preparedness data from Kenya report HIV prevalence figures for MSM much higher than their corresponding national prevalence estimates. In South Africa, HIV prevalence among Black, peri-urban township MSM was estimated at 13%, and 34% among the sub-set of gay-identified men. Many MSM are using condoms and water-based lubrication inconsistently; few MSM are aware of their HIV status; and among those who are HIV-positive, few are accessing available treatment. Across much of Sub-Saharan Africa, homosexuality is criminalized

to varying degrees, so MSM remain a particularly disadvantaged and marginalized population. Prevailing social attitudes that stigmatize same-sex sexuality further complicate MSM's access to educational and employment opportunities, and the accumulated effects of homonegative experiences contribute to MSM risk behavior.

HIV surveillance has typically focused on the general population; with HIV prevalence estimates calculated using data from antenatal clinics (ANC) and periodic probability-based surveys of the general population. These data provide useful information regarding HIV prevalence in Francisco by region, gender, age, and other socioeconomic and behavioral factors. The most recent national prevalence data suggest there is a stabilizing epidemic with an overall prevalence of 8% among adults 15-49 years and persistent regional variation with higher prevalence in the central and eastern regions and lower prevalence in the west. There is a wide variation in HIV prevalence, with women accounting for more cases than men, rising prevalence in urban areas, and certain high risk populations experiencing higher prevalence rates than the general adult population. While results from surveys of the general population provide valuable information about the HIV prevalence rates in the general population, less is known about the risk of HIV infection among key populations at higher risk for HIV infection, including men who have sex with men (MSM). Less information is therefore available to gauge the specific prevention, care and treatment needs of this population.

Data on HIV infection among key populations at higher risk for HIV infection are limited, although the existence of vulnerable groups and high risk behaviors has been documented. Men who have sex with men (MSM) are a vulnerable population that has been recognized as an at-risk group in the National HIV/AIDS Strategic Plan. As a hard-to-reach population with limited access to health and legal services, MSM are especially vulnerable to the transmission of HIV and other STIs. While seldom prosecuted, there are laws criminalizing homosexuality, and social stigma against MSM is high. In addition to inconsistent use of condoms and water-based lubricants, few MSM are aware of their status, and access to treatment among those who know they are HIV-positive remains low. In addition, many MSM report multiple



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sexual partners within the past year, though not necessarily concurrent partnerships.

Without knowing how many men have sex with men in [*INSERT location*] it is hard to evaluate the impact of MSM on national HIV prevalence or the necessary scope of programs designed to meet the needs of MSM. Some non-governmental organizations currently have programs that work with MSM in the city selected for surveillance. No national systematic population size estimates have been conducted of MSM. MSM are thought to be especially visible within specific urban centers, geographical regions, and specific neighborhoods.

To effectively design HIV/AIDS policies and interventions for MSM, reliable prevalence estimates of HIV and other STIs and related behavioral, social, and environmental risk factors are needed. Further, to appropriately allocate resources, estimates of the number of MSM are needed. This protocol proposes to conduct a cross-sectional survey among MSM in [*INSERT location*] using TLS. We envision that future serial cross-sectional surveys of the same design will be a part of the national behavioral surveillance system that tracks changes in the HIV epidemic among key populations at higher risk for HIV infection and the national response to the epidemic. Data from the formative assessment, the IBBS survey, and the size estimation efforts will enrich our understanding of MSM and their health needs in the local context.

TLS methods background

The following describe TLS methods that will be utilized. Type I and II enumeration as described below will have been conducted during formative assessment activities, this is an iterative process and we will conduct these enumerations again immediately prior to IBBS survey implementation to validate and update formative assessment data, specifically the sampling frame of VDTs.

The mapping portion of the formative assessment will serve to identify all potential venues and times where MSM may be recruited. Venues will be categorized into street locations, dance clubs, bars, taverns, pickup points, commercial establishments, businesses, social organizations, health clubs, and other public places (e.g., parks, beaches). Staff will visit these potential venues during potential times to validate information from formative assessment, carry out standardized

counts of patrons who appear to fit the eligibility criteria (enumeration), conduct brief interviews with venue owners and/or key informants on site, and obtain approval of venue owners or managers to conduct recruitment inside or outside these venues during the implementation phase. Once the initial list of venues and associated day-time periods are identified using the formative assessment venue enumeration form and reviewed by key stakeholders, a sampling frame will be constructed from the set of venues expected to yield at least seven eligible MSM during an average four-hour sampling event. The minimum of eight MSM is selected for cost and logistical reasons. A unique five-digit ID code will be assigned to each venue. The first two digits will identify the venue category and the last three digits will identify the specific venue. Only venue owners who agree to let the research team conduct recruitment inside or outside the venues will be included in the sampling frame.

For venues exclusively attended by MSM, type I enumeration will be conducted by one or two staff members who will count individuals attending venues during 30 to 60 minute periods. Counts produced in a 30-minute period will be multiplied by eight while counts produced in a 60-minute period will be multiplied by four to estimate the number of participants that might attend a four-hour sampling event at a specific venue. Duplicate visits by the same participant will not be counted.

For venues attended by a mix of people, type II enumeration will be conducted by two staff members. One will count individuals consecutively and one will systematically approach and briefly interview MSM on their eligibility to participate in the survey. Counts produced in a 30-minute period will be multiplied by eight while counts produced in a 60-minute period will be multiplied by four to estimate the number of participants attending a venue during a specific venue-date-time event. Duplicate visits by the same participant will not be counted.

The field coordinator will notify the venue owner and manager that the team will conduct the survey one or two weeks prior to recruitment and as soon as the team reaches the venue on the specific day and time. The coordinator will also be responsible in completing the recruitment event checklist, the data corrections log, the enumeration type I, type II, and type III forms, sample of universe venues



form, and the recruitment monitoring form to ensure the appropriate information is collected prior, during and after the recruitment event.

Findings from the formative assessment will be used to inform the best location to interview participants. Typically, TLS interviews are conducted in a mobile van or a private room at the venue. Regardless of the interview location, it will be selected to ensure the anonymity and confidentiality of the participant.

Prior to the launching of the full TLS survey, formative assessment will be conducted.

Ethical principles

Ethical issues related to research involving human subjects are supported by three basic principles considered as the foundation of all regulations and directives guiding ethical studies.¹ These principles are

1. Respect for people (including vulnerable people)
2. Beneficence
3. Justice

Studies involving vulnerable groups demand extra care to provide the protection required by these cases. Children, prisoners and mentally challenged patients are examples of vulnerable groups. This survey of FSW includes people from vulnerable groups such as: persons with low levels of education, poor persons, individuals with difficulty in accessing health services, women, and underage individuals.

Respect for people means recognizing each individual's capability and right to make his own choices and decisions. This principle is associated with the respect for the individual autonomy and self-determination of each human being, recognizing their dignity and liberty. The principle of respect for people is included in the information sheet for informed consent. Informed consent should involve building the individual's capacity to make a voluntary decision, based on relevant information and clarification regarding his

¹ Information retrieved is from Research Ethics Training Curriculum from Family Health International (FHI) accessed from www.fhi360.org/sites/all/libraries/webpages/fhi-retc2/RETCTraditional/intro.html. For further information, please see the manual kept by each field supervisor.

participation in the research. Potential research participants must be able to understand fully all the elements of the informed consent process.

Beneficence places the responsibility for the physical, mental and social welfare of the participant on the investigator, with regards to the survey. Any potential risks must be weighed against potential benefits. The researcher is required to provide information about the risks and benefits of participation to all participants. Recruitment and selection of participants must be done in a fair manner.

Justice forbids placing one group of people at risk solely for the benefit of another. Risks and benefits should be distributed equitably for both potential participants and communities.

Safety during the IBBS

General principles

- Always carry the survey badge, credential or identity card
- Plan ahead
- Always be alert
- Use common sense
- Whenever possible, three members of the survey team should be together in the office during business hours

Plan ahead

- Have an emergency contingency plan
 - Know what to do well ahead of time
 - Know who to contact in an emergency
 - Familiarize yourself with all the exits in the survey office
- Adopt a code word to use in case you need the help of a work colleague
- Be aware of what's going on around you
- Position yourself closer to the exit than participants
- Be friendly to the survey's participants, but also careful if you suspect anything
- Pay attention to your sixth sense



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Common sense

- Limit the quantity of valuable items on site
- Do not carry guns
- Do not work under the influence of alcohol or drugs
- Do not offer or accept gifts from participants or any people visiting the office
- Interrupt the interview at any moment in case of threat

Aggressive participants

- Use calming techniques
 - Let participants pour their heart out
 - Look for opportunities of interaction
 - Listen and acknowledge the participants concerns
 - Avoid being defensive
 - Reply to legitimate complaints
 - Lower your voice tone and volume

Sexual harassment

- Remind participants the purpose of the interview
- If the participant persists in harassing then terminate the interview
- Avoid letting the participants feel shame

Drunk or intoxicated participants

- They are not eligible if they are incoherent during eligibility screening
- If they become incoherent after this time, then thank them for their time and terminate the interview

Protection of electronic equipment

- When not in use, electronic equipment should be stored in a safe location
- Do not leave electronic equipment unattended
- Do not leave participants alone in any room with notebooks and cell phones
- Send encrypted data electronically at the end of each business day

Adverse events

- An adverse event is any event that causes serious physical or psychological damage to a participant in the survey or a staff member, as a result of their participation in the survey. Examples are
 - Violation of confidentiality
 - Harassment or violence
 - Negative reaction from the community (loss of home or job as a result of the participation in the survey)
- Notification of adverse events
 - In case of an adverse event, notify the relevant people/institutions
 - Fill out a report of adverse event form

Biosafety

Measures to be followed during handling of any potentially infectious material

Biosafety

- Always be aware of what you are doing
- Always wash your hands before and after handling any infectious materials
- Always use individual protection equipment like nurse's gowns and gloves to prevent contamination when conducting any activities
- Do not eat, drink and smoke during blood collection
- Use basic protective measures
 - Prevention of pricks, cuts and scratches
 - Protection of wounds and lesions on skin and mucous membranes
- Control contamination of work surfaces by following disinfection procedures
- Properly dispose biohazard waste

Precautions

- Always wear gloves and glasses when handling infected or potentially infected materials or when there is a possibility of exposure and/or contact with this type of material



- Disposal (in appropriate containers) of used gloves, whether they are knowingly contaminated or not
 - Do not touch the eyes, nose, mouth, other mucous membranes and the skin with the gloves
 - Do not leave the work area wearing gloves
 - Immediately wash your hands with plenty of soap after any contact with infected or potentially infected material, and after finishing work. If this contact takes place when wearing gloves, immediately remove the gloves and wash your hands with plenty of soap.
 - Do not open or close doors or handle personal objects while wearing gloves
 - Always use your gown protecting your clothes and wear closed shoes. Do not leave the work area wearing your gown. Try to disinfect your gown with a disinfectant solution before washing.
 - Leave the gown overnight in a receptacle completely covered with a disinfectant solution. Wash it the following morning.
 - Always keep the work room clean, dry, with good ventilation and free from unnecessary materials and furniture
 - Disinfect (with a disinfectant solution based on sodium hypochlorite, see at the end of this section) the work surface (bench or table) whenever you finish a procedure and at the end of the work day
 - Avoid using cutting objects (blades, knives or scissors) to open packages or other purposes. In order to collect samples securely, follow the instructions included in this manual to the letter.
 - Never use your mouth. Always use appropriate accessories (for example, pipette bulbs).
 - Follow all the technical procedures in order to minimize the chance of creating aerosols, droplets and spills
- Initially cover with absorbent materials (gauze, cotton or toilet paper)
 - Pour a disinfectant solution around the area and then over the absorbent material (gauze, cotton or toilet paper) and wait 10 minutes
 - After that time has elapsed, remove the mix of droplet or spill and the absorbent material and place it in a recipient for contaminated materials
 - Clean the surface again with a disinfectant solution
 - Always wear gloves when following these procedures
 - Immediately wash wounds from needle pricks or other puncture objects, cuts, and skin that has been contaminated by droplets or spills from samples, with plenty of soap and water
 - Immediately communicate all accidents (pricks, cuts), droplets/spills involving direct contact of the skin with potentially infected materials to the health unit director
 - Whenever possible, provide counseling to the injured person and provide a medical evaluation (including HIV testing on the spot and after four weeks)

Droplets/spills and accidents

- In case of droplets and spills of potentially infected materials

Handling and disposal of contaminated materials and waste

- Needles from blood collection systems must be placed in the receptacle for puncture materials (provided specifically for the duration of the survey). When full, the receptacles should be incinerated.
- Gloves and other materials used for blood collection must be placed in the plastic bag for biological waste

Survey staff behavior

- Survey staff reflect the image of organizations that collaborate under the survey. As such, all individuals working in the survey must always be presentable, professional and culturally sensitive.
- Staff should exhibit a professional demeanor
 - Abstain from the consumption of alcohol and drugs



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- Do not engage or participate in obscene conversations or behavior
- Do not engage in sexual behaviors or relationships with the MSM found during the investigation
- The participants may insinuate or talk to the interviewer in a sexually suggestive manner. Stay professional and remind participants that the aim of your visit is to share information.
- Survey staff should seek to establish an environment of trust and good relationships with both colleagues and survey participants.
- Interviewers must obtain informed consent from potential participants before starting the interview. Participants should have the opportunity to refuse participation based on an understanding of what they are being asked to do. There should not be no implicit or actual negative consequences for refusing to take part in the survey.
- Participants help the survey team by participating in our survey. They should never feel stigmatized or discriminated. The survey staff should never use pejorative terms to describe other employees or participants.
- It is our responsibility to ensure the protection of participants against any damage that may result from their participation in the survey. This means that we must make an effort to maintain their confidentiality, privacy and anonymity at all times (for example, do not use the names, write personal information that could be found by others, take home survey information with participants names , etc.).
- Field teams should ensure that only survey staff have access to survey information, and that information that may identify participants is separated from the information shared during data collection
- All field staff will sign a confidentiality agreement, by which they undertake to ensure the confidentiality of any personally identifying information about survey participants. The survey staff should not share any verbal communication, notes, or other survey documentation with individuals unrelated to the investigation.

