IBBA

Integrated Behavioral and Biological Assessment

Guidelines for Surveys of Populations at Risk of HIV Infection

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Integrated Behavioral and Biological Assessment:

Guidelines for Surveys of Populations

at Risk of HIV Infection

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This document is dedicated to the fond memory of

KATHLEEN KAY
Former Country Director, FHI India
(8 June 1959 -10 December 2007)

who inspired us to dream big and achieve it in real time

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Table of Contents

Appendixes

Tables

Figures

Acknowledgments

This manual on integrated behavioral and biological assessment (IBBA) was developed by individual contributors from FHI and the institutes of the Indian Council of Medical Research (National AIDS Research Institute, National Institute of Epidemiology, National Institute of Medical Statistics, National Institute of Nutrition, and Regional Medical Research Centre). The manual is based on the experiences of research agencies that have been implementing IBBA: ORG Center for Social Research, TNS India, Gfk Mode, Center for Operations Research and Training (CORT), Regional Institute of Medical Science–Imphal, and KRIPA – Kohima. We extend our appreciation to all who contributed to the development of this operational manual.

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Message

With technical support from FHI, five institutes of the Indian Council of Medical Research and Karnataka Health Promotion Trust joined hands to carry out the Integrated Behavioral and Biological Assessment Survey in six Indian states with high prevalence of HIV. Each round of the survey involved collection of behavioral and biological data from more than 25,000 respondents. This is probably the only survey in which both behavioral and biological data have been collected from a representative sample of population groups in these states that are at higher risk of HIV. The data were collected with scientific rigor and also with an emphasis on protecting participants from adverse effects. This survey involved many innovative approaches, and documenting these innovations had paramount importance. Many reviewers felt that the IBBA team should bring out an operational manual that would be helpful to others who would like to conduct such surveys, including program managers and personnel involved in monitoring and evaluation.

The team responsible for the development of this manual emphasized planning, community preparation, implementation, analysis of data, and documentation of survey processes. The team's tireless efforts made this important document possible. We are sure that the IBBA manual will be an important resource for similar studies.

Dr. Ramesh S. Paranjape
Director, National AIDS Research Institute

Preface

The India AIDS Initiative—Avahan—of the Bill & Melinda Gates Foundation started in 2003 with the aim of slowing the HIV epidemic through focused, integrated, large–scale prevention among higher–risk populations in six states in India. Avahan used proven intervention strategies: behavior change communication, services related to sexually transmitted infection, provision and promotion of condoms and needle syringes, community mobilization, and the creation of an enabling environment for HIV prevention. Two rounds of integrated behavioral and biological assessment (IBBA) have played an important role in evaluating Avahan, in order to measure and understand the impact of the Avahan interventions on high–risk population groups. IBBA is a pioneering study in India that measured both behavioral and biological indicators. The Government of India has further strengthened second–generation surveillance at the national level using methods and tools developed by the IBBA team of the Indian Council of Medical Research (ICMR) and FHI.

This manual is intended to be used by those who wish to carry out similar studies in India and elsewhere. It is operational in nature, without a heavy burden of theoretical and technical information. It is hoped that the manual will be useful for program managers, monitoring and evaluation personnel, and policy makers who want to use IBBA as a tool to monitor and evaluate HIV/AIDS interventions. FHI values the partnership with ICMR and its institutes (National AIDS Research Institute, National Institute of Epidemiology, National Institute of Medical Statistics, National Institute of Nutrition, and Regional Medical Research Centre) in putting together the experiences of implementing IBBA in the form of a manual. Efforts made by the individual contributors in preparing the manual are highly appreciated. Finally, the operational guidelines on IBBA would not have been complete without the valuable suggestions provided by the reviewers from ICMR, Avahan, and FHI.

Dr. Bitra George
Country Director
FHI/India

Acronyms

AIDS	Acquired immune deficiency syndrome
ANC	Antenatal care
BSS	Behavioral surveillance survey
CAB	Community advisory board
CCS	Conventional cluster sampling
CIS	Cluster information sheet
CL	Community liaison
CLO	Community liaison officer
CMB	Community monitoring board
CMOS	Cumulative measure of size
DBS	Dried blood spot
ELISA	Enzyme-linked immunosorbent assay test
EP	Equal probability
EQAS	External quality assessment tests for HIV-1 nucleic acid
FSW	Female sex workers
GCLP	Good clinical laboratory practice
HBV	Hepatitis B virus
HIV	Human immunodeficiency virus
IBBA	Integrated behavioral and biological assessment
ICTC	Integrated counseling and testing centers
ICMR	Indian Council of Medical Research
IDU	Injecting drug users
ISSA	Indian Academy of Social Sciences
LDTD	Long-distance truck drivers or truckers
MoS	Measure of size
MSM	Men who have sex with men
NAAT	Nucleic acid amplification test
NABL	National Accreditation Board for Testing and Calibrating Laboratories
NACO	National AIDS Control Organisation
NARI	National AIDS Research Institute
NG	Neisseria gonorrhea
NGO	Nongovernmental organization
PEP	Postexposure prophylaxis
PI	Principal investigator
PPS	Probability proportional to size
PPTCT	Prevention of parent-to-child transmission
PSA	Pre-survey assessment
PSU	Primary sampling unit
PT	Proficiency testing
RDS	Respondent-driven sampling
RDSAT	Respondent-driven sampling analysis tool
RMP	Registered medical practitioner
RPR	Rapid plasma regain
SOP	Standard operating procedure
SPSS	Statistical package for social sciences (software)
STD	Sexually transmitted disease
STI	Sexually transmitted infection
TLCS	Time-location cluster sampling
TOT	Training of trainers
TPHA	Treponemal test for syphilis
VCCTC	Voluntary confidential counseling and testing center
VCTC	Voluntary counseling and testing center

Introduction

An integrated behavioral and biological assessment (IBBA) collects these two categories of data from a single set of participants and interprets the information through the lenses of a couple of primary objectives: to illuminate the dynamics of epidemic HIV and to evaluate small- and large-scale health care interventions to prevent the spread of the virus. IBBA builds on past and current efforts to understand trends in the HIV epidemic through independently conducted behavioral surveillance surveys (BSS). BSS are cross-sectional studies implemented repeatedly over time to provide a long-term view of behavior. IBBA takes this process further, by including a biological component and linking the biological data with behavioral data.

IBBA is resource-intensive and suited to application in places where the prevalence of HIV is high. It focuses on groups who are at higher risk for HIV and considers them within a broader national context. IBBA makes it possible for researchers to find out the prevalence of HIV and other STIs in particular groups and to understand the groups' interrelated behavioral dynamics.

An IBBA, and repeated IBBAs, would be useful to a range of people: donors, health care program designers, government administrators, project managers, and community groups. The findings of an IBBA can be taken back to a community of study participants for discussion and a call for action to minimize HIV's impact. The findings of an IBBA would also help policy makers develop appropriate responses to the spread of HIV, especially in communities at higher risk of acquiring the virus.

IBBA in India

A large-scale IBBA was designed and implemented in India. The first round was conducted from 2005 to 2007 and the second round from 2009 to 2010. The IBBA in India is being implemented as part of an evaluation of Avahan–the India AIDS initiative funded by the Bill & Melinda Gates Foundation.

The IBBA in India has three objectives:

- To measure the major outcomes of the Avahan interventions, by collecting data on behavioral and biological trends in the populations targeted by these interventions
- To make available data that will be used to estimate the sizes of populations addressed by the Avahan project
- To make information available to an Avahan partner organization charged with modeling the impact of the intervention

The IBBA was implemented with technical assistance from FHI by premier national institutes of the Indian Council of Medical Research (ICMR) in 29 districts in six states and along the national highways. The ICMR institutes involved in IBBA were National AIDS Research Institute (NARI), National Institute of Epidemiology (NIE), National Institute of Medical Statistics (NIMS), National Institute of Nutrition (NIN), and Regional Medical Research Center (RMRC). In all, 56 assessments of various higher-risk groups in different districts were conducted. Of these, 24 were with female sex workers (FSWs), 10 with men who have sex with other men (MSM), one with transgenders *(hijras),* 12 with clients of FSWs, five with injecting drug users (IDUs), and four with long-distance truck drivers (LDTDs) on the national highways.

This document is a product of the experience of implementing IBBA on a large scale, investigating the behavioral and biological traits of more than 25,000 respondents/participants in each round.

What does this manual cover?

The manual focuses on the complex operational issues of designing, planning, implementing, and using data from an IBBA. It provides step-by-step guidelines for conducting an IBBA in a concentrated epidemic among the groups who are at higher risk of HIV, such as female sex workers, their clients, men who have sex with men, and injecting drug users.

The guidelines for successful conduct of an IBBA derive from actual experiences during a large-scale IBBA in India. They are offered in response to an observed need for such a tool when the IBBA in India was being developed. These operational procedures are meant to be easy to understand and adaptable to other scenarios for surveillance of HIV and AIDS without repeating much of the technical information available in other publications. The manual joins a group of distinguished publications on HIV surveillance and related topics produced by several organizations.

Who should use the manual?

This manual is intended for HIV and AIDS surveillance professionals who plan to implement an integrated behavioral and biological assessment in the future. It is most useful for those at national, state, and project levels who coordinate, design, monitor, and plan such surveys.

The reader may review only one chapter, a few chapters, or the entire manual. For example, someone whose responsibility is community preparation prior to an IBBA may choose to read about the pre-survey assessment (Chapter 1) and the dissemination of findings (Chapter 12) to gain insight into the project. Supplementing this information with other materials, such as the IBBA in India survey protocol (Appendix 1) and the local IBBA protocol would help this person to conduct community preparation operations.

What is the IBBA manual's structure?

Integrated Behavioral and Biological Assessment provides a basic framework and specific operational guidelines for anyone who wants to learn more about IBBA's interrelated functions. Minimal theoretical background is required. The manual explains how India has conducted IBBA and offers a model that policy makers in other countries can adapt to their local contexts.

The manual describes methods that can be used to assess both behavioral and biological indicators of STI and HIV among population groups at higher risk of exposure. It also outlines how IBBA data can be managed and used and how to set up the fieldwork venues and procedures required for the behavioral and biological components of an assessment.

The manual is divided into twelve chapters, each providing a detailed discussion of an IBBA component.

Chapter 1 describes aspects of the pre-survey assessment, including the need to understand the rationale for conducting IBBA among certain groups and what to assess prior to designing an IBBA.

Chapter 2 contains information on important aspects of the surveyed community. The rationale and process for involving the community at all stages of the IBBA are discussed along with measures to ensure that the populations under study are protected from adverse events.

Chapter 3 focuses on laboratories for the biological/clinical component of an IBBA, including design of a three-tiered laboratory network, the procurement of equipment and supplies, and quality assurance processes.

Chapter 4 covers the survey instruments, documentation, and guidelines required to conduct an IBBA.

Chapter 5 discusses sampling methods, calculating sample size, selecting appropriate sampling methods, and implementing the sampling of respondents in the field.

Chapter 6 describes how to use survey procedures to estimate the size of study populations that are marginalized, hard to reach, and hard to count.

Chapter 7 discusses the training of all team members involved in an IBBA.

Chapter 8 describes the fieldwork required for an integrated assessment, including planning and implementation.

Chapter 9 provides guidelines for the conduct of biological fieldwork, including the roles of field staff, clinical site requirements, health checkups, and a referral network.

Chapter 10 covers the management of data.

Chapter 11 offers detailed guidelines on data analysis: how data should be cleaned, stored, and retrieved; data analysis software; and triangulating sets of data.

Chapter 12 examines data dissemination, because sharing the findings of a survey is an important aspect of IBBA. This chapter explains how data can be customized for different purposes: policy making, planning, and monitoring HIV/AIDS programs.

Thirteen appendices present materials developed for the IBBA in India. These materials serve to exemplify or elaborate many of the manual's procedures. They should help administrators in other parts of the world develop their own IBBA guidelines. The appendices are listed in the table of contents and referenced throughout the text.

Chapter 1

Pre–survey assessment

1

- **Define the sampling domain and study groups**
- **Collect existing HIV/AIDS information**
- **Decide on the fieldwork venues and referral choices**
- **Address community preferences, concerns, and barriers**

A pre-survey assessment (PSA) gathers information to help a study team determine whether, where, and with what population an IBBA (integrated behavioral and biological assessment) is needed. Specific information on the location, behaviors, concerns, estimated size, and typologies of a potential study population helps the team decide how the IBBA should be implemented. By visiting the location of a potential study population and by interacting with and learning from the community, problems can be averted and decisions can be made about the study group, the sampling domain, and the appropriate sampling method.

For the IBBA in India, FHI—an international nongovernmental agency (NGO)—hired three consultants to lead the PSA team. This team of researchers gathered and reviewed all available mapping information for the selected districts and national highway segments that was available from various sources, including Avahan (the India AIDS Initiative) and its partners and other donor agencies. Based on a thorough and critical review of methods, coverage, and quality of mapping information, the Indian Council of Medical Research (ICMR) and its partners coordinated a rapid listing exercise to identify and fill gaps in comprehensive sampling frames for different respondent groups.

The PSA is a preparatory activity that helps researchers learn about a study population and begin to act on what they discover. The PSA involves:

- Determining the prevalence of HIV and other sexually transmitted infections (STIs) among the study population(s) based on existing information, if any is available
- Collecting geographic information pertaining to the study population (such as sites where members of the population can be found, landmarks, street addresses, and so forth) and learning whether some members of the population are hidden
- Estimating the size of the study population in a given area (e.g., town, district)
- Identifying typologies among the study population within a given area (for example, female sex workers—FSWs—who solicit at brothels and FSWs who solicit on street corners)
- Investigating the degree of mobility of the target populations: where they can be found (their accessibility), their permanent or transient association with sites, and their mobility between sites
- Making decisions about the study group and sampling domain (areas of inquiry)
- Selecting sampling methods based on such factors as the study population's size, geographical spread, accessibility, and mobility (see Chapter 5)

- Gathering comprehensive information about the venue or venues where the target population can be accessed or sampled (for example, brothels, bars, dance halls, parks, street corners, truck stops, and drug-injection locations)
- Scouting for available private locations for interviews, physical examinations, and the collection of biological samples
- Collecting information on the types of seeds or initial respondents who can be recruited if respondent-driven sampling (RDS) is used
- Discovering the languages and/or dialects that are spoken by the target group members in different parts of the district
- Learning the key characteristics that the survey's team members should have for the study group to be comfortable answering questions about gender, age, educational level, social standing, and facility with languages
- Identifying the stakeholders and gatekeepers in the study community: that is, people whose permission (either formal or informal) is needed for the survey team to gain access to the study population and secure its cooperation
- Determining the type of compensation for survey respondents that would be acceptable but not coercive (e.g., medical care, referrals, gifts, money, transportation costs)

The pre–survey assessment stages or steps are:

Step 1. Define the sampling domain

Step 2. Define the study group

Step 3. Define the study population

Step 4. Collect information to decide on a sampling method

Step 5. Collect existing information on HIV/AIDS

Step 6. Decide on venues

Step 7. Attend to the details that remain

Selection of districts and highways for the IBBA India

The six states and national highway segments used in the IBBA India were selected because Avahan was operating there. Within these six states, the districts selected had the following characteristics:

- Only districts where the Avahan program had a presence were included.
- Districts were organized by socio-cultural region following categories established by the government of India, so that the IBBA would capture at least one district per socio-cultural region (in regions where Avahan was in place) to ensure social, cultural, and economic diversity.
- Districts with the largest number of FSWs in the four southern states and the largest number of IDUs in the two northeastern states were selected. These groups were the focus of the intervention, and this ensured that a sufficient number of group members were present in the district to achieve the required sample size.
- Large cities (e.g., Hyderabad, Mumbai, and Chennai) within the selected states were automatically selected for the IBBA, given their probable status as drivers of the epidemic.

National highway IBBA was undertaken on four route categories (north-west, north-south, north-east, and south-east) traveled by long-distance truck drivers. Seven transshipment locations (where loading and unloading take place) along these routes were selected as sites for the survey to be conducted.

Step 1. Define the sampling domain

The sampling domain is the area that the IBBA study covers and to which the data could be applied. For example, if a district is the sampling domain, data are applicable to that particular district, and not to the state, the nation, or other districts. Deciding where to conduct an IBBA depends on the purpose of the assessment. IBBA can be conducted at a national or regional level to determine the overall STI/HIV prevalence among the selected subgroup population and to provide an indication of national trends. IBBA data can also aid understanding of the epidemic in a particular locale, detecting changes in behavior and biological trends that can sharpen the focus of interventions.

The sampling domain is decided based on information needed by those who make policy, develop intervention programs, and monitor the epidemic. Although collecting information at many levels is tempting, it is important to plan and anticipate exactly how the data will be used. Implementation of an IBBA is resource-intensive. Understanding the country's HIV–transmission dynamics will help prioritize areas for the IBBA and study groups. In districts with very low levels of HIV and risk behavior, it may not be wise to implement such a resource–intensive study. Instead, data collected through different services—e.g., public health, prevention of parent-to-child transmission (PPTCT), and voluntary confidential counseling and testing (VCCT) programs—and qualitative information can help monitor the epidemic. Table 1 highlights the advantages and disadvantages of conducting an IBBA at different levels.

Table 1. Selection of a sampling domain

Sampling domain	Possibilities and usefulness	Challenges and disadvantages
National	National indication of HIV prevalence May be useful in small countries with little variation in size and behavior of risk groups	Very large and resource-intensive sample sizes are required for data to inform decisions about the priority of states/districts for interventions Data will not be informative about behavior-change trends at the state level
State	State-level trends can be useful to plan programs and monitor state response to the epidemic Can spark state-level policy discussions	Unless the sample is stratified by district (which requires a larger sample size), the study will not provide district-level information that may be important in large countries or in countries with increased variation in behavior/biological trends
District or province	Specific district-level information can be used to plan programs, understand local trends, and identify key priority areas Easier to manage, implement, and monitor a study within one area	Unless the sample is stratified, it may be difficult to understand trends below the district level (e.g., discerning between street- and brothel-based sex workers within an overall FSW sample) This information may also come from other studies
Town/city specific	Useful when a major city is considered central to the transmission dynamics	May be too cost-intensive in smaller towns or cities where the target group's population size may be insufficient to support meaningful analysis
Along transport and mobility routes (e.g., truckers, migrants)	Useful for mobile groups that are difficult to access in one place	Sampling methods may be difficult to standardize Specific information on mobility patterns of the population is needed to ensure that the study includes all those eligible

Step 2. Define the study group

Defining the sampling domain and the study groups are parallel activities. Without knowing the key populations at risk of HIV and where these are located, it is difficult to choose a sampling domain. Conversely, without information on the sampling domain, it is difficult to specify which study groups to prioritize.

Selection of the study group depends on many factors, such as:

- Which subpopulations drive the HIV/AIDS epidemic in the country or region
- The prevalence of HIV within each target group at state and district levels
- The size of these target groups (accurate counts may not be available, but with existing mapping data the Delphi method can be used to estimate the population of these groups)
- The type and size of subpopulation groups in the area and information about which of these are covered by interventions
- The level of STI/HIV-related sexual risk behaviors for each identified subpopulation group: for example, among men who have sex with women, indicators would be the frequency of sexual activity with FSWs, condom use, types of sexual partners, the prevalence of STI/HIV, knowledge levels, and so forth
- The frequency of behavior associated with HIV/STI transmission within other groups: for example, for injection drug users (IDUs), indicators would be sharing injecting equipment and risky sexual behavior, both paid and unpaid
- The power structures in place that influence access to the survey population (e.g., types of gatekeepers)
- The cost in time and money to implement the study
- The ability to reach the groups when conducting the study

IBBA India: Merging districts

The sampling domain for the IBBA in India was generally one district, although in a few instances two or more districts were merged into one sampling domain. This merging occurred where the population size of the survey group was small, where the survey group's mobility between districts was substantial, or where target groups' risk behaviors were thought to be similar across districts.

In Tamil Nadu, the Avahan program worked with *hijras* (transgenders). This group's population was too small within a district. Nevertheless, the group had a high level of risky behaviors and information was needed for planning programs. Therefore, IBBA among *hijras* in Tamil Nadu was conducted with five IBBA districts covered under one sampling domain.

In order to select the study group, make qualitative assessments by talking with key informants: community members, representatives of nongovernmental agencies, and government officials. In many places, the existence of risk groups may be denied owing to fear of stigma and other adverse consequences. For example, sometimes the existence of sex workers is denied even though brothel areas and sex workers soliciting through pimps, on phones, or on the street may be obvious. The study team must be sensitive when they approach informants and identify groups that are most at-risk and groups that drive the epidemic in a particular locality.

Groups that are very small, considered insignificant in driving the epidemic, or have little crossover with other larger population groups may not be priorities for IBBA and may instead be monitored using other tools, such as behavioral surveillance surveys and assessment of information from intervention programs.

Step 3. Define the study population

Surveillance groups may include subpopulations identified by different names, working areas, and behaviors. For example, sex workers who work outside of brothels have been known as street-based sex workers, floating sex workers, and non-brothel-based sex workers. If the operational definition is too loose, it will be difficult to know how to use the data locally, but if it is too stringent, key parts of the population may be excluded. Therefore, define each population group and its eligibility criteria as precisely as possible. Otherwise data will be difficult to use and to understand once the study is completed. Such operational definitions include or exclude particular members from taking part in the study and thus establish the groups to which the results apply. These definitions also help to identify any overlapping identities among surveillance groups.

IBBA India: Operational definitions

For the IBBA in India, establishing the operational definition of each survey group was a critical step. This was done by consulting with local NGO staff familiar with the study population to review existing data and visit sites where the study population could be found. Survey populations were not defined in a similar fashion across the IBBA implemented in India owing to differences in the focus of interventions, local risk behaviors, and interest in covering those individuals playing a central role in the epidemic. This was the case with the sample of men having sex with men (MSM), where different definitions were used in Tamil Nadu and Maharashtra (see table 2).

Depending on the local situation, operational definitions can vary from one sampling domain to another, but not within one sampling domain. Criteria used to define a subpopulation could relate to many characteristics, such as the nature of the group's risk behavior, the places where they live or work, and their age group (see table 2). Age criteria can be especially useful, because age is often related to the prevalence of risk behaviors in study populations. Including population members under the age of eighteen raises ethical considerations. In the IBBA in India, the operational definition for clients of sex workers was men between the ages of 18 and 60.

Table 2. Examples of operational definitions used in the India IBBA

Brothel-based female sex workers	Any female, eighteen years or older, brothel-based (working/living/operating in brothels in red-light or brothel areas) or soliciting within 100 meters of a brothel, who sold sex in exchange for cash at least once in the previous month
Men having sex with men (as defined in the Maharashtra region)	Any male, identified at cruising points, eighteen years or older, who had any type of sex (oral, manual, or penetrative), paid or unpaid, with another male in the previous month
Male sex workers (as defined in the Tamil Nadu region)	Any male, eighteen years or older, who had anal sex with other males (in exchange for cash/or in kind) at least once in the previous month
Male injecting drug users	Any male, eighteen years or older, who had injected drugs for non-medical reasons at least once in the previous six months
Clients of female sex workers	Any male, eighteen to sixty years, recruited from solicitation points of female sex workers, who had paid a female for sex in the previous month

It is important to note the definitions in table 2, which specify age, type of risk behavior (e.g., selling sex, location of selling sex), and a time reference. These definitions may also contain geographical specificity based on the sampling domain.

Take care to identify any subgroups within a study population who need to be considered as a separate group because of their differential risk-behavior pattern and size. For example, MSM could contain subgroups such as transgender, male sex workers (MSW), gigolos, escorts, masseurs, and crossdressers. *Hijras* are distinct in their behavior, solicitation points, and knowledge of HIV prevalence. They can be considered a separate group for the purposes of an IBBA if their population is sufficiently large to meet the study's required sample size. When subgroups do not exhibit significantly different behaviors and no evidence suggests that HIV

prevalence among them will vary, they may be included within a single surveillance group. If multiple surveys have been conducted with a group over time, consider using the same definition as the previous surveys so that the new data will be comparable. Before choosing a definition used previously, make sure that it does not exclude a subgroup from the survey that would otherwise have yielded important information.

The study team also needs to decide whether to combine subpopulations in one group or consider those populations discretely. For example, the IBBA of MSM in Maharashtra and Tamil Nadu used two different definitions in certain districts. In Maharashtra, MSM and MSW groups were considered as one, because of the interaction between them and the similarity of their risk behaviors: high partner exchange; low condom use; similar solicitation points; and frequent overlapping behaviors, with men selling sex in one month and cruising for partners without pay in another month. In Tamil Nadu, the definition of MSM focused on men selling anal sex (see table 2).

Merging study population groups in the IBBA in India

Defining the study population groups was a difficult exercise and required knowledge about the size of the population and information on risk behavior. The estimated size of some key populations of interest to the interventions and important in the epidemic was small. Based on their similar risk behaviors they were considered as one group, although they were two distinct populations. This happened in a district of Pune where high-risk MSM (with high partner exchange and high prevalence of anal sex) and *hijra* sex workers were considered as a single study group. Although this allowed for district-level estimates, for subgroup analysis (e.g., separate analyses for MSM and *hijra* in this example), the loss of precision in the estimates was a major concern. Because data were analyzed at the district level, the limited sample size did not allow disaggregating observations by sexual identity (i.e., *hijra* or MSM). The advantage was that data was made available for these two study populations where no systematic quantitative information existed. Combining these two groups was justified, because they were thought to have similar sexual behavior in terms of the type and number of partner exchanges and frequency of receptive anal sex.

Step 4. Collect information to decide on a sampling method

The PSA team should learn the operational and behavioral characteristics of the study populations. Document these characteristics by talking to members of the community, stakeholders, and gatekeepers and by visiting sites where the populations are found. Decision making concerning which sampling method to use is based on this PSA. Sampling methods are discussed in Chapter 5.

The PSA team documents the following:

- What are the different types of sites where members of the study group congregate or can be found (e.g., places where users inject drugs, cruising areas, brothels, residential areas, sex solicitation sites, truck stops)?
- What proportion of study group members are available at different sites? And at what times are they both present and available?
- If some proportion of the study group is not available at these sites, where can they be found? Are they identifiable or hidden? Would a mapping exercise be able to capture almost all sites?
- What groups of people in power might affect the ability of researchers to conduct the IBBA at different sites (e.g., bar managers, police, truck owners, etc.)?
- Are members of the target population accessible at the sites? That is, can they be approached to take part in the study?

- Are members of the study group mobile? Do they visit multiple sites or are they affiliated with just one site?
- Can primary sampling units be defined to represent the population comprehensively? For example, in the case of long-distance truckers, can establishments responsible for providing consignments and goods to truckers be considered as the primary sampling units?
- Is transportation available for team members to visit different sites of a sampling domain?
- Are members of the study group interested in participating in the IBBA?
- Are members of the study group networked? That is, do they know other members of the study group not only at the site they frequent but also at other sites?

Step 5. Collect existing information on HIV/AIDS

Once the study groups are defined, it is essential to identify their geographic spread and the types of locations where they operate. Generally such information is available from existing HIV/AIDS interventions (if any). Although it would be useful to start with agencies that have larger coverage, grassroots organizations working directly with the study population yield specific information. Review existing mapping data, needs-assessment reports, and information from previous studies to ascertain what information has been gathered and when. Existing mapping information is useful for planning sampling-frame development exercises for each subpopulation before starting the IBBA.

For cluster-based sampling, the team examines when the last mapping was conducted and whether the information required for sampling-frame development (time-location clusters, cluster-size estimate, gatekeepers, landmarks for each cluster, types of sites excluded from mapping, any hidden groups, mobility of the group) was available in the mapping reports. The PSA team should also explore ways to collect the missing information and determine whether a complete sampling-frame development is required. Specific information about the study population subgroups, where they congregate, and places where they can be accessed for interviews should be gathered for use in the sampling-frame development.

If respondent-driven sampling is used, collect information pertaining to the profile characteristics of the study population (i.e., gender, age group, period of risk behavior, occupation of groups, class, and peer groups) that would help in selecting seeds who in turn recruit respondents for the IBBA.

Gather information about all HIV/AIDS interventions and other developmental programs among the study population for use in planning the IBBA. It is important to understand how the target groups will be reached in order to provide information and services through these intervention projects. Project documents (if accessible)—including monthly monitoring information systems—offer information about the study population (type and number) and the frequency and quantity of services provided to them.

Step 6. Choose the fieldwork venues

IBBA requires some local infrastructure: facilities with sufficient privacy and comfort for behavioral interviews to be conducted there; clinical facilities for physical examinations for STIs and for taking swabs; availability of electricity or ice to store and refrigerate the collected samples for a day or two; and a place to store documents and materials used in the field. List all basic venue requirements (space, privacy, accessibility, safety of the respondents and the data collection team, and necessary amenities such as water, ventilation, and electricity). Also list examples of possible venues that may be accessed by different study groups or subgroups. This research helps the PSA team suggest IBBA study venues during meetings with community members, stakeholders, and nongovernmental organizations (NGOs) at an early stage of IBBA planning.

Step 7. Attend to the details that remain

Identify the languages to be used in the IBBA

A multi-ethnic study group poses a challenge in terms of the language and/or dialect used in data collection. For example, the long-distance truckers (LDTDs) in the India IBBA traveled from different places but congregated in certain locations to load and unload supplies. These truckers had different local languages in which they felt most comfortable communicating, and no single language could be identified as suitable for all respondents. Often the meanings of words connoting sexual behaviors are both subtle and difficult for someone from another culture or ethnicity to decipher. The PSA team listed all the languages spoken by the truckers. They recruited field team members who spoke the local languages and translated the questionnaires into each language. Although this practice made central review of the questionnaires more difficult, it helped to ensure that the respondents understood the questions in order to answer them accurately. In another case, some of the FSWs came from outside India. Respondents who had relocated recently were not yet familiar with the commonly used local language and had difficulty responding to questions asked by interviewers when their local dialect was not used. It is important to have standby investigators or community liaisons who understand the languages the respondents speak.

Address community concerns and potential barriers

By identifying and addressing the concerns of the study group, the study team can plan appropriate community mobilization and fieldwork methods. Typical emotional barriers and beliefs are fear of giving blood, objections to drawing venous blood or finger-prick samples, mistrust of particular investigators, and a general fear of doing harm by giving out information. The team should explore whether study population members are willing to be interviewed for 30 to 40 minutes about their sexual behavior, and if so, what times of day and locations would be ideal for the interviews. In addition, the team must find out whether study-population members are willing to give biological specimens (e.g., blood or urine) or to undergo physical examination to identify STI, and what would be an appropriate location for doing this part of the IBBA.

Create a profile of the ideal field team member

Community members may be more comfortable speaking about sensitive subject matter with some people than others. Such preferences may be related to age, gender, educational level, or ethnic background. Arguments have been made for and against using male interviewers with FSWs. Decisions on the gender and characteristics of the team are made by considering what will be acceptable to the study group and the safety of the field team.

The experience of conducting behavioral surveillance studies (BSS) in India indicates that FSWs had no problems answering even sensitive questions posed by male interviewers. However, in many districts in the India IBBA, female interviewers conducted the interviews with FSWs whereas the fieldwork supervisors and doctors were male.

Choosing appropriate interviewers is challenging. It may be useful to involve some members of the study population as field staff, either as community liaisons or as interviewers, depending on local need and acceptability. When interviewers come from the target group, this may allow respondents to feel comfortable answering sensitive questions. Alternatively, other respondents may not want to share personal information with members of their own community and data may be biased as a result. When the interviewer is a service provider to the target group (e.g., government or nongovernmental health workers), respondents may provide biased answers on their use of services or on their risk behaviors in order to please the interviewer. Gather preliminary information about community preferences for interviewers. If community members are hired as interviewers, it may be worthwhile to use mixed interviewer teams that include both community members and outsiders. Neutral interviewers who have no vested interest in the success or failure of interventions are preferable.

Identify gatekeepers and stakeholders

Identify all the stakeholders associated with the study population. From these stakeholders, identify the potential gatekeepers—those whose permission, either formal or informal, is needed to gain access to and achieve the cooperation of the study population. Encouraging and fostering the involvement of these people in the initial planning stages onward increases a community's sense of ownership of the study. It would be convenient to engage the local and site-specific gatekeepers just prior to starting the fieldwork and after preparing the sampling frame (see table 3).

Table 3. Examples of gatekeepers in study populations

Brothel-based sex workers	Brothel owners and managers, pimps, regular partners of sex workers, NGOs working with sex workers, policemen
Men having sex with men (MSM)	NGOs working with MSM, police, regular partners, pimps
Intravenous drug users (IDUs)	Friends and family of drug users, drug suppliers, police, NGOs working with IDUs
Long-distance truckers	Truck owners, booking agents for goods, trucker unions

Identify referral centers to support the IBBA

As part of an IBBA, respondents/participants are provided referrals to different support services. The types of support structures are as follows:

- A voluntary counseling and testing center (VCTC) should be available for those who want to test for HIV, because an IBBA may not be able to provide HIV test results to respondents.
- STI clinics where respondents/participants feel comfortable, located close to the data collection venues, are helpful. Although it is possible to treat respondents with STI symptoms at the study clinics, follow-up and partner treatment may only be possible through an established STI clinic. The team may identify NGO clinics, government clinics, or local reliable doctors, depending on the category of provider the community trusts. The team may provide several options for the study group and refer each person based on his or her choice.
- The presence of NGOs working directly with the study population helps the study team access and mobilize the study population to participate in the IBBA.
- Local laboratory facilities for processing and storing samples and equipment must be identified. These may be government or private facilities.

The PSA team must secure permission from a key person at each support center to use the facility for IBBA respondent referrals. The team should develop a referral sheet with current information on the centers' services, including the location, phone number, hours and days of operation, and the key contact people at each center.

Determine appropriate compensation for the participants

Although some people are averse to compensating study participants, it is ethical to ensure that participants do not suffer any financial loss as a result of their participation in an IBBA. Seek suggestions from key members of the study population and other stakeholders on whether a need for such compensation exists, and if so, what the compensation should be. Take care to avoid giving compensation that would induce people to participate. Cash compensation is complex to handle and entails the risk of corruption. In India, MSM and FSWs who participated in the IBBA received cash as compensation in most districts, in amounts defined as acceptable to the local population and not necessarily covering time lost (i.e., Rs. 100/respondent, which is equivalent to approximately US$2 per respondent). In one state, no compensation was given, because the community members and NGOs felt that compensation would disrupt the NGO services and

other research projects. A similar sentiment was expressed in other states, but the IBBA community advisory board (CAB) generally encouraged compensation in those districts, once the purpose of the compensation was understood.

If compensation is to be given in kind, the type of compensation is important. Again, the cost of the gift should not be much, but the gift must be of value or use to the study group without constituting a reason to participate. For example, truck drivers in India were given a bag containing a towel, soap, toothpaste, and brush for participating in the study. Give compensation to all respondents—even those who complete only a part of the study. For example, a respondent who completes the behavioral survey but declines to give biological samples such as blood or urine should nevertheless be compensated.

Chapter 2

Community preparations

2

- Build community participation
- Identify stakeholders, gatekeepers, and community liaisons
- Establish community advisory and monitoring boards
- Minimize harm and adverse events

This chapter provides guidelines for planning an IBBA to ensure community participation and minimize harm to the survey population. In the context of an IBBA, the term community means the survey population and other stakeholders associated with that population—family, friends, work associates, health care agents, the police, and other social service agencies. Developing partnerships and engaging community participation at the earliest stages of planning an IBBA are essential, so that the survey team is respectful of the community, understands and addresses the community's major concerns, is equipped to prevent problems and deal with any that arise during the survey, and is not thwarted by unanticipated problems.

Partnerships with community members provide the survey team with insight on how to work with the larger community, on the community's concerns and methods of addressing them, and on how to minimize the chance of harm, misunderstandings, or other problems in the field. Moreover, these partnerships keep the community informed, prepared, and supportive of the survey.

Effective community teamwork also fosters a sense of ownership of the IBBA findings and encourages use of the findings in plans for programs at the local level. Engaging a community to participate in an IBBA requires an understanding of its social infrastructure and working with community health intervention programs, peer educators, outreach workers, community leaders, and volunteers. Different study populations are associated with different sets of community members (see table 4).

Table 4. Community members associated with specific study populations

Study population	Examples of community members
Female sex workers	Sex workers, brothel owners/managers, pimps, regular sexual partners, local shop owners catering to sex workers, taxi drivers, local doctors, NGO staff, FSW associations, opinion leaders, religious leaders
Men having sex with men	MSM, NGO staff, MSM community leaders, advocates
Injecting drug users	IDUs, drug dealers, NGO staff, friends and family members of IDUs, owners of tea shops and other shops in the area, police
Bar girls	Bar girls, bar owners and managers, stewards, pimps, taxi drivers, police, bar girls' associations, NGO staff
Truckers	Drivers, helpers, drivers' associations, brokers, staff at loading and unloading sites, local doctors, owners of tea shops and other shops in the area, mechanics, restaurant owners, bar managers

To develop community participation, follow these steps:

1. Identify the community and its stakeholders.
2. Meet with government officials.
3. Conduct an initial meeting of stakeholders.
4. Meet with local NGO staff.
5. Meet with gatekeepers (the key people who can promote or prevent participation by respondents).
6. Involve a community liaison (CL) to work with the survey team and the community (see Appendix 2).
7. Form a community advisory board (CAB).
8. Form a community monitoring board (CMB).

Step 1. Identify the community and its stakeholders

It is critical to identify members of the community in which the study population resides and that population's stakeholders. Stakeholders, in the case of FSWs, are state and district authorities, brokers, madams, lodge owners, community activists, local political leaders, NGO staff working with the study population, opinion leaders, and peer educators.

Before initiating fieldwork, the survey team lists all the NGOs, CBOs (community-based organizations), institutions, and individuals working with each of the study populations. Ideally the survey team maps the areas within a district or study area to show the geographical spread of the community and stakeholders. This information helps the team make plans to build rapport with the community, decide where and how many meetings to arrange, and schedule visits to the community when people will be available. Through these investigations, the team discovers the primary stakeholders who should be invited to the first stakeholders meeting (step 3).

Field experience: Building rapport

Conducting an IBBA among clients of female sex workers was a difficult task. The study team conducted several meetings with sex workers, brothel madams, agents, pimps, and local shop owners to learn more about clients and their typologies. Similarly, for the survey of bar girls, the survey team sought help from bar girls, bar owners and managers, bar-girl union members, and NGO staff.