- The interviewers involved in the implementation phase should clearly indicate that they are not healthcare providers and therefore cannot provide advice on health issues. At the end of the interview, survey staff may distribute information leaflets and refer respondents to the relevant health service to seek advice, and appropriate care and treatment;
- Survey staff should not answer questions about the investigation from the press. All media inquiries should be directed to the project coordinator.

Communication during the implementation phase

Communication during the implementation phase and the survey phase must respect the organizational chart of the survey and may vary according to whether the information is technical or logistical/administrative.

- Communication must be done daily using the most convenient means, such as email or by phone calls.
- All technical and logistical or administrative issues arising during field work shall be resolved by the field supervisor. In case a team member faces any difficulty or has any technical or logistics / management issues they should communicate directly with the field supervisor.
- The field supervisor shall report all technical issues they cannot resolve to the IBBS project coordinator. The IBBS project coordinator shall communicate with the principal investigators, as needed, for issues that need further clarification.
- In cases of incidents related to the safety of the survey team, the site supervisor shall, if possible, communicate with the IBBS project coordinator. Immediately afterwards, he/ she will contact local authorities, including the local police and administration. If contact with the project coordinator or principal investigators is not possible, the site supervisor shall immediately contact local authorities, using the most expeditious and convenient means.



National and international media communication

- Survey staff should not grant interviews to journalists or make statements to others about the survey. All members of the survey team who are approached by the media should direct them to the principal investigators who will be happy to speak with them.
- Requests for interviews should be directed to the principal investigators. They will review applications and refer to their respective organizations for the next steps.
- A prepared statement containing the talking points about the survey will be provided to participants at the stakeholder sensitization. This statement should only be distributed in consultation with the survey investigators.
- Any member of the survey team approached by the media should avoid providing details such as the precise location of the venues and key population being surveyed. Refer to the talking points for further guidance.
- Inform them that the survey has the approval by [*INSERT name of IRBs*]
- Highlight that the Ministry of Health authorized this survey.

Talking points

[INSERT talking points

- Who is conducting the survey
- Participation is voluntary and confidentiality is protected
- Objectives of the survey
- Why it is important for your country, etc.]



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Summary of staff responsibilities

Site supervisor

- Supervise the work of the team
- Ensure that field personnel are punctual and have a professional demeanor
- Support the field teams in the identification of suitable sites for the completion of the survey, and to ensure that there is a safe place to store materials and equipment
- Conduct daily debriefings with the team to assess the procedures for data collection, data quality challenges
- Conduct weekly meetings with all investigators to communicate and discuss the results and adjust the planning of the survey, if necessary
- Report any adverse events to the investigators who will report to the bioethics committees
- Manage expenses
- Ensure the availability of all survey materials
- Observe interviews and give feedback to interviewers in order to improve the procedures for data collection and fix problems found by the team
- Prepare and send the files of the interviews (QDS) and reports to the data manager within 24 hours after the completion of the recruitment and interviews
- Store the survey equipment and documents (consent form, field notes, the records of the survey) in a safe place at the end of each day
- Create the monthly fieldwork calendar
- During the sampling event
 - Decide the type of enumeration at each site (line-based, area-based)
 - Organize team
 - Conduct recruitment
 - Ensure security of team
 - Enter the information of participants who are not eligible and who have not given consent to the questionnaire
 - Monitor the quality of recruitment
- Enter the results of rapid tests

- Save the file and send daily to the team in The central office
- Write a daily report of fieldwork

Interviewer

- Support the creation of the monthly sampling calendar
- Ensure that the material is prepared for each sampling event
- Intercept and recruit participants for interviews
- Complete recruitment files
- Track eligibility
- Create individual codes for participants
- Conduct informed consent
- Conduct interviews

Counselor

- Conduct pre-test counseling
- Make fingerprick
- Prepare DBS
- Prepare rapid HIV tests
- Conduct post-test counseling
- Give referrals for participants with positive or indeterminate
- Give prevention information and incentives to participants

Community outreach worker (COW)

- Establish contact with the community
- Keep track of contacts
- Clarify any misunderstandings about the survey in the community. Consult the site supervisor if there are any problems in the community.
- During periods of recruitment
 - Conduct enumeration at the sampling event
 - Direct the interviewers to approach potential participants
 - If necessary, follow up with potential participants for interviews



Pre-implementation phase overview

In TLS, the purpose of the pre-implementation activities is to identify venues where MSM can be recruited and interviewed for the survey

A venue is a public or private location attended by MSM for purposes other than receiving medical, mental health, social or HIV/STI testing or prevention services.

At this stage, the purpose of venue identification and enumeration is to determine whether venues and their associated day-time-periods (VDTs) yield sufficient people to be included within sampling frames. The number of enumerations needed to determine which venues and VDTs to include in a sampling frame depends upon your knowledge of the MSM attendance patterns. For venues that are likely to be well attended, conduct just one enumeration. For other venues and VDTs, plan to conduct at least two type 1 or type 2 enumerations.

Use the information gathered through enumerations and qualitative assessments, such as safety and feasibility of conducting the survey and approval by venue owners to determine whether to include the venue and VDTs in the sampling frame.

At the end of this process, you should have a list of all eligible venues and their associated day-time periods for sampling. From this, a final list

of viable venues will be determined and used to create the monthly sampling frames. While the bulk of the venue-identification effort is done in preparation for sampling, survey staff should be careful to monitor the venues selected and also be able to identify new venues that open during the surveillance period.

Venue identification involves several steps

1. Identify venues through interviews
2. Draw a map of venues
3. Validate information on venues and venue attendees through key informant interviews with community members (who may be members of the MSM population)
4. Interview venue owners or managers to get approval to conduct the survey
5. Conduct type I and/or type II enumeration and observe the venue in operation to assess eligibility

The enumerations form the basis for the construction of the universe of venues. The list includes the name and description of each place of recruitment and times that the MSM frequent each location. We use this list to create the sampling frame. Not all venues in the universe of venues are included in the sampling frame.

Also, map the discrete places that can be used to do the interviews and counseling and testing.

Venue						VDTs		
Venue ID	Mapa ID	Name	Type	Address/Description	Contact/Phone	Mon	Tue	Wed
	MD1	Mercearia	Mercearia					
	MD2	Barraca	Barraca					
	MD3	Barbearia	Barbearia					
	MD4	Bar Zed	Bar					
	MD5	Barbearia Puff Daddy	Barbearia					
	MD6	Retiro de Saudade	Barraca/Quartos					
	MD7	Boutique	Boutique					
	MD8	Alfaiataria	Alfaiataria	Cossem roupa				
	MD9	Barraca Rosialla	Barraca					



6. Identify VDTs in which to conduct the survey
7. From the universe of venues, select venues appropriate for the sampling frame

From the list of venues created, select the sites eligible for inclusion in the sampling frame. Exclude sites where

- The venue owner has not authorized the surveillance team to conduct the sampling event
 - The site is not secure
 - The site does not have at least eight MSM during type 1 or type 2 enumeration
8. If some venues can be aggregated into one, do so
 9. Assign venue identification codes
 10. Create a monthly sampling calendar

Venue identification codes

A venue identification (ID) code is a unique four-digit code that identifies specific venues. Venue ID codes are fixed; that is, new venues may not be given identification codes of venues that have been deleted from sampling frames. The code incorporates codes for the venue category, and the specific venue.

Venue category: The first value of the code identifies the venue category. For example, MSM venues may include:

- A = Salon
- B = Bar
- C=Club
- D=Gym
- E=Park
- F=Street corner
- G=Other type

Specific venue: The remaining three numeric digits of the code identify the specific venue.

Example: The venue ID code E001 represents the first park, C003 represents the third club in the venue universe.

You should create definitions for each venue category because some may have multiple characteristics. One thing to keep in mind when classifying venues is the main purpose or primary activity of the venue.

Sampling calendar

Preparation for implementation

Update the universe of venues and determine which venues are eligible for sampling in the upcoming month by

- Checking the venue in person, if possible, or by phone, to see if some sites / stores have closed, changed the schedule, etc.
- Adding any new locations/establishments uncovered by the survey team. You can include in the survey instrument questions in order to collect information on the participants' locations/establishments in real time.
- Including only the locations that meet the minimum requirements (e.g. safety, minimum number of MSM, and venue owner permission)

Creating a monthly sampling calendar by random selection of venues

The next step is to create a calendar showing the days that are available for sampling events. The first two steps are determined by the needs of the survey personnel and any unique events.

1. Block out those days on the calendar for the upcoming month that staff are unable to conduct recruitment events (e.g., holidays, administrative requirements, etc.)
2. Block days for personnel training or preparation. Normally the team must be available to work evenings and weekends on a regular basis.
3. Remove venues chosen as non-random events from the monthly sampling frame before the next step to ensure they are not selected more than once
4. From the updated sampling frame, randomly choose without replacement the maximum number of venues staff expects to sample in the upcoming month. This can be done using a computerized venue selection program, index cards, a random numbers table, or with a die. Remember, a minimum of 14 recruitment events should be conducted each month.



5. Arrange the set of venues chosen in step 4 in order of increasing number of VDTs such that venues with fewer VDTs are arranged before venues with more
6. Beginning with the venue with the least number of VDTs, randomly select one VDT of that venue. Schedule the time and location of this VDT on the calendar, starting with the first possible day. If no days are available for that VDT, randomly select and schedule on any available day another VDT of the chosen venue.
7. Go to the next venue with the least number of VDTs and randomly select and schedule one VDT in accordance with step 6
8. Continue to randomly select and schedule VDTs from the set of venues arranged in step 5 such that venues with fewer VDTs are scheduled before venues with more. If a venue cannot be scheduled, replace it with another venue randomly selected from the set of venues not chosen in step 4. Randomly select and schedule one VDT of the replacement venue in accordance with step 6.

Scheduling alternate venues

9. From the venue-sampling frame, randomly select a venue with a VDT that **begins** on, within, or at the end of the first scheduled

recruitment event (if possible). Schedule this venue on the calendar as the first alternate for that recruitment event.

10. Repeat step 9 until a second alternate is scheduled (if possible)
11. Repeat steps 9 and 10 until all scheduled recruitment events have two alternates (if possible)
12. Conduct recruitment events in accordance with the calendar and protocol

Practical considerations for the sampling calendar

Sampling event conflicts

Although venues are scheduled for sampling in order of increasing number of sampling periods, as the calendar becomes filled, scheduling conflicts will arise. Sampling events are scheduled on the calendar from the first through the last week. If the sampling period of one venue conflicts with a previously selected venue, that sampling period is scheduled in the following week(s). If no other days are available, then the remaining sampling periods of that venue are randomly selected until an event is scheduled. If there are still conflicts, then venues are randomly selected from the

Sample monthly sampling calendar with a few days blocked off

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
		1	2	3	4	5
6	7	8	9	10	11	12
13	14	15	16	17	18	19
20	21	22	23	24	25	26
27	28	29	30	31		



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venues NOT yet chosen until the sampling calendar is full.

Canceling events

If a sampling event must be cancelled due to lack of staff, sickness, or other reason, the event should be rescheduled or replaced to meet the expected number of monthly sampling events. Events can be replaced by ones that have not been chosen for the month or by **non-random** events.

Alternates

Any sampling event may be unproductive due to various reasons such as inclement weather or sudden venue closures. Therefore, two alternate sampling events are usually scheduled with each primary event. Only venues with sampling periods that begin on, within, or at the end of, the primary venue's sampling period may be scheduled as alternates.

- If the primary venue is unattended or closed, staff may conduct sampling in an alternate venue. However, if there is a low traffic flow, staff must wait at least 30 minutes to determine if interviews are possible before moving to an alternate.
- The same rules apply for using a second alternate. In case the second alternate does not yield any interviews in the first 30 minutes, the field supervisor may choose to stay at the venue or return to the primary venue.
- On occasion, the primary venue and its alternates may not yield any interviews. In that case, the sampling event can be cancelled for the day. This rarely happens.

Non-random events

Sites may purposefully (non-randomly) sample up to a recommended maximum of three *different* venues each month. This will allow staff the flexibility to recruit the key population at events that occur infrequently or become known only a few days before their occurrence (e.g., gay-pride events, TG yearly events, raves, house parties).

- In choosing non-random venues, sites may only select from the set of venues included in the frame that have not already been selected for that month

- At the discretion of the principal investigator or field supervisor, the three non-random venues may be used as either primary or alternate venues, and they may replace scheduled or canceled sampling events.

Definitions of traffic flow

The flow of foot traffic can be defined as the number of possible eligible people who cross an enumeration area in a certain time period (i.e. the enumeration or clicker count). In a 15 minute interval, the flow of traffic is defined as:

- Low flow = <20 clicked
- Medium flow = 21-50 clicked
- High flow = >50 clicked

Flow is used to determine when to move to alternate venues, cease sampling or to adjust enumeration areas. We cover adjusting enumeration areas in upcoming steps.

All of the information generated during random selection and scheduling of sampling events should be kept on file. These documents serve to verify that procedures were followed correctly, avoid doubts in the future about the validity of the data, and help minimize worries about selection bias.

Enumeration during the sampling event

Systematic sampling



Enumerate and intercept each potential participant who cross the enumeration area/line during a four hour period:

1. The COW counts (enumerates) all eligible men passing through the enumeration area / line
2. The COW directs each interviewer to approach, in a systematic way, potential participants who have been enumerated. Potential participants are approached as the interviewers are free and ready to receive participants.

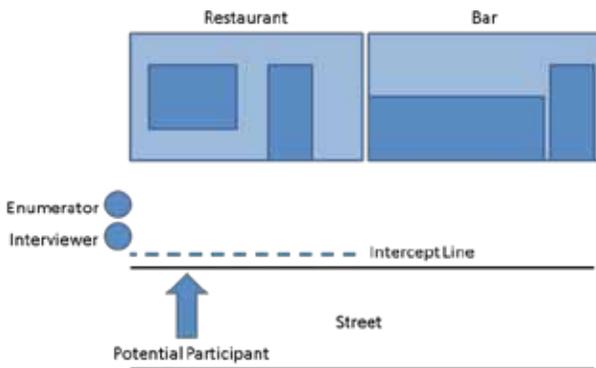


3. The interviewer introduces the survey and assesses the interest of the potential participant, and fills out the type III enumeration form, verifying eligibility
4. The COW continues to enumerate the potential participants even when the interviewers are occupied
5. When the interviewer is free, the next potential participant is intercepted
6. If there are problems, the site supervisor can guide the COW to stop enumerating
7. The enumeration ends after four hours and details of the event are recorded in the type I enumeration form

In general, there are three types of enumerations: line-based, area-based, and moving line.

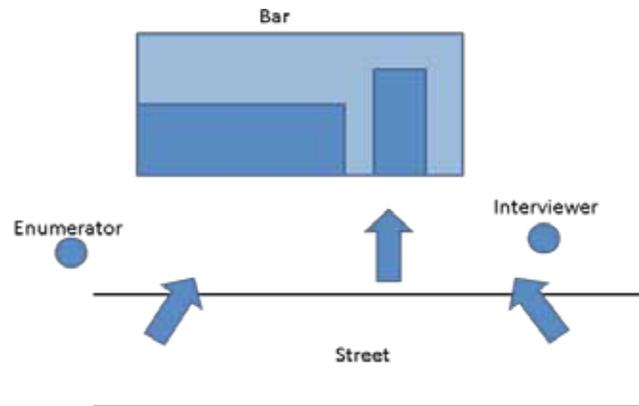
Line-based enumeration

During line-based enumeration, people are counted as they cross an imaginary line for the first time during a sampling event. Line-based enumeration is conducted in locations with high street traffic flow. At locations where the external flow includes a mix of populations, line-based enumerations help identify the MSM.



Area-based enumeration

In the case of area-based enumeration, people are counted when they enter a defined area for the first time during a sampling event. Area-based enumerations work best when there is a low flow of the population. The area can be small or large depending on the venue. In the figure below, all patrons entering the bar are enumerated as they enter the zone of the bar.



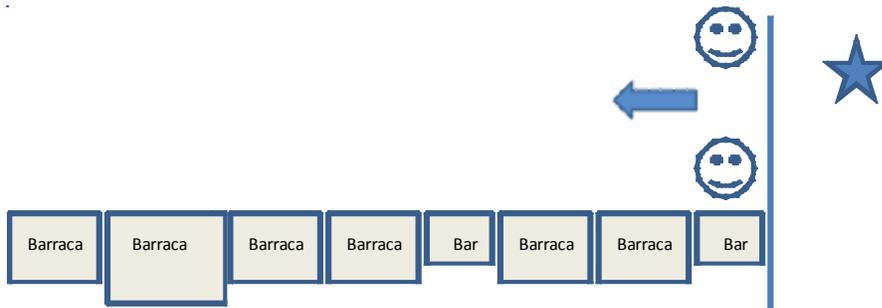


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Imaginary line-based enumeration

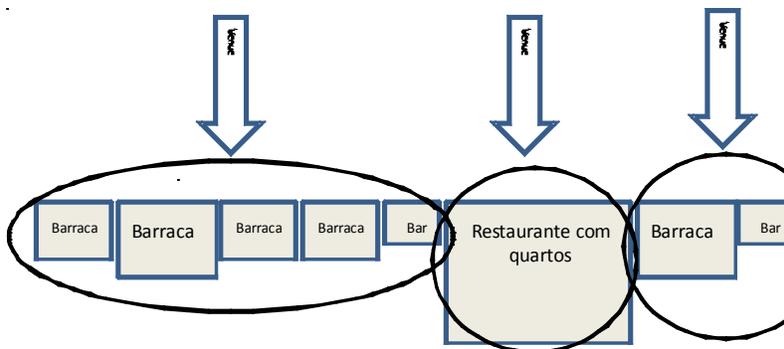
During the recruitment stage, a moving line can be used for enumeration and recruitment. Staff will start at one end of the area and slowly walk side by side through the area. All persons are counted as an imaginary line crosses the people. The figure below shows the start of a moving line enumeration. The star represents the enumerator and the smiley faces represent the interviewers. As the interviewers move through the crowd making intercept approaches, the enumerator systematically counts all MSM in the area.

Within the group, if there is a restaurant, perhaps, as shown in the example above, that on its own produces more than eight MSM in a four hour time block, this should be a separate venue in the venue universe. Likewise, if there is a particular venue where different types of MSM tend to congregate, for example all young MSM tend to eat at Restaurant Z, this should be counted as a separate venue in the venue universe.



Aggregating venues

A location may have many small venues, where there is no physical space to sit down or maybe there is only one table in a bar. In this case, contiguous venues can be grouped together to form one larger venue as shown in the figure below. During type I enumeration, you can see if this group of venues will produce at least eight MSM in a four hour time block.





Sampling event procedures

Summary table of responsibilities and survey procedures

Team members	<ul style="list-style-type: none"> • Prepare for the sampling event (set up tents if necessary)
Gatekeeper	<ul style="list-style-type: none"> • Obtain permission from venue official for use of sites for the enumeration and recruitment of participants • Address questions that the local community may have on the survey • Help the team to solve problems arising during fieldwork • Help participants to complete a survey quality assessment form (survey quality assessment form)
Community outreach worker (COW)	<ul style="list-style-type: none"> • Make a list of potential participants (participation enumeration form) • Guide the respondents in the recruitment of potential participants enumerated
Interviewers	<ul style="list-style-type: none"> • Intercept potential participants (type III enumeration form) • Check eligibility status (participant checklist) • Forward participant to interview area • Create participant UTC (individual participant registration form) • Obtain informed consent (information sheet) • Administer the questionnaire • Escort participants to counselor/nurse
Counselors	<ul style="list-style-type: none"> • Perform pre-test counseling • Perform fingerprick blood sampling • Prepare DBS cards (DBS transfer logbook) • Perform rapid HIV test (rapid test result form) • Perform post-test counseling and referrals (referral cards and referral vouchers) • Deliver prevention material and gifts and thank participant for their time



Site supervisor	<ul style="list-style-type: none">• Oversee procedure compliance by team members using supervision forms. Each day, observe at least one team member among different field teams. (participant supervision form)• Complete the ineligible participant log book (ineligible participant log book)• Complete the rapid test logbook, and enter the data on netbook and send to the data manager (rapid test logbook)• Enter the participants' UTCs in EpiData and copy the updated data onto the netbooks• Complete the survey monitoring logbook (survey monitoring logbook)• Make a backup copy of the questionnaires of each netbook, and send a daily email with data information and send the data to the data manager• Review all records of each participant, separate information sheets and rapid test result and store in a safe location• Lead daily survey team meetings
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Preparation for the sampling event

Prepare the necessary material

The following list of materials must be prepared before a sampling event

- COW
 - Counter
 - Type I enumeration form
- Interviewer
 - Netbook (charged)
 - Paper copy of questionnaire
 - Participant forms: participant checklist, UTC, information sheet for informed consent and rapid test result log book
 - Stickers (cards) for eligible and ineligible participants
 - Type III enumeration form
 - Appointment cards
 - Appointment checklist
 - Copies of approval letters from the bioethics committee and administrative approval
- Counselor
 - HIV testing kits (Determine and Unigold)
 - Ziplock containing: 1 pair of gloves, 1 DBS card, 1 bandage
 - DBS card storage/drying rack
 - Referral cards
 - Incentives and prevention material
 - DBS transfer form
- Site supervisor
 - Abstracts of the survey protocol
 - Brochures about the survey
 - Copies of approval letters from the bioethics committee and administrative approval
 - Quality assessment form
 - Extra equipment
 - Extra pens
 - Extra forms

- Paper copies of questionnaire
- Extra netbook
- Rapid test result form
- Ineligible participant log book and stickers for ineligible participants

Creating an enumeration area

- Arrive at least ½ hour in advance to set up the enumeration area and figure out locations for interviews and counseling and testing. Refer to the data collected during type I and type II enumeration during the pre-implementation phase. Re-assess the enumeration area and make a decision for the sampling event.
- Upon arriving at the venue, the team must inform the venue managers/employees that they intend to conduct a survey on location
- The community outreach worker/enumerator can begin enumeration, which consists of counting every potentially eligible person, once the entire team is ready to recruit participants
- Stop counting as soon as the last person is recruited during the sampling event

Each site will have unique physical characteristics. These characteristics must be taken into account when deciding on the placement and type of enumeration area and the number of personnel needed to adequately cover the area.



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Local gatekeeper procedures

Summary of procedures

- Inform venue officials of the dates on which the enumeration and recruitment of participants will take place at their site
- Probe on how the investigation is being received by the community
- Clarify questions that the local community may have on the survey, if any

Obtain permission from venue officials

Material required

- Abstracts of the survey protocol
- Brochure on the survey

Procedures

- Greet the owner or manager of the venue identified for the sampling event and inform them of the date on which the site was selected for enumeration and recruitment of participants
- Ensure that the enumeration and recruitment processes will not interfere with the normal activities of the venue
- Remind the owner/manager that the survey has the support of local government
- Provide an information leaflet about the survey and address questions, if any

Probe on community reception

Materials

- Survey assessment forms

Procedures

- Provide the survey participants a survey assessment form and explain how the participant should complete it.

- Without arousing public attention, keep an eye on the community's reaction to the survey (venue officials, local vendors, MSM and others);
- Inform the field supervisor and survey team during daily meetings on how the survey is being received by the community;
- Clarify questions the community may have in relation to the investigation. Addressing questions will be the responsibility of survey investigators upon being informed by the coordinator on what happened.



COW procedures

Summary of procedures

- Enumerate (count) all men who pass through the area /interception line
- Direct each interviewer to systematically intercept potential participants counted
- Continue to enumerate the potential participants even when the interviewers are busy
- If there are problems, the survey coordinator may direct you to stop enumerating
- The process ends after four hours and details of the event are recorded in the enumeration form

Enumeration of potential participants

Material required

- Enumerator form
- Manual counter
- Watch

Procedures

- Complete the enumeration form, inserting the enumerator ID, event #, name of venue/site, date of the sampling event, start time and end time of the event, day of week and # of people enumerated (click counted)
- Enumerate all potential participants. Potential participants are listed as they cross a line interception, enter an interception area or are sitting/ standing in a location – these people should be enumerated using a moving line. Use only one type of enumeration for each sampling event.
- Ask any interviewer who is free to intercept a recruit. Even when interviewers are busy with the participants, continue enumerating potential participants.

Completion or interruption of the enumeration

Procedures

- After four hours, conclude the enumeration process, tell interviewers that no more interceptions are needed and complete the enumeration form
- If there are problems, the field supervisor can direct you to terminate the enumeration. Inform the interviewers about closure of the enumeration process on that site.