Step 2. Meet with government officials

In India, support from the National AIDS Control Organisation (NACO) promoted cooperation by government at all levels. Government bodies can be involved in an IBBA in these ways:

- Take ownership of the project.
- Facilitate collaboration between partners (e.g., to minimize the number of surveys with different risk groups).
- Help address misinformation.
- Help build the community's confidence.
- Help reduce any risk to the community.
- Provide government facilities as survey sites.
- Help plan for data dissemination.
- Use the data and findings in local and national programming and in policy making.

This type of partnering and strategic involvement in the IBBA can range from giving information, sharing tools, helping gain the support of local service providers and stakeholders, and being involved in advisory boards. The team may also consider having national and state AIDS control organizations or health departments send letters of support to the service providers and stakeholders with whom they work to facilitate the team's entry into these organizations. A one-page summary of the IBBA's purpose, method, key populations, timeline, and measures to minimize harm can be prepared for distribution at meetings to clarify the most important take-home messages.

Step 3. Conduct the first meeting with stakeholders

Table 5. Typical agenda of an introductory meeting with stakeholders

■ Welcome address
■ Introduction to IBBA
■ Purpose/objectives of IBBA
■ Methods used
■ Minimization of harm/ethical issues
■ Benefits and risks to respondents
■ Community participation through advisory board, monitoring board, and community liaisons
■ Partners in implementation
■ Data dissemination
■ Questions and discussion on anything pertaining to IBBA
■ Discussion of the survey's implementation and any potential problems

The survey team plans an introductory meeting with all the stakeholders, including NGO partners, pimps, madams, and other community leaders. This meeting's purpose is to inform stakeholders about the IBBA (its objectives and methods, the aim of community participation, and the intention to minimize harm); to document all of the stakeholders' concerns; to assess how the study should be implemented; to address potential operational difficulties; and to answer all questions (see table 5).

Before this large community meeting, meetings with smaller groups of stakeholders help the team to plan and to anticipate and address concerns. Here are some examples of questions and comments that came up in such meetings during the IBBA in India:

- Why is blood collected?
- Will everyone have to give blood?
- What will the team do with people who are unwilling to give blood because of fear, lack of interest, stigma, or any other reason?
- Blood collection will have a negative impact on the community and it will hurt the relationship between the NGOs and the community. How will the survey team prevent this?
- Why are survey participants receiving financial compensation? That will have a negative effect on existing health services.
- Why is another survey needed when so much information is already available?
- How will these surveys actually help the community?
- Many people say they will share study information, but how do you actually plan to do that?

- Who will conduct the surveys?
- Will NGOs implement the surveys?

The meeting plan should be based on the extent and penetration of the HIV/AIDS programs within the study area. Generally, the survey team will encounter one of the following three situations:

- The community is empowered and HIV intervention programs are well established.
- An HIV intervention program exists but has not penetrated deeply into the community.
- No intervention program exists.

In a community with an established HIV intervention program, the survey team may work closely with the social services staff to understand concerns, identify key community leaders, and so on. Where a program is not well established, the team may work with NGO staff but also rely on independent work within the community to understand local scenarios. Where intervention programs are weak or nonexistent, the team can conduct interviews with key informants to help identify the stakeholders. Then they may hold meetings with these people to introduce the survey and to understand and address any concerns.

Field experience: Initiating community contact

In India, one survey team wanted to conduct meetings with brothel owners to initiate dialogues on IBBA. Group meetings were planned for each lane in the brothel area but they were unsuccessful. The survey team learned from the community liaison that the brothel madams were unwilling to leave their buildings to attend meetings, because they were unfamiliar with the survey team members.

Field staff also realized that a potential threat of outright rejection of the survey existed if one particularly strong madam protested against the survey. The survey team changed its strategy immediately, and visited brothel owners door-to-door, one by one (accompanied by a community liaison, to introduce the team members and to discuss the survey. This approach quickly built rapport with the community.

Step 4. Meet with local NGO staff

Since NGO staff work directly with the study's risk groups, they can provide important insights to survey staff into operational issues and concerns, and they also serve as a source of correct information for the risk group when the study is implemented. Early in the process, the survey team gives the NGO staff a timeline of activities and explains the role of NGO staff at each stage or activity of the study.

In meetings with NGO field staff (peer educators, outreach workers, clinic staff, and counselors), the purpose and methods of the survey, minimization of harm, community monitoring, and steps involved in conducting the IBBA could be discussed. Members of the study population may also be invited to the meeting.

As a result of these meetings the NGO staff should:

- Feel comfortable with the IBBA
- Be able to facilitate the process of addressing misunderstandings about the survey at the local level with the survey team field coordinator
- Be able to facilitate problem-solving during the survey, by involving the CMB or other survey personnel

Ideally, conduct these meetings at least two weeks before fieldwork—including mapping of hotspots (places with high concentrations of members of the study population)—begins. If the meetings are held too early, field staff may forget about the survey, whereas if it is held too late, their lack of involvement may upset them.

Encourage field staff to voice their concerns in these meetings. Tell them whom to contact when questions arise about the survey and give contact information. The IBBA survey team must be open, transparent,

and willing to answer any questions raised by the field staff and the survey population. At the end of these meetings the peers or survey population participating in the program should feel comfortable with the IBBA; fully supportive of the IBBA; able to refer members of the survey population who express concerns or doubts about the IBBA to the right person (coordinator or other survey team member); and willing to report to the survey team any suspicion, concern, or report of harm circulating in the community about the IBBA.

Step 5. Meet with gatekeepers

IBBA survey team members may need to sensitize influential gatekeepers (for example, police, pimps, local leaders, and madams) in the study area or specific sites that will be covered. In the initial assessment the survey team may have decided that a certain group (for example, pimps if FSWs are the study population) needs to be sensitized to the IBBA, because without that group's cooperation the IBBA could not be successfully completed.

NGO staff and members of the survey population may be willing to help identify gatekeepers and encouraging their participation. Early identification of gatekeepers, particularly at the local level, gives NGO staff a longer lead time to schedule meetings with the gatekeepers before fieldwork begins. The study team may conduct meetings in groups or individually, depending on the local situation, the willingness of gatekeepers to attend meetings, and the community's response to the survey. One-on-one meetings help avoid larger controversies that may occur if one person dominates the meeting. The survey teams should discuss the IBBA's survey activities, solicit support in implementing the survey, and understand their concerns. Strategic gatekeepers (other than government officials) may also be asked to join the community advisory board.

Field experience: Gain police support

Informing police about the IBBA was useful during surveys of street-based sex workers, because it prevented mistaken arrests of survey team members, ensured that participants in the survey were not harassed, and gained police support for the survey. In fact, the IBBA was an opportunity for police officers to develop sensitivity, by learning about HIV and about the community of sex workers.

Step 6. Involve community liaisons

A community liaison (CL) is a person from the survey group or community who is active in the community without being powerful, who acts as a link between the survey team and the community, and who facilitates the process of survey participation. Typical roles are to build rapport with potential respondents; help prepare for community activities; make sure that respondents understand the process; advocate for the potential respondent's concerns or questions; and assist the team by following ethical protocols and guidelines. The CL acts as an interface between the survey team and the community at all stages of the fieldwork. The CL reports to the field supervisor on his/her field team. See Appendix 2 for detailed information about the role of community liaisons on field teams.

How is a community liaison identified?

A CL is identified using a similar approach as for CMBs and should have the following characteristics:

- Be a person from within the community
- Have access to and good rapport with the community
- Have good communication skills and fluency in pertinent local languages
- Be willing to be associated with the project throughout the survey period, including training
- Be willing and able to work in unstructured situations and at odd hours and to travel extensively

In most instances, the CL should be from the survey group itself (as in the case of MSM and FSWs) but there may be times when others associated with the survey group are easier to recruit. For the survey of clients of FSWs that was part of the India IBBA, FSWs, regular partners of FSWs, local shop owners, taxi drivers, and madams served as community liaisons, not the clients themselves.

Each field team should have one community liaison who is aware of and can discuss all the aspects of the IBBA, including:

- The objectives and process of IBBA
- The topics of sexual behavior to be covered
- The biological tests to be done and the amount of blood required
- The consent process
- The voluntary and confidential nature of the IBBA
- How sites and respondents are sampled (i.e., randomly)
- How the respondent is recruited at the site
- General information on referrals for health services
- How the collected data will be used and shared with the community

Their specific roles can be categorized as:

- Engaging gatekeepers and stakeholders
- Assisting the supervisor and counter in identifying members of the survey group at different sites
- Building rapport with potential respondents (as selected by the supervisor)
- Witnessing the respondent/participant's consent
- Accompanying respondents to the biological sampling site
- Ensuring adherence to harm-minimization protocol
- Addressing concerns of respondents and community members

Step 7. Form a community advisory board

The IBBA team forms a community advisory board (CAB), by inviting key people from the community, including representatives of the survey group, to serve as members. The board's purposes are these:

- Safeguard the community interests and concerns prior to and during the survey
- Ensure that the survey team is aware of major concerns of the community
- Help the team address any adverse events that occur in the community as a result of the IBBA

Much of the activity of identifying advisory board members can happen while the team is identifying stakeholders and defining the community. Key individuals may suggest trusted community members who can serve; a snowball technique can be used whereby key people suggest others in turn. Some representatives from the survey group as well as local government AIDS organizations should be included on the board. About eight to twelve individuals can be selected for the CAB in consultation with the research supervisors.

Each survey population in a district should have one community advisory board. In a district that is very large or where commuting between towns is difficult, the survey team may consider forming several area-

specific CABs rather than coordinating between one larger advisory board. Any member who wishes to withdraw from the CAB at any given time can do so by informing the chairperson of the CAB.

Conduct the first meeting of the CAB before fieldwork begins. During this initial meeting, the board decides on processes for conducting meetings, method of work for monitoring the IBBA through the CMB, and decision making within the CAB. A chairperson of the CAB is selected by the members of the board and is responsible for conducting meetings.

Subsequently, board members meet one week after the IBBA begins, to review the initial progress and any implementation challenges. Later the board could meet bimonthly or a minimum of three times (for each of the subpopulation groups) throughout the data collection period in the study area. The CAB reviews the progress of the survey activities, examines the reports of the CMB and the field coordinator in relation to community questions and concerns about the IBBA, and addresses any that arise. Representatives from the survey team should be open in discussing field issues and should brief the board on the survey's progress at the beginning of the meeting.

In case of a severe adverse event, the survey team immediately calls for an emergency board meeting. For other adverse events or concerns, the field team consults with the board's chairperson regarding when to call the next CAB meeting. Any board member can convene or call an emergency meeting. The IBBA field coordinator should be present at all board meetings. A few representatives from the CMBs could be present at these meetings to provide feedback and address CAB members' questions.

The board should be kept informed by field staff of the rough plan for coverage without providing specific information on the sites, unless needed. The board gives attention to the issues and concerns related to:

- The consent process
- Protection of the individual subject's rights and interests
- Biological sample collection
- STI treatment at the time of survey
- VCTC referrals
- The survey team's work methods during field work
- Solicitation of police support and of local press support

The CAB may review complaints and problems brought up by community members during the fieldwork at any site. Such problems are documented by the supervisor at the time of the fieldwork and reported to the field coordinator. All meetings of the CAB are documented and include all key decisions taken by the group. All the decisions made by the board are communicated to the IBBA field coordinator who, along with the other key project staff members, ensures that the required actions are taken.

IBBA India field experience: CAB members resolve NGO objections to a survey

When one of the IBBA surveys started, a local NGO resisted the fieldwork even though the survey team had met with the organization's staff members several times, including the coordinator, peer educators, and outreach workers. At those meetings, the NGO promised support for the survey but the situation became problematic when the NGO instructed all individuals accessing their services not to participate in the survey. In the community, the result was active resistance to the survey to the extent that those individuals who chose to participate were harassed by other individuals. The advisory board met to discuss this issue and helped the survey team intervene. Board members met with the head of the NGO to try to understand concerns and to address them. The board's involvement was essential to addressing the NGOs concerns, helping the NGO understand the value of the survey and eventually gaining their support.

Step 8. Form a community monitoring board

A CMB consists of members of the key population who safeguard the community's interests; ensure that the IBBA protocol, its ethical guidelines, and harm-minimization measures for the survey are properly followed; and identify, report, and address the occurrence of any adverse events. The survey protocol for the IBBA in India provides detailed information about all aspects of an IBBA. (See Appendix 1.)

Identification of members

Locally involved NGO staff should be asked to suggest those whom they think would be appropriate members to serve on a monitoring board. The survey team and their community liaisons may also identify CMB members during the pre-survey assessment (see Chapter 1) and mapping (see Chapter 5), as they will be interacting with a number of people from the survey group. This will help to ensure that the CMB members and community liaisons are not always linked to the interventions in the study area. Assess in one-on-one meetings whether a potential board member understands the process and purpose of the IBBA, and select only those people who have both the interest and willingness to invest their time and who are willing to travel to the site to report and help troubleshoot problems.

The survey domain may have several monitoring boards depending on the size of the domain, the number and variation in sites, and the geographic spread (see Chapter 5 for more information on the survey domain). For example, in a survey that combined male sex workers and men having sex with men, the team might consider two separate CMBs depending on the existing relationships between these two study groups. In a district that is large and has difficult terrain, multiple CMBs will be needed to minimize travel and to ensure that the board members are familiar with the areas they cover. For each region, two to three members could be identified to be on the monitoring board.

At the initial orientation meeting, the CMB members schedule the dates of their meetings within their areas and decide how to conduct their meetings and how decisions will be made within the group. CMB meetings are facilitated by the IBBA survey team. A survey team representative such as the field coordinator or community preparation coordinator attends these meetings. The CMB is provided with dates when the survey team will be doing fieldwork in their region or area without specific information on sites to be covered.

The CMB develops a contact list with names, contact numbers, and addresses of the members in each area, which is provided to the community preparation coordinators. CMB members from a region meet weekly or as frequently as necessary to monitor issues and concerns. The local team leader files the minutes of the meeting of the local CMB with the field coordinator and sends reports quickly if any adverse event is discussed in the meeting.

After the survey begins, board members make field visits to some selected sites in their respective regions. During these visits, CMB members observe and question:

- Whether informed consent was taken from all respondents
- Whether community concerns and doubts were addressed by the community liaison
- Whether VCTC referrals were given to those who wanted them

Field experience: Community monitoring boards

Other than monitoring the actual surveys, CMBs helped the survey team to develop rapport with the community. When a FSW survey began in one of the main brothel areas in a district, the field staff was unable to gain entry into the brothels where sex workers of a particular ethnic background operated. The survey team consulted with monitoring board members who helped by introducing the survey team to the affected sex workers. The CMB was not present during the survey, but went with the team before the day of conducting the survey.

- Whether STI treatment was given
- Whether harm minimization guidelines were violated

Monitoring board members meet to discuss the following:

- The number of survey sites they visited that week
- Their observations and remarks on the conduct of the survey at that site, or in discussions with any community members
- Any community concerns or any adverse events (these should have also been reported immediately to the field representative)
- Interactions with survey team members, supervisor, or community liaison staff
- Other issues as they arise

Individual board members, with the help of the survey team, keep written records of the visit dates, the content of the discussion with the survey team or community members, and anything pertaining to monitoring issues. Written records are shared with the community preparation coordinator, who in turn shares the records at the CAB meetings.

Harm minimization

Harm minimization is a process by which efforts are made to prevent or reduce grievances or any adverse events experienced by the survey population during or after their participation in IBBA. One of the key means to avoid harm during the time of the IBBA is to inform and prepare the community (essentially representatives from the key population (KP) groups and other stakeholders) and gain their confidence.

To prepare for the IBBA, a carefully planned process is mounted to:

- Provide information about the survey to the community
- Reach mutual understanding and to address concerns
- Obtain input on how to implement the survey in a community-sensitive manner
- Establish community monitoring and advisory boards to ensure that any adverse events are addressed properly
- Help the community and its health partners use the survey data to evaluate, design, and implement HIV intervention programs

Protecting the rights and welfare of those who participate in the research study is a fundamental tenet of ethical research, and it needs to be one of the cornerstones of the IBBA methodology. Reports of harms that occur during the IBBA can be made by anyone, including people who participate in the survey, who work near the recruitment points, who act on behalf of participants, or who are simply observers. Reports can be filed with any member of the survey team, including the community liaison, NGO staff, and with members of the designated CMB (Appendix 2).

Adverse events

Adverse events are any unfavorable or untoward physical, psychological, or social event with some relationship to the IBBA that occurs during the study period or immediately thereafter. Adverse events can range from simple emotional distress to extreme physical or psychological pain suffered due to participation in the survey. Examples of adverse events are:

- A respondent/participant is emotionally disturbed by questions that are asked
- A survey team member is disrespectful toward the participant or potential participant
- A survey team member breaches the confidentiality, privacy, or anonymity of a participant (e.g., a participant's name is shared, an interviewer discusses a participant's behavior or responses during the questionnaire with others, or documentation with collected data are removed from a secure area)
- A survey team member sexually harasses or propositions a participant or potential participant
- Physical violence occurs at the hand of any survey team members
- A participant experiences unnecessary pain or disrespectful treatment (e.g., multiple pricks during a blood draw, rough treatment, etc.) during the biological/clinical component of the survey
- A participant feels weak or nauseous after giving biological specimens
- A medical technician or phlebotomist (a clinical professional trained to draw blood) is not following appropriate procedures for universal precautions (e.g., not using clean equipment, changing gloves between patients, or following standard operating procedures; see Chapters 3 and 9)
- Any survey team member puts undue pressure or coercive measures on a potential respondent to either participate in or continue with the survey (including pressuring a respondent who declines to give biological specimens)
- A survey team member creates visibility for participants at recruitment sites and expose them unnecessarily
- Increased harassment by police, local residents, or local rowdies as a result of the survey
- Eviction of key community members from their places of residence or work by the police, local authorities, or local residents
- A participant suffers a side effect of an onsite treatment for symptoms of an STI

Field experience: Gaining support and trust

In one of the surveys in Mumbai, India, well planned procedures for harm minimization helped gain the support of the survey population and its stakeholders. Initially resistance was high, because previous surveys had been conducted with the population by other groups, and especially because blood and urine samples were required for the IBBA. Harm minimization and ethical concerns were discussed in group meetings, boards meetings, and one-on-one meetings. Before and during the survey, an attitude of openness and transparency was adopted, which essentially involved asking for and listening to the advice of the community members. These measures helped to win the community's support and trust.

A system to address adverse events

Adverse events can be graded according to their severity, which depends on the intensity of the psychosocial symptoms, the degree of curtailment of the participant's daily activities, and the event's propensity to broadly affect the lives of the survey group. Grading the severity of adverse events helps guide the survey team in organizing plans for response and redress. The IBBA in India used a grading of mild, moderate, and severe.

A serious adverse event is defined as:

- Any occurrence of an untoward medical, psychological, or social event that results in limiting the capability of an individual

- An event that is life-threatening, requires or prolongs hospitalization, or causes persistent or significant disability or incapacitation
- An event that, in the opinion of the investigators, represents other significant hazards or potentially serious harm to research subjects or others—for example, psychosocial events such as severe depression, marital separation, suicidal or homicidal ideation and acts, serious episode of domestic violence, or complete isolation of an individual at his or her workplace or residence

Breach of confidentiality does not constitute a serious adverse event but it is a violation of protocol. The consequences that arise from a breach of confidentiality should be graded by their seriousness, as well.

Reporting of adverse events

Timely reports of adverse events is crucial for appropriate steps to be taken to address the immediate problems, ensure positive outcomes, and stop potential threats to the IBBA. Reporting adverse events to the local Ethical Review Committee is the sole responsibility of the state principal investigator at each site. All adverse events must be reported regularly to the principal investigator and the CAB. Serious adverse events must be reported within a reasonable period, as prescribed for each category (see Appendix 3).

Efforts to minimize adverse events including both passive and active methods should be listed out and put in place. Reports of adverse events can be made by any individual, either directly or indirectly affected. All reports are treated very seriously by the survey team. Reports can be filed with any member of the survey team, including the community liaison, NGOs and public health staff, or designated community monitors.

Field experience: A threat of exposure

During the IBBA in India, a member of the survey team entered a brothel area with a camera intending to document how the sites were set up for conducting the survey. Community members spotted the camera and were upset that someone was taking their photographs without their knowledge. People assumed that the person wanted to take pictures of sex workers for reporting in the newspaper. Men in the area gathered and protested against the survey. Although the field team tried to address the concerns of the community members they were unsuccessful, and were asked to leave the brothel area.

The incident was immediately reported to the chairman of the CAB and to the principal investigator of IBBA as per the protocol of harm minimization. Under the guidance of CAB members, the survey team contacted the key representative of the local NGO working among sex workers, explained the entire episode and sought their help in designing a suitable response strategy. The NGO staff, along with the field survey team, met the community to clear the misunderstanding about the event and resume the work.

Any survey team member who receives a verbal report of an adverse event or harm to a participant/respondent must document the complaint using a standardized form (see Appendix 3) that collects the following information:

- The date of the adverse event
- The date of the report
- The nature of the harm experienced/extent of harm experienced

- The name/description of the person who committed the harm
- A method for contacting the person who experienced harm
- The person to whom the complaint was made and that person's contact information

Dealing with adverse events

Survey team members' reports of adverse events are submitted to the team supervisor or appropriate higher authority. All reports from the team supervisor, monitoring board members, NGO staff, and others are sent to the field coordinator. The field coordinator ensures that all the reports are shared with the advisory board (and principal investigator) at their meetings. If a severe adverse event is reported, it is submitted to the advisory board and principal investigator (PI) immediately. See Table 6.

Table 6. Types of adverse events and report procedure

Type of adverse event	Example of adverse event related to participation in the IBBA survey	Reporting time to the CAB	Redressal time
Mild (grade I)	Brothel keepers getting angry and verbally abusing sex worker	Weekly	One week
Moderate (grade II)	Brothel keeper not permitting sex worker to move out of brothel	Weekly	Two days
Severe (grade III)	Sex worker thrown out of brothel	Immediately	Twenty-four hours

Severe adverse events are reviewed by the PI and the community advisory board, a plan for corrective action is devised, and initial action is taken within twenty-four hours of receiving the report. Immediate methods of redressing the adverse events are documented in an adverse event report form with long-term response as recommended by ethical committees, follow-up meetings of the advisory board, or the IBBA team's documentation in an adverse event resolution form. If the action taken by the survey team does not adequately address the harm, corrective action by the community advisory board is implemented. Appendix 4 presents the adverse event resolution form for FSWs that was used in the IBBA in India.

Chapter 3

The laboratory network

3

- Set up the laboratory network
- Procure supplies
- Manage specimens
- Implement external quality control

This chapter provides guidelines on how to establish laboratories, procure supplies, and implement a quality assurance system for an IBBA's biological component. It assumes that a multi-tiered model of national, state, and district labs will be set up when any large-scale survey is conducted in different states within a country.

An IBBA uses the standard medical procedures for clinical examination and specimen collection. More detailed information pertinent to clinical staff can also be found in subsequent chapters on training and biological fieldwork (see Chapters 7 and 9).

IBBA survey protocol includes the rationale for HIV and STI testing, and explains the key biological indicators measured in a survey. The survey protocol for the IBBA in India is shown in Appendix 1.

Establishing a laboratory network

The following pages describe the steps involved in establishing a laboratory network.

Step 1. Select tests for the IBBA

The number and type of STI and HIV tests to be conducted are decided based on the following facts:

- The existing information on prevalence, incidence, or evidence of disease (For example, if chlamydia is found to have very low prevalence in other studies, and if no other indications of increases in chlamydia occur, then it may not be useful or efficient to measure this throughout all samples. Instead, consider limiting tests to specific groups or to a sample proportion within a group.)
- Whether other studies have already collected similar information
- The importance of the HIV epidemic among members of the group
- The availability of resources and feasibility of collecting and testing specimens
- The sample size to be covered (See detailed information about survey design, sample size, and methodologies in Chapter 5.)

Step 2. Design the laboratory network model

The laboratory network includes the lab facilities and technical staff involved in coordinating and implementing the biological component of IBBA. The design of the laboratory network depends on numerous factors:

Number of surveys and sampling domains. If the IBBA surveys are limited to one sampling domain, then the team may be able to use one laboratory for processing, testing, and storing the samples. If multiple sampling domains are covered (e.g., several districts within a state), then the team may consider using the district laboratories for sample processing and supply storage and a state laboratory for testing, coordination, quality assurance, and long-term storage. Alternatively, if surveys are conducted on a larger scale, such as in several states, consider using three tiers of laboratories as in the India IBBA.

Number, types, complexity, and sensitivity of tests. If the survey is designed to perform many diagnostic tests— including some tests that involve complex procedures and require expensive equipment to perform, and/or contain sensitive information (e.g., HIV prevalence or incidence)—consider conducting these tests in one laboratory with the simpler tests and basic processes being performed locally.

In the India IBBA, the transcription-mediated amplification (TMA) assay for neisseria gonorrhea (NG), chlamydia trachomatic (CT), and HIV were tested at the national reference laboratory (also called the Apex laboratory). All other tests were conducted at the state laboratory, with the exception of the rapid plasma regain (RPR) test for syphilis, which was done at district labs so that test results could be returned to the respondents. This minimized equipment costs and ensured quality control, by limiting the number of labs conducting tests and protecting confidentiality of sensitive information.

Where and how lab samples are stored. If a laboratory specimen requires storage for longer-term use, such as for quality control or for future testing, then store the specimen in an Apex laboratory. Ideally the Apex laboratory will be an IBBA partner and have both the space and means to store samples for longer duration.

Whether test results will be returned to the participant. If some or all of the test results will be returned to the participants, consider early testing of the specimen in a quality manner. In IBBA India, syphilis test results (using RPR) were returned to respondents. Since RPR tests are simple and do not require expensive equipment, these tests were conducted at the district laboratories. This also ensured prompt return of test results to the respondents through the referral clinics, within seven days of participating in the survey.

Ordering and delivery of supplies. Logistic supply or supply-chain management is an important key to the IBBA's success. Carefully design, implement, and monitor the management of the IBBA supply chain. Give consideration to supplies with a short shelf life, and to kits and reagents that need refrigeration during transport and maintenance. Use log sheets to verify receipt and record the condition of received supplies.

Procurement of equipment and supplies. One question that needs addressing is whether to use centralized or decentralized procurement of reagents, equipment, supplies, and medicines. Another important planning consideration is the availability of repair and maintenance services for instruments. For expensive instruments it is often preferable to use central procurement where service plans may be available. For smaller, less expensive items it might be easiest to procure locally, based on need. Appendix 6 lists minimum equipment for network labs.

Initial storage and coordination facility for fieldwork. Store all survey supplies in one facility and allow the field team's regular access for their work. Develop an inventory recording system to track supplies and to assess when the ordering of additional supplies will bring timely delivery.

Confidentiality and harm minimization. All the staff members must maintain confidentiality and use established procedures to minimize harm to respondents as laid out in the IBBA protocol.

Roles and responsibilities. Clearly define the roles and responsibilities of all members of the lab network. Each staff member should be provided a documented job description that establishes a clear chain of command. Discuss and present job descriptions to team members during training and review before field enrollment meetings.

The laboratory network model adopted in IBBA India (and shown in figure 1) comprised the IBBA national reference laboratory, seven state laboratories, and one district laboratory for each IBBA district/highway site. Several local field lab venues were operated during the course of fieldwork.

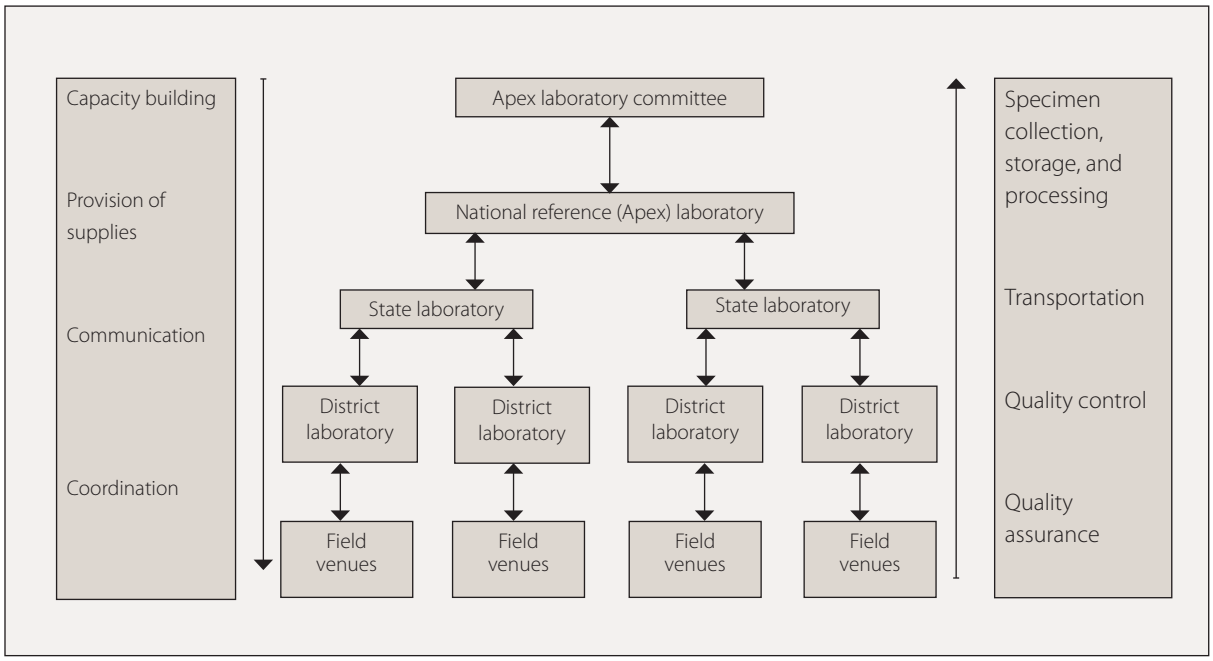
Step 3. Establish an Apex laboratory committee

The IBBA Apex laboratory committee (ALC) oversees the identification of the laboratory network partners and coordination among these partners. The committee is responsible for identifying requirements for collecting, testing, and storing samples; oversight of procurement (low-cost, high-quality products); supply-chain management and inventory tracking; and coordination of various activities within and among laboratories. Committee members may be from the specialized national reference laboratory or independent.

The ALC also establishes systems, guidelines, standard operating procedures (SOPs), training manuals, and the roles and responsibilities for each partner laboratory and its staff. The objective is to ensure quality in the collection and laboratory diagnoses of biological samples during the survey period. The ALC's scope of work entails:

- Identifying laboratory network partners, including assessment and negotiation if needed
- Providing advice/guide selection and procurement process
- Coordinating training and refresher training as needed
- Coordinating delivery of supplies, equipment, and maintenance needs
- Coordinating activities among state laboratories, district laboratories, and field collection sites
- Coordinating the specimen transport among and between sites
- Providing technical support to the state laboratories, district laboratories, and field collection sites
- Facilitating effective communication among IBBA laboratories
- Developing guidelines on supply-chain management, including roles and responsibilities, and procedures of collecting, processing, transporting, and testing samples
- Ensuring proper collection, storage, handling, and transport of biological samples collected from the field
- Troubleshooting assistance for laboratories during the survey period
- Managing inventory
- Developing a monitoring and supervision plan for state, district, and field laboratories
- Adhering to infection control and waste management guidelines at field collection sites, district laboratories, and state laboratories

Figure 1. Laboratory network model, IBBA in India



Step 4. Define the roles of the laboratory network partners

The structure of an IBBA laboratory network may consist of multi-tiered laboratories with varying infrastructure and technical capacities. The roles within this network will be modified by local IBBA survey requirements. The responsibilities of the laboratory partners in a network that follows the IBBA India model are as follows:

National reference laboratory (Apex Laboratory)

The national reference laboratory should be able to:

- Provide technical support to perform specialized tests for diagnosis of STIs and HIV (as per the protocol and test requirements)
- Conduct higher level STI/HIV tests as per protocol requirements
- Be willing to serve as a national reference laboratory for the IBBA
- Adhere to good clinical laboratory practices, including bio-safety practices
- Participate in national and international proficiency testing programs,
- Be willing to undergo an initial assessment by the IBBA team to evaluate technical and quality assurance competencies

The national reference laboratory has some specialized functions that should be adapted according to local requirements and that occur within a suggested timeline:

Three months prior to starting the survey:

- Act as a focal point for coordinating the biological component of the IBBA survey
- Develop and disseminate the scope of work for different tiers of laboratories
- Plan and implement external quality control and laboratory assessments

- Provide technical support in the selection and procurement of supplies
- Ensure that all supplies are in place before the survey begins

Two weeks to one month prior to starting the survey:

- Train clinical and laboratory staff
- Ensure that appropriate management systems are in place for equipment, reagents, and supplies

During the entire survey period:

- Coordinate the collection, processing, handling, transportation, and storage of survey samples to the designated laboratories
- Oversee the availability of supplies at all levels
- Provide feedback and conduct supportive supervision to participating network laboratories
- Provide troubleshooting support
- Conduct higher level HIV/STI tests as per protocol
- Conduct quality assurance monitoring visits and tests as per the protocol
- Organize regular meetings of members of the laboratory network committee

After the survey period:

- Conduct quality assurance tests
- Store samples
- Assess the amount of remaining stock and ensure implementation of storage plans
- Assess storage and maintenance of equipment

State laboratory

The state-level laboratory has overall responsibility for activities related to the biological component of the IBBA within the state. The lab manager and staff provide technical assistance and supervise district labs and field teams and should be able to:

- Assure adequate supplies of specimen collection materials
- Monitor use of supplies and stock of supplies at the site
- Monitor use of personal protective equipment for safety by lab technicians
- Monitor the test result quality
- Monitor collection and shipment of samples from the field through the district lab, to the state lab, and finally to the national reference lab for quality control and storage
- Perform laboratory tests, according to protocol In the India IBBA, these included TPHA (treponemal tests for syphilis); ELISA (enzyme-linked immunosorbent assay) for herpes simplex virus, type two (HSV-2), HIV, hepatitis B virus (HBV), hepatitis C virus (HCV); and NAAT (nucleic acid amplification test) for NG and CT.

- Provide troubleshooting support to district labs
- Ensure that district laboratories maintain quality control charts: temperature charts; equipment maintenance logs; records of all assay reagent lot numbers used in the lab; records of RPR control results; RPR result sheets and computer files; and sample storage forms

District laboratory

District laboratories have the following responsibilities:

a) Support IBBA field teams by:

- Ensuring adequate supplies of specimen collection kits
- Freezing gel packs for the cold chain
- Providing test results to the referral clinics in a timely manner
- Ensuring availability to give/receive supplies/samples as per the field team requirements

b) Process specimens by:

- Receiving biological specimens from the field
- Verifying temperature of cool box on receipt
- Sorting specimens and checking against field log
- Processing specimens as per the protocol
- Ensuring appropriate storage of specimens
- Packaging, documenting, and transporting specimens to the state laboratory as per the protocol

c) Perform laboratory tests by:

- Following the laboratory's standard operating procedures (SOPs) to test selected samples, if required
- Sharing test results with the IBBA field team according to protocol and ensuring confidentiality of the specimen and test results

d) Safely dispose of waste generated from field and district laboratories by following protocol.

Step 5. Assess laboratories for the IBBA

Prior to choosing network partners, the ALC will:

- Develop the tools for assessment
- Plan and coordinate the laboratory assessment in participating states and districts
- Analyze the assessment questionnaires and make recommendations
- Facilitate hiring staff and selecting laboratories for the network

Assess the competencies and infrastructure available in the state and district laboratories prior to selecting partner laboratories. It might be necessary to procure certain assessment instruments before implementing the IBBA. The objectives of the assessment are to:

- Determine the capacity of the functional laboratory for diagnostic tests, quality control, procurement, storage, and inventory control related to STI/HIV diagnosis

- Conduct a gap analysis and make an improvement action plan for issues emerging from the assessment

To conduct an assessment, follow these steps:

- Develop a plan of action– how and when the assessment will be conducted and by whom.
- Select or design an appropriate laboratory assessment tool (Appendix 5) including a scoring system.
- Conduct a mapping of the state academic, public health, research laboratories, and district laboratories in areas where the IBBA will be conducted. For each laboratory, record the name, the director's name, and the address, telephone number, and email address.
- Send a letter of invitation to all mapped state and district laboratories to participate in the IBBA.
- Select a list of potential laboratories for in-depth assessment.
- Inform each laboratory about the assessment and obtain concurrence.
- Identify the resource person(s) who will perform assessment of state and district laboratories.
- Conduct an assessment and score each lab.
- Sign contracts with all laboratory partners.

Depending on the structure of the lab network, district labs may be identified by the state lab rather than the ALC. In that case, the ALC may assist in assessments and other decisions.

A clear analysis and evaluation plan must be developed prior to laboratory selection. Table 7 lists minimum standards for labs. The standards for district–and state-level labs are developed along with the lab assessment tool, evaluating the following variables:

- Infrastructure: laboratory space, backup generator, timing, and security
- Equipment, including freezer(s), incubators, ELISA washer and reader, bio-safety cabinet, centrifuge, water bath, and autoclave
- Human resources: staff (the number and types of skills), existence of training and safety programs, support systems
- Quality assurance capacity: SOPs, quality control, equipment maintenance, and proficiency testing
- Type of laboratory tests performed and number per month and recording and reporting systems
- Access to the laboratory: from field site to district to the next level laboratory

Table 7. Minimum standards for laboratories

- Can perform simple to complex tests (depending on protocol and role of laboratory)
- Functional basic equipment
- Practice of infection control guidelines
- Quality control procedures in place
- Qualified laboratory staff conduct tests
- Sufficient laboratory bench space and storage room
- Participation in external quality assessment schemes
- Quality assurance systems in place

The IBBA ALC should select laboratories that meet minimum standards, are willing to be involved in the survey, and agree to the cost requirements. The committee establishes a memorandum of understanding which details the roles and responsibilities of participating district and state laboratories. This document is signed prior to the survey and contains the following elements:

- Ensure the provision of laboratory bench space, infrastructure amenities (electricity and running water), and storage area for IBBA supplies
- Maintain and ensure proper care of survey equipment and supplies
- Adhere to good clinical laboratory practices (GCLPs)
- Adhere to IBBA protocol and guidelines
- Properly store, handle, and transport biological samples in the laboratory
- Communicate regularly with partner laboratories and field teams in accord with roles/responsibilities
- Adhere to IBBA harm minimization and confidentiality agreements
- Supervise and monitor laboratory activities during the survey

Step 6. Collect field specimens

The survey team involved in data collection coordinate the collection of samples in the field and medical health checkups. Field specimen collection requires coordination with the district lab for collection of supplies, transportation of specimens, documentation, and returning results of biological tests. The field lab technician and doctor are part of a field team; their roles and responsibilities are discussed in Chapter 9. Obtain all required supporting documents for tax exemption during transportation in advance.