Summary of procedures

- Approach a potential participant as directed by the COW, briefly explain the survey and determine participant's interest in participating in the survey
- If the participant is interested, check eligibility status
- If eligible, take participant to a private/discreet location for an interview
- Create the UTC
- Obtain informed consent. Complete two copies of the information sheet. The interviewer signs the information sheet. Keep a copy in the participant's folder and give the other to the participant to keep. Record the consent on netbook and participant checklist.
- If the participant has not given their consent, complete the participant verification form and write "not consented" in the participant's folder. Go back to recruit the next MSM as directed by the COW.
- If the participant consents to the interview, administer the interview and clarify any questions. Use reference materials during the interview (condoms, lubricants) when necessary.
- When the interview is completed, if the participant has not given consent to the DBS and/or rapid test, explain the importance of these procedures and ask for consent again. If the participant consents at this point, note this change in the consent form (participant signs) and participant checklist form.
- At the end of the interview, thank the participant and escort him to the counselor

Approaching potential participants

Material required

- Narrative description of the recruitment process
- Survey brochures

- Type III enumeration form

Procedures

- Approach the potential participant and greet them as directed by COW
- Present survey briefly, highlighting the following information contained in the survey leaflet
 - Survey objectives
 - Survey procedures: interview, counseling, sampling for testing in the central laboratory
 - Confidentiality and data protection
- Create a rapport with the recruit, using a strategic approach and prepare to circumvent any reasons given for not participating
- Complete the type III enumeration form for all persons approached
- Ask all eligibility verification questions. Each question must be asked exactly as it is written. Checking eligibility status will help you know if a recruit is eligible or not eligible for the survey

Checking survey eligibility status

Material required

- Participant checklist form
- Appointment card
- Appointment checklist

Procedures

- If the recruit meets the survey eligibility criteria, take them to a private and secure place for an interview. In the participant checklist form, complete in the eligibility verified (interviewer) space, place an "x" in Yes and write your initials.
- If the participant refuses to do the interview at that time, try to schedule an alternative time for the interview on the same day, give them an interview appointment card, and complete the appointment checklist
- If the participant cannot do the interview on the same day, try to schedule another day and time to do the interview, give them an



interview appointment card, and complete the appointment form

- If the recruit is not eligible
 - Tell the recruit that unfortunately they cannot participate in the survey. Do not tell the recruit the reason for which they are not eligible for the survey. You can say it was the computer that determined it. There will be no interview or sample collection for this person and no survey coupon will be given to them. The survey ends here for this potential participant.
- The field supervisor gives the recruit prevention material and some condoms
- Complete the participation checklist form, in space 1, eligibility verified

Creating the UTC

Material required

- UTC Form
- Participant checklist form

Procedures

- For eligible participants, complete UTC. The UTC serves to
 - Check if the participant participated in any previous survey or not
 - Check the “identity” of the participant;
- The UTC is created from a series of questions
 - Province of birth of the participant
 - Mother’s first name of the participant
 - Day of birth of the participant
 - Participant shoe size
 - Month of birth of the participant
- Describe some physical characteristics of the participant in the UTC form. If the participant does not want or show difficulties or is reluctant to answer these questions, explain that this is the only way to check if they have participated before.
- Check the UTC in EpiData
- Complete space 2 in the participant checklist form, UTC created

- Save all UTC records for the day in a safe location, and send them to the site supervisor at the end of each day

Obtaining informed consent

No interviews, counseling, or blood sampling will be made without first obtaining the informed consent of the participant. Informed consent is important because it is an opportunity for the participant to know the objectives of the investigation, the procedures through which they will pass, the risks and benefits of participation. All this information that will allow them to make a conscious decision to participate or not in the survey. Informed consent is also evidence that the procedures of the survey were made voluntarily by the participant.

Material required

- Information sheet script
- Information sheet for informed consent (2 copies)
- Digital recorder containing the audio recorded consent in English
- Participant checklist form
- Netbook

Procedures

- Using the information sheet script, provide the participant information on the survey.
- Probe to check whether the participant understood the information
- The interviewer signs the two copies of the information sheet. Keep a copy in the participant’s folder and give the other one to the participant.
- Record the consent in the netbook and participant checklist form
- If the participant has not given their consent, complete the participant checklist form and insert not consented in the participant’s folder. Give him condoms, lubricants and reference material and go back to recruit the next MSM
- If the participant has consented to the interview, note the change in the participation



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checklist form and go to the next step:
administering the survey questionnaire

Administering the survey questionnaire

Material required

- Netbook (make sure the battery is charged)
- Paper copy of questionnaire and pen as back-up
- Participant folder (containing two copies of the information sheet for informed consent, screening form)

Procedures

- Complete the interview in netbook or on paper-based questionnaire
- When the interview is completed, if the participant has not given consent to the DBS and/or rapid test, explain the importance of these procedures and ask for consent again. If the participant consents at this point, note this change in the consent form (participant signs) and participant checklist form.
- At the end of the interview, thank the participant and escort him to the counselor

Other things to remember

- If possible, keep the netbook connected to AC power during the interview to ensure that the battery is not exhausted
- Try to create a rapport with the participant and make them feel at ease
- If a participant is disturbed for any reason, stay calm, apologize for any inconvenience caused and inform the coordinator
- If the participant does not want to use the netbook in the interview, explain that the method is secure and confidential, and that it facilitates the interview process. If he refuses to use the Netbook, use the paper-based questionnaire as a last resort.
- Record all problems that may arise in the course of the interview (skip errors, lack of responses in categories, etc.), and discuss with

the coordinator and colleagues during team meetings

- **REMEMBER:** The participants' responses to the questionnaire are confidential. Do not share personal information provided by the participant with others, including survey team members.



Field supervisor procedures

Summary of responsibilities of the site supervisor

The field supervisor is responsible for managing all of the day-to-day activities at the survey site, including recruitment of participants, eligibility verification, registration of participants, data collection (interviews and biological samples), HIV rapid tests, referrals for care and follow-up treatment, offering incentives to participants and management of survey data and records. The field supervisor is also responsible for direct supervision of field staff during the execution of the survey.

Daily

- Ensure that there is laboratory equipment, forms, equipment and other materials needed for each working day
- Enter the participant UTCs in EpiData and copy data onto the interviewers' netbooks
- Enter the ineligible participants' UTCs in the participant checklist form and ineligible participants' logbook, complete the ineligible participants' logbook, and enter data on ineligible participants in QDS and complete the log book
- Copy information on rapid test forms on to the rapid test logbook and enter the data from the site rapid test result log book
- Make a backup copy of the questionnaires in each netbook
- Review survey forms completed during the sampling event and complete the monitoring form and sent to the data manager
- Every day, send the following in ZIP format with password to the data manager with cc to the country manager and country coordinator
 - QDS questionnaires
 - Recruitment monitoring log book
 - Rapid test results
- Supervise staff using the supervision forms. Each day, observe at least watch a different member of the team.
- Oversee procedure compliance by team members using supervision forms. Each day observe at least one team member for quality of interview data collection.
- Lead daily team meetings and drafts minutes of the same

Weekly

- Check the DBS packaging quality, complete the DBS transfer form and deliver the samples along with the logbook to be sent to the central office
- Collect (without reading) survey quality assessments and send to the central office
- Write a weekly supervision report and send via email
- Manage survey supplies and request the material required at survey site in advance

When necessary

- Complete the adverse incident report
- Complete the questionnaire data change request form
- Get in touch immediately with the data manager, the country coordinator or survey manager by phone, in case of any question regarding the procedures

Manage stock and order materials

- Provide for use in the survey site, all the material necessary for the survey process, including questionnaires, incentives for participants (cash and credit recharges for mobile phones), survey forms, sample collection kits, etc.
 - At the beginning of each week, make an inventory of the items existing at the survey site and make a list of items to be "refilled" or ordered.
 - Coordinate supplying survey material to the survey sites with the survey investigators
 - Presented a list of materials needed for each site



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- Notify the survey manager or the country coordinator in advance when the amount of any material is reduced
- Manage, distribute and account for survey participants' incentives. The forms to be completed include the participant form, participant reimbursement form and participant reimbursement logbook.
- Protect all of the survey data and equipment (e.g., computers, netbook and USB flash drives used at the survey site)
 - All data must be password protected and accessed only by authorized users
 - Keep all the survey equipment in a closed and secure location at the survey site
 - The survey phone must be password protected
- Survey equipment maintenance
 - Because there may be power cut at any time, keep all netbooks which are not being used in stand-by mode or completely shut down
 - Save netbook batteries by darkening the screen brightness to low levels
 - Ensure that survey laptop and phone batteries are being loaded during use and at night, if necessary
 - Do not install any software that is not used for the survey
 - Do not turn off your anti-virus software
- In each interviewer's netbook, replace the old file with the updated one
- Enter the UTCs of ineligible participants in the participant checklist form and ineligible participant logbook, complete the ineligible participant logbook, and enter ineligible participant data in QDS and complete the log book

Material required

- Site supervisor's netbook
- Interviewers' netbooks
- USB flash drive
- Participant checklist form for ineligible participants or participants who did not give their consent to the survey
- Ineligible participant checklist
- Stickers for ineligible participants

Procedures

- Collect, every day, all logbooks for ineligible participants, or participants who did not give their consent to the survey
- On each ineligible participant's form, insert a sticker
- Insert a second sticker on the ineligible participant form and complete the logbook
- Enter each participant's forms in the coordinator's computer

Enter participant UTCs

Material required

- Site supervisor's netbook
- Interviewers' netbooks
- Information sheet for informed consent
- USB flash drive

Procedures

- Collect all UTCs of the day
- Enter UTCs in EpiData
- Copy the file onto the USB flash drive

Enter rapid HIV test forms

Material required

- Field Supervisor's netbook
- Site rapid test result forms
- Ineligible participant logbook

Procedures

- Collect all site rapid test results forms of the day
- Based on rapid test result form, complete the Rapid Test Logbook.
- Enter the data in the Rapid Test Logbook in the Coordinator's netbook.



Make a backup copy of the questionnaires in each netbook

Material required

- Field supervisor's netbook
- Interviewers' netbooks
- USB flash drives

Procedures

Surveys on paper

- The interviewers should fill in the paper interview questionnaires and hand them over to you immediately after the interview
- Check all interview questionnaires for accuracy and completeness of the information provided, and consult the interviewer and/or participant for any corrections before the participant leaves the survey site
- Enter all the data of the interviews on paper into the netbook before close of business each day (this will automatically convert them into computerized interviews)
- Store the data in a safe location

Netbook surveys

- Interviewers must fill in and save all the computerized questionnaires. At the end of each interview, they should respond "Yes" when asked if they wish to save the document or not.

On each computer/netbook

- Rename and copy each QAD interview document to the flash drive
 - Standard naming procedure: Rename the document with the name of the survey site, the number of the computer, followed by the date of the interview and the name of the survey. For example: MSM20120228
 - MSM = Survey on the Health of MSM
03 = Computer 03
Interview date = 20120228
[YearMonthDay]
 - Insert the flash drive into the netbook
 - Copy the renamed file into the flash. Do not delete the document in the netbook

until the copies are emailed to the data manager.

- Follow every step above in all netbooks used each day
- Copy the renamed files in the flash drive to the main computer of the survey site (local supervisor's computer)
 - Move all the renamed files to the folder C:\MTS. The files of all the previous interview days will be displayed here.
 - Check if every file in the netbook was properly transferred to the main computer. For example: If computers 2 and 3 were used on that day, make sure that two separate files (one for computer 2 and another for computer 3) display on the main computer for that day.

Review survey forms

Material required

- Supervisor's netbook
- Type I enumeration form (with COW)
- Type III enumeration form (with interviewers)

Procedures

- Collect enumeration forms used in the sampling event from the COW
- Collect type III enumeration forms from interviewers
- Open the file "MSM_Monitoring Registry.xls"
- Complete the monitoring logbook using the information in type III enumeration forms and sampling event enumeration form
 - Example of performance criteria
 - Collect data for at least two months and a maximum of four months
 - Complete 15 sampling events per month
 - A minimum of eight participants per sampling event
 - Complete 100% of sampling events
 - Cover $\geq 90\%$ of MSM in a sampling event



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- Interviewing \geq 75% of eligible MSM
- Prepare DBS samples for at least 80% of the participants
- Obtain at least 400 participants
- Cross-check to verify whether the data manager has received all interviews
 - Check your email for confirmation from the central office to verify that each completed interview has been received on the previous day
 - Work with the interviewer to fix any inconsistencies

Conduct data transmission

The site supervisor ensures ensure that the following documents are sent from the survey site, duly completed, to the data manager with cc to the country manager and country coordinator

- Records of interviews with questionnaires (at the end of each working day)
- Record of rapid HIV test results entered in EpiData (at the end of each working day)
- Record of monitoring data entered in Excel (at the end of each working day)
- Report on the activities of the participants (at the end of each recruitment week)
- Sample transfer forms (at the end of each recruitment week)

Data transfer to the central office

- Protect the file using the data encryption software
- Send each file by email to the central office
- In the subject line, write in site name interview date of the files you are sending
- Include an interview submission form in your email. This form will provide a list of the numbers of the coupons used that day and the results
 - Eligible participants and interviews conducted
 - Ineligible
 - Eligible but did not participate
 - Eligible, but the interview ended before the end of the survey
- Delete files from netbooks and flash drive
 - Once you have verified that all files were successfully emailed to the central office, you can delete the files from both netbooks and flash drive
 - Netbooks: Delete only the renamed file. Do not delete the file QAD used to administer new interviews.

Supervise staff

- Work in collaboration with survey staff (COW, interviewers and counselors/nurses) in the implementation and supervision of participant recruitment and data management
- Observe up to 10% of the interviews and provide feedback to interviewers about their interviewing skills. This should be done only with the verbal consent of the participant.