Briefly, venues for fieldwork require space and light to facilitate biological sample collection, confidentiality, and health checkups. Venues may differ depending on survey groups, sampling domain, field sites, etc. Some examples of venues used in the India IBBA include hotel rooms, brothels, halls, doctors' clinics during off-hours, hospital rooms, and mobile vans. These venues will be identified by the field team during the pre-survey assessment. The minimum standards for a field collection site are:

- Adequate light and ventilation
- Toilet facilities and running water
- Visual and auditory privacy
- Space for biological sample collection
- Space for health checkup

Step 7. Procure equipment and supplies

The essential components for the procurement of lab equipment, reagents, and consumables for the biological component of an IBBA survey are:

- Formation of a procurement committee
- Preparation of a laboratory test matrix
- Finalization of laboratory supply orders (specification and quantity) and required delivery schedule
- Call for tenders and finalization of the supplier
- Delivery schedule with date, location, and installation and maintenance plans

Form a procurement committee

A procurement committee, formed during the planning stages of the survey, should consist of members from the central laboratory committee and at least one member from the overall IBBA management team. This

committee plans for procurement (including listing equipment and supply needs), purchases supplies, and provides support for dispatching materials to local laboratories in a timely manner.

Prepare a laboratory test matrix

The laboratory test matrix provides details on the number and type of required tests. Information should be provided in a detailed matrix and a summary matrix. The detailed matrix includes information according to test type, sampling domain, and survey group.

Calculations are based on these variables:

- Sample size of the survey
- Number of surveys to be conducted
- Amount of expected wastage
- Percentage of wastage that is expected
- Percentage of quality checks that are done on tests

For calculating the percentage of quality checks that need to be done, the team needs information on the approximate expected prevalence of different biological markers. The matrix should also include information on approximate dates of survey commencement. This helps the team understand whether a bulk purchase should have phased delivery or delivery in one batch. Phased delivery may be done when an increased time lag between surveys exists and when certain reagents or test kits have expiration dates.

Procurement lists cover collection, handling, storage, transport, testing, waste management, data entry, and result reporting at each network level. The procurement committee prepares, in the following order:

- The name and number of test kits required (Table 8)
- A list of the type and number of consumables, supplies, and equipment required (Table 9

Table 8. Calculation of the required number of RPR test kits

Shown here is the calculation for the number of rapid plasma reagin (RPR) test kits when surveys are done among 10 groups, each with 400 members. Qualitative tests determining whether people are positive for syphilis are done for each participant. Quantitative tests, using the same RPR kit, are done on 10 percent of samples that are expected to be positive, based on previous surveys and published papers. Four dilutions are required for quantitative tests on each positive sample. Wastage, calculated by the number of tests for quality controls, repeat testing, and quality assurance testing, is 15 percent.

Name of test	Number of participants per survey (A)	Number of surveys (B)	Number of qualitative tests (C)	Number of quantitative tests (D)	Amount of wastage expected/ QC (E)	Total number of RPR tests
Standard	A	B	A * B	C * (percent of quantitative tests on total sample) * number of dilutions	(C + D) * (percent of expected)	= C + D + E
RPR Tests	400	10	4000	1600	850	6450

Table 9. Procurement list for RPR qualitative tests

Here is an example of the material required for conducting an RPR quantitative test. Note that the refrigerator and other equipment will be used for multiple tests. Make a separate list for each type of test and then cross-check to avoid unnecessary duplication of equipment.

Material required	Equipment required
■ Test tubes (100 x 13mm) for dilution of reactive serum samples ■ Pipette tips (universal, yellow) ■ Tips disposal bottle with bleach ■ 0.9% saline (100ml) ■ Marker	■ Micropipette (variable volume between 20 – 200µl) ■ Test tube rack for 48 tubes ■ RPR shaker ■ Refrigerator (4°C)

Material	Number of participants per survey (A)	Number of surveys (B)	Number of tests (D)	Amount of expected wastage (10%) (E)	Number of test material required (F)	Total
Example	A	B	D	D * 10%	D + E	F
Test tubes	400	10	1600	160	1760	1760
Yellow tips	400	10	5600	850	6450	6450
Saline	400	10	1600	160	0.2 ml per tube	350 ml
Micropipette	400	10			l per survey	10
Test tube racks		10			2 per survey	20
RPR shaker		10			1 per survey	10
Refrigerator		10			1 per survey	10

Calculate the quantity of supplies, reagents, test kits, and equipment for each test and group. The list should include:

- Name of the equipment/reagent/consumables, and size
- Quantity for each survey
- Total quantity required for the project

It would be useful to have these calculations available according to each sampling domain/survey group, for each laboratory in the network, and as an overall IBBA total. This first worksheet helps IBBA staff to calculate the required supplies, check stock, prepare for fieldwork, and ensure that any changes to procurement are easily accomplished. The second worksheet helps with distribution of stock, development of stock checklists, and monitoring tools. It is useful for budgeting and procurement. Linking the two worksheets for easy adjustments to any calculations would be helpful.

Finalize laboratory supplies and establish delivery

The laboratory supplies, test kits, reagents, and equipment can be finalized after prices are obtained. National and international suppliers can provide catalogues that have price lists. Select equipment, model, and manufacturer based on the following criteria:

- Quality of the product
- Suitability to the geographic area requirements – e.g., voltage, size
- Warranty and annual maintenance plans
- Same equipment available in other state/national institutions
- Recommendations from experienced people and institutions
- Cost

Compile the final list to include specifications such as model number, manufacturer's name, catalogue number, unit cost, quantity, and total cost for all laboratory supplies necessary for IBBA survey (Appendix 6). The procurement support committee decides on pack size for test kits and consumables based on the requirements. For example, some test kits or reagents may expire so the team should consider timelines for conducting the survey within the expiration dates and quantities desired.

Call for tenders and finalize the supplier

The procurement support committee reviews and approves the final procurement list. The committee decides on the procurement method based on national procurement policy. The modes of procurement are:

- International competitive bidding
- National competitive bidding (i.e., open tender)
- Limited international bidding
- Limited tender
- Shopping
- Single tender/direct contracting

Open tender is the competitive bidding procedure used for public procurement of goods and civil works in many countries and was used for the IBBA in India. The process for an open tender is outlined below:

- Publish an invitation/notification for bids in at least two daily newspapers with wide circulation. If there are different languages within the country, the bid should be published in the national language and in English. Bidders should be allowed the option to submit bids for any one or more schedules specified in the schedule of requirements and to offer discounts for combined schedules. The advertisement may also be placed on appropriate websites. Tendering period should not be less than thirty days.
- Require bidders to submit tenders valid for the period specified in the tender documents. Normally, the bid validity period should not exceed ninety days.
- Call for a meeting of the procurement support committee to review open tender documents immediately after the deadline for receipt of bids/tenders.
- Open all tenders received. Do not reject any tender at bid opening except for late tenders. Late tenders should be returned to the bidders unopened.

- The name of the bidder and total amount of each bid along with important conditions like excise duty, sales tax, transport cost, delivery terms, delivery period, any special conditions should be read aloud at the time of bid opening.
- A member of the procurement working committee should prepare and sign a spot comparative statement and the minutes of the bid opening meeting.

Examine the tender documents to confirm the following:

- Eligibility requirements have been met
- Documents are properly signed
- Documents include the required earnest money and are valid for the period specified in the tender document
- The group has responded to the requirements/needs listed in the tender documents
- The company had the technical and financial capability as per specified in the tender

The procurement support committee evaluates each tender to see if it meets the criteria to successfully execute the contract. The quality of each tender and its cost to the implementing agency are evaluated in a manner that permits comparison. The tender with the lowest evaluated cost that provides all specified supplies should be selected for the award.

Develop a schedule for delivery, installation, and maintenance

Develop a delivery schedule and provide the schedule to the supplier with necessary information. The delivery schedule should be communicated to the lab network along with the expected delivery so that the stock can be reviewed on receipt. The delivery schedule should cover:

- One-time deliveries of nonperishable items (equipment and laboratory supplies excluding test kits)
- Multiple deliveries of test kits with short expiry dates

Prepare a delivery schedule for a number of test kits with the timeline and place of shipment. The vendor should provide aplan for installation of all equipment in the testing labs and annual maintenance. The equipment should be tested on installation to ensure good working order.

Step 8. Create a system to manage inventory and destroy expired kits

Management of laboratory supplies and reagents includes organizing laboratory supplies, monitoring supplies in central and regional laboratories, and maintaining a buffer to avoid running out of stock. IBBA laboratory staff at all levels must understand their roles and procedures for management of laboratory supplies and reagents during the survey. Institute a system of inventory management and monitor it carefully. The first step is to train all laboratory staff in the preparation of a stock register listing the name of the product, catalogue number, kit specification, package configuration, lot number and expiry data, and condition of supplies on receipt (especially for diagnostic kits and sensitive reagents) and the quantity of reagents. Staff will list all equipment in a separate register with installation information. The second step in creating an inventory system is to establish a supply-chain system from the supplier to the central (national) laboratories and then to the regional and field laboratories. Plan to have in place the minimum laboratory supplies required for the survey and establish a system for reordering reagents.

Expired kits must not be used under any circumstances in an IBBA. Develop an SOP for discarding expired kits, maintenance records, and safety precautions. Label all diagnostic reagents and kits in bold letters. Make sure that laboratory staff are aware of the following points:

- Disposal of laboratory reagents and expired kit components must comply with all aspects of waste disposal requirements.
- Decontamination and disposal information is usually provided in the kit or product insert under the heading "Warning and precautions."

Step 9. Establish quality control standards

Quality control/assurance is the total process that guarantees the quality of laboratory reports during any national or international biological survey. The key elements of quality assurance are focus on systems and processes, use of data to analyze laboratory service delivery processes, an orientation toward meeting the expectations of stakeholders, and encouraging a team approach to problem solving and quality improvement.

In the context of an IBBA, good clinical laboratory practice (GCLP) is the laboratory quality system that ensures reliable, repeatable, auditable, and recognizable results.

GCLP standards cover:

1. Laboratory infrastructure (testing facility and operations)
2. Human resources (organization and personnel)
3. Preventive maintenance (facilities and equipment)
4. Specimen management and tracking
5. Test validation and performance specifications
6. Quality control
7. Laboratory safety
8. Data management (records and report)

Step 10. Implement GLCP standards and monitoring systems

Field specimen collection site/field laboratory. Specimen collection, handling, and transport to the next level of laboratory are the most important activities of the field site. The integrity of the biological samples collected from study participants is assured when these recommended steps are followed:

1. A plan for necessary infrastructure and supplies is always available at the site. A list of supplies and equipment for specimen collection and transport is prepared by the field team and a minimum one-week stock of supplies is available at the field site. Documentation of stock is one of the activities of the field team.
2. The medical officer and field laboratory technician each receives a job chart listing roles and responsibilities. The staff receive two days of training on IBBA field operations, including specimen collection, handling, storage, waste management, and transport to the district laboratories. For detailed information on training, see Chapter 7.
3. A standard operating procedure on the biological component of the field site is developed by the IBBA study team.

4. A quality control checklist ensures that all important clinical field activities are conducted.
    - Field supplies for one week held in stock
    - Collection of specimens/samples as dictated by the lab field manual, e.g., urine, swab, blood, etc.
    - Maintenance of the lab stock form
    - Adherence to waste segregation in the field
    - Identification of errors and documentation
    - Doctor and lab technician each received three doses of HBV
5. Completed specimen submission forms are tracked using a checklist. Minimum equipment is available to network laboratories prior to transport of specimens to the next level laboratory. (See Appendix 6.)

Activities of IBBA testing laboratories at each level

The district laboratory is the first to receive specimens from the field. This laboratory ensures that specimens are appropriately labeled, aliquoted, and transported correctly to higher-level labs. The district laboratory may also perform qualitative and quantitative serological tests for syphilis on participant's serum samples. The following steps are recommended to ensure GCLPs in the district/provincial laboratory.

Step 1. Agree on roles and responsibilities of all network laboratories

District-level laboratories:

- Ensure laboratory supplies at field site are adequate.
- Perform qualitative and quantitative syphilis serologic testing (rapid plasma reagin, or RPR) according to the SOPs.
- Verify samples received from the field collection site and record test results (including those of quality control testing).
- Aliquot samples and store samples properly prior to shipment.
- Package samples for transport to the state laboratories.
- Coordinate with the field staff.

State-level laboratories. State-level laboratories provide technical assistance and oversight to the district laboratories. The state laboratories have the following responsibilities to the district laboratories and field teams:

- Assure adequate supplies of specimen collection materials.
- Monitor use of supplies and current on-site stores of supplies.
- Monitor bio-safety practices.
- Monitor proper collection and shipment of samples.
- Maintain quality control records on site for the project duration.
- Ensure proper storage of samples.

National reference (Apex) laboratory. The national reference lab is responsible for coordination and implementation of the biological component of IBBA surveys. Additional responsibilities are:

- Coordinate all IBBA-related activities.
- Develop all laboratory-related documents (SOP, QA/QC manual and guidelines on long-term storage and access).
- Institute supply-chain management in all participating institutions.
- Establish a communication system with all network lab managers.
- Provide technical support to state laboratories.

Step 2. Coordinate laboratory infrastructure

The minimum laboratory space and equipment necessary for performing tests on specimens collected from survey participants must be determined for district, state, and reference labs. The factors to be considered are:

- Type of test(s) performed, from moderately complex tests (TPHA/HIV; ELISA) to highly complex tests (for example, the nucleic acid amplification test, or NAAT, and the reverse transcription-polymerase chain reaction test, or RT -PCR)
- Number of specimens to be tested by a particular method
- Number of lab staff
- Minimum lab equipment required for performing tests (Appendix 6)

Laboratories should fulfill all preventive maintenance of instruments and equipment in network laboratories and perform quality control according to the manufacturer's instructions and standards. A preventive maintenance program ensures both accuracy and longevity of equipment. To accomplish this, laboratories are encouraged to develop an SOP manual for all equipment. This should include the following:

- A list of all equipment in the respective labs, including serial number, and specific location in the lab
- Clear instructions on how to use equipment incorporated into the SOP manual
- Institution of periodic equipment for exact level of precision (e.g., micropipettes) and records of all calibration maintenance
- A schedule to clean equipment based on the manufacturer's instructions
- A record of quality control forms used to monitor equipment function
- A clear system to document equipment problems or errors, to resolve and correct them, and to avoid them in future

Step 3. Enhance technical capacities of laboratory staff

- Develop training curriculum for the district and state laboratory staff.
- Prepare appropriate training manuals and identify resource persons for the training program.
- Conduct hands-on training of lab staff to perform tests, including quality control.
- Incorporate principles of GCLP in training.
- Conduct pre- and post-training assessment of participants.
- Continuously build technical capacities of laboratory staff during monitoring visits (see Appendix 12).

Step 4. Adopt specimen management guidelines

Specimen collection

- Collect specific specimens in the appropriate containers under appropriate conditions.
- Collect all samples in the correct container according to SOP.
- Prepare guidelines on the use of appropriate collection for each specimen in tubes/cups/bags.
- If dried blood spots (DBS) are collected, provide necessary supplies and train technicians on how to collect DBS.

Specimen transport

- Ensure safe and proper specimen transport within the lab network.
- Maintain a specimen submission log sheet.
- Use an appropriate transport vessel kept at the required temperature.
- Organize samples for shipment to network laboratories.
- Inform the referred laboratory about the shipment of specimens.

Specimen storage

- Develop a time frame for shipment of samples and to maintain the sample quality.
- Organize specimen storage systems in all network labs.
- Document specimen receipt and storage.

Step 5. Organize testing methods

The laboratory advisory committee recommends tests that provide accurate and reproducible results. The choice of test is based on sensitivity, specificity, validity, reproducibility, availability, and the test's cost.

Regardless of level, the laboratory is encouraged to develop an SOP manual that guides all aspects of the IBBA lab work. The manual should be dated and signed by the survey lab manager and any changes in procedure/reporting should be endorsed by the manager.

- All laboratory technicians and research assistants should be thoroughly trained and competent to perform the specified procedures.
- A copy of the manual should be readily accessible to the technician.
- Every aspect of testing should be monitored, controlled, and documented: positive control, negative control, use of in-house controls, and use of instrument calibrator/s. All reagents and equipments should be controlled before testing (e.g., ELISA reader).
- The laboratory worksheet should be completed and retained for inspection during monitoring visits. The worksheet should contain the IBBA ID number, date of testing, the name of the test, batch and lot numbers, and, if kits are used, the expiry date. (See Appendix 12.)
- Interpret results in accord with the manufacturer's instructions.
- Record all results on a printed report form.

Step 6. Determine the frequency of quality control checks

The national reference laboratory provides guidance to the network laboratories on the frequency of quality control checks on equipment, reagents, and kits. Table 10 illustrates the frequency of quality control testing.

Table 10. Equipment quality control testing by laboratories in the India IBBA

Equipment	NABL India (national accreditation board for testing and calibrating labs) standard
Commercial kits (e.g., RPR and TPHA)	Lot or batch
Equipment:	Document that all function checks are performed in accordance with manufacturer's recommendations, perform calibration, and verification of results every six months or when reagents changed.
Temperature	Daily
Biological safety cabinet	Annual certification, daily air flow
Microtiter pipette	Calibrate initially before put into use and every six months
Thermometers	Check against National Institute of Science & Technology (NIST) standard before use
Automatic diluters	Calibrate initially before use, and every six months thereafter

Step 7. Implement external quality control systems

A referral laboratory uses an external quality assessment to validate test results obtained at district- and state-level laboratories by a referral laboratory. The following methods can be implemented by the IBBA labs.

A. Re-testing of serum samples at a referral laboratory

- Samples are selected according to WHO guidelines for EQAS (external quality assessment tests for HIV-1 nucleic acid).
- Samples are retested blindly by the same method and same kit in the reference lab.
- Results from both laboratories are compared for concordance and discordance.

B. Testing of an anonymous sample at the reference laboratory

- The manager of the reference laboratory could randomly select 10 percent of serum samples (reactive/positive or nonreactive/negative) received from the district laboratory.
- Divide these samples into two aliquots.
- Label one aliquot under the original survey participant ID number.
- Label the second aliquot with an anonymous survey participant ID number.
- Record participant ID numbers first and second in EQAS register (which should be maintained by the laboratory).
- Send both samples for testing.
- Record the results and date of reporting for both samples.
- Compare the results, test performed, and turnaround time on both samples at the reference laboratory.

Step 8. Assess the serological testing proficiency of laboratory staff

Laboratories are advised to assess the proficiency of district laboratory staff to conduct serological testing, by participating in an existing external laboratory proficiency testing program or by implementing their own programs. The national IBBA laboratory should facilitate or develop protocols for this assessment. The implementation of a proficiency testing (PT) program by the national reference laboratory includes:

- Enrollment of state/district lab participants in the PT program
- Determination of the frequency of PT sample testing
- Selection of samples (For example, five samples–two nonreactive, two reactive, and one highly reactive—should be sent to participating labs depending upon the duration of the survey and the type of the laboratory.)
- Shipping of samples and PT reporting forms, with a time frame for reporting
- Providing feedback on the performance of the participating laboratory in comparison with reference laboratory results and suggestions for improvement
- Summarizing results and building capacities of staff

Step 9. Strengthen IBBA laboratories to provide accurate reporting of results

IBBA labs must build capacities for accurate and timely reports on tests conducted on samples from survey participants. To provide reliable results, adhere to the following:

- Prepare a laboratory report format, which includes ID number, site number, date of sample collection, type of sample, type of test, result, and (if necessary) reference range.
- Establish an acceptable turnaround time for all tests done in the network labs.
- Monitor report accuracy by checking clerical and computer errors and comparing results reported with those recorded on lab worksheets.

Chapter 4

Survey instruments and documentation

4

- Protocol, ethical approval, consent, and other forms
- IBBA questionnaire
- Sampling frame development (cluster surveys)
- Respondent-driven sampling

IBBA instruments are developed and tested to make sure that they meet the requirements of the survey protocol and data collection. Prior to initiating the preparatory activities of any IBBA, a final survey protocol should be developed along with questionnaires and ethical clearance. For the India IBBA clearance was handled by the Health Ministry Screening Committee, the Indian Council of Medical Research, and the Protection of Human Subjects Committee of FHI.

The survey protocol for the IBBA in India is shown in Appendix 1. The reader can refer to it for details on the rationale, the objectives, the core teams, the protection of vulnerable subjects, and survey methodology.

This chapter discusses the specific instruments and documentation required to conduct an IBBA, including forms for consent, primary sampling unit (PSU), questionnaires, cluster information sheet (CIS), clinical formats, respondent-driven sampling (RDS) logs, laboratory sample transportation, referrals, and the RDS coupon. More detailed information on the forms and documentation for the district, state and national laboratories are discussed in Chapters 3 and 9.

The survey instruments required for respondent-driven sampling (RDS) and cluster-based surveys are slightly different. Table 11 summarizes the survey instruments by phase and sampling methods. Table 12 shows survey documentation by sampling method.

Survey protocol

A detailed survey protocol is required for ethical clearance and to guide the survey team on objectives, survey design, as well as ethical considerations and harm minimization. The survey protocol is developed in consultation with key stakeholders and provides an overview of the IBBA procedures. These guidelines provide more detailed information on implementation.

In India, the Indian Council of Medical Research was charged with implementation of the integrated assessment, with technical support and assistance from FHI. The principal investigator assembled a core team to direct the IBBA consisting of: a principal investigator with senior level medical epidemiological skills and experience, a research coordinator, and a research associate with strong knowledge of quantitative research, a senior microbiologist to supervise the specimen collection and transport procedures as well as the laboratory procedures of the IBBA, and a data analyst to oversee the data management process in the various states. Other teams were statewide, highway-based, or working around topics such as, the questionnaire, survey methodology, and data management to develop guidelines on different aspects of the survey. More detailed information about the protocol for IBBA teams, see Appendix 1.

For an IBBA covering multiple groups or geographic areas, decisions related to study group definition and sampling domain can be modified to suit the findings of the pre-survey assessment. Any changes to the study protocol should be documented and communicated to the ethics committees. International ethical guidelines for conducting research on human subjects must also be kept in mind while developing IBBA protocol.

Table 11. Survey instruments by phase and sampling method

Phase	Survey Instrument	Cluster	RDS
Survey preparation	Survey protocol	X	X
	Consent form	X	X
Sampling	PSU form	X	
	Cluster information sheet	X	
	Listing sheet	X	
	Eligibility form		X
	Noneligibility form		X
	Nonresponse form		X
	Coupon		X
	Financial log		X
	Coupon log		X
Fieldwork: Behavioral	Questionnaire	X	X
	Checklist	X	X
Fieldwork: Biological	Clinical form	X	X
	Biological specimen transportation form	X	X
	Stock indent	X	X
	Referral form	X	X
	Participation summary	X	X
Data management	Data confidentiality agreements	X	X
Laboratory documents	Lab forms, stock list, etc.	X	X
	Procurement forms	X	X

Ethical approval document

Collecting sensitive information from respondents in an IBBA is challenging. They may feel uncomfortable, fearful, or offended when asked to share information about their sexual behavior. Respondents in an IBBA are members of groups that are often marginalized. Discrimination makes them vulnerable to coercion, stigma, and even violence. Protecting the rights of individuals in the study population during an IBBA is an utmost priority. An ethical approval document details on how the rights of survey respondents will be protected.

Table 12. Survey documentation by sampling method

Phase	Survey documentation	Cluster	RDS
Survey preparation	Pre-survey assessment (PSA) report	X	X
	Survey domain and group, sampling method, and compensation decisions and definitions and sample size calculation	X	X
	Summary of biological test decisions	X	X
	Signed ethical approval	X	X
	Harm minimization protocol	X	X
Community preparation	Community advisory board (CAB) guidelines	X	X
	Community monitoring board guidelines	X	X
	Contact information for CAB members	X	X
Sampling	Sampling frame	X	
	Seed profile/rationale		X
Fieldwork	Field notebook	X	X
	ID numbers	X	X
	Size estimation methods and experiences	X	X
Data management	Code book including new variables, recoding, etc.	X	X
	Data confidentiality protocol	X	X
Data analysis	Weight calculation	X	
Other	Contact list for survey staff	X	X

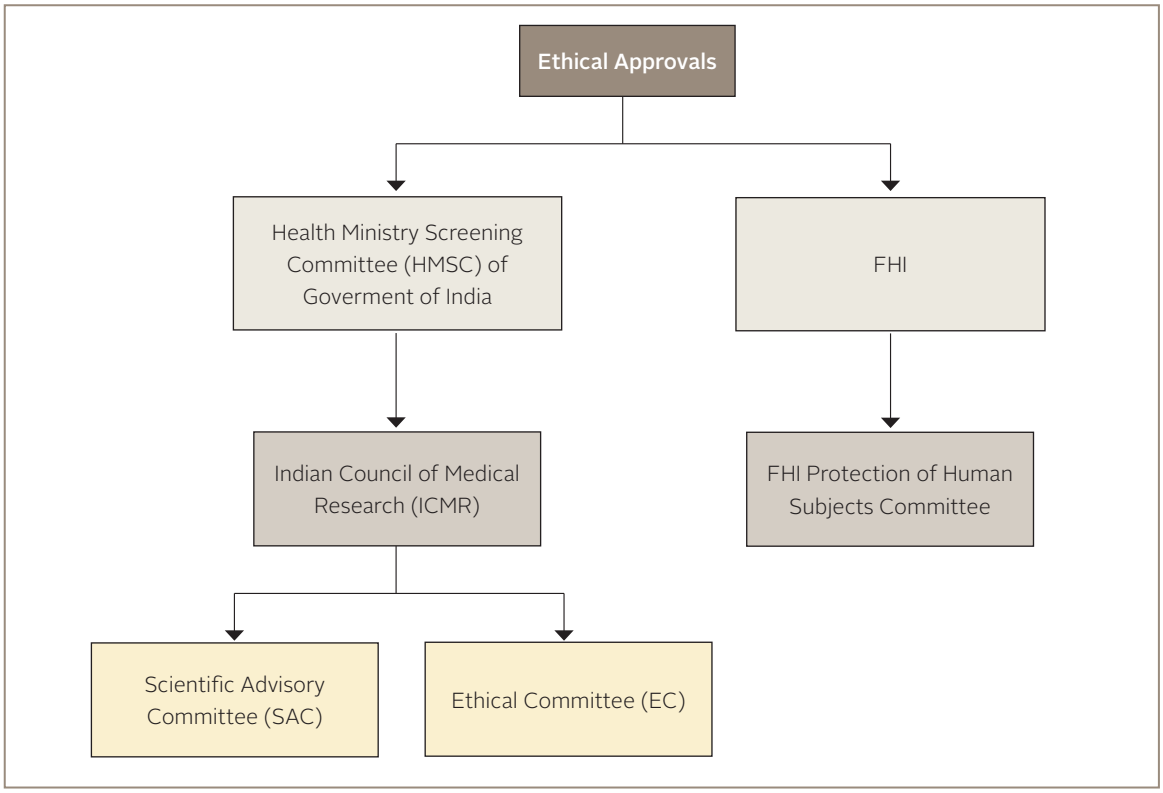
Field experience: Ethical approvals in IBBA in India

In India, the IBBA survey protocol was approved by the Health Ministry Screening Committee (HMSC), the Indian Council of Medical Research (ICMR), and the FHI Protection of Human Subjects Committee. Both the scientific advisory committee and ethical committee of the National AIDS Research Institute participated in the development of ethical measures adopted in the survey. Further, state implementing agencies sought approval from their local ethical committees. The consent and support of the National and State AIDS Control Societies was also obtained. The protocol was updated during the survey and approval was sought from these same agencies. See Appendix 1 for details about ethical issues and review.

With monitoring at the field level, training in ethics and harm minimization within the IBBA for all staff involved in the survey, and harm minimization reporting and response plans, the IBBA in India had a structured model of prevention, response, and resolution to ensure the rights of the participants.

HIV/AIDS studies that involve human subjects raise ethical issues such as voluntary and informed consent, rights during participation, preservation of confidentiality and privacy, and the appropriate end use of the collected data. A series of ethical approvals from the national government and ethical bodies of the partner organizations involved in the IBBA help establish study guidelines, consent procedures, and harm minimization measures. These include response plans at various levels that assist field teams in adopting the highest ethical standards. Ethical approval documents should indicate how to ensure that study groups or individuals are not stigmatized as a result their participation. As shown in Figure 2, a series of ethical approvals were obtained while conducting the IBBA in India.

Figure. 2. Ethical approval model, IBBA in India.



Consent form

It is important to obtain informed and voluntary consent from the respondents before proceeding with the IBBA. The consent form helps educate the respondents on the purpose of the study, its benefits and risks, its confidentiality, and what participation will entail. Respondents/participants can be given the option of written, oral, or witnessed consent. Further, participants (in cluster surveys) may choose how they will participate: for example, in only the behavioral component, in the behavioral and biological components, or in the behavioral component and specific parts of the biological component. In addition, participants may discontinue at any time, without penalty.

Consent forms contain the following information:

- Purpose of the study
- Organizations conducting the study
- Realistic potential for benefits to the participants
- Risks of participation

- Extent to which confidentiality will be protected
- Rights during and after participation
- Contact information for any queries or concerns

The consent form conveys to the respondents that the IBBA is conducted among the population who fit the eligibility criteria, the purpose of the study, and the fact that selection of respondents is random. Respondents are given every opportunity to ask any questions that may occur, and the consent form is administered in the presence of a community liaison. A copy of the consent form should be made available to the respondent.

The two-part sample consent form adapted from the IBBA in India is found in Appendix 7. Part A covers a behavioral and clinical investigation and part B covers permission to use blood samples in future research.

Questionnaires

Questionnaires are the instruments through which behavioral data are gathered. For different survey groups, questionnaires are developed or fine-tuned specific to the subpopulation, although many sections will be similar. Key information areas are summarized in Table 13. One needs first to decide how much profile or background information may be required. Further, it is important to decide what behavioral indicators should be included in the questionnaire. Carefully plan and draft the questionnaire in a way that is consistent with IBBA objectives, the behaviors being studied, and how the data will be analyzed and used for program planning and policy decisions. One excellent place to start is with existing IBBA or behavioral surveillance survey (BSS) questionnaires; these will show the key information areas and elaborate the types of questions.

Within a sampling domain, the questionnaire may need to be adapted to suit local scenarios. For example, translations should suit local terminology instead of being standardized. In the IBBA in India, questions on exposure to health interventions required fine-tuning in the sampling domain to ensure that the correct information was captured. Key indicators for the IBBA should be defined prior to implementing the survey and should meet the survey objectives. All information that is collected (key indicators and other questions) should have a clear purpose and plan for collected data use. It is important to consider international standards for time frames, question design, and so forth so that comparability between countries is possible. Further, much thought and planning has gone into developing these standard indicators. A sample questionnaire of the India IBBA appears in Appendix 8.

Designing a questionnaire

When developing questions for the behavioral survey, the team considers the following:

- **Time frame**. Questions for different behaviors should be asked within a specified time frame (for example, "Have you attended a private or public antenatal clinic in the past one year?" or, "In the past one month, have you had the experience of a condom breaking while it was being used?") for the data to be useable and to ensure comprehension of the questions. No specific time frame can be used across the different groups, because many responses depend on the frequency of behaviors. For example, questions for an FSW about consistent condom use with clients may be bound by a one-month time frame due to the high frequency of sex. Questions about consistent condom-use behavior with FSWs for FSW clients may require a longer time frame. However, it is important to identify a set of key indicators that can be compared across states/regions. For example, one may chose consistent condom use in the past month as a key indicator for FSWs. Including a question on consistent condom use in the past week for FSWs where partner exchange is high may help to validate the previous question. In that case the questionnaire would use both questions.
- **Ask specific questions.** Questions should be specific to ensure comprehension. Otherwise, the research team may have one understanding of a vague question and the respondents another understanding. For example, when asking about frequency of sex in the past one month—the question needs to include

frequency of sex with a specific type of sexual partner (e.g., wife, regular FSW, occasional FSW). Further, if asking about knowledge of HIV, the interviewer cannot simply ask, "Do you know how to prevent HIV?" Instead, the interviewer should mention specific means of prevention.

- **Define partner types**. Sexual partner types of groups vary. For example, in India, the sexual behavior of MSM included having male regular partners, male irregular unpaid partners, and FSW partners, as well as partners to whom they sell sex and from whom they buy sex. Clients of FSWs had wives, irregular unpaid partners, occasional FSW partners, regular FSW partners, and male partners. The team should assess the sexual behavior of the survey group during the pre-survey assessment to clearly understand the different partner types that exist. The definitions for different partners should be clear. Definitions may be included in the questionnaire to remind the interviewer and to guide the respondent.

- **Order of questions**. Present the questions in logical order to allow for an easy flow. Introduce the respondent gradually to the most sensitive topics, such as anal sex, purchase of sex, etc.

- **Length of questionnaire.** When the questionnaire lasts too long, respondents may lose focus and responses may become less accurate.

- **Coding.** Code the answer categories as consistently as possible to facilitate and avoid errors in the interview, data entry, and analysis. For example, no, yes, don't know, and no answer response codes can be standardized (the India IBBA used 00, 01, 98, and 99 for these categories). Also, the order of these categories should remain consistent—if no comes before yes, it is best to repeat this order for all questions to avoid errors in recording answers.

- **Clear instructions.** Certain questions may require probing whereas answers to others should not be probed. Generally, most questions do not involve probing. There will be times when the interviewer should read response categories and times when this should not be done. Further some questions allow a respondent first to answer questions spontaneously and then in response to prompts. This is done to see if survey group members have immediate recall of a topic (for example, how to prevent HIV) and, if not, if they recall upon prompting. The instructions for the interviewer must be clear and included in the questionnaire.

- **Multiple responses.** Some questions allow the respondent to provide more than one answer: for instance, "Will you name the ways to prevent HIV?" When questions allow for multiple responses, the instructions should be clearly stated. Some multiple-response questions involve ranking (for example, "What is the most common drug you inject? Second most common?"); others do not. The coding of multiple responses should be clear, so that in analysis, researchers can distinguish the first choice from the second choice.

Table 13. Information areas in an IBBA questionnaire

Information areas	Type of information
Site and interview details	Cluster number/RDS venue, interviewer name, date of interview, language of interview, consent status, status of completion of participation, typology of participant, status of reviewing questionnaire, editing, and data entry
Sociodemographic characteristics	Age, gender, literacy/education, sources of income, and marital and living status
Mobility and migration	Current and past places of residence and recent places traveled
Condom use and drug-injecting practices	Place of obtaining condoms, condom breakage and slippage, frequency of alcohol consumption, drug-use behavior, injection drug-use behavior (frequency, number of partners), place of drug use, frequency of needle sharing
Sexual behavior	Age of first sex and age of first paid sex, types of sexual partners, condom-use behavior (last time, consistently) by partner type, frequency of sex, types of sexual practices
Knowledge of STIs	Heard of STIs, ability to name STI symptoms, history of STIs, treatment-seeking behavior
Knowledge of HIV/AIDS	Heard of HIV, correct information on HIV transmission and prevention, has taken an HIV test, knowledge of antiretroviral therapy, risk perception
Exposure to interventions	Aware of and accesses intervention services

Pre-testing

Before data collection, questionnaires require pre-testing, which helps assess whether questions are understood, acceptable, defined correctly (partner type, time frames, etc.), obtain the desired information, and are translated correctly. All questions should be consistent enough to have the same meaning to all the respondents. Pre-testing helps assess the sequence of questions, the skip pattern, and coding of questions. It also helps the team to identify culturally suitable words for sensitive behaviors (for example, the act of anal sex).

Pre-testing is generally conducted among a small sample of the study population in a nonsample area to avoid interviewing people twice. The team practices using the consent form and the questionnaire, to gauge how long an interview takes to complete. Pre-testing consists of between eight to ten interviews among the study population who are selected in a nonrandom fashion. The interviewers take notes throughout to record problems, and the supervisor meets with the interviewers at the end of each pre-testing day to capture the information. Based on the findings, questionnaires are modified to incorporate changes.

In some countries, pre-testing the questionnaire is part of the training. Then a day is spent debriefing the interviewers after the pre-test. This creates a platform where those who will conduct the survey can bring their concerns about the questionnaire's design. Pre-testing also brings to light difficulties of both interviewers and interviewees. See also Chapters 7 and 8.

Data collection for sampling frame development (cluster surveys)

Primary sampling unit forms

Information about the primary sampling units (PSUs), such as brothels and street corners, is collected using PSU forms during mapping. PSU forms capture the characteristics of known sites and newly identified sites. Identifier information includes the name of the district/town and local area, unique identifier of the site (its specific address, the name of building/place, etc.), landmarks at or near the site, and a hand-drawn map of the site and the area around it, indicating boundaries and landmarks. (See Appendix 9.)

Hand-drawn maps and descriptions of the sites are both important. A brothel madam's name or house number recorded on the PSU form may change by the time fieldwork is initiated. Brothel madams do not generally tell the truth about their names. As a result, a name should not be a unique identifier. Instead the team should describe where the site is located: its address, the building or site name, nearby landmarks, etc. This, combined with a map, helps the team identify the site during fieldwork.

Characteristics of the site that are documented include:

- Type of risk group/site (survey group, fixed/mobile site)
- Number/range of eligible people associated with the site
- Operational times and peak/lean times
- Operational days and peak/lean days
- Mobility of the site members
- A detailed, hand-drawn map of the site

Further, information is collected on the availability of any private places in the area that could be used as a venue. For the team to conduct interviews and collect biological samples, such facilities require not only privacy but also adequate space, potable running water, and toilets. One PSU form is completed for each site; it will be used to construct the sampling frame and should be available with the field team during fieldwork.

Sampling (cluster surveys)

Listing sheet. The listing sheet is completed by the counter at the field sampling site. The counter lists the number of survey group members associated with the field site who meet the eligibility criteria. Listing is done by unique identifier information rather than by name. For a time-location cluster, counters list all individuals who visit the site during the field timing. The field timing will be shorter than the operational time, unless a take-all survey is done. For a conventional cluster sample, the counter lists all individuals affiliated with the site who meet the eligibility criteria, even if they are not present at the time of the field visit. A unique cluster ID number should be included on the form.

Cluster information sheet. The cluster information sheet (CIS) is filled out for every cluster visited during the conduct of cluster sampling surveys. The CIS is completed by the person responsible for sampling and recruitment of respondents at the field site. The counter and the community liaison at the site at the time of the survey can help fill out this form. The CIS captures the unique cluster ID, the number of eligible people visiting the site, the number selected for the survey, and the number agreeing, refusing, or not available to participate in the survey. The information is used to calculate selection probabilities, which are used in weighting the sample during data analysis.

The CIS also serves as a "control sheet," by providing information about the number of behavioral and biological interviews completed and refusal rates. This can aid survey monitoring, because it can be used

to update team members on survey progress as well as indicate challenges in implementing the survey. Guidance on filling out the CIS appears in Appendix 10.

RDS forms

Eligibility form. The eligibility form is used to assess whether people coming to the RDS center are eligible to participate in the survey. Although the form does not contain information about eligibility, it is during this part of the survey that the screener (with the CL) determines eligibility of the respondent through a series of questions. For individuals eligible for the survey, the screener fills in the form which includes information on coupon number and the participant's ID number. It also includes information on who gave the respondent their coupon and how long they have known each other. This information is primarily used to understand the relationship between the recruiter and potential respondent.

Noneligibility form. The noneligibility form is also completed by the screener for people who come to the center to participate but for some reason are determined to be ineligible for the survey. There are many reasons why people might not be eligible: for example, they might not have a coupon, or a valid coupon. The screener records the reasons for not being eligible and takes the individual's coupon.

Nonresponse form. The nonresponse form is completed for people who do not consent to participate in the survey although they are eligible and for people who discontinue participation in the middle of the survey. The nonresponse form is not used to pressure these respondents to change their minds; rather, it serves to capture the respondents' reasons for declining or discontinuing participation. This form may be used to identify trends in reasons why people do not want to participate in the survey. It should be completed even for individuals who do not give all the biological specimens. If size estimation of the survey group is taking place through a multiplier or capture-recapture method, the team may need to include information here on exposure to the specific multiplier or capture–recapture requirement. For guidelines on using surveys to estimate population size, see Chapter 6.

RDS coupon. The RDS coupon is used to recruit individuals into the survey and to track secondary compensation. Individuals who are recruiting give their recruits half of the coupon (the recruitment portion), which includes information on the venue or location, timing, and coupon number of the recruiter and the potential respondent. This coupon is used by the screener to ensure that individuals are recruited through a network and that they are not walking into the survey of their own accord. It also limits the number of individuals who can be recruited by one person. If a respondent can recruit three people into the survey, they receive three coupons (each coupon has a redemption and a recruitment portion). This coupon is the only document that tracks who recruited whom and it is essential for bookkeeping (see Appendix 11). More information on the RDS is found in Chapters 8 and 10.

The redemption coupon is used by the recruiter to give secondary compensation. It contains the respondent's coupon number and the coupon numbers of the people the respondent recruits. The coupon manager uses this information to find out if the respondent's recruits have participated in the survey. If they have, then the respondent is eligible for secondary compensation. See more detailed information on sampling methods in Chapter 5.

Coupon tracking log. The coupon tracking log is one system that was used in India to track coupon numbers given to the incoming respondents. The coupon manager, when completing the recruitment and redemption cards, can fill in the coupon ID number. The coupon ID numbers were not preprinted, because it is impossible to predict how many coupons are required and how many seeds will finally be required for the survey. The team should review this tracking log and decide whether it is helpful. The log does not eliminate the possibility of error in recording coupon numbers.

Financial log. The coupon manager also completes the financial log. This log tracks when primary and secondary compensation are given, the amount given, and to whom. The log helps the coupon manager and the team work together to recruit and track the survey. The log should be synchronized with the other RDS centers on a daily basis, because respondents can access services and compensation from any RDS center.

Coupon tree. The coupon tree is used to track participation in the survey, by helping to monitor which seeds are producing, which types of survey group members are coming to the survey, whether a need has arisen to introduce activation/expiration dates or to recruit more seeds, and so forth. Because respondents may visit any center, the coupon trees, like the financial logs, require daily updating by the coupon managers and coordination across the RDS centers. These updates are windows on the survey's progress. A coupon tree can take the form of a log or separate poster-size sheets with drawings of the tree (one sheet per seed). The visual representation afforded by the posters provides a quick understanding of survey progress and reduces paper use. If people come to the center to participate but are not eligible or have nonresponse, the team includes this information on the tree to show all parts of the survey progress.

Biological forms

Clinical and referral forms. Clinical forms are filled out by the doctor and are used for recording information on the health checkup component of the survey. The form includes information on patient history, whether a physical exam was done, and observations during the exam, diagnosis, and treatment. For more detailed information on the biological component forms and procedures, see Chapter 9.

The respondents who are referred to other services are provided with the referral form. Referral services would include counseling, HIV testing, follow-up STI treatment, and other such services. The cards that are given to the respondents provide the address, hours, and contact information for various referral centers. The India IBBA provided test results to participants and used one referral card for NGO referrals and for collecting test results.

More information on referral network forms and documentation is found in Chapter 8. Detailed information on the laboratory networks appears in Chapter 3. Forms and documentation pertinent to biological fieldwork are discussed at length in Chapter 9.

Chapter 5

5

Chapter 5. Sampling approaches and sample size

- Sampling methods
- Calculation of sample size
- Cluster sampling and respondent-driven sampling
- Recruitment of respondents

This chapter provides an overview of sampling methods, the calculation of sample size, and the steps to implement each sampling method. Of the two types of sampling available to researchers (nonprobability and probability sampling), surveys of high-risk groups generally use a probability sampling design.

Defining sampling

A sample is a subset of a population that is used to gain information about the group. A sample in this sense is a model of the survey population. Selecting some individuals (i.e., taking a sample) can provide information about the population without having to meet each and every individual in that population (i.e., conducting a census). Conducting a census is resource-intensive in terms of both time and cost, and is not required in many situations. (See Example 1.)

Example 1. "Is my food ready?" sampling

When cooking rice or pasta, many people pick up a few pieces from the pot after it boils to test whether it is fully cooked. They are using a sample of the rice/pasta to know whether the entire pot is fully cooked. We all apply these concepts in daily life.

The process of selecting some members of the study population to represent the population as a whole is known as sampling. Data collected in an IBBA using a census method will not be more informative than data collected using sampling (when the correct procedures are followed), because both census and sampling data will apply to the entire survey population. Sampling is time-saving and cost-effective. It has other advantages, as well. The amount of data that can be collected and the quality of the data may actually improve with sampling, because fewer people are required to implement the survey, monitoring is more feasible, and extra resources can be used on such pre-survey activities as training, survey instrument development, and community preparation. In addition, data management and data analysis will be easier to handle when sample surveys are done than when censuses are conducted.

If the survey group is too small to meet the minimum number required for sampling, conducting a census will be more useful, because in that case a census will yield more reliable and credible data. When mapping of the survey population is complete, the researcher can determine whether a census or sampling is in order.

If sampling is deemed to be in order, before beginning the researcher must calculate the number of people to select and how to select them. There are two ways to sample populations: nonprobability and probability sampling.

Sampling designs: nonprobability sampling

In *nonprobability sampling*, samples are selected based on the subjective judgments of the researchers to achieve particular objectives of the research at hand. Nonprobability sampling does not follow any rules of sampling. In nonprobability sampling, researchers are not able to project the findings of the survey to the entire survey group, because all members of the group will not have had a chance to participate. The most frequently used nonprobability sampling designs are summarized in Table 14.

In some situations nonprobability sampling is appropriate and may be the only method available. On occasions when we are truly interested in particular members of the population rather than the population as a whole, a nonprobability sample may be more appropriate. Nonprobability samples may also be used when a) a sampling frame —that is, a list of the members of the population—does not exist; b) it is not possible to develop a sampling frame; or c) the population members are so widely dispersed that probability sampling is not feasible.

Example 2. Sampling in a classroom

Imagine a classroom of students in which women are sitting on one side and men on the other. If we want to know the percentage of students who are female in the classroom, we can use sampling to figure this out. If we take the first four students on the left side (nonprobability sampling), we will conclude that the classroom is 100-percent male or 100-percent female. But if we select four students randomly, we are more likely to get a correct picture of the gender balance of students in the classroom (probability sampling).

Table 14. Nonprobability sampling design and selection strategy

Sampling design	Selection strategy
Convenience	Select cases based on their availability and the convenience of the researcher
Most similar/dissimilar cases	Select cases that are judged to represent similar conditions or, alternatively, very different conditions.
Typical cases	Select cases that are known beforehand to be useful and not to be extreme
Critical cases	Select cases that are considered key or essential for overall acceptance or assessment
Snowball	Group members identify additional members to be included in sample

The basic weakness of all nonprobability sampling methods is their subjectivity—their sampling bias, which precludes the development of a theoretical framework. In other words, no statistical basis exists for assessing the precision or reliability of estimates (Example 2). Nonprobability sample surveys are not replicable, as the population covered is not known. Repeated surveys using nonprobability methods may show changes that may be due to differences in who was sampled rather than actual differences in the populations. Nevertheless, nonprobability sampling may be useful when limited resources are available or when the need arises to establish the existence of a problem.

Researchers should be careful in analyzing and reporting data from these nonprobability sampling methods, because they can be misinterpreted and lead to bad decisions.

Sampling designs: probability sampling

The process of selecting some members for the survey in which everybody has a known and nonzero chance of selection is called *probability sampling*. Probability samples apply a randomized mechanism that produces samples independent of the researcher's subjective judgments and with known biases. Probability sampling does not mean that each person in the survey group has an equal probability of being included in the sample. Instead, it means the following:

1. Every individual has a certain probability or chance— equal or unequal—to be included in the survey.
2. The probability of selection for each sample unit is known.

Probability sampling's benefits

Data from a probability sample are best for policy and program planning and understanding epidemic patterns, because they show who was included in the survey and thus to whom the collected data apply. Nonprobability surveys can be misleading, because it is difficult to understand to whom the survey data should be applied and the type and extent of bias. Nonprobability sampling can lead to bad decisions if the data are not used carefully. This is true even when probability and nonprobability surveys produce similar results.

Probability sampling does not mean that everyone has an equal probability of being in the sample. Instead it means that each person has a chance of inclusion and that the probability of being selected is known.

Table 15. Probability sampling design and selection strategy

Sampling design	Selection strategy
Simple random sampling	Each member of the study population has an equal probability of being selected.
Systematic random sampling	Each member of the study population is either assembled or listed, a random start is designated, and then members of the population are selected at equal intervals.
Stratified simple random sampling	Each member of the study population is assigned to a group or stratum, and then a simple random sample is selected from each stratum.
Cluster sampling	A set number of clusters is randomly selected and then a set number of individuals (members of the study population) is randomly selected from the selected clusters. In IBBA, the clusters are the larger units (venues) where members of the study population gather.
Respondent-driven sampling	A modified version of snowball sampling where initially selected members recruit a set number of additional individuals from their networks. These individuals, in turn, recruit a set number of individuals from their networks, and so on. The method is based on network theory and is believed to capture visible and hidden members of a population. When analyzed using the respondent-driven analysis tool (RDSAT), the sample is considered a probability sample.

Compared to nonprobability sampling, probability sampling has two major advantages: it is less prone to bias than nonprobability methods, and it permits the application of statistical theories.

Conversely, probability sampling may be more resource-intensive, because it requires more preparation and adherence to specific methodologies than nonprobability sampling does. The five basic probability sampling designs are summarized in Table 15.

In the first three methods presented in Table 15, a comprehensive list of all *individuals* in the survey group is required. However, such a list is not always possible to obtain. Marginalized groups such as sex workers, MSM, and IDUs are hard to identify and difficult to locate. Mobile groups such as truckers and clients of sex workers are difficult, if not impossible, to list with precision. Therefore, these methods are not applied in either IBBA or BSS surveys. Instead, cluster sampling and, more recently, respondent-driven sampling are generally used to look at behavioral and biological trends among these groups.

Even with probability sampling, potential bias exists that the research team must work to reduce. Bias is anything that causes the measure to differ consistently from its real value. A *sampling bias* is a systematic error due to a nonrandom sample of a population, which causes some members of a population to be less likely to be included than others. For example, if a room is filled with people who have blonde, brown, and black hair and the researcher selects only blondes for interviews, a systematic bias (i.e., only blondes) occurs in the selection procedure. Table 16 lists the types of bias that may occur in probability sampling. Researchers should aim to minimize biases to the greatest extent possible.

Table 16. Sources of bias for probability samples

Type of bias	Description
Sampling bias	Biases resulting from a nonrandom sample, because some individuals were more likely to be chosen than others without the differences in their probabilities of selection being known.
Nonresponse bias	Bias occurring when individuals who chose not to participate in the survey have different characteristics of observation (demographics, behaviors, or biological results) than individuals agreeing to participate in the survey.
Measurement bias	Bias that occurs when inconsistent or poor quality measures (e.g., laboratory testing) produce estimates that are deviated from the real value in the population.

Probability sampling methods in an IBBA survey

Two types of probability sampling methods can be used for IBBA surveys–cluster sampling and respondent-driven sampling. Selecting the appropriate sampling method depends on the nature and dynamics of the survey group. A decision tree—shown in Figure 3—helps to facilitate the selection process.

Cluster sampling

A *cluster* is a naturally occurring unit or grouping within a population. Clusters can be of different types. For example, FSWs can be accessed at such clusters as brothels, lodges, hotels, homes, street corners, bus stops, railway stations, parks, and outside cinema halls. Injecting drug users can be accessed at places to use or buy drugs: for example, their homes and the homes of friends; dealers' homes; parks; and empty lots or buildings.

Clustering allows sampling of hard-to-reach populations, for whom a complete list of all individuals is not available but for whom it is possible to list the venues where they tend to gather. Cluster sampling allows for visible and accessible portions of the population (those who gather at venues) to be included in the survey.

Cluster sampling is less effective if all or a significant proportion of survey group members are hidden (that is, not identifiable at clusters) or if group members are not identifiable or distinguishable from other people. In these instances, the survey team could apply respondent-driven sampling (RDS). A cluster sampling survey can be implemented by either conventional cluster sampling or time-location cluster sampling.

Conventional cluster sampling (CCS). When members of a particular survey group are associated with clusters in a *fixed manner*—that is, they have a permanent affiliation with a venue—conventional cluster sampling can be used. For example, brothel-based and home-based FSWs generally operate from a more or less fixed venue (their brothels or homes). This means that the same set of FSWs is generally found at a particular brothel or home at any hour on any day of the week. Therefore, CCS gives all FSWs at that brothel or home a chance of selection. This is because the solicitation point, entertainment point, and the place of living are the same.

CCS is generally easier to implement than time-location cluster sampling, because field teams have more flexibility in the times of day that they can cover selected clusters. Conventional cluster sampling assumes that an exhaustive list of the target group operating at the venue (whether they are available or not available at the time of the survey team visit) was established. Survey participants are then selected randomly and the team collects data from them. In case some of the target populations are not present or are unavailable on the spot at the time of data collection, the survey team must perform subsequent visits to contact those missed at first visit.

Time-location cluster sampling (TLCS). Many groups covered in the IBBA are not associated with a cluster in a fixed manner but rather come and go freely from the cluster. If the survey team selects members of such mobile population groups at the team's convenience—visiting at any hour or on any day—the sample may be unrepresentative of the survey population as a whole and the survey's results may be misleading. In these situations, it is important for the survey team to consider when and where respondents are available in the course of selecting a sample. For example, different sets of FSWs might be visiting a cluster on different days of the week. Similarly, different sets of FSWs might be visiting the cluster at different times of day. If the survey team visits the cluster on any day at any time, all those who visit the site on other days and at other times will be missed.

Time-location cluster sampling is applied for most of the IBBA groups, including street-based FSWs, MSMs, clients of FSWs, and LDTDs. When the time and location dimension (day, time, and venue) is added, one venue generates multiple time-location clusters. Each time-location cluster forms a part of the sampling frame used for selection in the survey.

Combined sampling

Combined sampling is when both CCS and TLCS are applied within one survey group. The sampling method (CCS or TLCS) is applied based on the typology of the subgroup. For instance, suppose FSWs are covered as one group. The sampling domain includes both brothel- and street-based FSWs. Combined sampling would be appropriate in order to ensure that a probability sample is achieved. Two separate sampling frames should be developed–one for brothel-based and one for street-based sex workers. The sample size is allotted according to the proportion of the population that the subgroup represents. During analysis, the data can be merged with appropriate weights applied.

Respondent-driven sampling (RDS)

This sampling method is a form of chain referral sampling (similar to snowball sampling) based on social or peer networks of the survey population, wherein initial contacts, known as seeds, are selected purposively. Each seed recruits no more than three eligible respondents from his or her network so that no single individual can mobilize the recruitment (figure 4). A system of dual incentives—first (primary incentive) for self participation and later (secondary incentive) for recruiting subsequent eligible participants—is implemented to encourage participation. RDS incorporates features that compensate for the major limitations of snowball sampling. It results in a probability sample. Appropriate analysis techniques are applied for analyzing data according to the network chains using a respondent-driven analysis tool (RDSAT).

Figure 3. Sampling method decision tree

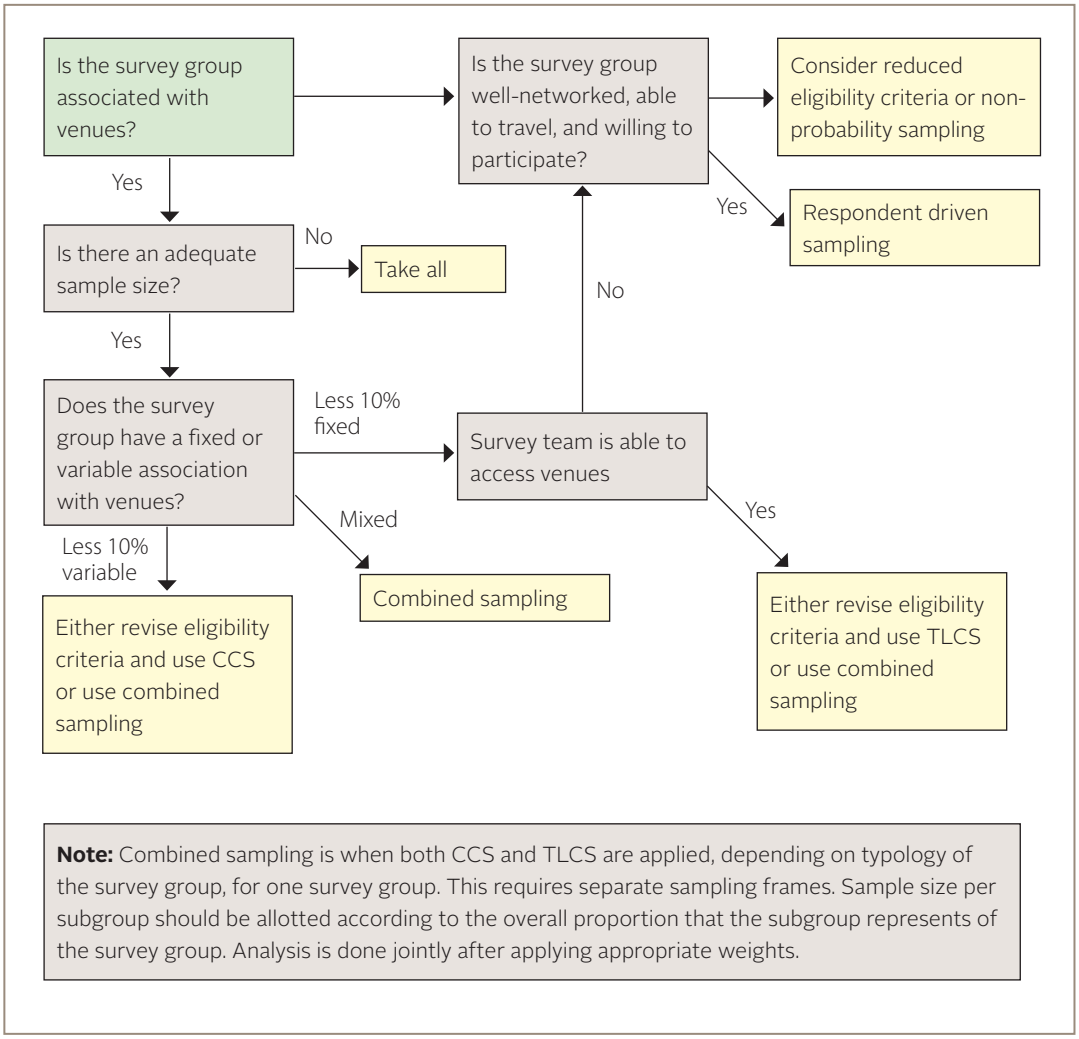
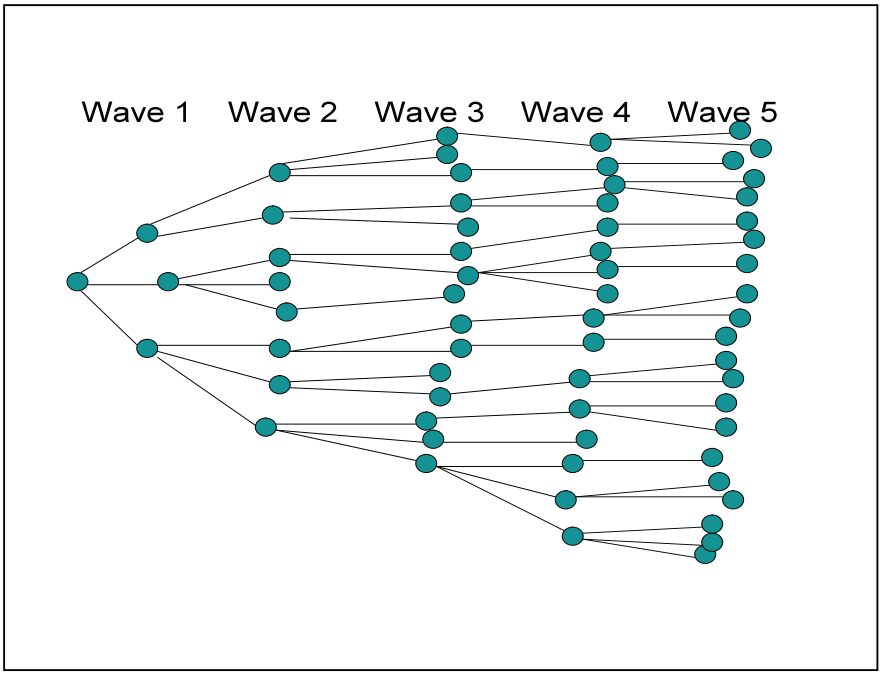


Figure 4. RDS recruitment waves from one seed



Calculating sample size

Detailed discussion of sampling methodologies requires an understanding of how to calculate the sample size required for the survey. For probability samples, the survey sample size is based on the following factors:

1. Expected baseline value of key behavioral indicators (e.g., consistent condom use with various partner types) (P1)

2. Desired magnitude of change that can be detected (P2 – P1)

3. Desired confidence level ($Z_{1-\alpha}$)

4. Statistical power ($Z_{1-\beta}$)

5. Design effect (D)

The following formula is used:

$$n = D\,\frac{\left[\sqrt{2P(1-P)}Z_{1-\alpha} + \sqrt{P_1(1-P_1)+P_2(1-P_2)}Z_{1-\beta}\right]}{\Delta^2}$$

Where:

D = design effect

P_1 = estimated proportion at the time of the first survey

P_2 = the proportion at some future date, such that the quantity (P2 – P1) is the size of the magnitude of change in key indicators that the study needs to be able to detect

$P = (P_1 + P_2)/2$

$\Delta^2 = (P_2 - P_1)^2$

$Z_{1-\alpha}$ = the z-score corresponding to the probability with which it is desired to be able to conclude that an observed change of size (P2–P1) would not have occurred by chance

$Z_{1-\beta}$ = the z-score corresponding to the degree of confidence with which it is desired to be certain of detecting a change of size (P2–P1) if such a change actually occurred

Normally, RDS surveys do not preset a sample size. Instead, the sample size is determined when the key indicators of the survey reach equilibrium. *Equilibrium* is the point in the survey in which key indicators will not change even if more recruits are added to the survey. To measure equilibrium, fieldwork, data entry, and data analysis should take place simultaneously. This requires having strong systems for feedback, trained data entry operators and analysts, and large teams in place to be able to support this activity.

Because data entry and analysis are more intensive for RDS than for cluster sampling, in the IBBA in India, analysis was not done during the fieldwork. Instead, a sample size was approximated. It was assumed that this would be the upper estimate required to reach equilibrium. Referring to a preset sample size was useful, due to the number of surveys implemented. The analytical team checked whether the key indicators reached equilibrium during analysis and confirmed that this had happened for all surveys by the time, or before, the sample had grown to 400 respondents. Other studies have shown that RDS surveys generally reach equilibrium between the fourth and sixth wave. Example 3 shows how the survey sample size was calculated for the Indian IBBA surveys (cluster and RDS).

Example 3. Sample size calculation in the IBBA in India

The IBBA in India used the following assumptions for calculating the sample size:

Variable	Value	Reason
P1	50%	Measurements require the largest sample size to detect change when the baseline is 50%. This figure was used because information for baseline indicators was unavailable. If it can be safely assumed that baseline values of all indicators are significantly lower or higher, then sample sizes could be lowered.
$Z_{1-\alpha}$	0.05	This corresponds to a 95% confidence in the observed estimates.
$Z_{1-\beta}$	0.10	This corresponds to 90% power.
D	1.7	Design effect for cluster sampling.

The calculations showed that the IBBA was to cover 400 individuals for each survey group/sampling domain.

Sampling approaches for IBBA

Cluster sampling

Cluster sampling has four main steps:

1. Conduct a rapid field assessment to update PSUs.
2. Develop the sampling frame and select the PSUs.
3. Finalize the list and the cluster information sheet.
4. Select respondents.

The following steps outline a cluster sampling design that occurs in two stages. First, the clusters are selected from the sampling frame, and second, the individuals are selected during fieldwork.

Three-stage or other cluster sampling designs may be used in surveys. A three-stage design may start with selection of segments or areas, followed by clusters, and then respondents. In India, three-stage cluster sampling was used for two surveys.

Step 1. Conduct a rapid field assessment

To implement cluster sampling, a complete list of clusters is required. A list of clusters, or primary sampling units, may already be available from the mapping information collected by any of the ongoing HIV/AIDS interventions among the population of interest to the IBBA study. However, any available information must be validated and updated. If necessary, the IBBA team should complete a rapid field assessment to identify and list the clusters.

For the purpose of the IBBA, the *primary sampling unit* (PSU) is any identifiable location where the respondent group members congregate. For example, the PSU for brothel-based sex workers is the brothel and for home-based sex workers, the home. PSUs should be defined very clearly, since this definition will be used to understand who is and is not represented in the survey.

For most survey groups, the entire sampling domain is mapped. Yet, the team may consider abbreviating the geographic coverage or simplifying the activity when too few resources exist for a complete mapping or when the distance to certain areas is larger than the small chance of finding survey groups members in those locations warrants traveling. For example, in the IBBA India, towns with a population of less than 7,500 were not mapped for MSM and FSW surveys, because covering them would be too resource-intensive against the small chance of finding survey group members in towns that small.

The team documents how the sampling frame is developed and the justifications for selecting those methods. The existing data may be old or may lack the complete information required for the survey, so it is important to visit each site to update the information about it and to identify additional PSUs. Depending on how old and/or comprehensive previous data sets are, the team may be able to simply validate and update the mapping data; this would be faster than completing a full mapping. In the first round of the India IBBA, a full mapping was conducted, which took from four to six weeks per survey group. In the second round, an updating of the previous sampling frame was done. The teams still had to visit each site and identify new sites, but they were able to spend less time at each site.

Developing the sampling frame requires a complete list of venues, estimated population at different times of the day, estimated population on different days, operational days and hours of the sites, and detailed information on site locations.

The objective of rapid field assessment is to identify all the locations where the survey group members may be found on a regular basis for use as PSUs and to estimate the size and variation in size at different times of day and days of the week at these PSUs. Rapid field assessment has three major parts: 1) to validate and update information about the known PSUs; 2) to document the specific reasons for inactive PSUs; and 3) to identify the additional PSUs.

Rapid field assessment steps

Collect existing mapping information (from NGOs and previous studies). NGOs may hesitate to share mapping information with the IBBA survey team owing to concerns about confidentiality. The team can reassure such organizations, by sharing the strict IBBA confidentiality procedures. The team might also offer an agreement that the updated mapping information would be shared with these NGOs for use in their programs after the survey is completed. Others— research organizations and community-based organizations, for example—may have mapping information useful to the IBBA. The team should explore these potential sources.

Form a field team. Each field team has one field investigator, one community liaison (a member of the survey group), and a supervisor who oversees the entire field activity. The team needs to be sensitized about the survey group and trained in field assessment. See detailed information about planning and implementing the pre-survey assessment in Chapter 2 and staff training in Chapter 7.

The community liaison helps the field team build rapport, identify and visit field sites, and initiate discussions with key informants and community members. This helps the team gather more accurate information easily and quickly. See also Appendix 2.

Visit known PSUs. The team visits known PSUs (identified from previous mapping data and information from NGOs) to collect required information. Apply the following techniques simultaneously at each venue:

1. Interview the key informants (see Example 4) from various segments of the population to identify sites and understand population dynamics.
2. Speak with the members of the study population, gatekeepers, and other knowledgeable people at each site to estimate size, learn operational days and hours, understand site dynamics, and identify new sites.
3. Triangulate data to arrive at consensus on the estimate of the study population's size at a particular PSU.

Document the following information for each PSU:

- Maximum number of individuals affiliated with a particular site
- Minimum number of individuals affiliated with a particular site
- Operational days (days of the week when the survey group members are at the site)
- Peak days (days of the week when the maximum number of individuals are found)
- Lean days (days of the week when the minimum number of individuals are found)
- Operational times (times of day when the survey group members are at the site)
- Peak times (times of the day when the maximum number of individuals are found)
- Lean times (times of day when the minimum number of individuals are found)
- Exact location of the site (including a drawn map)
- Seasonal variations
- Mobility

A detailed map with the specific address of the site (with landmarks) is useful, because perceived unique information may change by the time the survey is implemented. For example, the names of madams (brothel owners) may change or if there are numbers outside houses/ brothels, these may change. Also, the people conducting the rapid field assessment for developing the sampling frame and implementing the surveys may be different.

During the rapid field assessment, document the relevant services in the area, such as NGOs, government hospitals, STI clinics, and voluntary counseling and testing centers (VCTCs). List potential sites that can be used as venues for the survey. The PSU form is the instrument where all this information is gathered (see Appendix 9).

During the rapid field assessment, the teams also record any sites that pose safety concerns; are too big to be covered as one site by a field team; or whose members shift from one site to another during a single day or period of time in response to the availability of clients and/or the presence of police. The teams should note such concerns on the PSU forms and share them with the supervisor.

Gather information using multiple qualitative techniques and triangulate to arrive at a consensus. It is unlikely that a clear consensus on the PSU's size and days and hours of operation will be easily reached. Thus, the team should discuss results with several people before drawing a conclusion, to help validate information and ensure the data's accuracy.

Example 4. Key informants for the rapid field assessment

- Members of the study population
- Staff of the District AIDS Cell
- Staff members of NGOs
- Shopkeepers and local leaders
- NGO networks
- Auto/rickshaw drivers
- Taxi drivers
- Transport workers
- Individuals in the vicinity of the cluster

Document information on closed sites. PSUs are dynamic and many close or change their location over time. In the case of MSMs, IDUs, and FSWs, this may be due to recent police raids, local violence, changes in stigma, seasonal variations, drug availability, and so forth. Gather information on sites that are closed during mapping but were listed as part of previous data sets. The field team documents (at the end of the PSU form) where this closed site was located and the possible reasons for closure, gleaned from discussions with stakeholders at the site. Before declaring a site closed, the team revisits the site at different times and days, talking as well to local stakeholders to ensure that it is, in fact, inactive.

Identify new PSUs. Discussions with community members and key informants at each mapped PSU and at PSUs previously identified by associated groups reveal new PSUs. Teams should visit any sites where members of the survey group are likely to be present. For example, with street-based sex workers, the team should visit parks, bus stops, cinemas, and so on, even if no information exists about solicitation at these sites. The steps for documenting information required for a new PSU are the same as those outlined on the previous page for updating known PSUs.

Review collected data: The team meets, especially early on, to address questions or problems faced by the field team and to review maps and data in PSU forms. The field team reviews field issues in detail with the researcher. This helps to ensure better quality data and identifies gaps in the methodology.

After completing the rapid field assessment, the field team and researchers meet to review the maps and the data to ensure that the information they have collected is complete. For sites identified as potentially difficult (because of the mobility of the survey group, the size of the site, or safety concerns), the researcher may revisit these sites with the field team to understand how to deal with these PSUs in the sampling frame.

Where safety concerns arise, consider excluding that site from the survey. If a site is identified as too large to be a single PSU, consider dividing it into at least two sites, if possible, with clear boundaries. In doing this, take into account the paths of mobility and the logical cutoff points for boundaries. If separating the site into two parts is not feasible because survey group members are mobile throughout the site, then the research should help define how fieldwork might best be done there.

Summary of the data. Unique site numbers (PSU numbers) are recorded on the PSU summary sheet (and the PSU forms) for easy reference (see Appendix 10). List sites in geographic order on the summary sheet. For example, moving from north to south in a district, list each site on the summary sheet. Use this sheet to develop the sampling frame. Table 18 shows sample formats used in the India IBBA.

Table 17. Summarizing mapping data: typical format

PSU number*	Name of PSU*	Address/ location of PSU	Lean day	Peak day	Lean time	Peak time	Min. no. of individuals associated with the PSU	Max. no. of individuals associated with the PSU
e.g., 12	RK circle	AB road	M-F	Sat, Sun	1200-1700	1700-0200	5	5
e.g., 13	PR movie theatre	LS road	M-Thu	Fri, Sat, Sun	1200-1700	1700-2400	5	10
Etc.								

*Ensure that the name and site number of each PSU is unique.

Step 2. Develop the sampling frame and select the PSUs

A *sampling frame* is the exhaustive list of PSUs that includes information on each site's size, location, and days and hours of operation. List the sites in geographic order on the sampling frame. Use the following steps to develop a sampling frame and select the PSUs. See Appendix 9 for a PSU form.

How many times should each PSU be listed on the sampling frame? If CCS is used, list each PSU once on the sampling frame. Each cluster (before selection) should have a unique cluster ID number that will be used for fieldwork and analysis. This is important, because the team may have to reselect clusters if the required sample size is not reached by the end of the fieldwork. The format given in table 18 may be used for this purpose. Note that the cluster number and site number may be the same for CCS.

Table 18. Format of a conventional cluster sampling frame

Cluster number	PSU number	Name of PSU	Address/ location of PSU	Days of operation	Operational times (start-end)	Number of individuals associated with the PSU
e.g., 12	12	RK circle	AB road	M-Sun	1200 – 0200	5
Etc.						

Table 19. Recommended sequence of PSUs for a time-location cluster sampling survey

Day/Time	Estimated size
Peak day and peak time	Maximum estimate
Peak day and lean time	Average estimate
Lean day and peak time	Average estimate
Lean day and lean time	Minimum estimate

If TLCS is used, the team needs to decide how many times a cluster should be listed on the sampling frame, based on the extent of the mobility pattern that was observed within the site. The same PSU can therefore become several time-location clusters. In the IBBA carried out in India, time-location clusters were listed as many as four times, depending on the individual characteristics of a given site (Table 19). Specific clusters were sometimes listed with less frequency if mapping data showed that no changes in peak days, peak times, size, or individuals from the population occurred at that particular site.

There are other ways to list the population in a TLCS survey. For example, discrete lists could be made for each site for each of the operational days at peak times and another set for lean times. Enough variation in the population must exist at the site to warrant this level of detail.

Table 20 is an example of what can be used to develop the sampling frame of a TLCS. As with conventional cluster surveys, list each cluster in geographical order. Assign each cluster a unique ID number whether it has been selected for the survey or not. Because one PSU is listed as a different cluster depending on the day/time unit, assigning unique ID numbers to clusters as well as to sites is important, especially because one site can be selected more than once as a cluster.

Table 20. Format of a time-location cluster sampling frame

Cluster number**	PSU number	Name of PSU	Address/ location of PSU	Day/time*	Days of Operation	Timing	Estimated size

*Day/time refers to the "peak day/peak time", "peak day/lean time", "lean day/peak time", and "lean day/lean time" listing that is recommended. Days of operation, timing, and estimated size refer specifically to the information applicable for the "day/time" of that cluster.

**The cluster number should be unique for each time-location cluster.

How should we select clusters? The number of survey group members at a cluster is called the *measure of size* (MoS). This is equivalent to the "estimated size" in Table 18 and Table 19.

Two methods are used to select clusters: equal probability (EP) and probability proportional to size (PPS).

- Use EP when there is minimal variation in MoS between clusters within a survey group.
- Use PPS when there is high variation in MoS between clusters within a survey group.

To gauge the variation in MoS, look at the minimum and maximum size of clusters in the survey group. For example, if the smallest brothel has a size of two and the largest has a size of five within a survey group, EP can be applied. If, in another survey group, the largest cluster is fifteen and the smallest two, then PPS should be applied. In India, PPS was used for all survey groups.

How many clusters should be selected from the sampling frame? No standard rule exists for deciding how many clusters to select. It is generally better to select more clusters than too few. This helps avoid a reselection of clusters if the required sample size is not met during fieldwork. One note of caution: Selecting too many clusters reduces *field efficiency* (e.g., the number of interviews completed in a day) and increases the cost and time of the survey.

In deciding how many clusters to select, consider the required sample size for the survey, and how many FSW can be selected, on average, from each cluster. A simple calculation can facilitate this:

Average calculated MoS = (total MoS)/(total number of clusters)

Number of clusters to select = (required sample size)/(average calculated MoS)

The average calculated MoS indicates how many individuals, on average, are expected to visit any cluster. For example, if we want to sample 400 truckers and the cluster size ranges from ten to twenty, we would use PPS

sampling. With an average calculated MoS of fourteen, the number of clusters to select should be:

Number of clusters = 400 / 14 = 28.6: that is, 29 clusters should be selected

Applying EP and PPS. The following two options outline how to apply EP and PPS to the selection of clusters.