Lead meetings and notify of adverse events

- Conduct daily debriefing sessions with the survey team to identify the problems experienced, solutions or processes that must be implemented and plan for the next day's activities. Draft minutes of meetings.
- The supervisor will also serve as liaison between ongoing activities at the survey site and investigators from partner institutions. Remain in constant communication with the project coordinator and principal investigators, if necessary. Have weekly debriefing meetings with the investigators, either in person or by phone, for an update on the current activities at the survey site.
- Be familiar with who to contact in case of occurrence of various types of emergencies. Have the phone numbers of police stations, the local emergency department, the local hospital, and the survey investigators pre-programmed on your phone.
- Be familiar with the types of adverse events that must be reported in order to make a proper communication of the same, if any
- Have a thorough understanding of both the survey protocol and operating manuals, and ensure the faithful execution of



these documents, as well as quality for all components of the survey

Oversee laboratory/test procedures

- Coordinate with counselors on-site to ensure that all DBS cards are sent to the central office. You are responsible for checking DBS transfer forms, as well as the quality of the DBS packaging before transfer to the national lab.
- Monitor performance criteria on an event- by- event basis to provide feedback to survey staff in order to achieve the most successful site data collection possible. Share progress reports with survey staff so they can contribute to achieving those objectives.



TLS operations manual

Counselor procedures

Summary of procedures

- Explain the counseling procedures
- Conduct the health orientation and pre-testing counseling
- Place the labels with the laboratory's code in the lab materials
- Prick the finger and fills a test tube with blood from the finger
- Prepare two filter papers for dried blood spot (DBS) sampling with blood from the finger
- Conduct the HIV rapid test [*Determine*] with blood from the finger
- If the Determine test is positive, conduct the HIV confirmation test [*UNIGOLD*] with blood from the test tube
- Give the result of the HIV test to the participant and provide post-test counseling and referral
- Next morning: store the DBS specimens from the previous day
- Once a week: prepare the DBS specimens to send to the testing lab

Explain the counseling and testing procedures

Required supplies

- Samples of DBS Cards
- Samples of rapid test cards
- Lancet for demonstration

Procedures

- Explain the steps of the HIV health counseling and testing
 - Health orientation
 - Pre-test counseling
 - Finger prick and dried blood spot (DBS) preparation for HIV testing and other related tests in the lab.
 - Rapid HIV testing

- Post-test counseling
- Answer any of the participant's questions

Conduct HIV orientation and pre-test counseling

Required supplies

- Participant's folder
- Information sheets

Procedures

- Inform the participant about signs and symptoms, HIV and STD means of transmission and prevention in general, and focus on FSW
- Speak about the importance of and the means to reduce the risk of STD and HIV infection
- Provide information about health services available to people living with HIV and AIDS, people infected with STD, and FSW living with HIV/AIDS/STD
- Provide information about the available services or organizations providing support to FSW
- Raise the participant's awareness about the importance of counseling and testing for HIV and the use of available health and social services
- Speak to the participant about risk behaviors for HIV and STD
- Speak to the participant about how she can prevent infections by HIV and STD
- Explain to the participant what the rapid HIV tests and the tests in the INS are
- Tell her the pros and cons of doing the rapid HIV test
- If the participant has not previously given her informed consent, ask for her consent to draw blood for the rapid tests and the lab tests
 - For participants who accept doing the DBS but refuse to do the HIV rapid test, offer them the opportunity to do the HIV test without recording any of the information about the test results in the survey forms. If the participant accepts, the conduct the test without recording the results in the



forms. In the space for Comments in the rapid tests results sheet and in the rapid tests record book the note “not recorded”.

- In case of refusal, thank the participant for her time, gives her the participation gift and prevention materials and escorts her to the receptionist

Label materials

Required supplies

- Adhesive labels
- Participant’s folder
- DBS cards
- Rapid test results book
- DBS samples sheet

Procedures

In each participant’s folder there are five adhesive labels with the participant’s lab code. These labels will be placed on the following materials. The codes should be used in sequential order, starting with code 001 until code 450.

1. 2 DBS filter paper cards (write on the paper the date and age of the participant)
2. 1 DBS sample sheet
3. 1 rapid test results sheet
4. 1 rapid test results book
5. 1 participant checklist



Prick the finger

Required supplies

- Disposable gloves
- Cotton dipped in alcohol
- Lancet
- Cotton
- Band-Aid
- Trash bags for non-puncture materials
- Plastic container for puncture materials

- Test tube
- 2 DBS filter cards
- One pen

Procedures

- Number the DBS filter cards with adhesive labels N° 1 and N° 2 and write the date and age of the participant on the filter paper with a pen
- Put on the disposable gloves
- Have the participant sit with her finger pointing down
- Draw the blood to the tip of the finger
- With the cotton dipped in alcohol, disinfect the puncture site
- Remove the lancet cover
- Press the lancet against the tip of the finger and wait until it clicks
- Place the test tube in the puncture site and fill it with blood

Prepare the DBS

Required supplies

- 2 DBS blood collection cards with adhesive labels and the date and age of the participant
- DBS drying rack

Procedures

- Check that the two blood collection cards have the adhesive label, the date and the age of the participant
- Holding the DBS filter paper N° 1 with one hand (without letting the paper touch the table or the station), apply one drop of blood from the finger to each circle in the filter paper
- Let the blood flow freely and be absorbed in each circle, never repeating applications in one spot of the paper



- Place the filter paper N° 1 in one compartment of the drying rack
- Holding the DBS filter paper N° 2 with one hand (without letting the paper touch the table or the station), apply one drop of blood to each circle in the filter paper
- Place the filter paper N° 2 in the compartment below filter paper N° 1 in the drying rack
- Allow them to air dry horizontally
- Keep the specimens away from heat, air conditioning, lights, direct sunlight and humidity
- **NEVER TOUCH THE BLOOD CIRCLES!**

Conduct the rapid Determine test²

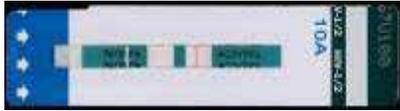
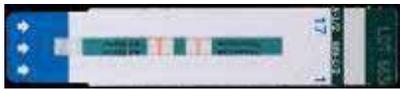
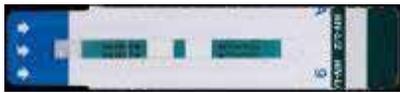
Required supplies

- Chronometer
- Determine kit
- Determine chase buffer drop
- Pen
- Rapid test results sheet
- Rapid test results book

Procedures

- Before pricking the finger, remove one Determine individual test, remove the aluminum paper and place it in a flat and clean spot
- After pricking the finger and filling one test tube and the DBS cards with blood, place 1 drop of blood in the window box of the Determine test
- Apply 1 drop of the chase buffer to the specimen pad
- Set the chronometer for 15 minutes and wait to read the result
- Dispose of the supplies used in the plastic bag for non-puncture supplies
- If a pink or red line does not appear in the test window box, repeat the test

² This is an example of an HIV testing algorithm. Adapt all testing algorithms in this protocol to your own country.

Determine	Unigold	Result
		Negative
		Positive
		Invalid



- Record the result in the rapid test results sheet. The rapid tests results sheet will be removed from the participant's folder after the rapid test and placed in the results sheets file in sequential order using the participant's coupon number, and only nurses, counselor and supervisor can have access to that file. The file will be locked in a safe drawer at the end of each day.
 - Record the result in the rapid test result book. The rapid test results book will also only be accessible to nurses, counselor and supervisors. These records will also be locked in a safe drawer at the end of each day.
 - PAY ATTENTION AND DO NOT MIX THE DILUENTS AND THE TESTS!**

Conduct the Unigold rapid test (only for positive Determine)

Required supplies

- Test tube with blood
- Chronometer
- Unigold kit
- Drop of chase buffer of the Unigold
- Pen
- Rapid test results sheet
- Rapid test results book

Procedures

- Remove the Unigold test from the cover and place it in a flat and clean spot
- Using the test tube with blood, apply 2 drops of blood to the test area
- Apply 2 drops of the wash solution
- Mark 10 minutes in the chronometer and wait to read the results
- If a pink or red line does not appear in the test window box, repeat the test
- Record the result in the rapid test results sheet
- Record the result in the rapid test results book
 - PAY ATTENTION AND DO NOT MIX THE DILUENTS AND THE TESTS!**

- DO NOT READ THE RESULTS OF THE UNIGOLD TEST AFTER 20 MINUTES!**

Conduct post-test counseling and referral for positives

Required supplies

- Pen
- Prevention materials
- Gift
- Referral guide
- Rapid test results sheet
- Rapid test results book

Procedures

- Prepare the participant for the results of the rapid HIV tests
- Tell her the results of the rapid HIV tests and explain what they mean
 - If the result is HIV-negative: Talk to the participant about how she can remain HIV-free
 - If the result is HIV-positive: Talk to the participant about where to seek additional care, treatment and support; tell her the action plan, including how to live well with HIV, avoid infecting sexual partners and her own re-infection
- Fill out a referral sheet and hand it to the participant [*INSERT a copy here of the local referral sheet, if applicable*]. Do not include the participant's name or address in the sheet. Remember that the survey is anonymous.

HEALTH SURVEY REFERRAL SLIP

Site:

Coupon number:

Reason for referral:

Name of counselor referring:

Contact number of counselor referring:



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- Fill in a referral card. Explain to the participant that she should hand over this card along with the referral sheet and that the health unit will keep all the cards so that we can know how many people visited the health units referred by the survey.
- Clarify any doubts and answer the participant's questions
- Give her the prevention materials and the gift
- Thank the participant and escort her to the reception desk
- Place ten small ZIPLOCK bags with the wax paper envelopes in a large ZIPLOCK bag and add 20 desiccant packets and one humidity indicator card
- Store the specimens in a safe location, away from heat, lamps, direct sunlight and humidity until shipment
- Fill in the DBS specimen shipment notice
- Hand it all to the supervisor once a week
- The supervisor should check if the specimens are well stored and accurately recorded in the DBS shipment notice and prepare package for specimen shipment, delivering it to the specimen shipment company once a week

Store and prepare DBS specimens

Required supplies

- 2 DBS filter papers with blood drops
- Specimen shipment notice
- Disposable rubber gloves
- Permanent marker
- Cooler for storing specimens
- Desiccant
- Humidity indicator cards
- Wax paper envelopes
- Small ZIPLOCK bags
- Large ZIPLOCK bags

Procedures

- Every morning, remove from the drying rack the DBS filter papers you placed the day before
- Insert each filter paper into one wax paper envelope
- Place the two wax paper envelopes with the filter papers with the same code of the same participant in a small ZIPLOCK bag. Add ten desiccant packets and one humidity indicator card.
- Write down on the outside of the small ZIPLOCK bag the code of the specimens and number of DBS prepared that correspond to that code
- In each small ZIPLOCK bag you can place a total of ten DBS (which would be two DBS for each of five participants)

- **CHECK THAT THE SPECIMEN IS DRY BEFORE STORING**
- **DO NOT TOUCH THE DRIED BLOOD DROPS WHILE YOU'RE HANDLING THE DBS SPECIMENS**
- **REMOVE ALL THE AIR FROM THE ZIPLOCKS BAGS BEFORE CLOSING AND CHECK THAT THE ZIPLOCKS BAGS ARE REALLY CLOSED**
- **CHECK THAT THE RECIPIENTS OF THE HUMIDITY INDICATOR CARDS AND DESICCANT PACKET ARE TIGHTLY CLOSED**
- **IF THE 30% HUMIDITY INDICATOR CARDS ARE PINK, ADD AT LEAST FIVE MORE DESICCANT PACKETS IN EACH ZIPLOCK**



Participant folder

Participant checklist

Coupon number			
Lab code (attached by the counselor)		Attach lab code here	
1st visit			
Today's date (DD-MM-YY)		(DD-MM-YY) _____ - _____ - _____	
Time		Entrance: _____ Exit: _____	
		Staff initials	Comments
1. Validate coupon (CM) Verify in the coupon registry that this coupon has not yet been used. If it has not been used, write 'USED' on the coupon and put it in the box labeled 'USED COUPONS'. If the coupon has been used, write 'NOT VALID' on the coupon.		Valid:	Not valid: Why is it not valid?
2. Complete screening questionnaire (CM)		Eligible:	Not eligible: Why not eligible?
3. Create a UTC (CM)		UTC created: <input type="checkbox"/> Yes <input type="checkbox"/> No	
4. netbook and couple registry (CM) UTC in registry (CM)		UTC in netbook (RDSCM): <input type="checkbox"/> Yes <input type="checkbox"/> No UTC in coupon registry: <input type="checkbox"/> Yes <input type="checkbox"/> No	
5. Review & sign information sheet for informed consent (Interviewer)		Which components consented to: <input type="checkbox"/> Interview <input type="checkbox"/> HIV rapid test <input type="checkbox"/> DBS	
6. Behavioral survey (Interviewer)		Complete: <input type="checkbox"/> Yes <input type="checkbox"/> No If no, why?	
7. Pre-test counseling for HIV (Counselor)		Counseling complete: <input type="checkbox"/> Yes <input type="checkbox"/> No	
8. Biometric (Counselor)		Fingerprick complete: <input type="checkbox"/> Yes <input type="checkbox"/> No	
9. DBS prepared: <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2		10. HIV red: <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2	



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10. HIV rapid test (Counselor)		Rapid test complete: <input type="checkbox"/> Yes <input type="checkbox"/> No
11. Record HIV test results (Counselor)		Test results recorded: <input type="checkbox"/> Yes <input type="checkbox"/> No
12. Specimen labeling/documentation and prep for transport (Counselor)		Registered: <input type="checkbox"/> Yes <input type="checkbox"/> No
13. Issue RDS coupons (CM)		Coupon #: Coupon #: Coupon #:
14. Give incentive to participant (Supervisor)		Incentive given: <input type="checkbox"/> Yes <input type="checkbox"/> No
15. HIV post-test counseling and HIV test results disclosure and referrals (Counselor)		Complete: <input type="checkbox"/> Yes <input type="checkbox"/> No
16. Prevention literature, materials, and snack (Counselor)		Complete: <input type="checkbox"/> Yes <input type="checkbox"/> No

DO NOT WRITE THE RESULT OF THE HIV TEST ON THIS FORM!