Option A: Selecting the clusters with EP

Table 21. Examples of India IBBA sampling frame development

Survey group	Sampling method	Types of PSU	Number of times a PSU was listed on sampling frame	EP vs. PPS	Equal or unequal cluster size
Brothel-based FSW	Conventional cluster sampling (CCS)	Brothels	Once	PPS	Unequal
Street-based FSW	Time-location cluster sampling (TLCS)	Public sites	Up to 4 times	PPS	Unequal
Men having sex with men	TLCS	Cruising and solicitation points	Up to 4 times	PPS	Unequal
Truckers (on specific route categories)	TLCS	Trans-shipment locations	Number of operational days	PPS	Unequal
Clients of FSW	TLCS	Brothels and public sites	Number of operational days	PPS	Unequal

1. Prepare a sequentially numbered list of clusters, preferably ordered geographically. (See tables 18 and 20).

2. Calculate the number of clusters to select:

   $$\text{Number of clusters to select} = \frac{\text{Required sample size}}{\text{Average MoS}}$$

3. Calculate the sampling interval (SI) by dividing the total number of clusters in the domain (M) by the number of clusters to be selected (a).

   That is, SI=M/a (For example, suppose M=400 clusters and a=25, then SI=400/25=100.)

4. Select a random start (RS) between 1 and SI.

5. Select the cluster according to the unique ID number on the numbered list of clusters corresponding to the RS. This becomes the first sample unit (that is, the first selected cluster). For example, if the RS is five, then the first cluster to be selected will be the one where the PSU's unique ID number is five.

6. Select the subsequent clusters by adding the SI to the RS. In other words:

   Cluster 1 = RS

   Cluster 2 = RS + SI

Cluster 3 = RS + 2SI

Cluster 4 = RS + 3SI (and so on)

7. Continue the previous step until the list has been exhausted.

Option B: Selecting the clusters with PPS

To select the clusters using PPS, follow these steps:

1. Prepare a numbered list of clusters, preferably ordered geographically. (See tables 18 and 20.)
2. Start at the top of the list, calculate the cumulative MoS (CMOS), and enter these figures in a column next to the MoS for each cluster.
3. Calculate the number of clusters to select:

$$\text{Number of clusters to select} = \frac{\text{Required sample size}}{\text{Average MoS}}$$

4. Calculate the SI by:

$$\text{SI} = \frac{\text{MoS}}{\text{Number of clusters to select}}$$

5. Select a random start (RS) between 1 and the SI.
6. Compare the random start with the CMOS. The selected cluster will be that which the RS falls within, but is not greater than the CMOS. For example, if the CMOS for one cluster is seven and for the next ten the random number is nine, then the team should pick the second cluster. As they have established that they are rounding up to select the cluster, this should be followed throughout the sampling procedure.
7. Select subsequent clusters by adding the sampling interval to the previously calculated interval. For example:

   Cluster 1 = RS

   Cluster 2 = RS + SI

   Cluster 3 = RS +2SI (and so on)

8. Continue this procedure until you finish going through the sampling frame.

For both EP and PPS, save the selected clusters with their unique cluster IDs on a separate worksheet for planning fieldwork. Maintain the original sampling frame for reference, and in case a second round of cluster selection is required. Document the sampling information in accord with the steps above.

Note: ***When selecting clusters, the RS/ unique ID number and SI will not always add up to a calculated CMOS. The team should round up or down in a consistent manner. For example, if the RS is six but the first CMOS is two and the next CMOS is eight, and the team selects the cluster with a CMOS of eight, then for the rest of the selection they should continue to round up.***

Some clusters may be selected more than once when using PPS. If this occurs, a unique ID number (that is, different from ones already used on the sampling frame) should be given to those clusters. The team should cover the cluster twice, on different days. This might happen when a cluster size is very large and the sampling interval is short.

How many individuals should be selected from each cluster? Once the clusters are selected, two options are available when selecting individuals: *equal size,* where the same number of individuals are selected from each cluster; or *unequal size,* where a different number of individuals are selected from each cluster.

We should study the variation in MoS of the selected clusters in order to decide how many individuals should be selected from each cluster. If the MoS varies significantly across the selected clusters, choose unequal cluster sizes. And if MoS does not vary significantly across the selected clusters, choose equal cluster sizes.

For example, if the range of MoS of the selected clusters is as big as four to thirteen, we should choose unequal cluster sizes. We can choose equal cluster sizes if the range is ten to thirteen. With unequal cluster sizes, we can allocate the total sample size proportionate to MoS across the selected clusters. There is no formula for this – it is based on the judgment of the team—but planned sample sizes should be allocated ahead of time. If we choose equal cluster sizes, the cluster size will be the total size of the survey sample size divided by the number of clusters selected.

Example 5. A sample of unique identifier information for FSWs

1. Black sari
2. Red sari and white blouse
3. Blue sari
4. White skirt
5. Green salwar with yellow kurta
6. Blue jeans with red t-shirt
7. Pink skirt with stars printed on the shirt
8. Pink skirt with a heart printed on the shirt
9. Blue jeans with a cream t-shirt
10. Red sari and green blouse
11. Orange salwar
12. Green salwar with black kurta
13. Black jeans

Step 3. Finalize the listing sheet and cluster information sheet

Listing sheet. The listing sheet (LS) is the form used to record information on the number of individuals who visit and are eligible to participate in the survey at a particular cluster. The sheet is filled out by the counter during the survey; the community liaison may help with the counting of eligible individuals at the site. The counter records the number of individuals visiting the site using a unique identifier system and not by name (see Example 5). The counter does not speak to potential respondents to fill this out. One listing sheet will be completed for each cluster covered in the survey. For a TLCS, the counter should be at the site from the beginning of the fieldwork until the end (regardless of when the sample size for the site is achieved) to count all eligible individuals coming to the site when fieldwork is under way at that site. The fieldwork period is during the operational period (peak or lean times, depending on the cluster selected) but is generally shorter than the entire operational period. For example, if the operational period is from 1800 to 0100 hours, the field team may cover the site from 2000 to 2300 hours. The counter would have to be at the site from 2000 to 2300 hours even if the cluster sample size is achieved before 2300.

Example 6. Format of a listing sheet

Cluster number:	Cluster name:	Date:	
Time of visiting cluster:	start –	end –	
Name of counter:		Type of cluster: CCS TLCS Take all	
S. number	Unique identifier	Selected?	Result* (if selected)
*Result = Agreed, refused, or not available			

Cluster information sheet. The field supervisor documents sampling information on the cluster information sheet (CIS) during fieldwork. One CIS is used for each cluster in the survey. It contains information about the number of eligible people at the cluster, the number who were selected, and the number who refused. Appendix 10 presents a sample CIS with instructions. The supervisor keeps a small book to note various activities during the fieldwork but once fieldwork is over, the supervisor fills out the CIS for the cluster.

The survey team carries the PSU forms with them in the field to help identify sites. These forms have maps that will be useful to the supervisors.

During site visits, the supervisor should note observations of the general characteristics of people who refuse to participate. For example, if the supervisor notices that older men who have sex with men refuse to participate in the MSM survey at a particular cluster but younger ones agree, this is an important observation that will help in interpreting the data.

The CIS captures important information used to apply weights to the data by calculating the probability of selection. Spend ample training time on practice exercises for the field supervisor and practice in the field if possible. The researchers are encouraged to spend the first few days of fieldwork at the selected cluster with the field supervisor to help build rapport, to observe selection, and ensure correct documentation. The researchers review data in the CIS early on in the survey with the supervisor, to ensure correct documentation.

Step 4. Select respondents

Field experience: Ideal times for CCS in brothel areas

In the IBBA in India, CCS was used for brothel-based sex workers. Selected clusters were visited two days prior to fieldwork to build rapport, request support, identify venues, and inquire about convenient days/times. Generally, the team was asked to visit during the afternoon, when fewer clients were present. This was easy for the team to accommodate and helped gain support from the community.

When implementing CCS during field work, the survey team has the flexibility to visit the sites at times that are convenient for the people affiliated with the cluster (see Field Experience), since the respondents are associated with the PSU in a fixed manner. Therefore, for each cluster or grouping of clusters in a given area, the team finds out the times of day and days of the week most convenient for the respondent group to participate in the survey. This is done when the site is visited to complete community preparation activities and identify venues just prior to fieldwork.

While recruiting the respondents at a selected conventional cluster, the supervisor might face one of two kinds of situations, depending on how the PSUs were defined for the survey group. Each cluster may represent one dwelling or unit (for example, a single brothel) or a group of dwellings or units (for example, multiple brothels). The supervisor, the counter, and the community liaison visit the cluster for sampling. The recruitment process for each type of cluster is discussed below.

One or two days before conducting the survey, the team visits the clusters to build rapport, understand potential field issues that have been identified, clear up and ward off misunderstandings, and prepare the people at the cluster for the survey. In the IBBA in India, the teams visited areas where fieldwork would take place and spoke to people both in the selected and the nonselected clusters, to build their awareness of the survey and support for it.

Recruitment in which a PSU is defined as one dwelling or unit. Once the supervisor, community liaison, and counter reach the selected cluster, the following steps occur sequentially:

1. The supervisor and community liaison talk to the key person (for example, the brothel owner or madam in the case of a survey of brothel-based FSWs) in the selected cluster. They introduce themselves and explain the purpose and objectives of the survey.

2. The supervisor and the community liaison ask this key person whether they can meet or see all individuals who are associated with this dwelling. In the case of FSWs, this includes everyone who solicits from, has sex with, or lives in the same dwelling. Furthermore, they ask if anyone is absent from the site at the time of the visit, so that they can note the absentee on the LS for selection in anticipation of the survey to come.

   For example, let us say that the team visits a site at 1400 hours and the madam introduces the team to eight FSWs. Another two FSWs who work in the brothel have stepped out before the team arrives. The counter should list all ten FSWs on the LS, including some unique information about the two FSWs who are absent, so that those two can be distinguished from others if they happen to be selected. For example, the supervisor may inquire what the FSWs were wearing, where they sleep, and so forth.

   The counter prepares a list of the eligible respondents on the LS with reference to their unique identifiers. To preserve confidentiality, names are not recorded on the LS (see Example 6). List only eligible individuals, in accord with the survey's definition of eligibility.

3. The supervisor randomly selects the required number of eligible respondents, including those who are eligible but not present at the time of selection, for the assessment. To avoid bias, sampling is only done by the supervisor and not by the community liaison or the counter.

   Respondent selection should be a quick and simple process. The objective is to give an equal chance of selection to all of the eligible respondents on the list—that is, to select participants randomly. The key person at the site may suggest individuals who can participate in the survey, but the supervisor should explain that selection is based on a lottery system and that the supervisor has to independently select individuals. Certain individuals may look more willing to participate or appear easier to approach. Nevertheless, the supervisor follows the random sampling method to avoid bias. For example, if the LS includes ten FSWs and the supervisor needs to select three, the supervisor could select every third (10/3=3) member from the list.

   If the field team has fewer interviewers than there are individuals to select from a cluster (for example, the team has two interviewers but needs to select three from this cluster), the supervisor can select all three individuals (only when implementing CCS) at one time, but approach two of the potential respondents first for participation. Then, on completion of participation, the supervisor can approach the third individual. This helps ensure that respondents are not waiting at the venue for one person to finish the interview. If either or both of the first two respondents who were approached refused to participate, the supervisor should approach the third respondent before continuing with reselection.

4. The supervisor and the community liaison speak with each person selected. Rather than talking to each potential respondent in a group, they aim for one-on-one conversations so that the person has the freedom to decide about participation without pressure from others. They build rapport with the respondent; discuss the survey, including its purpose and benefits; explain the random selection process, and ask whether the respondent is willing to participate.

5. A respondent who agrees to participate is escorted to the venue.

6. If a selected individual is absent from the site, the team should visit the cluster three times within two days to follow up with that person. This two-day limitation ensures a quick follow-up and completion of the survey at the cluster. If the absentee is still unavailable, the supervisor selects another person from the list of eligible people who remain.

7. If a respondent refuses to participate in the survey, random selection is done again from the remaining list, after removing those who have already been selected, even if they refused or were determined not to be available.

8. The supervisor completes the CIS.

Recruitment in which a PSU is defined as a group of sites. When the PSU is a group of sites, the supervisor must visit all the dwelling units (brothels or homes) at the cluster before selecting people for the survey.

1. The supervisor and the community liaison find out the number of different dwelling units at the cluster and identify the key person (the brothel owner or madam) at each unit. Ideally this will be done at least one day before the survey is conducted, to give the supervisor and community liaison time to build rapport and assure the community's support on the day of fieldwork.
2. The supervisor and community liaison meet these key people and explain to them the purpose of their visit.
3. On the day of the survey, after initial discussion with the key people, the counter compiles a list of all eligible respondents (see Example 6) from all of the units at the selected cluster without explicitly identifying the eligible respondents—by name or in some other precise way.
4. The remaining steps match those described on the previous page for PSUs defined as a single dwelling or unit, beginning with step 3.

In a CCS survey, if the team visits all of the selected clusters but is unable to recruit the number of people required for the sample, reselection of clusters will be required. To accomplish that, create a new sampling frame with the list of clusters in the same order as the previous sampling frame. Those clusters that were selected in the first round are removed from the second sampling frame and then reselection proceeds. Retain both sampling frames for reference.

Time-location cluster sampling

Time-location cluster sampling (TLCS) provides an opportunity to capture heterogeneity of risk behavior in a given cluster across different times of day and different days of the week. This type of sampling is appropriate for PSUs whose members are mobile, moving in and out of the site. Unlike CCS, it is not possible to list everyone associated with a time-location cluster (TLC). To adjust for the mobility of members of a TLC, the IBBA team applies TLCS and lists sites on the sampling frame according to time and days.

The amount of time for fieldwork is defined in advance based on the expected sample size and peak and lean times and days. In India, a site at peak time was covered for three hours and a site at lean time was covered for four hours, even if lean or peak operational times were longer. (Because more potential respondents are available at peak times, the survey team needs to spend fewer hours at the cluster.)

The supervisor carries a notebook to document sampling during fieldwork and fills out the CIS after completion of the cluster. The supervisor and the field team should use the following steps for TLCS:

1. The field supervisor, counter, and community liaison should reach the PSU at least thirty minutes before the starting time for selection. For example, if the field work at the selected TLC is set for Monday, 2000 to 2300 hours, then the field team should reach the cluster by 1930 hours. The team requires at least this much time to familiarize itself with the cluster, to understand boundaries, identify locations for the counter, and to prepare for the initial tasks.
2. At 2000 hours, as soon as the TLCS begins, the counter starts counting people on the listing sheet, recording (by unique identity) the number of people who visit the site throughout the survey period—even if the sample size is achieved before the survey has been set to end. For example, if the team members are scheduled to be at the site from 2000 to 2300 hours and need to select two participants, they may accomplish this early in the survey period. Regardless of the speed of their work, the counter must stay at the survey site for the full survey period and count the members of the population who visit there.

3. If there are *fewer* than the required number of respondents at the beginning of the survey period (2000 hours), the sampling supervisor selects all those present at that time (provided enough interviewers are present) and then selects the remainder consecutively—that is, in the order in which respondents appear at the site and when the interviewers are available. Consecutive selection of respondents is nevertheless random, because the eligible people who appear at the site are not turning up in a determined or particular order.

   For example, if the team needs to select five FSWs at a site but only two FSWs are present at the beginning of the scheduled survey period, the supervisor selects both of them. Then, as more FSWs come to the cluster, the sampling supervisor selects them so long as interviewers are available. This reduces the chances of failing to achieve the sample size at the cluster and spares people a wait at the venue for their turn to participate.

4. If *more* than the required number of respondents are available at the beginning of the survey period, the counter should rapidly list them (using unique identifiers). The supervisor randomly selects the required number of respondents from the list. The supervisor selects people according to the number of interviewers who are available. For example, if three interviewers are on the team and the sample size needed for the site is five, the supervisor should first select three people. When they complete their interviews, the supervisor can select two more. The counter continues recording the number of people who visit the site throughout the scheduled survey period.

5. The supervisor fills out the CIS after fieldwork at that cluster ends. In a TLC survey, given the mobility of potential respondents at the cluster, the supervisor should select people from the listing sheet. For example, let us say that ten MSMs are on the listing sheet, three have been approached, one refused to participate, and two agreed. The sampling supervisor should remove these people from the list in his or her notebook (not the official listing sheet) before proceeding with random selection. The supervisor documents whether individuals are available, agree to participate, or refuse to participate once selected. This information is helpful when the supervisor fills out the CIS.

   Each cluster is treated as an independent unit. If a site is listed multiple times as different TLCs in the sampling frame and is selected more than once, the location of the site will be covered separately, on different days, and the cluster sampled each time will have a different cluster number and a separate CIS.

6. As with CCS, reselection should be done if the survey team does not achieve the required sample size. If an unequal number of people are selected from each cluster, the field supervisor can cover the shortfalls by selecting additional participants in the next clusters, even if they are not sampled on the same day and at the same time. In spite of this, the team may have to reselect clusters if the overall sample size is not met. If an equal number of people are selected from each cluster, the team's only choice is to reselect clusters. A TLC cannot be revisited to cover shortfalls, because the factors of time and day are critical. The TLC cannot even be revisited on the same day and at the same time in the following week. Instead, shortfalls can be addressed by increasing sample size in future clusters or by reselecting clusters after completion of the first round of selection.

Fieldwork with long distance truckers and clients of FSWs was slightly different, and is described in the "Field Experience" sidebars on pages 76 and 77.

Take-all approach

The take-all approach is used when the maximum estimated size of the survey population (based on mapping data) is less than the required sample (based on survey sample size) in a survey domain. For example, if the sample size calculation requires 400 participants, but only 200 members of the risk group are identified in mapping, the team should consider whether to conduct the survey at all. If the decision is to go forward, the team should use the take-all approach, which is described in more detail in Chapter 11.

For the take-all survey, there is no sampling. All survey group members fitting the eligibility criteria will be approached for participation in the IBBA at the site. The standard IBBA procedures, including voluntary and informed consent to participate, should be followed. The field teams, therefore, must have flexibility in their field plans to allow for revisits of sites and apply the following guidelines. (See Example 7.)

For fixed clusters (for example, brothels) at least three call-backs are required for any unavailable respondent. This should be done as close as possible to the first day of field work to avoid disrupting the site, to reduce the possibility that individuals might discuss the content of the interview with others, and to maintain rapport. Count all individuals associated with the cluster as eligible even if they are not present when the field supervisor, counter, and community liaison visit the cluster.

Each cluster with a mobile population (that is, a floating cluster) should be visited on at least two days (the peak and lean days). The field team spends the entire operational hours at the floating cluster on both days. The counter, field supervisor, and community liaison have a challenging task, because there is likely to be a lot of mobility. They must count individuals only once, even if they visit the cluster on multiple days and times during fieldwork. The supervisor can cover the cluster again (unlike TLCS, in which this cannot happen) if he or she feels that some individuals associated with the site have not been given a chance to participate during the first two visits.

Only one cluster information sheet is completed for each cluster even if multiple visits are necessary to completely cover the site. The supervisor works with the counter to do this. If the same person is seen at the site on multiple days, that person is counted just once. Some people who refuse to participate on the first day may decide to participate during subsequent visits, perhaps because they have heard positive feedback from other survey group members. The supervisor should allow this flexibility and make sure that the individual is counted once on the CIS as *eligible,* and *accepted participation.* The supervisor should not, however, try to convince anyone who refuses to participate during the first visit to reconsider his or her decision.

Example 7. Take-all survey at fixed and floating clusters

Fixed clusters: Suppose a home is visited where FSWs solicit and the key person reports that six FSWs are associated with the site (that is, solicit from, have sex in, or live at the site). Yet, when the team is at the site, only four FSWs are present. The key person reports that two have left for some personal work. The supervisor makes a note of this and ensures that the team visits the site at least three more times to follow up with the remaining two people. The supervisor tries to ascertain when the FSW will return so the team can plan accordingly. Document this in the same cluster information sheet even though the follow up is done on different days.

Floating clusters: Suppose the team covers a garden where MSWs solicit and the operational time is 1800 to 2300 hours on all days of the week. Peak days are Friday, Saturday, and Sunday, and other days are lean. The team should visit the site once between Monday and Thursday and once between Friday and Sunday. During both visits, the team should be at the cluster throughout the operational period. If some people remain unaccounted for after these two visits, the team should revisit the site. One CIS should be completed for this cluster. The counter, liaison, and supervisor should be the same for each day this cluster is covered for consistency and to try to ensure that everyone associated with the cluster is approached for participation, and no one is repeatedly asked to participate. Each person should be counted *once* on the CIS even if that person visits the cluster at multiple times/days while fieldwork is taking place there.

Field experience: IBBA on highway corridors

Sampling of long-distance trucker drivers (LDTDs) on highways for the IBBA in India was conducted in a unique way. The LDTDs were defined as those who deliver goods to destinations more than 800 kilometers from their point of origin, and according to the particular routes they drive. Four survey groups were identified, associated with the four major highway routes included in the survey.

Cluster sampling was used. The PSUs were defined as transshipment establishments (TEs) at truck stops, border crossings, and points that provide consignments and goods to truckers at different times. TEs were listed for each of the days of the week in which they were operational and were dispatching LDTDs along the routes specified for the IBBA. A single TE could be the location of seven clusters. Time-location clusters were listed in the sampling frame geographically and in order of day of the week. The TLCs were selected by following standard methods and applying PPS.

Conducting fieldwork proved as challenging as defining the sampling frame. Truck drivers are not permanently affiliated with any establishment; they are busy loading and unloading their vehicles, resting after long drives, looking for new consignments, and maintaining their vehicles. However, identifying truck drivers at the TEs seemed logical. Because drivers spend more time at TEs than at other stopping points, more could be captured for the IBBA there than elsewhere, and mapping and listing would be easier. The IBBA team planned to visit TEs and note on the listing sheet any LDTD driving an IBBA route who was registered and present at the TE during listing or who arrived while fieldwork was being conducted.

Even though a pre-survey assessment was carried out to develop the sampling frames, the field team faced difficulties. The number of drivers who passed through the TE during fieldwork did not always match the number that had been estimated. Moreover, many truckers were tired or not interested in participating in the survey during their limited free time. Truckers were not often found at the TE office at the times listed during fieldwork. The team relied on talking with other drivers and TE staff and monitoring license plate numbers to find the truck drivers. The team tried to involve the community liaison and the community monitoring and advisory boards to improve rapport, but all proved to be too busy to be actively involved.

In addition to the challenges this population group posed for defining the sampling frame and conducting fieldwork, monitoring fieldwork with LDTDs became a primary concern. Applying correct sampling methods is essential, and the obstacles to doing so in this population are great.

Field experience: Conducting surveys with clients of female sex workers

Defining how to conduct surveys with clients of FSWs to maximize coverage and reduce refusal rates was a challenge. After testing four different approaches – coverage at solicitation points, coverage at sex points, by intercepting clients, and through a modified version of respondent driven sampling–it was decided to apply coverage at solicitation points. Sex points were difficult to include as PSUs, because comprehensive mapping would be challenging if not impossible, and clients would be unlikely to take the time (just before having sex) to participate. Response rate was very poor for the intercept method. The modified RDS survey did not work, because clients were not connected with one another.

Using coverage at solicitation points, the field teams took advantage of mapping data that existed from the surveys of FSWs and built on the relationship in the community that existed as a result of these surveys. In some districts, certain sites were excluded from the sampling frame (bars, for example), because the team would not have been able to conduct fieldwork there. Each PSU was listed for each day of the week that it was operational. Thus a site could be listed as many as seven times as different time-location clusters. Sites were covered either at peak or lean times, depending on the sample size to be covered.

Recruitment of clients involved a lot of rapport building with the local stakeholders, FSWs, and clients. One FSW from the area was included on the team as the community liaison. Prior to covering any TLC, the team met with community members to clarify the purpose of IBBA, build relationships, and discuss concerns the clients might have. Clients were listed and selected randomly from sites, but individuals at the sites helped make the introduction to the client or helped build rapport. Then the supervisor and community liaison would independently speak with the client about actually participating in the survey.

The advisory board was the same group that developed for the IBBA with FSWs and FSWs also served on the monitoring board. The team was very concerned about how to recruit clients without negatively affecting the community. They built on past experiences and knowledge about local areas gleaned from surveys of FSWs, past relationships with key stakeholders, and the positive regard that they had built in the community over the course of previous FSW surveys. Although refusal rates were high, the teams were able to meet the required sample size and adhere to sampling procedures and did not receive any reports of adverse events during or after any of the twelve client surveys. See also Chapter 1 (pre-survey assessments) and Chapter 2 (community participation).

Respondent-driven sampling

RDS, as stated earlier, is a sampling method used when a majority of the population is hidden or inaccessible at venues. It is feasible only if the target population is *networked*–that is, they know and interact with one another within a social network. Because an RDS depends on respondents recruiting other respondents, the team has no control over the time the survey will take. In India, to ensure that the surveys did not continue indefinitely, the researchers stipulated that the RDS would stop either upon achievement of the survey sample size or after three months of fieldwork, whichever was first. (See the following “Field Experience” sidebar.)

Field experience: Defining the sampling domain in RDS

The size of the sampling domain should be determined when applying RDS. Members of the survey group should have overlapping networks throughout the survey domain and be willing to travel to participate. It was unclear during one IBBA survey conducted in a large city in India whether participants in the survey primarily came from one area due to the large distance and amount of time it takes to travel throughout the city or whether people who did not work or reside close to the venue also attended.

In another survey, FSWs from the main city and from two towns where venues were located participated in the survey. The team observed that FSWs from neighboring towns did not participate and were unlikely to receive coupons, because the network was not very strong between towns and travel was both costly and difficult. The team later realized that they had not considered whether FSWs traveled or not; they only noted that the district had public transportation that seemed cheap. Further, when FSWs said they knew FSWs in other towns, the team took that as signifying a strong network. They realized later that they needed to probe the depth of these relationships and the frequency of direct interaction.

Preparatory activity

RDS does not require development of a sampling frame, so it needs less start-up time than cluster-based sampling does. However, a rapid exploratory assessment of the study group—in partnership with NGOs and public health groups already working with the study group and other gatekeepers and using qualitative techniques (focus groups; key informant interviews; rapid appraisal)—is essential to the actual RDS survey. These exploratory assessments should address the following issues, and much of the information needed may be available through the PSA:

- The proportion of the survey group that is estimated to be hidden
- The types of survey group members and behaviors according to typology and whether visible or hidden
- Whether members of the survey group know each other (that is, have spent time together in the past three months and can contact each other) and have relationships with each other within his or her own network
- Whether members of the survey group are willing to recruit each other
- What amount of compensation is adequate without being coercive
- Whether members of the survey group are willing to travel to the survey venue to participate in the survey
- Whether group members travel within the sampling domain, how they travel, and how often they travel
- Whether existing power structures or lack of interest in the survey could obstruct or prevent participation
- The type of places and particular places where venues could be located

Example 8. Inadequate preparation for RDS of bar girls in the India IBBA

In one district in India, a survey of bar girls was planned and RDS was chosen as the sampling method, because recent legal issues prevented the survey from being conducted in bars. During discussions held with bar girls, bar managers, and NGOs, RDS emerged as the ideal method for conducting the survey. Later, the dynamic of how bar girls operate and how open bar girls and bar managers were to the surveys changed. Over a three-month period, only forty people (of the desired 400) participated in the survey. An assessment at the end of the survey revealed some reasons for this lack of participation:

- The residences and workplaces of bar girls are spread throughout the district, making travel to the survey venue both costly and time consuming.
- Bar girls are well-paid and the compensation offered by the IBBA did not repay the time and cost of traveling to the survey venue.
- Bar girls do not identify themselves as part of a larger community.
- Bar girls do not discuss openly whether they sell sex.
- Bar girls have little or no interest in surveys.

Selection of seeds

Seed selection for RDS is purposeful, to ensure that the seeds present diverse sociodemographic or behavioral characteristics. The team should understand the extent of personal/social networks within the study population in an area. This information helps the team understand the types of subgroups that exist in a study area. For example, FSWs and MSM may be categorized by their mode of operation, where they live or solicit, their income categories, their language, their ethnicity, and so on. These categories help to identify the different types of seeds that could be involved. The more diverse the seeds are, the lower the number of waves required for the survey to reach the representative sample. Seeds should be people who have strong, extensive, and diverse networks in the community. They should be interested in the survey's purpose and able to convince others to participate.

There is no ideal number of seeds to recruit, although too many seeds can keep the survey from penetrating deeply into different networks, or cause the survey to finish before it reaches equilibrium. Also, too many seeds may lead to fast recruitment, which the team may be unable to handle, and to a sample that is not representative of the group at large. In the IBBA in India, where the estimated sample size to reach

Note: ***Members of the survey group should be networked. In other words, they should know other people who meet the study's eligibility criteria. Knowing another survey group member means recognizing, speaking to, being friends with, and having seen that person in the past one month. These distinctions are important; if they are not clear, the RDS may fail. Not only should seeds be networked—their networks must be diverse. The team should explore whether networks exist across different geographical areas in the sampling domain (for example, towns). Networks may exist, but if they are limited in geographic scope, the team must think about how venues will be established and whether to limit the sampling domain.***

equilibrium was 400, between eight to twelve seeds were selected to initiate the survey. It is recommended that the team plan for back-up seeds in case those selected are unable to recruit respondents and new seeds are required. Back-up seeds were enrolled in the India IBBA surveys when ad chain died out after one or two waves or when the survey otherwise stagnated.

The survey team may seek help identifying seeds from NGOs and local networks they have formed during the pre-survey assessment and by visiting sites where members of the survey group congregate. Prior to conducting the survey, it is good to demonstrate appreciation of the important role of the seeds in the survey so that they are motivated for participation and recruitment. This can be done by having a dinner and inviting the seeds to meet the survey team.

Venues

The study team selects places for setting up RDS venues in consultation with the local NGOs and the members of the study population. The RDS venues should be easy to access for the survey group and places where community members feel comfortable visiting. (See "Field Experience," below.)

In the IBBA conducted in India, FSWs or IDUs were found to prefer venues not closely situated to a police station, a military establishment, or any other law-and-order agency. Brothel-based FSWs did not like to go out of their neighborhoods. Conversely, the street-based sex workers did not like to come to an RDS venue set up in a brothel area. In general, two to three venues were set up for each RDS survey in the IBBA in India depending on the geographic spread of the population and the willingness of survey group members to travel to different venues. Venues included hospitals, hotel rooms, doctors' clinics, and empty halls.

Compensation

Recruitment in RDS involves dual compensation. A respondent receives his or her first payment after participating in the survey (behavioral and biological) and the second payment for each person the respondent recruits who comes to the RDS center with the recruitment coupon and participates in the survey.

Field experience : Venue considerations

During the IBBA of IDUs in India, three teams implemented the survey. Two teams were located in their venue six days a week and the third team divided their time between two venues (three days per venue). Prior to the survey, it was thought that this would allow for wider presence, because the sampling domain was large.

In the field, this plan turned out to be difficult. IDUs were unable to remember which days the third and fourth venues were open, resulting in interrupted chains of recruitment. The survey team, in response, posted a team member outside the closed venue to ask people to return another day. Although this strategy was not tracked, several respondents did not return to the venue when it was open. The team felt it would have been better to keep one venue open six days a week for six weeks and then the last venue open on that schedule for the next six weeks. This strategy may also pose difficulties depending on the survey group size within the area and whether chains are given enough time to produce recruits. Alternatively, more venues could have been opened from the start. That method was followed in another survey in India with more success.

In setting up venues, it is important to be accessible to the survey group and be in locations where survey group members feel comfortable and are willing to travel. The survey team should ask group members what hours and days of the week are convenient for them to participate. For example, for FSWs dry days, when alcohol is not available, may be good survey days, because FSWs have fewer clients on these days.

Compensation is an important incentive for respondents to participate in the study and also to serve as recruiters. Compensation should not be so high that they motivate respondents to sell coupons to strangers instead of recruiting a survey group member or coerce respondents to participate. But compensation should also not be so low that it discourages participation altogether. The study team should discuss different types of remuneration with local leaders and NGOs to understand what amount is adequate without being either an incentive or coercive.

Normally the first compensation is larger than the second—the one given for each successful survey recruit. For example, in one district, the maximum total compensation was INR 250; The first payment was INR 100 and subsequently INR 50 was paid for each of three recruitments. Respondents are encouraged to accompany their recruits to the venue so that they can collect their secondary compensation and to ensure that the recruits visit the center. A designated staff member is in charge of incentive payments or a specific time allocated for this compensation (not always feasible with IDUs or when people have to travel to get their money). It should be noted that nobody may collect a recruiter's fee for more than three coupons. This is because in some countries the coupon stub became an opportunity to extort the reward.

Coupon design

The coupon in RDS serves as a referral card to authenticate that the bearer was recruited for the survey and as validation for the recruiter to receive secondary compensation. The coupon is an important part of the IBBA, because knowing the network chains (that is, who recruited whom) is essential for using RDSAT for analysis. The coupon number allows this to happen without recording any personal identity information. (See Appendix 11).

Print the coupon in color so it is not reproducible using a photocopier. The RDS coupon should have two parts perforated in the middle. The upper portion is the recruitment coupon that the recruiter gives to those whom he or she wants to refer to the study. This part contains the venue's address and hours, the coupon's activation and expiration dates, and a coupon number for the person who is being recruited. The lower portion is the redemption coupon, which allows the recruiter to receive secondary compensation after the successful participation of his or referred candidate. The lower portion bears the coupon number of the recruiter and the coupon number of the person recruited.

Detailed descriptions of the parts of the coupon follow:

1. **Coupon numbering system.** This is a critical part of the RDS survey for the screener, coupon manager, and supervisor. The numbering system starts with a unique number provided to each seed. For example, in a study with ten seeds, the seed numbers will be 01, 02, 03, 04, and 05 through 10.

   Each seed can recruit as many as three people. For seed one (coupon number 01), the coupon ID numbers of the three people the seed can recruit are 01.1, 01.2, and 01.3, representing the first, second, and third person recruited. It does not matter if these people all go to the same survey center or if they arrive in sequential order. Rather, the coupon numbering system is used to track the recruitment chains in the survey. Unique survey ID numbers may also be given to the respondents when they participate to maintain IBBA protocols. See Figure 4 on page 61 for an illustration of RDS recruitment waves for a single seed.

   Seed one's first recruit (01.1) can recruit three people: 01.1.1, 01.1.2 and 01.1.3. In this same way, seed two can recruit three people: 02.1, 02.2 and 02.3. Each of seed two's recruits can recruit three people – their coupon numbers will be:

   02.1 ►02.1.1, 02.1.2, 02.1.3

   02.2 ► 02.2.1, 02.2.2, 02.2.3

   02.3 ► 02.3.1, 02.3.2, 02.3.3

A seed's recruitments compose a wave. When organizers look at the coupon numbers, they show which chains are recruiting, which chains are not recruiting, and what wave each chain is on.

For example, say that a participant presents the coupon number 10.1.2.3.1. The sequence of numbers shows that the recruitment chain started with seed 10. It shows that three more participants in that particular chain having coupon numbers 10.1.2.3.1.1, 10.1.2.3.1.2, and 10.1.2.3.1.3 can be expected at the center. And it shows that the recruitment chain has completed four waves (e.g., 10.1.2.3.1).

This information lets the supervisor know when recruitment of new seeds is needed, when the waves of recruitment are increasing, and when the recruitment chain has come to a stop. This tracking system also shows which seeds were successful in initiating chains.

It is important to note that if more than ten seeds are involved in the RDS, seed numbers 11, 12, and 13 should not be used, because it will be impossible to distinguish these primary seed numbers from coupon numbers 1.1, 1.2, and 1.3 in the data entry program. This also holds true for seed numbers 21, 22, 23, 31, 32, 33, and so on (although it is unlikely that the survey will need so many seeds).

2. **Activation dates.** Activation dates are used to manage the recruitment and slow down the survey if recruitments are happening too fast. For all recruitments, the activation date should be at least twenty-four hours after the respondent participates in the survey, so that the respondent has time to think about whom to recruit. According to the coupon's activation date, a recruit can visit the RDS site only on or after the specified date. This helps in scheduling an optimum number of interviews each day for staff. In addition, the activation date curtails the temptation of recruiters to engage in coupon trading outside the site, because many would-be participants might come over and wait outside to be recruited. In case of very slow rate of recruitment, the interval between activation dates may be reduced.

   The activation date can be assigned to all coupons or according to seed number or wave number, as the supervisor instructs to manage the flow of participants.

   Nevertheless, before deciding to slow down the survey, the supervisor should consider:

   a) How long the survey has been moving quickly (Introducing new activation dates may negatively affect recruitment, by reducing incentive or interest in participating.)

   b) How much delay will be introduced (How much time can the recruitment be slowed without negatively impacting the survey?)

   If recruitment has been moving fast for only a short time, it may be worthwhile to wait and see what develops before deciding to slow the survey down.

   The activation date is not meant to exclude people from the survey. If someone comes to the center before the coupon's activation date, the screener and supervisor should admit the respondent to the survey rather than risk breaking the recruitment chain. (See "Field Experience" on the following page.)

3. **Expiration dates.** An expiration date encourages people to participate within a certain time and helps maintain the survey pace. In India, the standard expiration date for many IBBA surveys was ten days after activation. This helped the supervisor monitor whether waves were continuing and whether recruitment of new seeds was necessary. Expiration dates *do not* exclude eligible people from participating; they should be eligible to participate even after the expiration date.

4. **Coupon tuning.** When the survey is approaching completion in terms of achieving the targeted sample size, coupon tuning is used to limit the number of assigned coupons. This avoids too many unused coupons circulating when the survey ends. The tuning process can taper the number of assigned coupons at the later waves of a chain, when recruitment is proceeding at a steady pace and several recruitment chains are still active. However, if all seeds are producing at a steady pace, coupon tuning may need to begin after the third or fourth wave, so the recruitment pace will taper off. However, if

Field experience: Use recruitment coupon activation dates

In one of the RDS surveys of IDUs in India, activation dates with a one-week delay were introduced for specific recruitment chains. For a two-week period, recruitment had been proceeding very fast with one or two seeds but with others it was slower. The one-week delay proved too long for the recruiting IDUs, and those recruitment chains stopped abruptly and altogether. Also, recruiters had difficulty remembering assigned times to visit the center and they quickly lost interest in the survey. Since identifier information is not recorded, follow-up with those recruiters was impossible, so the delay stopped the strong recruitment chains and new seeds had to be recruited to revive the survey. In retrospect, it would have been better either *not* to use an activation date in order to motivate IDUs to recruit or to set the activation date only forty-eight hours hence.

In another survey with sex workers, activation dates were introduced within one week of the survey for two recruitment chains that were recruiting very fast. By not observing the situation longer, the team was unable to see that the initial speed of recruitment might not be sustained. Adding an activation date here had a negative impact on this survey, too. The FSWs lost interest in participating, recruitment of new seeds became difficult, and FSWs misunderstood the activation date's purpose and were upset by it.

certain seeds are producing very well and others not at all, then coupon tuning is unnecessary. Allow the few very active recruitment chains to continue, because long recruitment chains help the sample achieve sociometric depth.

5. **Additional RDS questions.** To understand network size and calculate approximate probabilities of a selection used for RDSAT analysis, additional required questions for the questionnaire are detailed in Chapter 4 on survey instruments.

Chapter 6

6

Estimating the size of hard-to-reach populations

- Direct and indirect methods
- Interpreting the results

In many countries with concentrated HIV epidemics, highly vulnerable and marginalized groups such as sex workers, IDUs, and MSM are most often the focus of HIV interventions. Understanding the risk for further spread of HIV, the need for intervention programs, and coverage of risk groups by these programs requires an estimate of the size of these groups. No perfect method for estimating the size of high-risk populations exists, because these groups are generally stigmatized, hard-to-reach, not easily identifiable, marginalized, and involved in illegal activities. Estimating the population size becomes a difficult activity. This chapter explains the importance of size estimation activities and describes survey methods of population size estimation. Public health organizations, field research agencies, and programs working with these vulnerable groups are generally involved in size estimation activities.

Estimating the size of populations at risk for HIV: Issues and methods was produced by a working group on HIV/AIDS/STI surveillance convened by the Joint United Nations Programme on HIV/AIDS (UNAIDS) and the World Health Organization (WHO). It provides an excellent overview of survey and non-survey methods to estimate population size as well as concerns. To supplement what has been learned from the IBBA conducted in India, some information from that publication has been adapted and incorporated here to support the discussion that follows.

Purpose of population size estimation

Reliable estimates of the size of populations at higher risk of acquiring HIV are necessary for resource planning, advocacy, measuring coverage, modeling trends in epidemics, projecting the risk of transmission, assessing program needs, and monitoring and evaluating programs. More specifically, estimating population size has been used in the realm of HIV prevention to:

- Mobilize political support for HIV programs
- Increase funding by clarifying the risk of the epidemic's spread
- Estimate HIV prevalence (across regions and population groups)
- Plan HIV programs for vulnerable populations locally and nationally
- Evaluate programs in terms of coverage and effectiveness

Estimating the size of populations at risk of HIV infection should not be an end in itself. Instead, it should be an integral part of HIV prevention initiatives that can influence both overall policy and specific programs.

Without estimates of the size of a subpopulation, it is difficult to understand the magnitude of risk for HIV. Programs may miss hotspots. Programs may not be able to reach certain areas in need of interventions, or they may allocate too many resources to relatively small and less vulnerable populations, diminishing the impact those resources might otherwise have had. Size estimations cannot be used in isolation to understand and plan for programs. Instead the data are used with an understanding of both strengths and limitations; data must be triangulated with other information from programs and surveys when used for decision making.

Size estimates are done for high-risk populations in a concentrated epidemic, but not for generalized epidemics. The information, in a generalized HIV epidemic, is less useful, because HIV has already spread to the population at large.

Key considerations

Regardless of the estimation method used, these are some overarching considerations to take into account in plans for an activity to estimate the size of a population:

1. **Definition.** The population group that is being estimated requires a clear definition, which takes into account the behaviors that put the population at higher or lower risk of HIV infection (for example, injection drug use and selling or buying sex). Such eligibility criteria as gender, age, geographic location, and behavior help to determine the definition. Develop the definition by considering which groups are at high risk for HIV infection and can be covered in a size estimation exercise. For survey-based methods, the size estimation definition should match the survey group definition. The definition and coverage area of the survey needs to be the same for the definition of the group whose size is estimated using the survey method. In identifying a second or third source of data, the definitions of the groups who are included need to match the survey definition for all criteria, including period of time, eligibility, coverage, access points, and so forth. Differences in these definitions will make the data inapplicable. Before conducting an IBBA survey, the research teams should review in detail how data are collected to ensure that they can be used.

2. **Mobility.** Certain survey groups, or parts of the survey group, may be very mobile. Including them in an estimation of population size may be problematic if the team does not understand the nature of the group's mobility. Size can be underestimated or overestimated depending on whether members of the group were present at the time of the survey. For example, certain groups may have a seasonal presence depending on holidays, weather, and so forth instead of a permanent presence. The team attempts to understand and document this prior to implementing the survey, because knowing these variations will aid understanding of survey data as well as size estimations.

3. **Access points.** The team considers the definition of the access point for the group whose size will be estimated (for example, brothels or street sites). Certain groups may be excluded from an access point by the nature of the access point, and not by the intrinsic definition of the group. For example, if IDUs are reached at public injecting sites within a city, those who inject exclusively in their homes or who inject while staying in prison will be excluded. This may be an acceptable distinction for the survey group, but the survey team should be clear about whom the access point attracts and excludes.

4. **Previous size estimation activities.** If size estimations (survey and non-survey) have been implemented with the same group in the past, the team reviews the methodology and definitions used during those exercises prior to defining the methodology for their own size estimation. The review helps the team make approximate estimates of size and aids its understanding of the risk group. It also should reveal to

the team the strengths and weaknesses of those previous exercises. The team may decide to estimate only the size of a subgroup that is covered in the survey, in order to match definitions applied in previous size-estimation activities. For example, for a survey of FSWs, the team may decide to estimate only the size of the population of street-based FSWs. Alternatively, the team may use a different method or definition, because the local scenario of risk and the need for estimates have changed.

The population size estimate will not be an exact number, regardless of the method used to calculate it. Even though a perfect estimate is out of reach, approximate estimates are useful. Keep the following in mind:

- The estimated number could attract criticism, either for appearing to be too low or high. Some stakeholders might discredit or want to discredit the findings, even if robust methods have been used.
- Size estimations from the IBBA are compared with existing size estimates and contextualized as much as possible to disclose the reasons for any variation. Differences in methods of calculation, changes in the population over time, coverage of target groups by programs or interventions, and limitations in the conduct of the estimations may explain a variation. The team attempts to explain variation and tries to understand which estimates are more accurate.
- Estimating the size of high-risk populations who may also be marginalized, stigmatized, or involved in illegal activities should be done carefully. Information about the size and the potential impact of this estimate could be misused or misconstrued and the research team should address confidentiality and harm minimization to avoid causing problems.

Size estimation methods

Methods of size estimation applicable for high-risk groups can be broadly classified into (1) direct methods (census and enumeration), and (2) indirect methods (for example, capture-recapture and multiplier methods). In the direct methods, population groups are counted, whereas indirect methods use data from different resources to estimate size. (See Table 22.)

Table 22. Size estimation methods for groups at higher risk of exposure to HIV

Method	Strengths and weaknesses	Survey method or non-survey method
Census and enumeration	A quick and easy-to-apply method, but less useful for large, geographic areas, or for groups that are mostly hidden. Hidden subgroups cannot be enumerated.	Non-survey
Nomination	Similar to the snowball method. Easy to apply, because members of the risk group recruit each other. Applicable when groups are hidden and highly networked. It requires a special event for the target population, which will serve as a starting point. Nomination requires good identifier information to avoid duplication and isolated subgroups (those unattached to the bigger network) may be missed. Not generally considered accurate for estimating the size of high-risk groups when population sizes are large and/or the population is loosely networked.	Non-survey
Capture-recapture	Often used for high-risk groups, because it is simple to understand and apply when the criteria are met, but meeting the criteria can be difficult.	Survey and non-survey
Multiplier	Relatively easy to apply when other non-survey sources of data have accurate and reliable records that match information captured in the IBBA survey. Requires a designed sequence of questions included in the survey questionnaire.	Survey
Multiple sample	This capture-recapture method uses multiple data sources to calculate the size of the population.	Survey and non-survey
Truncated Poisson	Relying on one source of data, this method makes assumptions about who has been missed from this data source (based on available information). The application of statistical methods is required. The major limitation is that certain assumptions must be met, which are difficult to guarantee.	Non-survey
Compartmental methods	The group whose size is estimated is divided into various subgroups in order to calculate the size for each subgroup. A lot of data are required to apply this method; for high-risk groups whose members are generally hidden, this information may not be available.	Non-survey

Direct estimation: census and enumeration

Although not survey-based, direct estimation methods are outlined here. A census counts each and every individual in the population. Enumeration uses a sampling frame to count a select number of people associated with a site and multiplies this by a variable representing the proportion of sites counted and the structure of the sampling frame. Advantages and disadvantages of direct methods are shown in Table 23.

Note: All individuals in the survey population must have a chance of being included in both the survey (data source A) and the second data source (data source B) in order to use the multiplier method.

Table 23. Direct methods of size estimation: advantages and disadvantages

Advantages	Disadvantages
Census methods work well when it is possible to identify, access, and count each person in a given subpopulation	Limited application for hidden populations or those with limited accessibility (e.g., incarcerated people)
Enumeration works better when it is the only possible or feasible method to reach a fraction of the subpopulation; less resource-intensive than census methods	Limited application for geographically diverse or widespread populations
May be less time consuming for visible, easy to identify, homogenous populations, and when a sampling frame exists	Resource-intensive in general, and more so for geographically widespread populations
Easy to apply	Useful at smaller scales (towns, districts)

Indirect methods for an IBBA survey

Select size estimation methods only after a careful review of the available data and ensuring that the method meets the required criteria. Give adequate time and resources to reviewing different data sources, methods of data collection and recording, designing questions to insert in the survey, and so forth. Simple errors can render size estimates unusable. Two indirect methods of estimation are covered here: multiplier and capture-recapture.

Multiplier method

The multiplier method is relatively straightforward. Identification of two corresponding data sources with matching criteria (for example, coverage, definition, and time references) is required. There must be a clear understanding of how the data sets overlap and that each data set contains unique information (that is, there may be no duplicates).

One source of information (A) is from the population group in question, and the other comes from an external data source (B), which overlaps with A in a known way. As the IBBA is a probability sample survey that is representative of the population within a certain geographic area, this can be used as the data source B. Other studies that do not have IBBA-type information available may use larger databases that are representative of the population (for example, health insurance programs) with exposure to the project (for example, membership in insurance programs) if the data can be linked. Example 1 illustrates this method.

These indirect methods make use of many different sources of information. For example, if two surveys are done – one with the survey group in question (for example, IDUs) and the other with another group (for example, IDU service providers), then these data sources may overlap in a known way. The IDU survey may provide the proportion of IDUs reporting that they have accessed services from drug treatment centers in a given period. The other source could come from IDU service providers who give the number of (unique) IDUs who have been treated for drug use within the same period. Alternatively, if health insurance providers give insurance to taxi drivers in a country, the number of taxi drivers with auto insurance can be data source B, and a national survey of taxi drivers can be conducted that includes a question asking if they have health insurance (A).

In a size estimation using a survey, data source A will come from questions included in the questionnaire relating to data source B. Data source B must meet the following criteria:

- The data are for unique individuals (that is, double counting does not take place)

Calculating a population size estimate using the multiplier method

Background information:

Data Source A: Suppose that an NGO called Good Samaritans is working with IDUs in District X. The NGO's services include needle and syringe exchange, detoxification, counseling, and abscess management. The NGO provides services to males of all ages who are currently IDUs. Good Samaritans enrolls all IDUs in their program, by registering each IDU and giving him a green registration card. At the Good Samaritan center, staff record the ID number of the IDU, the date he was enrolled in the program, and his age.

Data Source B: The IBBA covers currently injecting male IDUs who are at least 18 years old in District X. Several questions have been included in the questionnaire:

"Have you ever heard of an NGO called Good Samaritans?"

"Have you ever been enrolled or registered in the NGO called Good Samaritans (interviewer to show a sample of the green card)?"

"When were you enrolled in the program?"

Findings:

Good Samaritans (A): The records of the Good Samaritans show that 43 IDUs, age 18 or older, were enrolled. That is, 43 green cards were given out to IDUs in that age group in the past six months (January through June 2008).

IBBA (B): The IBBA shows that thirty percent of the respondents know about Good Samaritans and seven percent of all respondents report having been issued green cards in the past six months (January through June 2008).

Size estimate:

The formula for calculating the size of the IDU population in this district would be as follows:

n = 43: number of IDU (18 years or older) receiving Good Samaritans green cards in the past six months

p = 7%: proportion of IBBA respondents who report receiving a green card in the past six months

S =estimated size = 100/p * n

S=100/7 * 43

S=614

There are 614 male IDUs who are 18 years old or older in District X.

Note: ***This size estimation procedure captures anyone who has a nonzero probability of being captured by both source A and source B. People who are outside of both systems will not be accounted for.***

Field experience: Application of the multiplier method, IBBA in India

The multiplier method was applied at the district level for the surveys of FSWs and MSMs. It was thought that this method would be easy to apply, given that the surveys were taking place in districts where Avahan—the India AIDS Initiative program—was working. The Avahan program registers participants and each program has a logo that is distinct and well-known in the community.

In the IBBA survey, people were asked whether they had heard of the Avahan program or NGO (using the local terminology of the survey population), if they received any services from the NGO, and then specifically, which services in the previous one month or three months, depending on the service. Respondents were shown the project logo and registration card during the interview to confirm exposure. This became data source A.

Data source B was to be collected from the Avahan NGOs in each district where the survey was conducted. The plan was to collect information on the number of people ever registered with the program, the number of people registered with the program in the past one month, and the number of people accessing the STI clinic in the past three months.

During data analysis, the research team realized that the data for certain survey groups was problematic. For example:

- The IBBA questionnaire had specified exposure to services in a three-month period whereas the information for people at the program level was available for the past one month. Although the implementing organizations had documented information on people accessing services, it was difficult to discern whether, over a three-month period, the same people had accessed the service in question more than once. As a result, there was no guarantee that this data source did not include duplication.
- In other districts, multiple Avahan NGOs provided services to members of the target group. Some people may have accessed services at more than one site, thereby resulting in duplication of information. However, the extent of duplication could not be discerned from the program information systems. In some districts, it was difficult to guarantee that the target group members were able to distinguish between Avahan NGO services and non-Avahan NGO services, which may result in either under- or over-reporting.

The multiplier method was applied selectively based on local assessments of data. An improved preparation that involved reviewing documentation systems at the NGO would have helped. Such a review had been discussed with NGO staff but the level of detail required was not grasped.

- The data are available for members of the same population (that is, using the same definition or eligibility criteria) as used in the survey
- Data are available for the period referenced in the survey (for example, accessed service in the last one month)
- The geographic coverage (catchments) for the data sources are the same
- The service/survey/second source of information is memorable, such that survey group members would recall accurately whether they had been exposed to data source B within the given period

As long as the period in data sources A and B match, it will not matter if the data sources refer to exposure to data source B–in the last one month, or last one year, or last three years–because the number exposed and proportion reporting exposure change accordingly. If the period is too short, people may not have time to be exposed if data source B refers to a service or program. If the period is too long (e.g., exposed in the past two years) people may overestimate or underestimate their exposure, because they do not recall specific dates. The survey team tries to understand what period is appropriate, by speaking with community members and with the service providers.

The survey questionnaire must include questions that allow for assessment of reported exposure to data source B. By means of the survey, the team needs to know the proportion of people who have accessed or taken part in the project activity, services, or survey referenced in data source B (see Table 22). Once the information is collected, the size estimate is calculated with the following formula:

S = n*100/p

S = size estimate

p = proportion of survey group reporting exposure to data source B during the IBBA interview

n = number of survey group members exposed to the data source, whether it is a service, project, survey, or activity (data source B)

The multiplier method accounts only for people within the given geographic area. If people have a zero probability of being included both in data source A and B, then they are not included in the overall estimate. The research team spends time thinking about what the accurate catchments are for both data sources. This exercise is easier if done jointly with an IBBA survey, because it is well-defined already. Except for services, programs, or even distribution of unique objects, the team needs to think carefully about definitions.

For instance, suppose a survey covers the entire district including the largest city and smaller towns and villages. Suppose one public health organization is well established in providing services in the center of the district, and mobility within the district is negligible. The survey team may want to talk with the NGO or governmental staff about who accesses these services, if people visiting from outside the town ever access services, if outsiders would be aware of these services, if other service providers partner with them, and so forth.

Capture-recapture method

Capture-recapture is a size-estimation method that is based first on a *capture* (or tagging) of one of the survey group members and then a *recapture of* some of them during the survey. The proportion of overlap is used to calculate the size estimate. With an IBBA survey where probability sampling methods are used, data from the survey can be used to calculate proportion of recaptures (B). Therefore, the team must identify another source of information that overlaps with this as the second data source (A). (See figure 5.)

The population size estimate is calculated using the following formula:

N = (C1 x C2)/C3

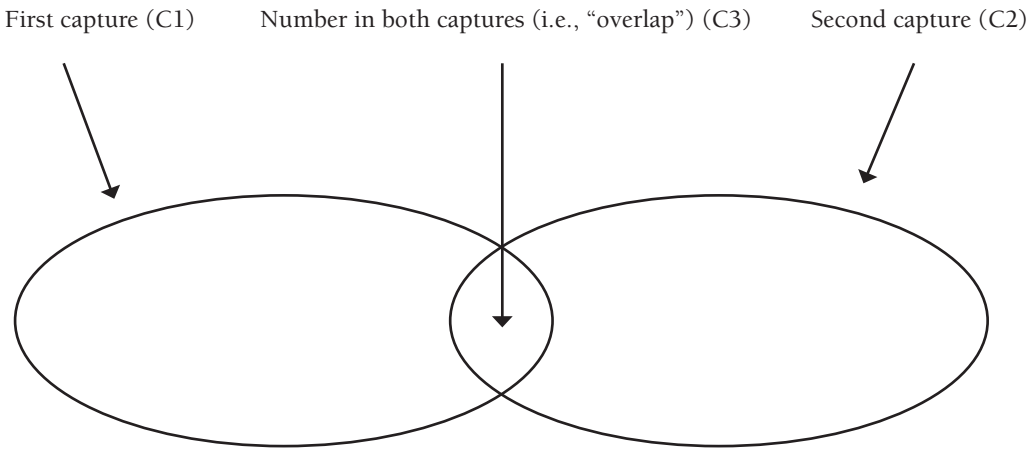
N = Size estimate

C1 = Number captured in first capture

C2 = Number captured in second capture

C3 = Number in both captures

Figure 5. Capture–recapture approach



Field experience: Capture-recapture method as used by the IBBA in India

In India, unique objects (A) were distributed to members of the survey group. The team was concerned that members of the survey group would forget whether they had received an object; would not be able to distinguish it from other similar, common objects; would give it to their friends; or would lie about having received it. To overcome this, the objects were identified as those which were distinguishable, memorable, and valuable, but not too valuable, such as key chains and small ornaments—bells and stars. When objects were distributed, those who received one were told to retain it, that they might be asked by someone else if they had received it, and that this was a gift from the IBBA survey.

Before the survey, team members counted the objects which were distributed. Objects were only distributed two weeks prior to the survey, only within the geographic coverage area of the survey, and only to members of the survey population. In some areas, members of the survey group and research team distributed objects separately. When members of the survey group distributed objects, it was both difficult to track and to guarantee the number of objects distributed. When the survey team distributed the objects, it was hard to know if the geographic areas matched and if random distribution had taken place.

In the survey, interviewers showed the respondents the unique object and asked whether they had received it within a given period. A question about this was asked at the end of the interview. By including this question, the team could calculate the proportion of individuals reporting having received the unique object (B).

This method was useful, because it did not rely on collecting data from an external source, which would have been challenging. In all of the districts, the IBBA team was not sure if each person had had an equal chance to be included in the capture. Random distribution making use of the sampling frame to define the areas of distribution would have helped. Instead, when community members and research field team staff were given objects to distribute, they were also given freedom to distribute the objects as they wanted. This would have enabled distribution in sites the distributors were familiar with and felt comfortable in or to people whom the distributors knew well.

The team was confident that the samples (distribution and participation in the survey) were independent, because the sampling supervisors were not the people who distributed the objects. Surveys were also conducted very soon (within one week) after distributing the objects, to reduce recall bias and the chance of in- or out-migration.

Certain criteria must be met for capture-recapture to be applied:

- Independent samples (C1 and C2 must be independent from each other. Any correlation between C1 and C2 would lead to an underestimation or overestimation of the sample size.)
- Each member of the population should have an equal, nonzero probability of being included in the "capture" (C1)
- Recaptures must be correctly identified
- No major in- or out-migration from the population can occur between the capture and recapture

Guaranteeing that the criteria are met for capture is rare in populations covered by an IBBA, owing to the already-clandestine nature of the survey groups. Research teams applying this method must review their methodology carefully, because any violation of the criteria will lead to an overestimation or underestimation of the size of the population and that can affect programming or policy or both. (See the Field Experience on page 93.)

In India, a unique object was distributed by team members among survey populations. In many instances the data from capture-recapture were more reliable than the multiplier method used in India, but it was difficult to know if people had an equal chance to be included in the capture.

The unique object must be something that can be remembered by the survey group and distinguished from other, similar objects. It cannot be such a common item that survey group members are unable to distinguish it from other items that they already have, or that have been given to them by other groups.

There is no ideal number of these unique objects to distribute. The team should keep in mind the criteria for the method. If too few objects are distributed, then the confidence interval for the size estimate will be very wide. If too many objects are distributed, it may be hard to achieve distribution in a short period.
In many districts in India, from 100 to 500 objects were distributed to each survey group. It was felt that 100 to 200 objects were too few in districts where the estimated survey population size was thought to be large.

During distribution of the object, the team must ensure that the people meet the eligibility criteria and that they have not received the object from a team member. (Because they may have received the object from a peer, the investigator always enquires about the source when speaking to someone who has the object.) The person distributing the object explains that the objects are distributed as part of a survey. The person must know that he or she should keep the object, not give it to anyone else, and, if anyone asks, to report if they have received it. It should be clear that this exchange is not a threatening activity.

Questions about whether the person has received the unique object (within the period when the objects are distributed) should be part of the survey questionnaire. The survey team ensures that interviewers show the unique object to help trigger recollection and then ask for confirmation that the participant has received one. The interviewers may need to be trained to ask a few follow-up questions to ensure that the respondent has received the object: *When did you receive it? Who gave it to you? Did you keep it?* Capture-recapture methods appear easy to apply, and given the right situation, they are. But good planning is imperative for proper implementation of capture-recapture surveys to meet the key criteria. These methods can be adapted for local scenarios.

Interpreting size estimates

After the survey, data for the size estimate are collected and rapidly reassessed for quality. The research team also reviews methodology that was implemented in the survey (questions, unique object distribution) with the survey team to ensure that the protocol was followed. This is not meant to be a full exercise or a repetition of previous activities, but rather a way to make sure that the data are applicable for calculating an estimate of size.

Once the data are validated for use, and before finalizing the size estimate, it is useful to compare data with other size estimates (direct and indirect), and to discuss size estimates with key members of the community and stakeholders.

The estimates may match other data, or they may be higher or lower than other estimates. Keep in mind that factors such as seasonality, migration, bias, and police activity may affect size estimates. These external factors are in addition to errors that may occur in survey implementation.

Information related to behavior of the survey group and any unusual occurrences during fieldwork documented during the pre-survey assessment and during the survey respectively helps inform whether any other external factors could affect the size estimate. For example, round-ups of IDUs in neighboring districts may lead to an increase in the IDU population in the survey district during the survey period. Although the team may find that the survey was supposed to reach everyone, limitations in the methodology may have prevented people from participating. For example, phone-based FSWs were excluded from an FSW survey by default, because they were so hidden that the sampling frame did not capture them.

If other size-estimate data exist, compare the estimates. But first the team needs to know:

- When were previous estimates conducted?
- Who conducted them?
- What specific methodology was followed for each method?
- Who was covered for each size estimate?
- What were the strengths of each size estimate?
- What were the limitations of each size estimate?
- Has anything changed in the environment that might affect the size of the survey group?

Even if the survey group definition is not precisely the same for each size estimate, it is still useful to compare data, because the survey group definition remains a reference point. Understanding the differences in the data helps extract how the data can be compared and interpreted for future use. Chapter 11 on data analysis provides more insight on how to triangulate data.

Field experience: India IBBA experience in interpreting and triangulating size estimates

In the states where IBBA was conducted in India, not only the IBBA research team but also the implementing programs calculated size estimates. It was found that these program size estimates varied from the one calculated from IBBA results. Moreover, because the IBBA itself involved more than one method of estimating the size of risk groups and yielded different estimates at the district level, some interpretation of each and triangulation were required to decide the final estimate to use. After completion of surveys a few members of the research team carried out an exercise in validating the size estimates from a subset of districts covered in IBBA.

This process involved:

- Review of every field procedure in IBBA that contributed to the various size estimates
- Review with implementation programs on their procedures for arriving at size estimates
- Discussions with program teams at district level on the issues that could affect the size estimates, such as patterns of mobility and migration among risk groups or any other events that could have affected the availability of the risk groups at the time when survey estimation procedures were conducted

Following these reviews the research team reached consensus on which estimate was most valid and would be reliable.

Chapter 7

7

IBBA teams and field training

- IBBA training methods, venues, topics, and schedules
- Test-run survey trainings

This chapter presents an overview of training for an IBBA. This training equips staff with a common understanding of objectives, key concepts, study population, data collection methods, how the data will be used, ethical issues, and harm minimization strategies. Given the diversity of expertise, roles, and responsibilities of IBBA staff, training requires an integrated approach. It should build everyone's sensitivity to issues related to the surveillance of at-risk populations, cover the specific content that staff must know to fulfill their assigned roles, and address the variety of training needs, duration, and objectives appropriate for individual staff members.

IBBA training

IBBA has many field staff who collect data and provide quality assurance during the survey. The staff required for different surveys depends on the survey methodology used and the scope of the IBBA. Table 24 offers an overview of the roles and responsibilities of most field staff members. This table does not cover the specialized training required for laboratory staff; see Chapters 3 and 9 for information about that. Details on the role of the community liaison are provided in Appendix 2.

Table 24. Roles and responsibilities of IBBA field team members

Staff	Roles and responsibility in IBBA
Staff for all surveys	
Laboratory technician	Ensure that consent was given, take biological specimen (blood and urine), complete documentation, maintain stock for the biological component, ensure proper sample storage
Doctor	Perform health checkups, diagnose and treat STIs, complete documentation, supervise lab technicians, offer referrals, maintain stock of medical supplies, provide information on HIV/AIDS, demonstrate condom use
Courier	Ensure safety of and transportation of biological samples to lab, provide documentation
Staff where cluster sampling is used	
Field coordinator	Plan for fieldwork, coordinate field teams, monitor and supervise the survey's implementation, guide survey teams, ensure adherence to protocol and ethical standards, review all documentation and field work procedures, identify venues for fieldwork, and manage finances
Supervisor	Complete the CIS form, select and recruit respondents, build rapport with respondents and other concerned individuals
Counter	Count and record the number of survey group members at a site
Community liaison	Provide information on survey sites, assist in identifying survey group members, build rapport, provide support to respondents, escort respondents to venue
Interviewer	Take informed consent, assign participant/respondent ID number, conduct behavioral interviews and record answers on the questionnaires, store completed questionnaires in secure location
Staff where respondent driven sampling is used	
Supervisor	Recruit seeds, plan for fieldwork, coordinate field teams, monitor and supervise survey, guide survey teams, ensure adherence to protocol and ethical standards, review all documentation and fieldwork procedures, identify venues for fieldwork, manage finances
Community liaison	Assist with seed recruitment, build rapport, provide support to respondents
Screener	Check coupon validity, determine respondent's eligibility, take consent and assign IBBA ID number, manage documentation, prepare questionnaires in secure location
Interviewer	Conduct behavioral interviews, store the completed questionnaires (behavioral interviews), provide for informed consent for biological samples
Coupon manager	Produce recruitment coupons, explain recruitment process, complete primary compensation transaction, conduct exit interview, fulfill any secondary compensation

The staff listed in this table are for one field team. If multiple teams cover one survey group, then the number of field staff should be increased accordingly.

Depending on the expected daily coverage, a field team may need more than one interviewer. The IBBA in India had two to three interviewers per team.

Table 25. Training topics for IBBA staff

Groups	Training topics
All staff	Basic training on HIV/AIDS, objectives of IBBA, sensitization on risk groups, ethics, confidentiality and consent, flow of fieldwork, and harm minimization For an RDS survey; this also includes an explanation of the sampling procedure
Managers	Monitoring, documentation, logistics, survey overview including both behavioral and biological aspects
Supervisors	Consent, sampling, referrals, compensation, laboratory procedures for handling biological samples, post-exposure prophylaxis, biological data collection, quality assurance, interviewing, universal precautions, documentation For an RDS survey, this also includes coupons, coupon management, monitoring flow of RDS
Investigators	Mapping and documentation
Screeners	Consent, rapport building, documentation
Coupon managers	Recruitment procedures, coupon management, compensation, documentation
Laboratory technicians	Specimen collection, laboratory procedures for handling biological samples, universal precautions, and documentation
Doctors	STI management and treatment, universal precautions maintenance of stock, documentation, specimen collection, referrals, post-exposure prophylaxis
Community liaisons	Rapport building, role in sampling, role in consent, referrals

Focus training on adult learning principles

Any training design should incorporate adult learning principles, as follows[1]:

- Use small-group work frequently and inform trainees what is going to happen next, how, and why. Trainees are more likely to be actively involved when they have an opportunity to express themselves and work together.
- Trainers should share their own experiences and ask trainees to share theirs. Motivate the group and help them understand complex concepts.
- Stimulate those in training to employ all their senses (hearing, seeing, and touching) to increase impact and learn most effectively.
- Avoid competition among the trainees, and encourage participation.
- Challenge and support the trainees, particularly while doing exercises to motivate them to learn more effectively.
- Keep the training structure informal, by allowing participants to call breaks, to stretch, and to move around freely.
- Be flexible about the training so that trainees can discuss and spend more time on certain topics as needed.
- Avoid too much training standardization, by encouraging and focusing on individual learning needs and style.

[1] Klatt B. A Comprehensive Guide to Leading Successful Workshops and Training Programs. New York:McGraw Hill,1999.

Planning IBBA trainings

In the planning stage, identify who will participate in the training, identify facilitators for individual sessions, finalize the agenda, and cost the activity. Make efforts to involve members of organizations associated with the IBBA–governmental and nongovernmental agencies, community members, and donor organizations–in the general sessions, such as those on HIV/AIDS. Involving people from these organizations improves the quality of the training by adding both field expertise and support for the survey. Technical specialists can be invited to provide training on specific issues (for example, sampling and taking consent).

Training venues

Locate the training venue at a distance that can be accessed easily by both the trainees and trainers. There should be enough light and fresh air in the training rooms. Make sure that potential sites have no noisy air conditioners or fans that would distract the attention of participants and trainers. Further, avoid conducting training in venues located in noisy bazaars or near roadsides with noise and fumes from heavy traffic. Several nearby rooms should be available to accommodate multiple sessions, meetings, or group work held at the same time. Other amenities such as food, water, and convenient toilets should be available at the venue. Organizers should keep in mind the cost and the availability of the venue for the entire duration of training. Further, if possible, make efforts to locate the venue close to the place where any outdoor sessions will be conducted.

Indoor and outdoor training

In addition to indoor workshops, investigators of IBBA need hands-on practical training in the field. Classroom sessions would consist of presentations, discussion of key concepts of the survey, interactive sessions with the trainees, and test-run sessions. Issues of a complex nature (for example, identification of respondents and sampling) require interactive, outdoor sessions to help trainees visualize and understand the topics and theories covered in the indoor sessions better. For example, interactive sessions can consist of asking interviewers or community liaisons to translate and phrase the questions in vernacular language used for eliciting responses.

Test runs

Practice helps participants learn by experience, become more confident with a new process, find answers to questions, overcome anxieties, and learn to anticipate difficulties that can occur in fieldwork. Role-playing interviews can be very useful for interviewers to learn how to administer questionnaires. Practice exercises in the classroom and in outdoor sessions can help managers identify the strengths and weaknesses of individual members, highlight any need for refresher training, resolve timing issues in the fieldwork, and help people develop more assurance during the actual survey.

Table 26. Examples of indoor and outdoor training sessions

Indoor sessions	Outdoor sessions
Narrative sessions	Practice interviews
Presentations	Interaction with the community
Interactive sessions	Mapping of study population
Mock sessions	Test runs

A test run or pilot survey can be used for training where the team members practice the (almost) full flow of fieldwork using the facilitators and trainers as the participants. Other options for similar fieldwork test runs could be conducted using willing members of the survey population, the community liaison, or members of the community monitoring board as participants in the survey. To avoid any misunderstandings, conduct all outdoor training sessions in the areas not included in the final list of sites to be sampled.

Duration of training

Plan the duration of the training–the number of hours and days it takes to complete different sessions. All trainings require an itemized budget that includes the cost of venue, trainers, training materials, audio-visual equipment, venue, and food for participants. Allow for flexibility and adjustments in the schedule and the cost estimates to accommodate needs that arise.

In India, the IBBA trainings were initially planned for five days. After the test run on the sixth day, it was sometimes necessary to add one more training day, because the team was not ready for fieldwork (for example, problems with the questionnaire were not yet resolved). During the test run, when minor problems were observed, a group discussion was held to discuss these problems and a refresher session on key problem areas was held.

The training duration varies depending on the type of training conducted and the experience of the field staff. Although an independent training for doctors can be conducted in one day, laboratory technicians require a three-day training (two days of discussion and a one-day practice session) on processing biological samples.

All the trainings should include time for lunch breaks and smaller breaks. Ideally, provide the lunch at the venue to avoid delays that occur when the participants leave the venue.

IBBA survey training

A five- or six-day survey training on IBBA fieldwork can be conducted for all field staff of IBBA, including interviewers, supervisors, managers, community liaison, coupon managers, screeners, laboratory technicians, and doctors. Sessions on the first and last day are for all field staff; otherwise, sessions are designed for specific field staff roles.

On the morning of the first day of training, an overview on the basics of HIV/AIDS/STIs, vulnerable groups, study population prevention initiatives, survey methodologies, and purpose of the IBBA is offered. In the afternoon, research ethics, confidentiality, and voluntary participation are discussed.

By the second day, multiple sessions for specialized teams take place. The second day of the training is primarily for interviewers and supervisors. The focus here is on administering consent forms, key areas of inquiry, and the survey questionnaire. The trainer conducts practice sessions on filling out questionnaires. However, doctors and laboratory technicians may sit in on the first part of these sessions so that they are conversant with the key concepts of the survey. The doctor's training is also held on the second day. On the second, third, and fourth days, community liaisons do not need to attend the training. The district laboratory technician does not participate in training on the second day. (See Chapter 4 for detailed information on IBBA instruments and documentation. Appendix 8 offers an IBBA questionnaire.)

Field experience: The study population

Sensitization sessions were part of the training curriculum. Members of the study population (represented by community monitoring board members and the community liaison) actively participated in the training and shared knowledge of the study group. This helped the field team become familiar with the community before going to the field for data collection. It also improved the team's confidence and sensitivity to the study participants.

On the third day, training is conducted in two separate groups. While supervisors and interviewers continue working with the questionnaire, field laboratory technicians and doctors are trained in the laboratory technicians' responsibilities.

Field experience: Training sessions

A group of MSM were involved as investigators in IBBA in India. During the training, MSM investigators interacted with other team members, providing insights into the MSM group. Their participation in training helped conduct more realistic mock interviews to assess the data collection process. In RDS surveys, community liaisons did the screening for eligibility checks and coupon validation. They were trained for screening, taking consent, and RDS procedures during the training.

On the fourth day, interviewers continue with practice sessions. Supervisors train on the eligibility criteria of respondents, sampling, cluster information sheets, questionnaire scrutiny, data confidentiality, data management, and coordination with the central laboratory. For the survey test sessions, facilitators and supervisors can act as respondents. Training for the other two groups (doctors and district laboratory technicians) can be conducted separately on their separate roles and responsibilities.

The fifth day of training is an inclusive session for all IBBA fieldwork staff: interviewers, supervisors, laboratory technicians, and doctors. The topics to be covered are field logistics, setting up field sites, the referral networks for STI treatment and HIV testing, participants' ID numbers, harm minimization, involving community advisory and monitoring boards, problem-solving in the field, and dealing with media.

The sixth day is devoted to the test-run practice of the full fieldwork.

Chapter 8

Integrated assessment fieldwork

8

- The field team, the community networks, and the venues
- RDS and cluster-based surveys
- Implementation of the surveys
- Monitoring and supervision of the fieldwork

Fieldwork— identifying the fieldwork team and conducting the survey—is the essence of the IBBA survey. It should be planned and implemented with care.

Some of the steps discussed in this chapter are specific to RDS or cluster-based surveys. Issues that come up in the identification, sampling, and recruitment of respondents were discussed in Chapter 5.

Step 1. Prepare for fieldwork

Identify the IBBA fieldwork team

Recruitment of the field team members depends on the type of sampling, the survey group, the number of surveys to be covered simultaneously, and the number of field teams that will be used for a single survey. Some staff are common to all surveys, but the composition of the field team differs slightly for cluster-based surveys and respondent-driven sampling (RDS) surveys. If several surveys are planned within a district or in neighboring districts, these could be covered simultaneously, allowing for joint staff trainings and simpler monitoring plans.

Options for planning a survey:

1. When one team covers different survey groups, that team's previous IBBA experience helps to ensure high quality and reduces the number of training days. For staff retention, this single-team approach requires surveys to be scheduled in close succession. This approach may increase the overall duration of fieldwork, because fewer surveys can occur simultaneously.
2. Alternatively, different field teams can cover multiple survey groups at once so long as the conduct of one survey does not impact the conduct of another. Supervision and monitoring can be more difficult when multiple surveys are conducted.
3. The survey can be initiated in two sampling domains: one domain to be covered following completion of the training and another on a test-run or pilot basis. After these, other sampling domains can be taken up for the survey proper. Conducting these preliminary surveys yields lessons that can be applied in the surveys to come. Staff who conduct surveys early in an IBBA can serve later on as co-trainers and bring their experience to bear on training for the district surveys. They can also be part of the field team for subsequent surveys.