Participant folder

Unique testing code

Instructions: Ask each question to the participant and fill in the boxes to the right of each line with two letters or digits.

SAY: "I would like to ask you a few questions with easy to remember answers. We will ask you these same questions when you next visit this survey, so we can check who you are. We do this to make sure we are giving compensation to you and not someone else. Please remember your answers and provide the same answers on your next visit."

Province of birth (or abroad for foreigners)

If the participant doesn't know, write 'ZZ'

[INSERT provinces with code]

<input type="text"/>	<input type="text"/>
L	L

The first two letters of your mother's first name

If the participant doesn't know, write 'ZZ'

<input type="text"/>	<input type="text"/>
L	L

Day of birth

For example, January 9 would be 09

If the participant doesn't know, write '99'

<input type="text"/>	<input type="text"/>
#	#

Shoe size

If the participant doesn't know, write '99'

<input type="text"/>	<input type="text"/>
#	#

Month of birth

If the participant doesn't know, write '99'

<input type="text"/>	<input type="text"/>
L	L

- | | |
|---------------|----------------|
| JA = January | JL = July |
| FE = February | AG = August |
| MA = March | SE = September |
| AB = April | OU = October |
| MI = May | NO = November |
| JU = June | DE = December |

Instructions: Transfer the numbers and letters from the boxes above to the boxes below. Enter only one letter of number per box. Check if the above and below entries match exactly. The unique testing code (UTC) should have three letters (from A to Z) and four numbers (0-9). Insert this UTC in the coupon registration along with the date of the first visit. The date of the first visit may be used to check the identity in case of UTC duplication.

Unique testing code (UTC)

<input type="text"/>									
L	L	L	L	#	#	#	#	L	L



Information sheet for verbal informed consent for IBBS-MSM TLS survey

Men's Health Monitoring Survey

Survey information sheet for informed consent
(Flesch-Kincaid grade level: 6.5)

Title of survey: Men's Health Monitoring Survey

Principal investigators: [LIST here]

The name of this survey is the Men's Health Monitoring Survey. This paper tells you about the survey. A counselor will also talk about the survey with you today. We want you to ask **ANY** question about **ANY** part of the survey that you do not understand. After you understand the survey, we will ask you to decide if you want to be in any part of it, or not. We will give you this paper to take home with you.

You can choose if you want to be in the survey or not. If you say yes, you can also later choose to say no at any time you want to. You do not have to do all the survey.

Why do we do this survey?

Many adults have HIV and other diseases from sex. This survey is to find out what adults do that can make them get HIV and other diseases from sex. In this survey, we will learn about types of sex men who have sex with men have, the way people act to people that have HIV, and the use of alcohol and drugs. We will also know how many men who have sex with men (MSM) have HIV. This survey will help the ministry of health and its partners know more about HIV. Then they can make programs that can help prevent HIV. These programs teach people to use condoms all the time. They give counseling and testing for HIV. They help people with HIV live a healthy life.

You were invited to do the survey because you may be at risk for HIV. Only the interviewer who asks you the questions will know the answer you give. Your name or identity will not be asked at any time.

What will happen if I choose to do this survey?

This survey will take less than 90 minutes of your time. In this time you will

- Get a survey code so nobody can know who you are. The code is made of a mixture of letters and numbers known only to you.
- Take a survey with a trained interviewer. The interviewer will ask some info like your age and habits. The interviewer will ask about alcohol and drugs, sex and sex partners, HIV and diseases from sex, and health care.
- Get information about HIV prevention, HIV testing, and HIV treatment
- Have a fingerprick to do an HIV test and to put some drops of blood on a card that will be sent to the national lab for HIV tests. You can be in the survey and not do the HIV test or the card with the blood spots.
- Receive the test results with a trained counselor who will help you make a plan that is best for you, and talk about treatment options and medical referrals if needed
- Get a gift worth approximately [INSERT incentive amount here] for being in the survey today. You will get this gift even if you do not do all parts of the survey.



What risks may I have from being in the survey?

There may be some risks or discomforts from being in this survey.

- The most important risk is that someone you know can see you coming to the survey and treat you badly because they do not understand what this survey is for. Although the information from this survey is not shared with anyone, this could still occur. If you know the interviewer, you may ask for another interviewer so that you can feel comfortable that the information you tell is won't be known to anybody you know.
- There is a small chance that someone outside of the survey staff could find out about your HIV test results and you experience bad treatment. But we have taken many steps to make sure that this does not ever happen.
- The survey includes personal questions about sex and other private things that may make you feel uncomfortable or embarrassed. If any question makes you feel uncomfortable or embarrassed, you can refuse to answer it, and you can terminate the interview at any time. Doing this will not have bad consequences for you, and you will not be asked to leave the survey because of this request.
- A fingerprick may hurt and will make you bleed. You may feel faint but this is very rare. To make it not hurt so much the nurses have been trained especially to do this.
- If you test positive for HIV you may feel anxious or depressed. The counselors working for this survey can help you with these feelings. You may also be referred to local counselors or support groups to help you with these feelings.

Are there any benefits from taking part in this survey?

Yes. If you choose to be in this survey, you can receive

- Free counseling and testing for HIV and learn your test results
- Referral to clinics that can provide you with medical care and/or treatment as needed
- Free condoms, lubricant, and educational information on HIV and STIs
- There is also a benefit to health professionals and others in your community who will learn more about who is most at risk for HIV and STIs to help plan better education, prevention, and medical programs

Does it cost me for me to be in the survey?

It does not cost anything to be in this survey.

Will I be compensated for taking part in the survey?

You will be offered a snack, and a hygiene and prevention kit worth approximately [*INSERT incentive amount here*] for your time and effort today.

What if I want to stop being in the survey?

You can stop being in the survey at any time. You can choose to be in all parts of the survey, or only some of them. We will give you a chance to do this at the end of this form. Also, you may be asked to leave the survey if we feel it is best for you or you are not able to do the survey.

Will my information be kept a secret from others?

Being in a survey may involve you telling someone things about you that are private. But, this is a survey that other people cannot know that it is you that shared this information. To make sure that nobody knows it was you that gave the information

- We never ask for your name or write it on any survey documents, lab tests, or specimens
- Only a survey number will be placed on your survey, survey records, and laboratory specimens



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- All the written information you give us will be kept in a file cabinet that is locked at all times
- Nothing about your health status or your test results will be told to anyone except the researchers in this survey
- We do the survey in a space that nobody can see or hear you except the person doing the survey

Who can answer my questions about the survey?

You can ask the survey staff any questions that you have at any time. You may also contact the people in charge of this survey.

[ADD contact here: name, phone, email]

If you have any questions about your rights as a survey participant, about ethical matters, or wish to complain you can call [ADD bioethics committee contact information here], who reviewed and approved this survey.

Interviewer: Answer the participant's questions about the survey before proceeding to the informed consent authorization.

INFORMED CONSENT AUTHORIZATION

Interviewer: Ask participant to document response to each question by checking the appropriate box.

Participants may consent or decline each part of the survey.

1. Do you agree to participate in part or all of the survey or do you decline participation?

- 1. YES, agree to participate in part or all of the survey.
- 2. NO, decline to participate. [if NO participant not eligible to participate].

If declined:

We're interested in knowing why people do not want to do this survey. Would you mind telling me which of the following best describes the reason you do not want to do this survey?

- I don't have time q 1
- I don't want to talk about these topics q 2
- Some other reason; Specify _____ q 3
- I would rather not say why q 9

2. Do you agree or decline to complete the survey questionnaire?

- 1. YES, agree.
- 2. NO, decline. [if NO participant not eligible to participate].

3. Do you agree to a fingerprick to prepare a blood sample that will be sent to the national laboratory for additional HIV-related testing?

- 1. YES, agree.
- 2. NO, decline.

4. Do you agree to rapid HIV testing to receive your results today?

- 1. YES, agree.
- 2. NO, decline.



I have explained to the participant the survey purpose and procedures and we have discussed all the risks involved. The participant has read this document or had the document read to them.

The participant has agreed to participate in the above procedures (as marked).

- I have informed the participant about the nature, conduct, benefits and risks of this survey
- I have informed the participant that the results of the survey including personal details regarding sex, age, HIV status will be anonymously processed into a survey report
- I have informed the participant that they may, at any stage during the interview, without prejudice, withdraw consent and participation in the survey
- The participant has been given the chance to ask any questions and I have answered to the best of my ability

Name of person obtaining consent _____

Signature of person obtaining consent _____

Date ___/___/___ Time ___/___

- Copy to:
- Participant
 - Investigator's file



Information sheet for written informed consent for IBBS-MSM TLS survey

Men's Health Monitoring Survey

Survey information sheet for informed consent
(Flesch-Kincaid grade level: 6.5)

Title of survey: Men's Health Monitoring Survey

Principal investigators: [LIST here]

The name of this survey is the Men's Health Monitoring Survey. This paper tells you about the survey. A counselor will also talk about the survey with you today. We want you to ask **ANY** question about **ANY** part of the survey that you do not understand. After you understand the survey, we will ask you to decide if you want to be in any part of it, or not. We will give you this paper to take home with you.

You can choose if you want to be in the survey or not. If you say yes, you can also later choose to say no at any time you want to. You do not have to do all the survey.

Why do we do this survey?

Many adults have HIV and other diseases from sex. This survey is to find out what adults do that can make them get HIV and other diseases from sex. In this survey, we will learn about types of sex men who have sex with men have, the way people act to people that have HIV, and the use of alcohol and drugs. We will also know how many men who have sex with men (MSM) have HIV. This survey will help the ministry of health and its partners know more about HIV. Then they can make programs that can help prevent HIV. These programs teach people to use condoms all the time. They give counseling and testing for HIV. They help people with HIV live a healthy life.

You were invited to do the survey because you may be at risk for HIV. Only the interviewer who asks you the questions will know the answer you give. Your name or identity will not be asked at any time.

What will happen if I choose to do this survey?

This survey will take less than 90 minutes of your time. In this time you will

- Get a survey code so nobody can know who you are. The code is made of a mixture of letters and numbers known only to you.
- Take a survey with a trained interviewer. The interviewer will ask some info like your age and habits. The interviewer will ask about alcohol and drugs, sex and sex partners, HIV and diseases from sex, and health care.
- Get information about HIV prevention, HIV testing, and HIV treatment
- Have a fingerprick to do an HIV test and to put some drops of blood on a card that will be sent to the national lab for HIV tests. You can be in the survey and not do the HIV test or the card with the blood spots.
- Receive the test results with a trained counselor who will help you make a plan that is best for you, and talk about treatment options and medical referrals if needed
- Get a gift worth approximately [INSERT incentive amount here] for being in the survey today. You will get this gift even if you do not do all parts of the survey.



What risks may I have from being in the survey?

There may be some risks or discomforts from being in this survey.

- The most important risk is that someone you know can see you coming to the survey and treat you badly because they do not understand what this survey is for. Although the information from this survey is not shared with anyone, this could still occur. If you know the interviewer, you may ask for another interviewer so that you can feel comfortable that the information you tell is won't be known to anybody you know.
- There is a small chance that someone outside of the survey staff could find out about your HIV test results and you experience bad treatment. But we have taken many steps to make sure that this does not ever happen.
- The survey includes personal questions about sex and other private things that may make you feel uncomfortable or embarrassed. If any question makes you feel uncomfortable or embarrassed, you can refuse to answer it, and you can terminate the interview at any time. Doing this will not have bad consequences for you, and you will not be asked to leave the survey because of this request.
- A fingerprick may hurt and will make you bleed. You may feel faint but this is very rare. To make it not hurt so much the nurses have been trained especially to do this.
- If you test positive for HIV you may feel anxious or depressed. The counselors working for this survey can help you with these feelings. You may also be referred to local counselors or support groups to help you with these feelings.

Are there any benefits from taking part in this survey?

Yes. If you choose to be in this survey, you can receive

- Free counseling and testing for HIV and learn your test results
- Referral to clinics that can provide you with medical care and/or treatment as needed
- Free condoms, lubricant, and educational information on HIV and STIs
- There is also a benefit to health professionals and others in your community who will learn more about who is most at risk for HIV and STIs to help plan better education, prevention, and medical programs

Does it cost me for me to be in the survey?

It does not cost anything to be in this survey.

Will I be compensated for taking part in the survey?

You will be offered a snack, and a hygiene and prevention kit worth approximately [*INSERT incentive amount here*] for your time and effort today.

What if I want to stop being in the survey?

You can stop being in the survey at any time. You can choose to be in all parts of the survey, or only some of them. We will give you a chance to do this at the end of this form. Also, you may be asked to leave the survey if we feel it is best for you or you are not able to do the survey.

Will my information be kept a secret from others?

Being in a survey may involve you telling someone things about you that are private. But, this is a survey that other people cannot know that it is you that shared this information. To make sure that nobody knows it was you that gave the information

- We never ask for your name or write it on any survey documents, lab tests, or specimens
- Only a survey number will be placed on your survey, survey records, and laboratory specimens



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- All the written information you give us will be kept in a file cabinet that is locked at all times
- Nothing about your health status or your test results will be told to anyone except the researchers in this survey
- We do the survey in a space that nobody can see or hear you except the person doing the survey

Who can answer my questions about the survey?