The field teams should work together to develop a detailed plan for fieldwork that makes the roles and responsibilities of various members clear. During the IBBA in India, fieldwork for cluster surveys (not including the pre-survey assessment, mapping, or community preparation) took from three to five weeks to

complete, depending on the geographic spread, number of field teams, site-specific data collection schedule, and so forth. For an overview of the roles of IBBA field staff, see Table 24 in Chapter 7. This table also shows the staff for all surveys, for conventional cluster sampling (CCS) surveys, and for respondent-driven sampling (RDS) surveys.

Identify venues and decide operational times

In most IBBAs, identifying the right types of venues happens in the beginning, during the stage of the pre-survey assessment (see Chapter 1). However, in some cases—cluster surveys, for example—sampling must be completed before venues in close proximity to selected clusters can be scouted. For a cluster survey, the team may need to find a different venue for each cluster that will be covered.

Field experience: Identification of venue

Locating ideal venues for a survey in Mumbai was difficult, especially in congested areas where affordable space accessible to the survey population was scarce. Field experience had shown that FSWs generally were unwilling to travel far from their places of work (areas of solicitation). Distances that the survey team had deemed close —five minutes by car—were not close from the point of view of the survey population. Therefore, the survey team worked with local stakeholders and community liaisons to identify acceptable sites. Rooms within brothels were the most acceptable venues for interviews with brothel-based sex workers, whose madams did not allow them to go far from the brothels and who were uncomfortable traveling to venues with field staff members. Brothel-based venues were also most acceptable to clients, who did not want to be identified outside of the solicitation area and were quick to refuse when field staff approached them elsewhere to ask for their participation. Rented hotel rooms, clinics, and halls served well as venues for street-based sex workers.

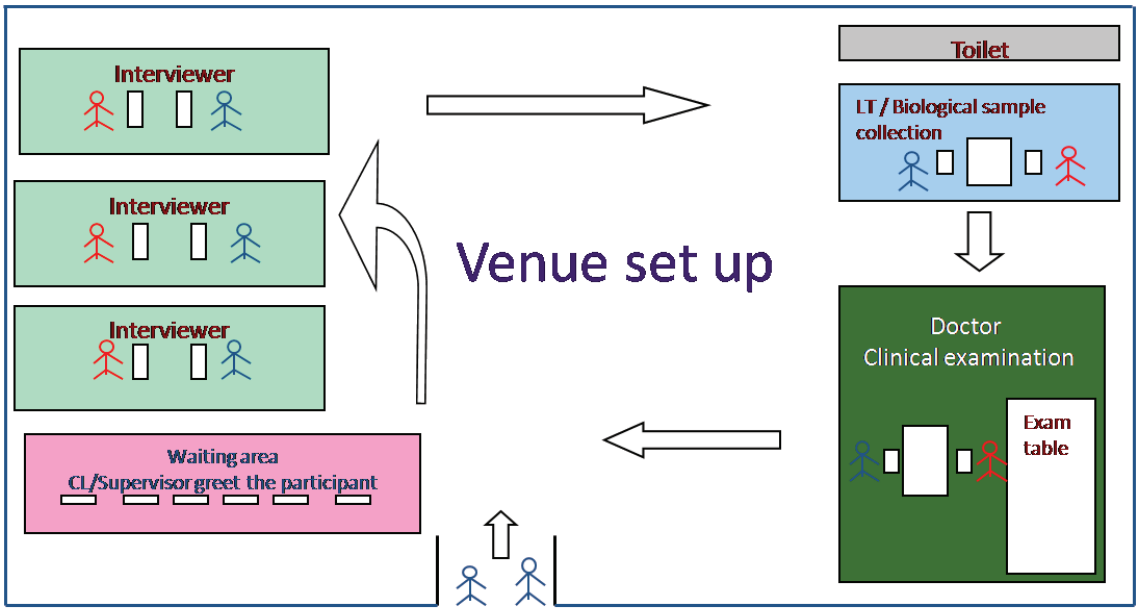
For *hijras* (transgenders), mobile vans served best. Other types of venues had been rejected, for several reasons: operational hours of sites, distance, prohibitive cost, and the *hijras*' hesitation to be involved in the survey—often related to a concern about encountering misconceptions and stigma. The team had to be especially careful not to draw attention to the vans. The team discussed these issues with community members and NGOs as part of the assessment of venue acceptability.

When scouting for required survey venues, consider:

- The opinions of the study population and its stakeholders about the venue's type, location, distance from community residences (brothels) and solicitation points, and operational schedule
- The possibility of using a local government facility if one is convenient and acceptable to the study population (This would require sensitizing governmental staff.)
- The importance of easy access and comfort to the study population
- Whether the venue could be intimidating or stigmatizing
- Whether the venue could be kept open as long as respondents are being recruited for the survey
- The basics: sufficient air and light inside the rooms; privacy; toilets
- Discretion (for example, no exterior signs), to avoid drawing attention to the venue

As illustrated in Figure 6, venues require waiting space for the recruited respondents; separate, private spaces for conducting interviews; a private space for health checkups with the doctor; and a private space where the laboratory technician can collect samples. A toilet with running water should be close by, for respondents to use when providing urine samples. Venues should have complete audiovisual privacy for the protection of a vulnerable study population. Respondents must feel safe and comfortable enough to talk about personal behaviors that are sensitive and clandestine.

Figure 6. Sample layout of an IBBA venue



The large survey space depicted in Figure 6 has the advantages of privacy, comfort for the team, and comfort for respondents. Such a large space may not be possible if the team wants to be close to places of recruitment. The team has to weigh the advantages of a large venue against the advantages that a small venue closer to the survey selection point offers. The shorter the distance respondents must travel, the easier it will be for them to visit the venue and the more willing gatekeepers will be to permit their participation.

In the IBBA in India, the team sometimes rented halls where curtains or partitions were put up to separate team members. In other instances, the team adjusted to local constraints by renting many small rooms. In a highly congested area, not only was a room separated by partitions to ensure privacy but also the number of team members at the venue was reduced. When a mobile van was used as a venue, only those actively participating in the survey—an interviewer and a respondent—were permitted inside, and the remaining field team members waited outside. Windows were covered and battery-operated lights were used to supplement the built-in interior lighting.

Selection of an appropriate venue is critical to an IBBA when RDS is used. Type, accessibility, and hours of operation make a difference in the ability of respondents to take part. It is useful to consult the study population about places where they feel comfortable, the times they prefer to visit, how they

Examples of venues used in the India IBBA

- Offices at government hospitals
- Rented clinics (during off hours)
- Hotel rooms
- Halls
- Brothels
- Schools
- Mobile vans

travel, places they think would serve well as venues, and so forth. Avoid changing venues during the course of the survey, because doing so can confuse the participants and result in broken RDS chains. The venue should be available for the survey's duration and allow a consistent schedule of operation.

Respondent/participant identification

A system for assigning ID numbers to respondents/participants is needed so that data collected from documents and biological samples/specimens can be linked to participants anonymously. Throughout the survey each ID number should be unique to the person to whom it is assigned. It should appear on all documents relating to that person, including biological tests and analyses. Any biological reports that are provided to the participant must be relayed by means of this ID number.

Field experience: Respondent/participant identification numbers

For the India IBBA, preprinted, unique ID numbers were created for respondents. The ID number was seven characters long. For example, if the ID number was "1101001," the first two digits were the district code (11), the next two (01) were the survey group number, and the last three (001) were the respondent's serial number. Because multiple venues were operating simultaneously, the team was not concerned if the ID numbers were not issued in sequential order. The purpose of the numbering system was to make sure that a unique ID was assigned to each respondent for use on every document or sample associated with the respondent. For that reason, for each ID number generated, fifteen labels were printed for use on consent forms, questionnaires, blood and urine samples collected in the field, and processed blood and urine samples. In addition, an ID number dictionary was developed as a reference. When surveys were conducted with multiple groups simultaneously within or across districts, some mix-ups occurred.

In the India IBBA, labels were given to each participant for use on the documents that were generated as the participant moved through the survey from the interview to the laboratory technician to the doctor. The ID labels were used on biological samples sent to the district and state laboratoriess for testing. A similar process was used in RDS surveys, but the ID number was also recorded (by hand) on the coupon and on some of the RDS documents (for example, on the eligibility form).

Biological supplies

The team coordinates the collection of field work supplies, the delivery of samples, and the delivery of laboratory test results with the local or district laboratory. Interaction with the laboratory occurs daily, so that samples can be stored upon completion of field work and to ensure that cold packs and thermacol/storage boxes are available for field work. Before field work begins, the supervisor should meet with the local laboratory technicians and other staff. For details on biological field work, see Chapter 9.

A clear plan should dictate how specimen delivery will take place and who should be contacted about that each day. Delivery can happen late in the night during TLCS surveys. The courier and laboratory technicians should know one another, because they will coordinate the collection and delivery of materials. The technicians should understand the procedures to deliver test results (for example, which forms they should complete and the information required), be able to complete the stock request forms, and be aware of their obligation to keep frozen gel packs ready (if these are used).

In addition to collecting gel packs from the local laboratory, the team may explore storing additional packs at sites near the field work. This will make a back-up supply of thermacol boxes available to the team if a problem arises on a given day with the transport of specimens. Field storage is also helpful if the distance between the field site and the laboratory is too great for travel twice a day. In India, freezers in clinics, shops restaurants, and hotels were used for this purpose. (See Chapter 9.)

At the beginning of each day, the laboratory technician ensures that an adequate stock of consumables is available for the day's work. The technician should make a daily list of supplies to facilitate this.

In India, each interviewer was expected to be able to survey three or four participants a day. Because each field team had three interviewers, it followed that ten to twelve participants per team per day would complete the survey. Blood and urine specimens, and sometimes an ulcer swab, as well, were collected from each participant. The laboratory technician needed to ensure a supply of consumables, instruments, and equipment (allowing for breakage, loss, and so forth) that would be adequate to each field team's needs.

It is desirable to maintain a minimum three-days supply at the data collection venue, to cope with any unforeseen interruption in delivery. In addition to consumables, some basic facilities should be made available at the field work venue (as described in Chapter 9).

If gel packs are used, they should be kept in a shaded and cool place to keep them from defrosting. During the survey they should also be stored in the closed thermacol box. Make sure that local facilities are available that can freeze the gel packs thoroughly.

At the end of each day, the laboratory technician assesses the supplies and makes a list of those that will be needed. The technician collects and deliver these supplies on a daily basis. Consumables should be requisitioned from the local laboratory using the field requisition form.

Step 2. Establish referral systems

If treatment and test results are returned to respondents, the team needs to establish a referral system. Places that are selected as referral sites should be accessible and comfortable and should follow standard treatment procedures. The IBBA team may consider providing an orientation on treatment protocols to staff from referral sites. Contact information for the clinic and its hours of operation should be recorded.

As part of management of STIs, IBBA staff should have a detailed list of referral clinics in and around the survey area where members of the survey group say they feel comfortable visiting for services. These may be NGO, government, or private clinics. All referral centers should be aware of the IBBA and agree to serve as a referral or treatment center. The clinic staff should be sensitized about the IBBA and the respondents' need for confidentiality. They should be familiar with the referral cards that respondents carry, know when test results will be reported and whom to contact when problems occur, know what to do to keep the required medications for treatment of STIs in stock, and be trained on the IBBA treatment protocols.

Field experience: Building rapport in the field

Building rapport with the community was crucial in the survey of clients of FSWs. Continuous efforts were made to gain the confidence of community members (pimps, madams, FSWs, regular partners of FSWs, and others affiliated with a site, such as shop owners) so that the survey would not disturb a site's routines. Group meetings with brothel owners, agents, and FSWs were arranged. One-on-one meetings with FSWs were conducted to gain the FSWs' support. With the help of key community members and FSWs, the survey team was able to build rapport with clients and approach them about participating in the survey.

The identity of respondents should be confidential; information given during the survey must not be shared with referral centers. In the India IBBA, the results of syphilis tests were given to respondents at the referral centers along with treatment for syphilis. Test results for other STIs could not be given to respondents, so a syndromic approach was recommended and adopted at the IBBA site and at the referral centers.

The team will need to design a referral card to give to respondents. The card should have spaces for the participant's IBBA ID number, the name and hours of the referral clinic, and the reason for referral. Respondents will use these cards to collect their syphilis test results. The team will need to determine how long it will take to deliver test results to a referral clinic, given the length of time needed to conduct tests. In the India IBBA, respondents who were interested in an HIV test were also referred to integrated counseling and testing centers (ICTC). The team had two options for these respondents: they could be referred directly to the ICTC or to an NGO, which would designate someone to escort them to the ICTC.

Connecting to the community at the field site

It is important to build relationships with people in the community before, during, and after the survey. This helps the team to understand the dynamics of the community, reduces misunderstandings about the survey and refusals to participate, increases community support, helps the team understand how the survey can be implemented at a specific site, allows the team to identify people at or near the site who may be useful in building support for the survey, and sets up good relationships for future surveys.

At every opportunity, team members should explain the purpose and benefits of the IBBA, emphasize safety and confidentiality, and address questions and concerns about the survey.

Field team identification cards

Each team member should be given an ID card and a letter of support from the partner agencies. These documents can help a team member if problems arise in the field. Because many of the team members will be traveling at odd hours (especially for TLCS surveys), or in areas where they may not feel comfortable, the team should make safety a priority. The team should receive guidance to deal with problems they may encounter. Moreover, each field team member should have the contact information for every other member and for members of the research team. With so much community preparation, it is unlikely that anything untoward will happen, but precautions are nonetheless important. For example, field team members might consider accompanying one another to and from the venue.

Compensation

The research team, in consultation with local NGOs and community members, will need to decide how to compensate participants in cluster based and RDS surveys. Compensation should not be so lavish that it coerces people to participate. Nor should it be so meager that it discourages people from participating. Local scenarios differ in terms of the amount of compensation that is appropriate and the consequences of offering compensation.

In India, compensation was given to all groups after consulting with the ethics committees, NGOs, stakeholders, government agencies, and community members. Compensation was given in appreciation for the time that community members spent on the survey. This was clearly stated to respondents so as to avoid misunderstandings later or create an expectation that all NGOs would or should give participants money. Truckers, following consultation with their community groups, received in-kind compensation: a towel, toothbrush, and bar of soap.

All respondents received the same compensation whether they participated only in interviews about their behavior or they participated in interviews and gave biological samples. Those who discontinued participation were also compensated. This was done to avoid rumors that money was being used to push people to participate in the biological part of the survey. Respondents who required assistance were escorted to ICTCs by participating NGO staff for counseling and testing.

For RDS surveys, compensation is given twice: primary compensation for participation and secondary compensation for referring people who then participate in the survey. Primary compensation is generally higher than secondary compensation. The purpose of secondary compensation is to interest participants in recruiting their friends for the survey.

The team needs to decide:

- The type of compensation
- The value of compensation
- Messages regarding compensation
- Who will manage compensation at the field site
- Who is eligible for compensation

Step 3. Implement the survey

The following guidelines should govern the treatment of respondents in the survey after selection (cluster sampling) and at the venue (RDS).

Setting up the venue

The venue is arranged to meet the requirements of the survey—to simplify the participation process and ensure that respondents are comfortable. Partitions can be used to create private spaces for executing different components of the survey. It is important to keep a list of all the basic materials needed at the venue: pens, a cabinet with lock and key, chairs, table, tablecloths, screens, and so forth.

The survey team makes sure that refreshments such as juice, tea, and biscuits are available for the survey participants. To protect the participants' privacy, do not post signs advertising the venues or the survey or place publicity in local newspapers. Survey teams may post a staff member outside an RDS venue to facilitate the participants' identification and entry to the venue. A small sign with the letters 'IBBA' and an arrow can be useful inside a government facility or large center to help people find the survey room. Otherwise, the survey team avoids attracting public attention, because that could increase stigma and decrease participation in the survey. Set-up of the venue should be completed before it opens.

Screening for respondent-driven sampling

When a potential respondent walks into an RDS venue, the community liaison and the screener should be ready to greet and interact with him or her. The screener asks for the coupon and checks to make sure that it is intact and authentic. The community liaison takes a secondary role in the screening process, assisting where needed. More information on the role and training of the community liaison appears in Appendix 2.

The screening ensures that participants in the survey are eligible for inclusion—that they meet the criteria established for the study and have not participated in it previously. With IDUs, a community liaison may be more comfortable than the screener asking such questions as what types of drugs the potential respondent injects, how long the potential respondent has been injecting, the potential respondent's age, the date of the last injection, the frequency of injections, how and where the potential respondent injects, and where the potential respondent buys drugs. With sex workers, the community liaison may ask when and where the potential respondent has sold sex, how the potential respondent knows the person who provided the referral to the RDS center, and how often the potential respondent sells sex.

Some people who come to the RDS center to participate might not be eligible. For example, those who participate in the survey may not do so more than once. Because of the compensation offered in RDS surveys, past participants may attempt this.

If the screener has any doubt about a potential respondent's eligibility, the screener should discuss the matter with colleagues at the venue. The screener, coupon manager, supervisor, and community liaison spend a lot of time with participants; one or another of them is likely to recognize someone who has already been surveyed.

From each person who visits the center, the screener collects the referral coupon and stores it in its own envelope (see Figure 7). If the person is eligible to participate in the survey, the screener fills in the eligibility form and then proceeds with the consent process. If the person is not eligible to participate in the survey, the screener should complete the noneligibility form. Respondents should be accepted for the survey if they:

- Have not yet participated
- Are willing to recruit their friends for the survey after participation
- Are willing to give behavioral interviews and biological samples
- Have valid coupons
- Meet all other eligibility criteria

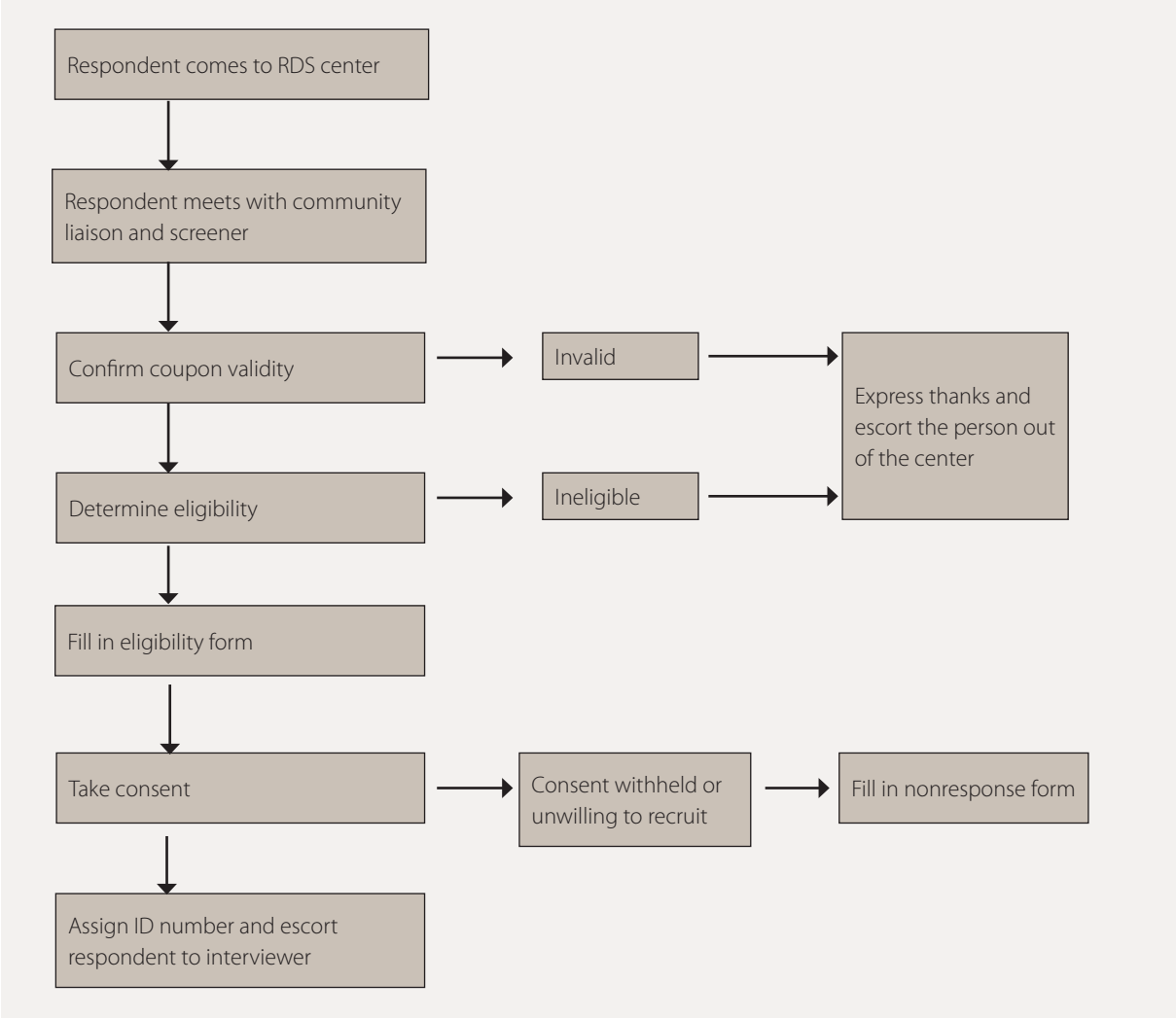
The CL may remain with the screener during the consent process if that seems useful or if the potential respondent wishes. If the respondent chooses to participate, oral witnessed consent or signed consent (depending on local protocols) should be taken. At this point, the screener assigns the respondent's unique and permanent ID number.

The nonresponse form should be completed for people who are eligible for the survey but do not consent to participate in it. The screener, with the supervisor, completes this form. Once the consent process is finished, the screener begins the survey checklist. (Many survey forms and the documentation they require are discussed in Chapter 4.)

The screener needs the following materials:

- Eligibility forms
- A list of eligibility criteria and screening questions
- Noneligibility forms
- Nonresponse forms
- Survey checklist
- Consent forms
- ID numbers/stickers
- Envelope for storing primary coupons/referral coupons
- ID card for screener
- Pens
- An envelope for each of the filled forms listed above

Figure 7. Screening process for respondent–driven sampling



Consent for cluster sampling

After a potential respondent is selected at the survey site, he or she goes to the venue with the community liaison or supervisor. There the interviewer builds rapport with the person. If the potential respondent is eligible for the survey, the consent process should start. If not, the interviewer expresses thanks for the person's time and ends the process. If desired, the CL can be present for the consent process.

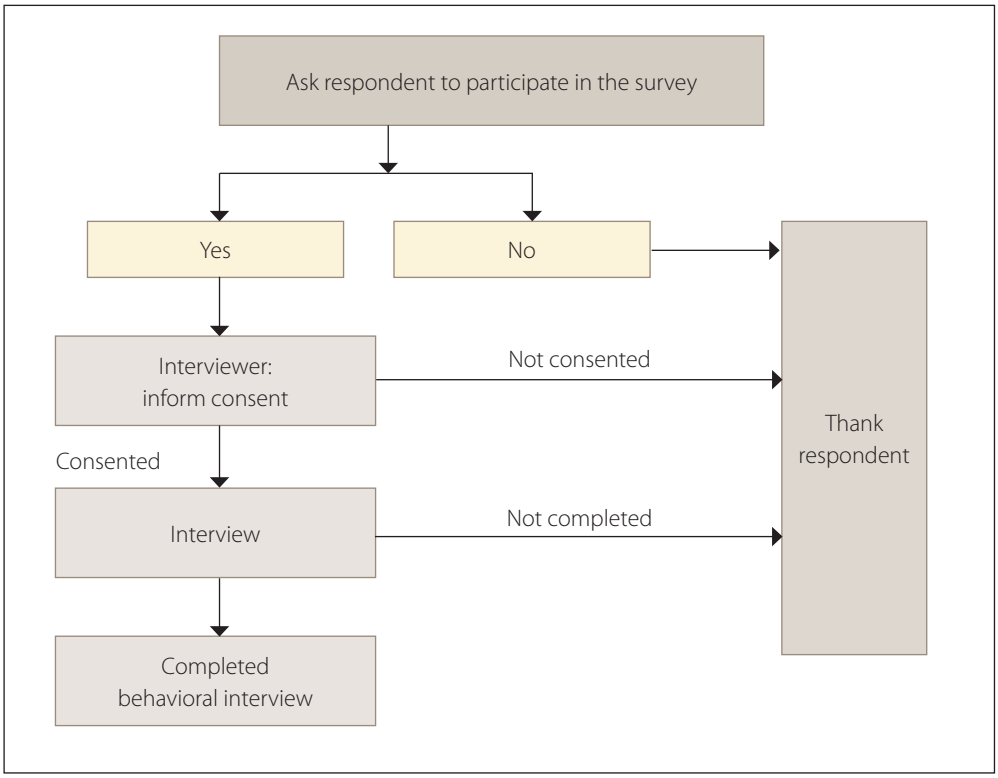
In cluster-based surveys, the interviewer administers the consent process. The interviewer describes the survey's protections for confidentiality and privacy. Depending upon the survey protocol, the respondent may give oral witnessed consent, signed consent, or both. A consent form used in an IBBA in India is provided in Appendix 7.

Conducting interviews

For RDS and cluster sampling surveys, all those who consent to take part are interviewed. Normally the interviews are held in private, with only the interviewer and the participant present. To determine the quality of interviews, the research team may consider having the supervisor witness a few interviews; in such cases consent for this should be taken from the respondent. Having a third person present to observe the interview process may make the participant uncomfortable and affect his or her willingness to answer sensitive questions, so this quality control step should be approached cautiously.

During the course of an interview, either the interviewer or the participant may have questions or concerns. The supervisor and CL can be brought in to address them. People who decide not to take part in the survey or who stop the interview before it is over are politely thanked for their cooperation and then compensated and (RDS) escorted out of the center or (cluster sampling survey) escorted back to the sampling site. The supervisor should document the ID number associated with the person who withdrew and, for an RDS survey, fill in the nonresponse form. The consent forms should be separated from the questionnaire and stored separately immediately after the interview. All the completed forms should be kept in a secure place under lock and key in order to maintain the confidentiality of data. The steps involved in conducting interviews are shown in Figure 8.

Figure 8. Steps in conducting interviews for a cluster sampling survey



Some general guidelines for the interviewer follow:

- Explain the survey's objectives clearly
- Strictly adhere to the consent process and answer all of the respondents questions or concerns
- Remember that participation is confidential and voluntary
- Remember that the respondent has the right to refuse to answer any question
- Strictly adhere to the survey's confidentiality and harm-minimization plans
- Ensure privacy and confidentiality
- Respect the respondent
- Dress modestly and appropriately

- Make the respondent feel comfortable by building rapport and maintaining eye contact
- Do not react with shock or disbelief to any of the respondent's replies
- Do not prompt a respondent with possible answer categories if doing so is not prescribed by the questionnaire
- Probe only when guided to do so by the questionnaire, but do not suggest answers (For example, do not say, "Do you mean…." Instead ask, "Can you elaborate?")
- Do not change the wording of any question, because this may alter the meaning
- Use local terminology when asking questions, keeping the meaning unchanged
- Do not hurry
- Allow the respondent to express his or her feelings, reactions, or concerns, and then take time to respond
- If you do not know the answer to a respondent's question, pass it on to the supervisor for response

The interviewer needs the following materials:

- An ID card
- A letter from organizations supporting or implementing the IBBA
- A contact sheet, including telephone numbers of field team members, the project coordinator or manager, and other team members
- Copies of questionnaires and consent forms
- Any supplementary materials for the interview (for example, project logos, ID numbers, health cards if asking about exposure to interventions, or unique objects that are used to estimate the size of the population through the multiplier method
- Referral information, including the addresses of ICTCs
- Addresses and contact information for local NGOs
- Pens (all questionnaires should be completed in pen so that the data cannot be changed)
- ID stickers (for cluster surveys)
- Consent forms (for cluster surveys)
- Folder(s) for the questionnaire and consent forms after an interview

Collection, packaging, transportation, and storage of biological specimens

After completing the behavioral interviews, respondents who have consented to take part in the biological component will meet the laboratory technician to give biological samples and then the doctor for a health checkup and referrals to other services. Laboratory technicians should give the respondents refreshments after taking samples. All the biological samples are collected in appropriate containers and stored for dispatch after completing the day's survey. Guidelines for biological fieldwork are discussed in Chapter 9. Laboratory networks are discussed in Chapter 3. Following biological sampling, a doctor gives each respondent a free health checkup focusing on STI (discussed in Chapter 9).

Referrals

In IBBA participants consenting to give blood samples will be tested for HIV. If the results are shared with the participants a complete protocol of HIV testing, counseling, and referral for treatment must be followed. If results are not given, provision must be made to ensure that participants have the opportunity to know their HIV status through the ICTC. The India IBBA adopted the latter strategy, because HIV test results took too long to return and there was no provision for counseling or follow-up support and services.

If certain test results and treatment are given to respondents (for STI, for example), then the doctor, using a referral card, explains where test results can be collected. If the participant can collect the results at any of several locations, he or she should be directed to the one that is most convenient, and the doctor should record that location on the test result referral form so that local laboratory staff will know where to deliver the results. The doctor circles the name of the referral center on the referral card so that the participant knows where to pick up the results. The doctor tells the respondent when the test results will be available. All the respondents should be referred to local NGOs after completion of the IBBA. The IBBA doctor and interviewers should keep referral cards with contact information for NGOs on hand so that they can let the participant know about the services available and when and where to access them.

Coupon management for a respondent-driven sampling survey

After the participant has completed each of the required steps in IBBA (behavioral and biological), the coupon manager issues coupons to the respondent for recruitment. The coupon manager needs to explain the recruitment process to the respondent and record information in the coupon logs. The steps are as follows:

- On the coupon the coupon manager should write the coupon ID number, the activation and expiration dates (if needed), the referred respondent's coupon number, and the IBBA ID number.
- The coupon manager should explain the recruitment process for the IBBA to respondents in a simple, straightforward way. Their task is to refer people they know (that is, people they have encountered at least once in the past one month, with whom they speak, who recognize them, and who they recognize). These people must meet the eligibility criteria and be interested in participating in the survey. The coupon manager also explains that participation is voluntary, and that if the potential recruit declines to participate, then the the same coupon can be used to recruit another person.
- Each respondent will receive a set number of coupons and should limit referrals to that number. The coupon manager may encourage respondents to escort their recruits to the center. This will help to ensure that people come to the center and also that the respondent receives secondary compensation. The respondent should understand that referrals, participation, and secondary compensation are void if the respondent misplaces the coupons.

More information on coupon management appears in Chapters 4 and 10.

Compensation for participants in cluster sampling surveys

The supervisor gives compensation to the respondents after thanking them for their participation and ensuring that their participation is complete (by checking the questionnaire, the documentation forms, and so forth).

If respondents receive any money to cover the cost of transportation to referral centers, the supervisor should provide it after explaining the purpose of compensation and transportation money.

Compensation for participants in respondent-driven sampling surveys

The coupon manager pays primary and secondary compensation to the RDS survey respondents. After a respondent has completed all steps in participation, the coupon manager reviews the checklist and explains the recruitment process. If the respondent declines to recruit, then the coupon manager pays primary compensation but should not offer a coupon for recruitment.

Primary compensation is given after completion of all components of the survey. The coupon manager explains the purpose of the compensation and thanks the respondent for his or her time. This is recorded in the financial logs. If money to cover the cost of transportation to referral services is offered, the coupon manager should provide it.

The coupon manager pays secondary incentives to respondents who have used their referral coupons and successfully recruited their peers to visit the RDS center for participation in the study. The recruit must present his or her redemption coupon in order to receive secondary compensation. The coupon manager verifies and files the redemption coupon. Secondary compensation is only given when the people referred are determined to be eligible and complete full participation in the IBBA. If those who refer potential respondents have escorted their recruits to the center, they are asked to stay apart in the waiting area while the recruits go through the survey process. This helps prevent any peer-to-peer coercion.

Before paying secondary compensation, the coupon manager checks the coupon logs to see how many of the recruiter's recruits were enrolled and participated fully in the IBBA. Secondary compensation is recorded in the financial logs. The coupon manager refers to the financial tracking log before paying compensation to make sure that the recruiter has not already been paid.

If the center is very busy, the coupon manager may encourage recruiters to go to the RDS center only during specified hours to collect their secondary compensation. This should be considered and explained carefully as to avoid misunderstandings. The coupon manager is responsible for ensuring that an adequate supply of compensation money is available each day.

Friends or family of the recruiter may go to the RDS center and ask for secondary compensation on behalf of the recruiter. The coupon manager must decline these requests.

Scenarios in which the recruiter will not receive any compensation are:

- If coupons have not yet been redeemed
- If the recruiter has no redemption coupon
- If the people referred did not participate fully in the IBBA
- If the redemption coupon appears to be fake (in which case, the coupon manager should take it from the recruiter)

When a recruiter comes for secondary compensation, the coupon manager should ask if one or more people refused to accept a coupon. If the recruiter says yes, the manager should also complete a coupon refusal tracking form. On this form the manager will record the number of people who refused coupons and the primary reasons why they refused.

Delivering test results to participants

If test results are shared with participants, a courier is given responsibility for delivering the results to the referral centres on a regular basis. The results must be delivered on time in sealed envelopes (each to be opened only by the respondent) and to the appropriate clinic staff. The courier maintains a notebook tracking all transactions by ID number, noting the date when samples were dropped off at the local laboratory, the date test results were picked up from the laboratory, and the date of delivery to the referral clinic, signed by a member of the referral clinic staff. If any delay in receipt of results occurs, the courier

discusses this with the supervisor. The team may want to track, from the referral clinics, the number of people who have come to collect their results. Read more about roles and responsibilities in an IBBA in Chapter 7.

Step 4. Monitor and supervise the fieldwork

The objective of monitoring and supervision in an IBBA is to verify that the study adheres to protocol and guidelines, in order to ensure the quality of the study. Monitoring and supervision also aims to identify deficiencies, if any, and to provide timely advice on feasible corrective actions with regard to community preparation, survey methodology, protection of the rights of participants, and data collection. The monitoring and supervision activities are conducted by all the partners involved in the survey and members of the field team.

Monitoring and supervision are performed daily or periodically, depending on who is responsible for the tasks. Addressing monitoring and supervision as a teamwork exercise, a capacity building opportunity, and a way to find solutions rather than to police field activities will improve the quality of the survey. Field team members will feel more comfortable presenting problems, suggesting solutions, and responding to recommendations. The field team should consider creating a checklist for monitoring activities that addresses issues in the field. A notebook may be maintained at each venue to note observations that may prove later to be significant and worthy of follow-up and analysis.

Chapter 9

Biological fieldwork

9

- Roles of the biological field staff
- Clinical site requirements
- Field supplies, equipment, and the district laboratory
- Referral options for participants
- Health checkups, treatment, and referrals

Guidelines to prepare for and conduct the biological or clinical component of an IBBA are discussed in this chapter. Although the behavioral and biological components are conducted by one team, the members' qualifications and training and the details of the operations that each component involves differ. Job responsibilities of each team member are clearly defined so that all members can work together as a team to implement the study smoothly, with good quality, maintaining appropriate rapport with the community, abiding by the protocol, respecting confidentiality, and taking care to minimize any harm. For an overview of IBBA field teams and the roles of various staff, see table 24 in Chapter 7.

This chapter focuses on the clinical site, the roles of field lab technician, doctor, and courier. Guidelines cover specific staff procedures, the coordination with the district lab, test results, and a referral network for survey participants will be discussed. More information on IBBA establishing lab networks, standard operating procedures guidelines, and quality control systems, is available in Chapter 3.

Fieldwork preparation

Identification of venue

Venues for the IBBA fieldwork must be suitable both for behavioral and biological components. In particular, the doctor and laboratory technician will need a venue with the following characteristics:

- A place where community members feel comfortable visiting
- Privacy and confidentiality
- Private space for conducting health checkups, discussing personal health with respondent/participants, and taking biological samples
- Adequate ventilation and light
- Consistently available electricity
- Reasonable proximity to sites where the respondents are selected
- Availability of a clean toilet
- Availability of running water

Sometimes a less-than-perfect venue can be improved with adequate planning. For example, if electricity is not consistently available a generator can be considered, or if lighting is inadequate, the team can bring battery-operated lights or rechargeable lights to the venue.

Venues used in India ranged from large halls to brothel rooms, private clinics, government hospitals, and hotel rooms. Sometimes, mobile vans were used when other venues could not be identified. Although some venues were ideal in that they were not too costly and met all of the above criteria, in others, the team was cramped for space. For example, in mobile vans only one interview could take place at a time. The interviewer would then leave the van and the laboratory technician would enter to take biological samples (if the respondent consented). Then the technician would leave the van, and the doctor would enter to conduct a health checkup. This situation compromised the comfort of the participants, so mobile vans were used only in the absence of a better alternative. Teams were cut back on these days so that fewer people would be lingering at or near the site to draw public attention. Mobile vans were located near public toilets so that urine samples could be taken.

For all venues, but especially in more open, public settings, it is important to inform the police about the survey to avoid creating confusion about the IBBA activities.

Develop a flow chart

The IBBA team should develop clear flow charts for use by all staff. A flow chart depicting the movement of a respondent/participant through the survey, from the consent process to collection of compensation, can be an especially helpful tool for participants and new staff. Flow charts can also be helpful for staff who have many responsibilities, or who must execute their tasks in a specified order.

Field team roles and responsibilities

In an IBBA field team, the doctor reports to the field supervisor and the field laboratory technician reports to the doctor. The doctor should, therefore, oversee the quality of the laboratory technician's work and provide input and feedback as needed. This means that the doctor should be trained in the laboratory technician's role, and the supervisor's training should cover all staff members' responsibilities. Responsibilities for the biological field team are shown in Table 27.