You can ask the survey staff any questions that you have at any time. You may also contact the people in charge of this survey.

[ADD contact here: name, phone, email]

If you have any questions about your rights as a survey participant, about ethical matters, or wish to complain you can call [ADD bioethics committee contact information here], who reviewed and approved this survey.

Interviewer: Answer the participant's questions about the survey before proceeding to the informed consent authorization.

INFORMED CONSENT AUTHORIZATION

Interviewer: Ask participant to document response to each question by checking the appropriate box.

Participants may consent or decline each part of the survey.

1. Do you agree to participate in part or all of the survey or do you decline participation?

- 1. YES, agree to participate in part or all of the survey.
- 2. NO, decline to participate. [if NO participant not eligible to participate].

If declined:

We're interested in knowing why people do not want to do this survey. Would you mind telling me which of the following best describes the reason you do not want to do this survey?

- I don't have time q 1
- I don't want to talk about these topics q 2
- Some other reason; Specify _____ q 3
- I would rather not say why q 9

2. Do you agree or decline to complete the survey questionnaire?

- 1. YES, agree.
- 2. NO, decline. [if NO participant not eligible to participate].

3. Do you agree to a fingerprick to prepare a blood sample that will be sent to the national laboratory for additional HIV-related testing?

- 1. YES, agree.
- 2. NO, decline.

4. Do you agree to rapid HIV testing to receive your results today?

- 1. YES, agree.
- 2. NO, decline.



If you have read this document or had the document read to you, have been given the chance to ask any questions, and agree to participate in the above procedures (as marked), please sign below.

- I have been informed by the interviewer about the nature, conduct, benefits and risks of this survey
- I have also received, read and understood the above written information regarding the survey
- I am aware that the results of the survey including personal details regarding sex, age, HIV status will be anonymously processed into a survey report
- I may, at any stage during the interview, without prejudice, withdraw my consent and participation in the survey
- I have had sufficient opportunity to ask questions and (of my own free will) declare myself prepared to participate in the survey

Signature or mark of participant _____

Date ___/___/___ Time ___/___

I have explained to the participant the survey purpose and procedures and we have discussed all the risks that are involved. I have answered questions to the best of my ability that the participant had.

Name of person obtaining consent _____

Signature of person obtaining consent _____

Date ___/___/___ Time ___/___

- Copy to:
- Participant
 - Investigator's file



Participant folder

Rapid test results

Instructions: This form should be filled in only for rapid test results, removed from the participant folder and filed in the results folder under the supervisor's responsibility.

Adhesive label with the lab code	Insert here
Date	(DD-MM-YY) - -
HIV	
1. Consent	Did you agree to have a DBS sample made? <input type="checkbox"/> Yes <input type="checkbox"/> No If not, why? Did you agree to be tested for HIV using a rapid HIV test? <input type="checkbox"/> Yes <input type="checkbox"/> No If not, why?
2. DBS samples	Number of DBS prepared <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 If 0 or 1, why?
3. Rapid HIV test	Screening rapid test 1 <input type="checkbox"/> Negative <input type="checkbox"/> Positive <input type="checkbox"/> Not done Confirmatory rapid test 2 <input type="checkbox"/> Negative <input type="checkbox"/> Positive <input type="checkbox"/> Not done
4. Final HIV results	<input type="checkbox"/> Negative <input type="checkbox"/> Positive <input type="checkbox"/> Undetermined <input type="checkbox"/> Not done If there is no final result, why?
5. Referral for HIV-positive or undetermined HIV participants	<input type="checkbox"/> Yes <input type="checkbox"/> No If not, why?



Gatekeeper forms

Guide to gain venue owner approval for the survey

Staff will need to obtain the approval of venue managers or owners for many entertainment and commercial venues that are included in sampling frames. Approval is necessary to conduct type 2 enumerations and recruitment events just outside of or within these establishments. In meeting with venue managers or owners, staff should emphasize individual and community benefits of the survey and that sampling activities will be conducted in ways to minimize burden on venue management and patrons. Below are procedures for contacting and working with venue managers/owners and outreach programs.

Determine the appropriate contact person(s) for each identified venue in the database

The appropriate contact person(s) is the individual responsible for activities at the given venue, including allowing the surveillance to be conducted at that location. Such persons may own or manage the bar or other establishment. These individuals will need to be determined for each of the venues in the database. Often a venue will have more than one venue owner. Local areas will need to decide which venue owners are appropriate for gaining access to areas in or near the venue for the purpose of conducting Type II enumerations and sampling events.

Not all venues will have obvious venue owners (e.g., parks and street locations). For example, when conducting the surveillance on a busy street, owners or managers of nearby businesses may be appropriate venue owners as the sampling events could impact their business. Also, the police may be appropriate venue owners when conducting the surveillance in street locations.

Introduce the survey and get approval

Project staff must gain the support of the venue managers/owners for the project. Distribute a survey brochure and describe the survey process. Ask if he/she would be willing to speak to you in more detail and set up a time to talk in person.

Since the HIV behavioral surveillance will be ongoing in the community, local areas should work hard to gain the support of the venue owners for the project. Conducting Type II enumerations or sampling events without first obtaining appropriate support and acceptance for conducting these activities may seriously impact the ability to conduct future sampling events. Because Type II enumerations can disrupt business, local behavioral surveillance teams should introduce the project to the venue owners prior to conducting Type II enumerations. Also, venue owners should be informed that a number of venues are being observed and that the venue may or may not be included in the final sampling frame. Use the **Venue Owner Guide** to assist with approaching the venue owners about conducting the behavioral surveillance.

Venue owner guide

The primary objective in meeting with venue owners is to gain their acceptance of conducting the sampling events for the behavioral surveillance just outside of or within the venue(s). Therefore, it is important that the behavioral surveillance team members are professional, cordial, and flexible in their interactions with venue owners. If the behavioral surveillance team is working with an advocate such as a venue patron or employee who is known by the owner, that advocate should attend the meeting. The presence of this known person may help to establish trust and permission to conduct the survey. In scheduling meetings, staff should

- Assure the venue owner(s) that the meeting will be short



TLS operations manual

- Keep the meeting informal (dress casually but appropriately)
- Limit the number of people who attend the meeting

Below are potential discussion items for the initial meeting. Staff should thoroughly address the stated concerns of the venue owners.

Overview

- The HIV behavioral surveillance of MSM is a local effort to measure levels and trends in risk behavior of MSM
- Surveillance findings will be used to direct and improve local HIV prevention efforts for MSM
- Participation is completely anonymous; names are not maintained on participants
- Recruiting at the venue will be discreet as possible; patrons will not be harassed in any way
- Recruiting will take place in blocks of four hours during which at least eight MSM can be interviewed.
- All participants must give consent to participate
- Participants will be interviewed with a brief questionnaire and will receive compensation for their time in the form of a hygiene kit and hearty snack

Surveillance findings will be presented in aggregate form only; the names of businesses or other venues will NOT be identified in the surveillance system.

Behavioral surveillance is being conducted in collaboration with national and local health departments, CIDI, universities, and the CDC.

Recruiting and interviewing

- Participants are recruited consecutively
- MSM will not be pressured to participate
- To ensure random sampling, flyers or information about the survey will not be posted within the venue
- Interviews will be conducted in private locations inside or outside the venue where interviewing will not interfere with business, maintain the privacy of patrons, and keep survey activities discreet

Needs

- Permission from the venue owner(s) to recruit participants at different times and different evenings, based on the surveillance protocol
- If possible, one or more private, adequately lit, and reasonably quiet locations within the venue to conduct the interviews. (Ask about this only if it is necessary to conduct the interviews inside the venue.) Possible interview locations include unused rooms, or secluded or closed sections of the venue. Also ask about possible locations around the venue to set up a tent.
- Information about other outreach programs that may be working in the venue, including the day and times these programs are present and contact information of someone at the program so the projects can be coordinated
- Determine high-attendance periods



Gatekeeper forms

Quality assessment survey

Instructions: Give each participant this form to fill in. This is optional. The assessment is anonymous. After filling in, she should fold the form and seal it with tape and place it in one of the boxes for the assessment forms. These forms should not be read by anyone at the survey site, including the supervisor.

Quality assessment

Please circle your responses, fold this form in the middle and seal it with tape; place it in the assessment form box. The information in this form is fully anonymous and will not be read by anyone at this survey site.

Service provided by the **interviewer**

- 1. Very good
- 2. Good
- 3. Not very good
- 4. Terrible
- No opinion

Service provided by the **counselor**

- 1. Very good
- 2. Good
- 3. Not very good
- 4. Terrible
- No opinion

Service provided by the **supervisor**

- 1. Very good
- 2. Good
- 3. Not very good
- 4. Terrible
- No opinion

General opinion about participating in the survey

- 1. Very good
- 2. Good
- 3. Not very good
- 4. Terrible
- 5. No opinion

Would you recommend this survey to a friend?

- 1. Yes
- 2. No

Suggestions?



TLS operations manual

COW forms

Type I enumeration form

Sampling event # _____ Venue code: _____

Date (DD-MM-YYYY) #: _____

Type of selection: Primary venue 1st alternative 2nd alternative

Venue contact person: _____

Name of enumerator: _____

Begin time: ____:____ a.m./p.m. End time: ____:____ a.m./p.m.

Total # counted: _____

Comments (activities, safety, operational barriers such as flow patterns, lighting, noise level, etc.): _____

Draw area of intercept line/area below and the physical space for conducting enumeration, recruitment, interviews, and C&T

Interviewer forms

Type II enumeration form

Staff ID#: _____ Event #: _____ Venue ID #: _____ Venue Name: _____

Date: _____ S-Time: _____ a.m. p.m. E-Time: _____ a.m. p.m. Day of the Week: Sun M T W Th F Sat # Clicked: _____

#	Refused Intercept	Age	Ethnicity	District of Residence	Previous Encounter	Speaks survey language	MSM	Had anal and/or oral sex with a biological male in the past 6 months	Survey Eligible	Willing to participate
1	Y N		Add codes here		Y N U	Y N U	Y N U	Y N U	Y N U	I O B
2	Y N		Add codes here		Y N U	Y N U	Y N U	Y N U	Y N U	I O B
3	Y N		Add codes here		Y N U	Y N U	Y N U	Y N U	Y N U	I O B
4	Y N		Add codes here		Y N U	Y N U	Y N U	Y N U	Y N U	I O B
5	Y N		Add codes here		Y N U	Y N U	Y N U	Y N U	Y N U	I O B
6	Y N		Add codes here		Y N U	Y N U	Y N U	Y N U	Y N U	I O B

Contact Person (Name, title, phone #)

Reviewed by:





Staff ID#: _____ Date: ____/____/____

Clicker #: _____ Date: ____/____/____

Supervisor #: _____ Date: ____/____/____

Year of Birth _____ Age if birthday is on or before today _____ Age if birthday is after today _____

Comments (Weather, safety, etc.): _____

Draw intercept line/area in box below and the physical space for conducting enumeration, recruitment, interviews, and C&T.

CODES:

Willing to Participate? (Yes)

I —In-field Interview at Site	O —Other-Day Appointment (Why?)	B —Both
--------------------------------------	--	----------------



Interviewer forms

Type III enumeration form

Front	Back
Event: _____ Venue ID#: _____ Staff ID#: _____	
Date: _____ Method: R N Type: P 1A 2A Page#: _____	
B-Time: _____ am pm E-Time: _____ am pm Count: _____	
REC/BSI: R / B	
1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/> 6 <input type="checkbox"/> 7 <input type="checkbox"/> 8 <input type="checkbox"/> 9 <input type="checkbox"/> 10 <input type="checkbox"/>	
Refused Intercept: Y / N	
<input type="checkbox"/>	
AGE:	
<input type="checkbox"/>	
Race/Ethnicity: A / B / H / N / W / U*	
<input type="checkbox"/>	
Resident: A / CC / M / SF / SM / SC / SCz / NI / SA / SO / O*	
<input type="checkbox"/>	
Previous Respondent (Enrolled): Y / N / U	
<input type="checkbox"/>	
Previous Non-Respondent (Eligible, asked, but refused enroll.): Y / N / U	
<input type="checkbox"/>	
Eligible: Y / N / U	
<input type="checkbox"/>	
Enrolled: Y / N*	
<input type="checkbox"/>	
ODA/LDE: O / LC(Mark C and Card #)* / LN(Mark N and Card #)* / N	
<input type="checkbox"/>	
	Race/Ethnicity: _____ Resident: _____
	Other: _____ Other: _____
	1. _____ 1. _____
	2. _____ 2. _____
	3. _____ 3. _____
	4. _____ 4. _____
	5. _____ 5. _____
	6. _____ 6. _____
	7. _____ 7. _____
	8. _____ 8. _____
	9. _____ 9. _____
	10. _____ 10. _____
	<u>Reason for Study intercept or enrollment refusal:</u>
	1. _____
	2. _____
	3. _____
	4. _____
	5. _____
	6. _____
	7. _____
	8. _____
	9. _____
	10. _____



Interviewer forms

Recruitment narrative

- Have a strategy for approaching potential participants. A good way to start that can be greeting “Hello. How are you?”
- Have answers prepared for cases where potential participants have a reason they cannot participate, such as “If your friend is also eligible, both of you can participate at the same time”
- Prepare to circumvent reasons for non participation, saying for example “all your information confidential and will not be shared with others”
- Keep options for the potential participant as in “if you prefer to come back after lunch or later, we can arrange a time for you”
- Focus on the positive aspects of participation, for example, “you will be participating to help your community”
- Be realistic, but also describe the best situation, saying for example “Thank you for taking the time to participate. We’ll do our best to not make it long.”

Here are some answers to potential participants who give reasons for not participating

- **Time:** “I don’t have time”
 - Retort: “It will only take 15 minutes”
- **Disinterest:** “I am not interested”
 - Retort: “This is valuable for the whole community”
- **Friends and partner:** “I don’t want to leave my friends”
 - Retort: “Your friend can hang out with my coworkers while we do the interview and have a coke”
- **Privacy:** “I don’t want to give my name”
 - Retort: “This is an anonymous survey – you don’t need to provide your name”

Here is a script to intercept potential participants

SAY: “Hi, how are you? I’m [INSERT name] from [INSERT institution], and we are doing survey on MSM for the Ministry of Health. Would you be interested in participating in our survey today? The survey will take an hour and includes a free HIV test.”

If he is interested

SAY: “Great! Let me ask you some questions to see if you are eligible to participate.”

If he is not interested

SAY: “Please, let me know why.”

NOTE: To get an idea of why people do not participate, interviewers may ask the reasons. Maintaining control of responses allows interviewers prepare their answers/arguments. There are reasons for not recruiting, including various forms of aggression, a firm refusal, physical security. The following are examples of when not to recruit.



When not to recruit

- Worried about security
- He is walking very fast (like a marathoner)
- He's on his cell phone or listening to music
- Physical gestures/body language
- Very drunk or high
- Very firm refusal
- If possible, obtain the reason for refusal
- Find out if there is a possibility for participating later



Lab test algorithm

Serological testing for HIV will follow national serology laboratory SOPs used for surveillance surveys in Francisco. Participants will consent separately for preparation of a DBS, on site HIV testing, and for HIV surveillance testing at the national laboratory. HIV rapid/point-of-care tests will be conducted on site using capillary blood from a finger prick.

HIV rapid testing will be conducted at the survey site after completion of pre-test counseling by certified personnel. Rapid testing will be conducted using a serial testing scheme based on the Francisco national algorithm and approved commercial test kits. All participants who consent will be tested using Alere Determine™ HIV-1/2 rapid test kits. Non-reactive results will be considered negative, and reactive results will be confirmed with Uni-Gold™ HIV rapid test. If Uni-Gold results are nonreactive, results will be recorded as indeterminate. All participants will receive post test counseling, with specific messages tailored to their test result. Persons with any reactive result, or indeterminate result, will be given referral to HIV care services and further counseling and testing

Dried blood spots creation: Creation of dried blood spots (DBS) specimens on Whatman filter paper for HIV surveillance testing in the National Laboratory will be done with the explicit consent of the participant only, using a dried blood spot card prepared at the same time as the rapid tests. DBS specimens will be labeled with cryogenic bar-coded labels containing the participant's laboratory code. If participants give consent to have a DBS card made, they will be informed that they may not request that the DBS be destroyed once it has been sent to the national laboratory. Specimens will be stored in waterproof boxes on site and sent on a weekly basis to the National Laboratory.

Centralized HIV testing: A serial testing algorithm will be used for HIV surveillance testing of DBS samples. Screening will be done with Vironostika HIV Uniform II plus O (bioMérieux, France). Positive samples will be confirmed with Murex HIV 1-2-O. (Abbot/Murex, Germany). Discordant samples will be tested with Genscreen HIV ½ Version 2 (Bio-Rad, França). Internal quality assurance procedures and external quality assessment procedures will be carried out to guarantee the quality of laboratory testing. Test results will be entered into a CSPro data entry program.

Testing quality assurance: The National Laboratory will receive and process a proficiency panel of DBS filter papers before initiating HIV testing for the round. Proficiency testing on a monthly basis will continue until testing for the round concludes. Negative and positive DBS controls are included in each ELISA batch test run. These serve as an internal control measure in addition to those that are included and used in the commercial test kits. In addition a random selection of 10% of samples negative with the screening ELISA will be tested for confirmation of the negative result for internal quality assurance.

External quality assessment for HIV will be done on a simple random sample of 2% of negative specimens and 5% of positive specimens tested each month. DBS spots are separated for these samples and shipped to an external lab approved by _____. A CSPro data entry program will be used to randomly select the specimens. The samples will be sent without test results in order to blind them to the external lab. After the samples are tested results will be returned to the central lab in order to calculate the discrepancy rate (number of specimens with different test results over total number of specimens tested). Discordance above 10% will trigger an investigation as to the cause of the discrepancy. Re-testing of some or all samples at an external laboratory may be required. In addition training will be provided to the national laboratory to prevent future testing errors.³

³ This is an example of an HIV testing algorithm. Adapt all testing algorithms in this protocol to your own country.



No	Adhesive labels with lab code	Age	Date of preparation	DBS	Checked by	Comments
				0 1 2	site: _____ lab: _____	
				0 1 2	site: _____ lab: _____	
				0 1 2	site: _____ lab: _____	
				0 1 2	site: _____ lab: _____	
				0 1 2	site: _____ lab: _____	
				0 1 2	site: _____ lab: _____	
				0 1 2	site: _____ lab: _____	
				0 1 2	site: _____ lab: _____	



Supervisor forms

Interviewer supervision form

Instructions: The supervisor is required to check one in each ten interviews carried out by each interviewer. Always ask the participant’s permission first before participating in the interview. Send supervision forms weekly to the data manager with cc to the national manager, the national coordinator, and the survey coordinator.

Criteria		Y=Yes, I=Needs improvement N=Not done	Comments
Preparation			
1.	Interviewer had all necessary materials including: consent forms, handheld or laptop device, labels, blood collection and DBS preparation kits, HIV testing kits, educational materials and referrals.		
2.	Confidential materials were stored in a locked container before and after the interview.		
3.	Interviewer greeted participant in a friendly manner.		
Consent process			
4.	Interviewer followed all aspects of informed consent according to local protocol.		
5.	Interviewer gave the participant a personal copy of the consent form.		
6.	Interviewer inquired about and if applicable addressed any questions or concerns about the consent form.		
Questionnaire administration			
7.	Interviewer read questions exactly as written.		
8.	Interviewer read questions at an appropriate pace.		
9.	Interviewer avoided leading the participant to a particular response.		
10.	Interviewer demonstrated a neutral attitude.		
11.	Interviewer followed instructions: “READ CHOICES” and “DO NOT READ CHOICES” .		
12.	Interviewer read Say boxes verbatim.		
13.	Interviewer used all response cards when indicated.		
Rapport			
14.	Interviewer established a good rapport with the participant at beginning of interview and maintained it throughout interview.		
Closing			
15.	Interviewer provided educational materials and referrals when appropriate.		
16.	(If applicable) Interviewer clarified any factual errors expressed by the participant during the interview.		



Additional comments:

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Supervisor forms

Template for daily questionnaire email

Instructions: Fill out the daily questionnaire and send it as an email to the data manager at the end of the day with the electronic questionnaires attached addressed, with cc to the national manager, the national coordinator, and the survey coordinator.

Title of the E-mail: FSW City and Date (format YYYYMMDD). Example: FSW City X 20110815

Number of the netbook				
Total number of questionnaires conducted by netbook on this day				
Completed questionnaires <i>(Write down the numbers of the coupons)</i>				
Ineligible questionnaires <i>(Write down the coupon numbers)</i>				
Incomplete questionnaires because a participant refused to consent to the interview <i>(Write down the coupon numbers)</i>				
Incomplete questionnaires because the participant/ interviewer decided to terminate the interview before finishing <i>(Write down the coupon numbers)</i>				

Comments:



Supervisor forms

Recruitment monitoring registry

Instructions: Fill the Excel table with the day's data sheet using the type III enumeration form and sends this to the data manager and the project coordinator.

Event #	Date	Venue code	Venue type	Start time	End time	Total Number:											
						People enumerated	People intercepted	Accepted to participate	Did not participate	Participated	Eligible	Accepted participation	Completed the interview				
						#	%				#	%	#	%	#	%	
Ex.	1/2/2013	M01	C	13:00	17:00	25	15	2	13%	0	1	10	83%	9	90%	8	89%
1																	
2																	
3																	
4																	
5...																	



Supervisor forms

Rapid test registry

Date	Adhesive label with lab code	Age	DBS	HIV			Comments
				Test1	Test 2	Final	
	Insert here		0 1 2	P N	P N	P N I	
	Insert here		0 1 2	P N	P N	P N I	
	Insert here		0 1 2	P N	P N	P N I	
	Insert here		0 1 2	P N	P N	P N I	
	Insert here		0 1 2	P N	P N	P N I	
	Insert here		0 1 2	P N	P N	P N I	



Weekly supervision of IBBS activities report

Period: from ____/____/____ to ____/____/____

I. Activities carried out (brief description)

- Describe the flow of participants per day. Flow variation throughout the week. Check for tendencies, ex: the respondents with interviewer x do not give their consent. Check if there is any systematic tendency that may be occurring.
- Describe why the participants are ineligible, for example, age, participated before
- Describe the reasons why the participants are not consenting to do the DBS test for HIV, for example, they don't understand the purpose of the survey, they are afraid of the result.
- Describe any geographical concentration of participants. Is that what you expected from the data of the formative assessment?
- Do you think we're seeing diversity in the sample? Comment on the level of schooling/employment/sexual identity of the participants.

II. Difficulties/needs

- Difficulties (recruitment, ineligible participants, management of the flow of the participants)

III. Feedback from the community

Community agent

- Ask if people are discussing the survey in the community? If they are, what do they say?
- In social locations and among groups of friends, ask:
 - If they heard about the survey
 - What do they think of the survey

Community agents should be prepared to provide information about the survey and encourage people to take the coupon if anyone gives them one.

At the end of the interview or session, try to find out

- What was the experience like at the venue? Were you happy with the customer service received?

Supervisor

- How many referral cards were collected from the health center?



Supervisor forms

Request for data changes in the questionnaire

Instructions: Each time you find an error in the data of the questionnaires, fill in the request for data changes in the questionnaire and send it to the data manager with cc to the national manager, the national coordinator, and the survey coordinator.

For supervisor use	
City	
Coupon number	
Interviewer code	
Interview date	
Reason for change	
Change requested	



For data manager use			
	Initials	Date	Comments
Completed changes			
Confirmation of change sent to the supervisor			



Supervisor forms

Adverse/unusual event report form

Instructions: Report adverse incidents to the IRBs and to all partner institutions. Potential incidents may include protocol violations, security incidents harming recruits or staff, breach of confidentiality, or adverse physical or mental reactions to HIV counseling and/or testing. Report any adverse events from the field sites to the principal investigators within 24 hours of occurrence. These events will be reported to the IRBs within 10 days or according to local reporting requirements.

Name of person writing report	
Date of writing report	
Date of incident	
Staff involved	
Location	

Adverse/unusual event category (Check all that apply to incident)	
Client harmed or threatened	Blood draw incident
Staff harmed or threatened	Blood draw difficulty
Incentive/compensation issue	Specimen transport or storage issue
Theft or loss of equipment	Confidentiality issue
Other safety issue	Other

Narrative description of incident

Recommendations

Resolution



Glossary

HIV prevention activity	Any effort made to prevent HIV infection. Such efforts may be indirect. For example, reducing drug use may indirectly lead to lower rates of unsafe sex.
Key informant interview (KII)	A type of in-depth interview conducted with stakeholders or members of the MSM community.
Sampling frame	A sampling frame or list of all the identified venues in the local area that yield at least eight MSM in a given VDT, are safe for enumerating and recruiting MSM, and where, if applicable, behavioral surveillance staff have been given permission to conduct the behavioral surveillance. This includes a list of all the elements (e.g., persons, telephone numbers, organizations, venues or VDTs) to be used for sampling a population for inclusion in a survey.
Survey site	A venue selected for inclusion in the sampling frame.
Type I enumeration	Type I enumerations are conducted at venues and VDTs with unknown attendance patterns of the target population. Type I enumerations are conducted by one person who counts the number of people who appear to meet the eligibility <u>criteria</u> and who attend the VDT during a 30- to 60-minute period. Type I enumeration data are used to determine if venues yield sufficient people to be included in sampling frames.
Type II enumeration	Type II enumerations are conducted at venues and VDTs that are suspected of being attended by ineligible people such as community members. Type II enumerations are conducted with teams of two. One team member counts people who appear to meet the eligibility criteria during a 30- to 60-minute period, and the other member conducts brief eligibility interviews (BEIs) on a sample of counted people. BEIs collect information necessary to determine attendance by eligible people.
VDT	Venue-Day-Time manageable four-hour blocks of time that are venue, day, and time specific.
Venues	Locations where MSM congregate. They may include parking lots, discos, street locations, restaurants, motels, and customs office. Excluded are clinical or other settings that routinely provide medical, mental-health or social services, or HIV/STD diagnostic or treatment, and other prevention services.
Venue universe	A map of all the possible places, days, and times that the key population can be found. The venue universe, or universe of venues, serves as the foundation for the sampling frame.