Table 27. Responsibilities of biological field staff

Staff member	Responsibility	Reports to
Field laboratory technician	Ensuring consent for giving biological samples; building rapport; taking biological samples; completing documentation; ensuring adequate stock/storage of consumables/nonconsumables; correct storage and labeling of biological samples; managing gel packs; ensuring proper waste disposal; following universal precautions; coordinating and assisting as a team member	Doctor
Doctor	Rapport building; giving respondents health checkups (if desired), including diagnosis and treatment of STIs; completing documentation; supervising laboratory technician; giving referrals; maintaining the stock of medicine supplies; following universal precautions	Field supervisor
Courier	Ensuring safety of and transportation of biological samples to laboratories; completing documentation; collecting and delivering stock materials to the field site; collecting and delivering test results to referral centers	Field supervisor

When selecting staff doctors and laboratory technicians, look for the following characteristics:

- Sensitivity about HIV and its related risk groups
- People with whom the study population will be comfortable with (for example, consider age and gender)
- Ability to accommodate the survey's schedule (for example, some surveys happen at night)

- Willingness to adhere to survey guidelines and protocols
- Respectful of the rights of respondents/participants
- Qualified according to the laboratory manual standards
- Attended the IBBA field training

The referral network process

The referral network for the IBBA is important. All respondents, whether they participate fully or not, should be referred to other support services. These services can include both health care facilities and NGO services. In India, FSWs, MSM, *hijras*, and IDUs were referred to whatever NGO services were available in the locality. Depending on the sites where the study population was identified, they were referred to the closest service center, although they were informed about all the services. Clients of FSWs were referred to government health facilities. Before setting up the referral system, the field team identified potential referral services by talking with community members. The IBBA field supervisor then met with staff at the short-listed referral agencies to inform them about the IBBA survey, gain their support for it, ask whether they were interested in having the agency serve as a referral center, and secure agreement to do so.

Referral centers are expected to:

- Greet referred participants while maintaining confidentiality about IBBA participation and not discussing the survey with them
- Have a clinical facility with a doctor willing to abide by IBBA protocol on referral centers
- Receive test results in sealed envelopes from an IBBA courier
- Keep test results in their sealed envelopes until the participant arrives
- Check the IBBA referral card for the identification number, and for any information from the doctor
- Confirm that the identification number matches the received test results
- Have a doctor speak with a participant about his or her test result
- Provide STI treatment in accord with the IBBA protocol (when needed) using free medicines delivered by IBBA staff
- Document how many people (according to identification number) collect their test results
- Communicate as soon as possible with the IBBA field coordinator if any problems arise
- Make sure the participant is paid for the cost of his or her transportation

An IBBA referral card will include:

- Contact information and address for the referral
- A space for listing the participant's IBBA identification number
- Space for the doctor to sign his or her name and to record any observations or medications given
- The date when the participant can collect results

The card should be small so that a participant feels comfortable either carrying it to the referral center or taking it home. All participants in the India IBBA received a referral card whether or not they gave biological samples. For those who did not give samples, the doctor crossed off the information about when to collect test results but recorded STI symptoms and a treatment course (when necessary).

Emergency medications

Emergency medications, if deemed necessary for the fieldwork, should be available on a daily basis and included in the general procurement. In India, medications to treat anaphylactic shock were procured and provided to referral centers that would treat syphilis. That was because injection penicillin—which was one of the medications the IBBA supplied to referral centers for treatment of syphilis—can cause anaphylactic shock in rare circumstances. Thus, clinic doctors who received supplies of injection penicillin also were supplied with treatment for anaphylactic shock. (Some doctors were not willing to treat with injection penicillin because of the risk of anaphylactic reaction.) In addition, a plan was devised with the referral center to be prepared to treat anaphylactic shock and, if need be, for transport to an emergency room.

At the IBBA field site, the doctor was provided with medications for HIV post-exposure prophylaxis (PEP), along with a defined protocol on how to treat individuals. Documentation forms for this were developed so that the survey could track all instances of provision of PEP. The drugs/kits were kept at the site for use in the event of accidental exposure to HIV during blood collection by the laboratory technician.

Fieldwork procedures

List of field supplies

The doctor and laboratory technician maintain an easy-to-access list of field supplies required for each day's work. This list serves two purposes:

- Prior to starting field work each day, the doctor and technician refer to the list to make sure they have all the supplies required to conduct fieldwork.
- At the end of each day, the doctor and technician use the list to take stock, so that supplies needed for the next days' fieldwork can be reordered from the district laboratory.

For each day of fieldwork, the doctor and technician should have enough supplies to cover the potential maximum number of participants at their venue. For the IBBA in India, one field team, which consisted of three interviewers, could conduct a maximum of 15 interviews (regardless of consent for the biological component). This number was calculated based on the assumptions that each interviewer could complete a maximum of five interviews a day and that the laboratory technician could collect 15 biological samples. In actual practice, the teams generally covered fewer participants.

The list of essential drugs for syndromic case management of sexually transmitted infections and anaphylaxis management should be kept at the field site

Biological equipment storage

Depending on the venues arranged for the survey and whether storage facilities are available for biological supplies, the team will have to decide whether biological supplies such as urine containers, vacutainer tubes, and so forth can be stored at venue sites, must be kept by the supervisor for delivery to the sites each day, or must be returned to the district laboratory each day. Overnight storage at the laboratory is burdensome for the courier and should be avoided. In India, at sites where the team was situated for the duration of the survey, cabinets with locks were obtained for storage of supplies. The cabinets were also used to store questionnaires and consent forms (only the supervisor kept the key) until they were sent to a central place for data entry.

Setting up a field site

The field site for the biological component should provide space for the technician to collect biological samples and for the doctor to conduct health checkups. Both procedures must be private and confidential.

In general, the doctor's work requires:

- Two chairs
- A table for documentation, storing medicines, and examination equipment
- A cot for medical examinations
- A screen for privacy during examinations
- Medicines (as directed by IBBA protocol for medical treatment)
- IBBA referral cards
- Health checkup forms
- Pens—blue or black ink
- Biological-component flow charts
- A doctor's manual
- An IBBA contact information list for field team members
- Letters of support (from partners, government agencies, and so forth)
- Access to running water
- Soap for handwashing
- Latex gloves
- A supply of condoms to give to participants
- Identification cards for participants
- Any other equipment/materials for the conduct of medical exams in privacy

In general, the field laboratory technician's work requires:

- Equipment for collecting biological samples (in accord with the SOP manual)
- Laboratory submission forms
- Laboratory technician's manual;
- Biological-component flow chart
- Access to running water and soap
- A table
- Two chairs
- A screen for privacy
- Pens—blue or black ink
- Identification cards for participants
- Letters of support (from partners, government agencies, and so forth)
- An IBBA contact information list for field team members

In general, the courier requires:

- Contact information for the district laboratory and field team members and the venue address
- Bags to transport biological samples and laboratory wastes
- Identification cards
- Letters of support (from partners, government agencies, and so forth)
- A notebook to document transfer of biological samples and delivery of test results
- Contact information for referral centers

Initiating field work

Prior to starting the fieldwork, make sure that

- The venue set-up for the doctor and laboratort technician is complete
- Consumables, nonconsumables, drugs, and infrastructure are adequate for the day's work
- The courier has delivered the required laboratory supplies, including a thermacol box for storage of specimens, to the field team so that they can collect biological samples (Starting fieldwork before supplies arrive is problematic, because participants may have to wait at the venue. Therefore, the courier should collect the samples on time and arrive at least 30 minutes before the venue opens.)

The team requires the following documents at the field site:

- Manuals
- Flow charts
- Stock register of supplies on hand (filled out by the doctor and laboratory technician daily)
- List of essential drugs for syndromic case management and anaphylaxis management
- Laboratory and indent forms (see Appendix 13)

Building rapport

The doctor and laboratory technician should spend time building rapport with a participant before starting the biological part of the IBBA. The participant has been at the venue waiting and then being interviewed. The participant may be tired and may be fearful of providing urine or blood samples or of having a health checkup. Both the doctor and laboratory technician should make sure that the participant

- Is comfortable
- Has consented to participate in the biological part of the survey
- Is aware of what participation involves

Taking specimens

Participation in the IBBA is voluntary and confidential. The laboratory technician checks the consent form to confirm that consent was given and that the interview was completed in full in a private setting. During the collection procedure, the technician should explain each step in the process so that there will be no surprises. Some people may be averse to blood collection and worry about how much blood is collected. In

India, participants who were scared were informed that the equivalent of two teaspoons of blood would be collected. The technician demonstrated this by filling a sample vial with that amount of water.

The technician should follow the procedures for biological specimen collection in strict accord with the laboratory manual. The technician should report any problems encountered during the collection process to the doctor, rather than aggravate participants by ignoring their concerns and risking loss of their confidence.

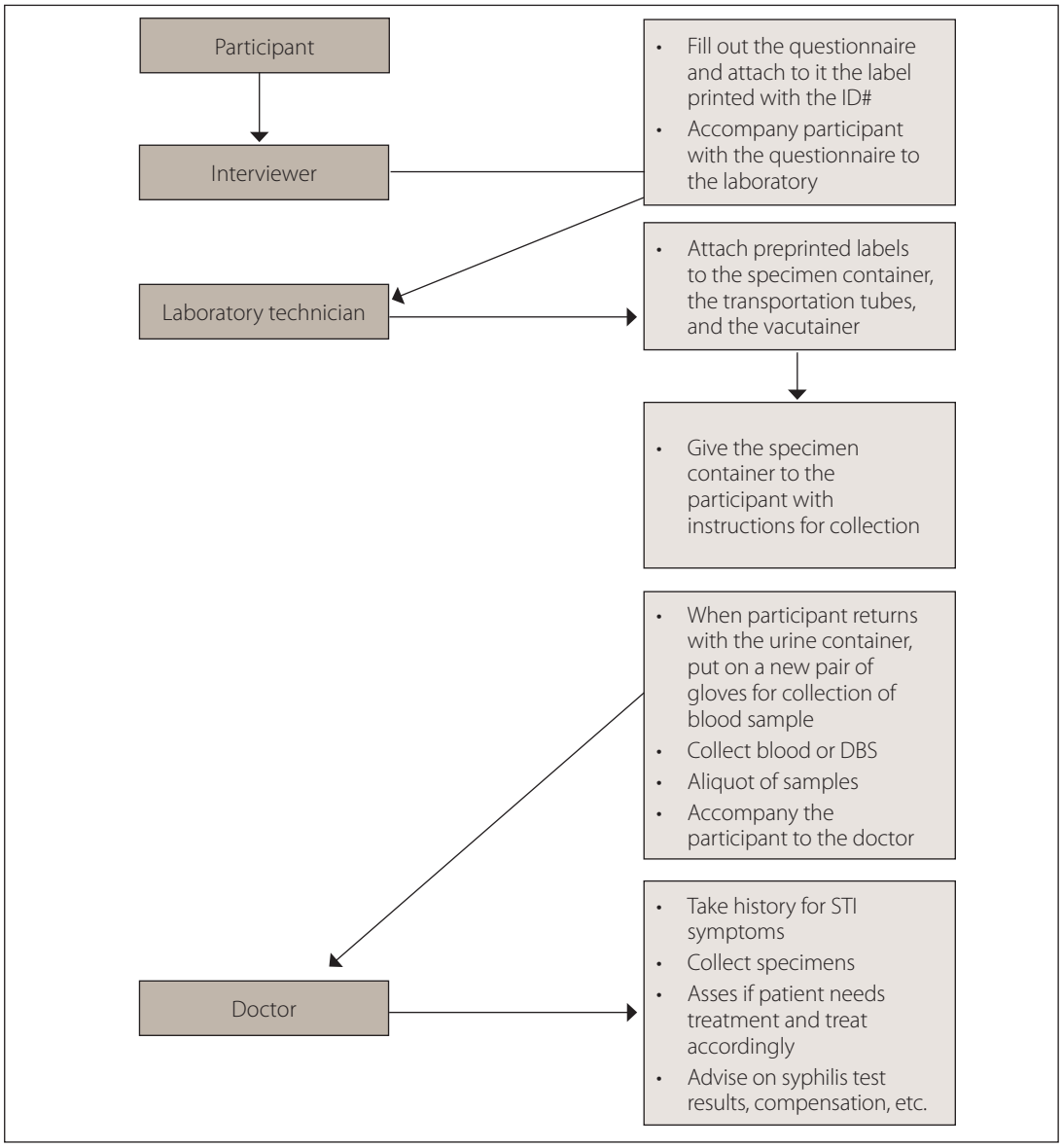
Health checkups

The doctor greets the participant and asks whether he or she is interested in a health checkup. Some participants may not want a physical exam, but in India the option of management based on self-reported symptoms was offered, so that doctors were able to treat people who reported STI symptoms.

Treatment, test results, and referrals

If the participant reports symptoms of an STI, or if the doctor finds symptoms during the examination, the doctor must follow the IBBA protocol to treat the STI. The doctor explains how to complete the course of medications and provides referral information so that the participant can follow up with treatment at another center. The doctor records the participant's symptoms and the treatment provided on the IBBA referral card. If no symptoms were identified, the doctor documents this on the card as well. (See Appendix 1 for the IBBA India survey protocol.)

Figure 9. Work flow for taking biological specimens in an IBBA



The doctor should offer participants several options of places to visit, so that they can choose to go where they feel most comfortable.

If participants can collect their IBBA test results at the referral sites (for example, in India, syphilis test results were reported), the doctor should explain to participants the process of collecting the results. (The doctor will know if this guidance is called for, because the technician will have relayed information to the doctor about whether the participant provided any samples or not.) The doctor should tell participants when the results of specific tests will be available, that free treatment will be given (if needed) at a referral center, and when to visit a referral center. The doctor should stress that the participant must retain his or her personal referral card, must not give it to anyone else, and must not take anyone else's card. In India, sometimes participants held each other's cards when visiting a referral center. Once this happened, it was impossible to trace whose card was whose, because the identification numbers are not linked to participant names. The test results could not be given.

Participants who wish to be tested for HIV but are not comfortable visiting a referral center can be directed to local government facilities or reputable private facilities for the test. In India, such participants were referred

to various partner NGOs. Lacking their own testing facilities, these NGOs had agreed to escort individuals to government-run integrated counseling and testing centers (ICTC). These NGOs were already providing this service as part of their own projects, so it was not an added burden.

Ending the visit to the survey venue and compensating the participant

After meeting the doctor, the participant is escorted to the supervisor, who ensures that:

- All questions about the study, to the tests, or to the survey have been answered
- Information about HIV, other STIs, and AIDS has been provided
- The participant understands where to collect the test results

The supervisor also provides compensation for participation (in RDS surveys, the coupon manager handles this). The supervisor notes on the record with the particpant's identification number that compensation was given.

District laboratory: supplies and consummables

All supplies and consumables for field activities are delivered to the district laboratory in accord with the requirements for fieldwork, processing, and testing for the district. The team should ensure that a secure and protected room is available in the district laboratory for storage. Field activity supplies should not be mixed with other laboratory materials, because it will be difficult to differentiate them later. Any equipment sent to the district laboratory should be clearly marked as part of the IBBA survey and maintained according to the instruction manual. Detailed information about laboratory networks is available in Chapter 3.

A laboratory technician is in charge of the field supplies (stores) kept at the district laboratory (in addition to the responsibilities of accepting, storing, processing, and dispatching biological samples). Managing the store of supplies entails the following responsibilities:

1. **Stocking consumables received from the state laboratory**. This involves:

- Confirming receipt of all consumables as noted on the delivery list
- Storing consumables safely in the designated area and in accord with protocol, which states proper temperature and place
- Preparing a list of locations for all items in storage (rack number or drawer number, for example)
- Maintaining appropriate documentation for the stock list (see Appendix 13 for a laboratory stock form)

2. **Maintaining the district laboratory stock supply.** This involves:

- Ensuring the security of supplies
- Updating the stock list throughout the survey period to monitor consumption
- Communicating with the district laboratory-in-charge regarding consumption of supplies, need for reordering, and so forth

3. **Providing supplies to district field teams.** This involves:

- Checking the laboratory stock form before sending materials, to make sure that the laboratory technician and the doctor have signed it
- Maintaining documentation of stock dispatched to field teams
- Preparing daily consumable requirements according to protocol (For example, in India, gel packs had to

be frozen at a specific temperature for a specific period before they were sent to the field each day. In that survey, at least 25 gel packs were kept frozen at all times, to keep field staff supplied and for packaging samples in thermocol (cryostorage) boxes for transport to the state laboratory.

- Coordinating with the field team courier to collect and dispatch supplies
- Being flexible in relation to the timing of the field team's needs
- Reporting any problems to the district laboratory in charge, and to the field team coordinator

4. Receiving specimens/samples from the field teams. This involves:

- Coordinating with the courier on the schedule for delivering samples
- Checking transportation conditions
- Checking the quantity of samples against information on submission forms
- Ensuring that submission forms are correct
- Checking the physical condition of the samples and noting any problems
- Checking identification numbers of the samples
- Signing the three laboratory submission forms (one each for the field laboratory technician, the district laboratory technician, and the state laboratory) to confirm acceptance of the biological samples, having first noted any problems with the samples on each of these forms
- Storing the samples at the proper temperature and in the proper place
- Processing and storing samples in accord with the laboratory technician's manual

The laboratory technician is responsible for maintaining the supplies needed for the survey. When stock falls to a level deemed to require reorder, the technician immediately prepares a stock form, sends it to the appropriate district laboratory, and follows up on the order's status on a regular basis.

Cold storage of supplies and samples

At the field site

Many biological samples collected in an IBBA have to meet certain requirements for storage to retain quality. All of the guidelines for processing, storage, and transportation must be strictly followed.

In the field, adhering to the guidelines can be challenging. In India, after taking blood and urine and settling the samples, IBBA staff had to keep the samples at a temperature close to 4^0 C. To that end, thermacol boxes were kept at the field site with the expectation that a maximum of five samples could be stored in one box without compromising quality. Each box contained two gel packs. These were frozen at the district laboratory for a specified period and dispatched to the field teams by courier on a daily basis. The thermacol boxes were opened only when material needed to be placed inside, in order to keep the contents frozen. Any problems with the gel packs had to be reported immediately by the field laboratory technician to the district laboratory technician and field supervisor so that they could be addressed.

At the end of a day's work, all specimens should be packed as directed by the specimen package guidelines and dispatched with specimen submission forms to the district laboratory. The maximum time a gel pack stays frozen is about 24 hours. In India, because some sites were too far from the district laboratory for samples to be dispatched on a daily basis or because fieldwork finished late after the laboratories closed, provisions had to be made to keep a supply of frozen gel packs at or near the survey site. The team started storing extra gel packs near the field venues, to draw from if a supply of gel packs arrived from the district

laboratory that were not fully frozen, or if venue hours ran long and samples could not be dispatched the day they were collected. Restaurants, health clinics, hotels, pharmacies, and other places that had freezers were enlisted to provide storage. These facilities had to be open at times convenient to the survey team. Such an arrangement would be valuable for any IBBA.

At the district laboratory

A designated technician in the district laboratory should be in charge of receiving the specimens. The technician will check them for volume, temperature, leakage, and proper labeling. All the specimens received will be logged on a specimen submission form sent from the field. One signed copy of this form will be retained in the records of the district laboratory; another signed copy will be sent back to the field laboratory technician to confirm that the condition of the specimens upon arrival was correct. If the specimens arrive in substandard condition, then corrective actions must be taken by the field team and documented on each specimen submission form.

Occasionally specimens may arrive late at the district laboratory. The field team supervisor should coordinate with the district laboratory and the courier when it becomes apparent that this will happen. The samples must be stored and processed before the temperature changes in the samples and, as stated earlier, the team may consider storing extra frozen gel packs near field venues in case of late deliveries. All specimens must be sorted and stored as directed by the laboratory guidelines.

When specimens that reach the district laboratory cannot be processed for some reason (the quantity is too small, the quality is compromised, and so forth), the problem is discussed with the district laboratory in charge, and reported to the state, to the field team coordinator, and to the researcher. Response plans include:

- Addressing the reasons why samples cannot be processed
- Documenting the reasons
- Informing the field team and researcher so that sample size as directed by the protocol can be adjusted accordingly
- Informing the health referral center that a sample for a given identification number will not be available for testing

Power shortages

Power shortages can be a problem in the field and the laboratories. In the laboratories (state and district), if a backup generator is available, it must be turned on immediately to maintain the required temperature of all refrigerators or freezers. The design of an IBBA should include plans for local response to power shortages and other such emergencies.

In India, when a backup generator was not available, the specimens which had been stored in a refrigerator at a temperature of 2-8^{0}C were shifted to thermacol boxes with frozen gel packs after one hour of power interruption. Specimens can be stored this way for up to 24 hours. If a power interruption lasted for more than one day, arrangements for transportation to the state laboratory were made immediately, to avoid loss of quality.

Also in India, to minimize the impact of power fluctuations on the fieldwork, gel packs were frozen locally. This was done only when it was certain that power would return by the time fieldwork concluded. Further, provision was made for battery-charged lights so that collection of biological samples could continue. This tactic was itself a challenge, because the lights required a consistent source of power to be recharged. Moreover, there had to be enough lights so that some could be used while others were being charged. These portable lights were also useful in venues with poor lighting.

Delivery of biological samples to the state laboratory

Guidelines for transporting specimens from district to state laboratories should be prepared and all staff in these laboratories should be trained in these procedures. More information about IBBA laboratory networks, standard operating procedures, and quality assurance systems appears in Chapter 3.

The transportation of samples entails the following steps:

1: All involved should come to an agreement on the frequency and day of shipment

2: Decide how the samples will be delivered from the district to the state laboratory

3: Ensure that samples are documented properly and that a courier accompanies the delivery person, to deflect problems with police and others

4: Follow specimen package and shipment guidelines

5: Fill out the specimen submission form in duplicate

6: Let the state laboratory know the the date and shipment tracking number either by phone or email

Chapter 10

10

Data management

- Safeguarding data
- Handling data: from the field to the computer
- The process of managing data for an IBBA

Managing data, especially when multiple IBBA surveys are conducted with different survey groups or in different sampling domains, is a challenging task for an IBBA team. The tools used to collect information vary from one survey group or sampling domain to another. The team must have clear plans for processing, compiling, transporting, storing, and ensuring the confidentiality of data, whether biological or behavioral, in both hard and soft copies.

The content of IBBA data and the survey groups from whom they are collected are sensitive. The teams must take steps to keep the data confidential throughout the processes of collection, analysis, and storage. Even though the people from whom data are collected in an IBBA are anonymous, careful management is necessary to avoid harm to the studied community, misunderstanding of the survey within the studied community, improper release of data, misreporting of data, or distortion of IBBA activities in the local or national media.

To that end, systems should be in place to ensure confidentiality of data prior to implementing any field activities for the IBBA. A data confidentiality plan is needed to govern the handling of data in each step of the survey.

Systems to protect confidentiality

Training. All IBBA staff members must receive formal training to ensure that they understand the sensitive nature of the IBBA surveys and the importance of protecting the confidentiality of the data they handle. Their training should also cover procedures to minimize harm. If a breach of confidentiality occurs, staff must know how to report the problem and respond to it. A list of each staff member who has attended the training should be maintained. For more information on IBBA training, see Chapter 7.

Confidentiality agreements. Ensure that each IBBA staff member understands the data confidentiality agreement and accepts its terms. This instills understanding of the importance of confidentiality and makes each staff member aware of the consequences of breaches in confidentiality. Confidentiality guidelines include, but are not limited to, the following:

- Contact information for all IBBA staff members must be collected.
- Team members must not discuss or share any information collected for the IBBA projects. The only exceptions are when a problem or need for clarification arises during an interview and a supervisor must be consulted to resolve the issue.
- Team members must not collect or record any identifying information from respondents.

- Team members must not retain hard or soft copies of any data. All data must be stored in a locked cabinet accessible only by the supervisor or data manager. Upon completion of the surveys, hard and soft copies of all information must be given to the lead institution.
- Any information regarding survey participants or those who refuse to participate may not be shared.
- IBBA data are never entered, opened, reviewed, transferred, or shared on a public computer.
- All respondents must complete voluntary consent forms before they begin the survey. These people have the choice of whether they want to participate, and they can also end their participation at any time without penalty.
- Clinical specimens must be delivered only to designated people. Upon receiving a specimen, the designated person must sign a receipt confirming the delivery.
- Test results from biological specimens are safeguarded and discussed only with designated people on the IBBA team.
- Transportation and storage of data must follow established guidelines.

Each IBBA staff member—mapping staff, coordinators, community liaisons, supervisors, interviewers, doctors, laboratory technicians, and data management staff—signs a confidentiality agreement. The field manager maintains a master list, which records that each staff member has understood and signed the agreement. Hard copies of the signed agreements are sent to the project manager. The master list of staff members who have signed the agreement is sent to principal investigators.

Field documents. The main survey collects a lot of information in consent forms, questionnaires, and clinical forms. This information is sensitive and should be handled as the guidelines dictate. Refer to Chapter 4 for more information on IBBA forms and documentation.

The questionnaire for each respondent is handled primarily by the respondent's interviewer. On occasion, the field supervisor accesses the questionnaire to help the interviewer with problems and to review the questionnaire for completeness. There may also be times in the field when the supervisor or other senior staff members review the questionnaire for problems. In these instances, they may want to discuss specific questions with the interviewers and may choose to do so with all interviewers to improve data quality.

The field supervisor collects the questionnaire once the interview is complete. The supervisor checks the questionnaire and stores it in a locked cabinet at the field site. Some remote field sites might not have secure storage. In such a case, the supervisor identifies a secure location to store the questionnaires until the end of fieldwork that day.

Generally, only the doctor and the field supervisor have access to the clinical forms used during the biological component of an IBBA. During data quality reviews, the supervisor and other senior team members may review this information. The clinical forms are given to the supervisor after the medical checkup so that these can be stored with the questionnaire.

The supervisor maintains a list of documents received in the field, recorded by their identification numbers. Once the supervisor has confirmed that a respondent's questionnaire is complete, the supervisor places it and all other documents (consent form; clinical format) bearing that respondent's identification number in an envelope that also bears the respondent's identification number. Storing all documents related to a given respondent in one place makes data entry and data management more efficient. The supervisor seals the envelope with tape so that no one can open it undetected.

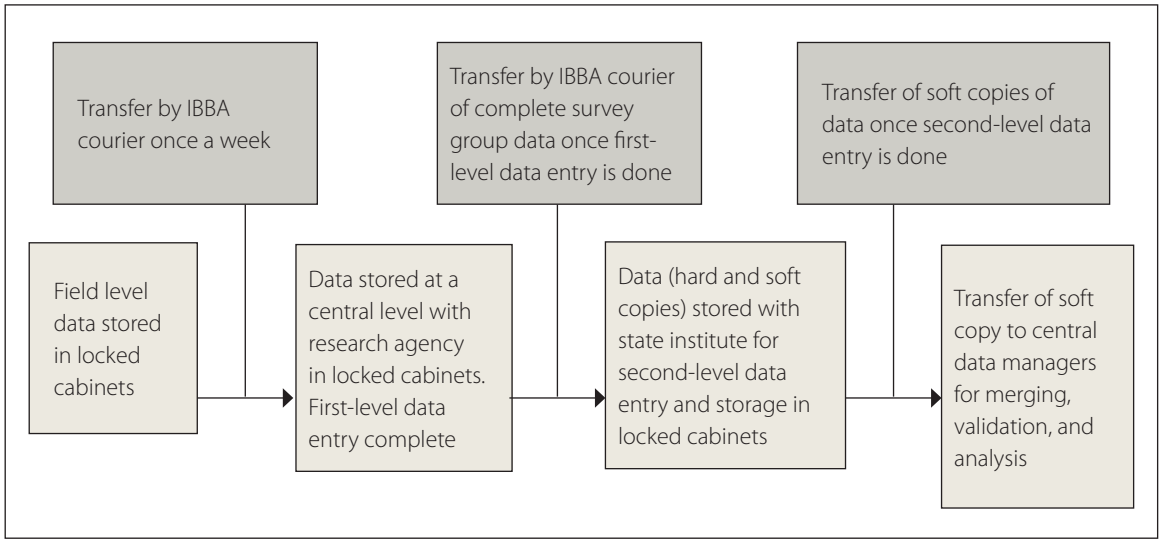
Sampling frame. Mapping data contain information on site locations where survey team members can be found, and at what times, as well as area maps. All documentation relating to mapping, including hard copies

of PSU forms, soft copies of mapping data, and the sampling frame are stored under lock and key. Soft copies are password-protected and only the data manager should know the password.

The supervisor is responsible for the sampling frame and ensures its confidentiality. On a day-to-day basis, the supervisor gives site information to the field team for conducting fieldwork. Staff of local NGOs and others may request information from the mapping data or sampling frame, but this information must not be shared with them, for two reasons. To do so would violate the terms of the confidentiality agreements. Moreover, the NGOs should not know in advance which sites the IBBA will cover, because that information could bias the survey. At the end of the survey, the team may consider sharing mapping data with NGOs to supply them with the latest information on various sites with risk groups.

Transportation and storage of field documents. The filled-in field documents (PSU forms, CIS, questionnaires, consent forms, clinical forms, laboratory forms, and so forth) are transported under lock and key to a central, secure place for storage. The survey team determines the appropriate methods to transport documents—including how and how often this will happen—to ensure data security. Several options exist. For example, documents from the field can be transported directly to the data manager for data entry. If data entry takes place far from the field sites (for example, in a different district), then the documents may be transported to a central place within the sampling domain and transported to a central location for data entry and storage. Alternatively, if a secure cabinet is available in the venue, documents can be stored there until they are transported to a central location.

Figure 10. IBBA data transfer: field documents to data entry



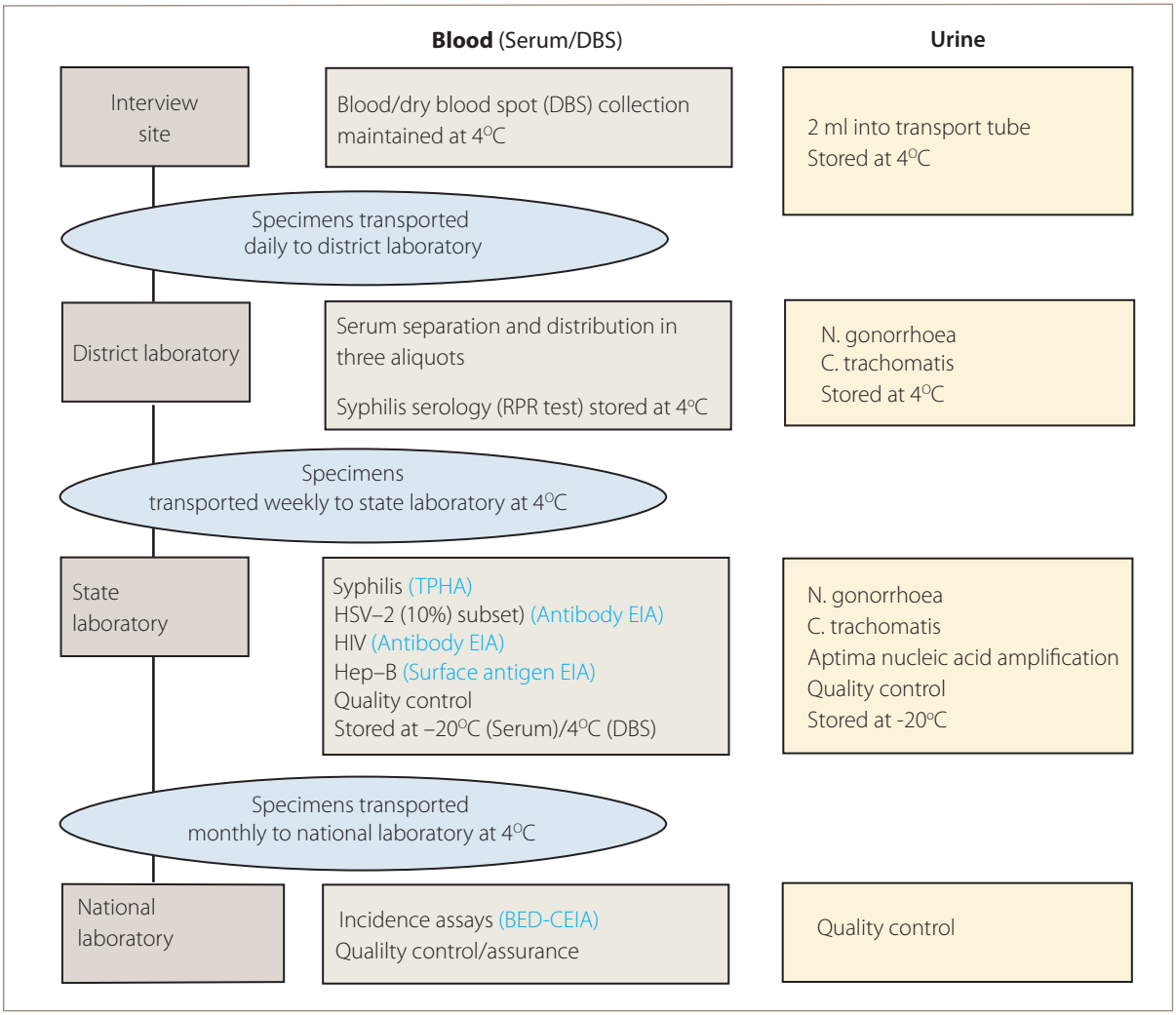
Where field sites are close to the central data management facility, the field team may send the documents on a daily basis. Preferably, the same person will always be responsible for sending documents to the facility. Documents must be securely wrapped and sent with a detailed list, organized by identification number, of the transport's contents. The supervisor signs off on the shipment and keeps a copy of the list for his or her records. When the documents arrive at the data management facility, the person designated to receive them checks the shipment and verifies that it is complete. That person then signs a receipt for the IBBA courier and keeps a copy of it for the facility's records. Figure 10 outlines the transportation and storage of field documents to the data entry office that was followed in the IBBA in India.

Similarly, Figure 11 outlines the IBBA procedure for laboratory testing and storage of a biological specimen. Once data are entered by the data entry team, they are saved in the appropriate location, compared, validated, and corrected and then deleted from the computers the team used to enter the information.

No public-access computers. Any data pertaining to IBBA should not be saved, transferred, or stored on computers in the public domain. Such devices have the potential for misuse by others. If exceptions to this rule are required, the IBBA team must approve them.

Raw data. Raw data from an IBBA should not be shared with anyone who is not involved in the assessment, to protect the data from misinterpretation or misuse. Raw data are shared only with members of the IBBA team who are allowed access, in accord with established data policy. It is always preferable to share with the public the results of a study rather than raw data. This should be done in an organized manner once the data have been understood and approved for release.

Figure. 11. Laboratory testing and storage protocol



Data management

The number and location of the surveys being conducted directly influence decisions on how and where data entry will take place. For the IBBA in India, in each state first-level data entry was done by the research agency that implemented the fieldwork and second-level data entry was done by the government partner in that state. Data analysis and cleaning took place at a central level in one institute (Figure 10).

The process of data management in an IBBA involves the following nine steps:

1. Establishment of a data processing unit
2. Preparation of a questionnaire

3. Development of a data entry program
4. Management and editing of questionnaires
5. First-level entry of data
6. Second-level entry of data
7. Comparing and cleaning of first-level and second-level data
8. Secondary editing of cleaned data
9. Merging of behavioral and biological data

These steps assume that CSPro software is used for first- and second-level entry of behavioral data and Microsoft Excel software for first- and second-level entry of biological data. They also assume that IBM SPSS software is used for advanced statistical analysis. Where other software programs are used, the steps will be similar but may require some adaptation. (CSPro is a software package in the public domain that is used for entering, editing, tabulating, and mapping census and survey data. For more information, see Resources and References.)

Establish a data processing unit

Set up a data processing unit to handle all management and data processing activities: reviewing final versions of the questionnaires, editing the questionnaires, designing the data entry program, entering data into the data entry program, data checking, data cleaning, and data analysis. The data processing unit is staffed by a data manager and a group of three or four data-entry operators. The unit is equipped with the necessary equipment and facilities—computers, printer, and secondary data storage devices such as CDs, UPS, and locked cabinets with sufficient space for storing questionnaires and other fieldwork documents. Depending on the model followed for data entry and the number of surveys, the team may explore having a local data processing unit (for example, at the state level) and a national level unit. In a less complex survey, one unit will suffice. The India IBBA used two data processing units—one with the research agency and one with the state institute—as well as a central data management group that managed soft copies of data, cleaned and merged data sets, and analyzed data. First-level data entry was done by the research agency that implemented the field work and second-level data entry was done by the ICMR state institutes that managed the research agencies. The data management group consisted of four people with a background in statistics and strong data management and analysis skills.

A plan should be made for first- and second-level data entry to ensure that the person who enters data for a particular questionnaire does not enter data from that questionnaire again. This is achieved by recording who enters first-level data for each questionnaire and then assigning a different data-entry operator to second-level data entry. Data processing teams are provided training on confidentiality, management of field documents, editing of the questionnaire, post-coding of open-ended questions, use of the data-entry program, backing data up, and other related aspects of data management.

The data manager must have a good understanding of the questionnaires, the survey goals, and the software programs used for data entry. The data manager should have participated in the interviewers' training, to be able to visualize how and what kind of data are being collected through the questionnaires. Interviewers' manuals should be provided to the data manager to aid this process.

The data management group along with the research team establishes a standard data flow, which includes details of who, how, and how often hard copies of data will be transferred from the field to the data processing unit.

Prepare the questionnaire

The layout of the questionnaire affects the way the data entry program is created and eventually how easy it is to analyze and use data from the surveys. Data management personnel should be involved in the questionnaire's design, suggesting modifications related to layout, structure, question numbering, skipping patterns, multiple-answer response, and pre-coded responses.

Develop the data entry program

The data management group develops the data entry program. A test run of the program should be done on twenty-five to thirty questionnaires so that modifications can be made as needed. The public domain software CSPro was used in the India IBBA for entering and editing the survey data.

CSPro combines and expands on the capabilities of both ISSA and IMPS software. It takes advantage of the power and flexibility of both of these programs, but adds the friendliness, ease, and intuitive nature of Microsoft Windows. CSPro provides a more visual approach to the creation and manipulation of data and reduces programming needs. This software facilitates defining data structures, developing applications, entering and checking data, and generating reports. CSPro also provides for consistency checks and double data entry, because it has a built-in module called "Compare data." More advanced users, such as computer programmers, can access the full CSPro language to perform complicated tasks.

Because the volume of biological data is low and the test results of different biological parameters may not be received together, use Excel or SPSS for data entry. Either program will allow biological data to be merged with behavioral data at a later stage. Both programs allow for consistency and range checks. Similarly, coupon entry for an RDS survey can be carried out in Excel.

In CSPro, dictionaries describe the data structure. A record (or block) consists of a group of related variables (questions). A group of blocks contains all the questions in the questionnaire considered for the survey. These are stored using a dictionary data structure—extension: *dcf* (see Figure 12).

Figure 12. Example of a data dictionary in CSPro software

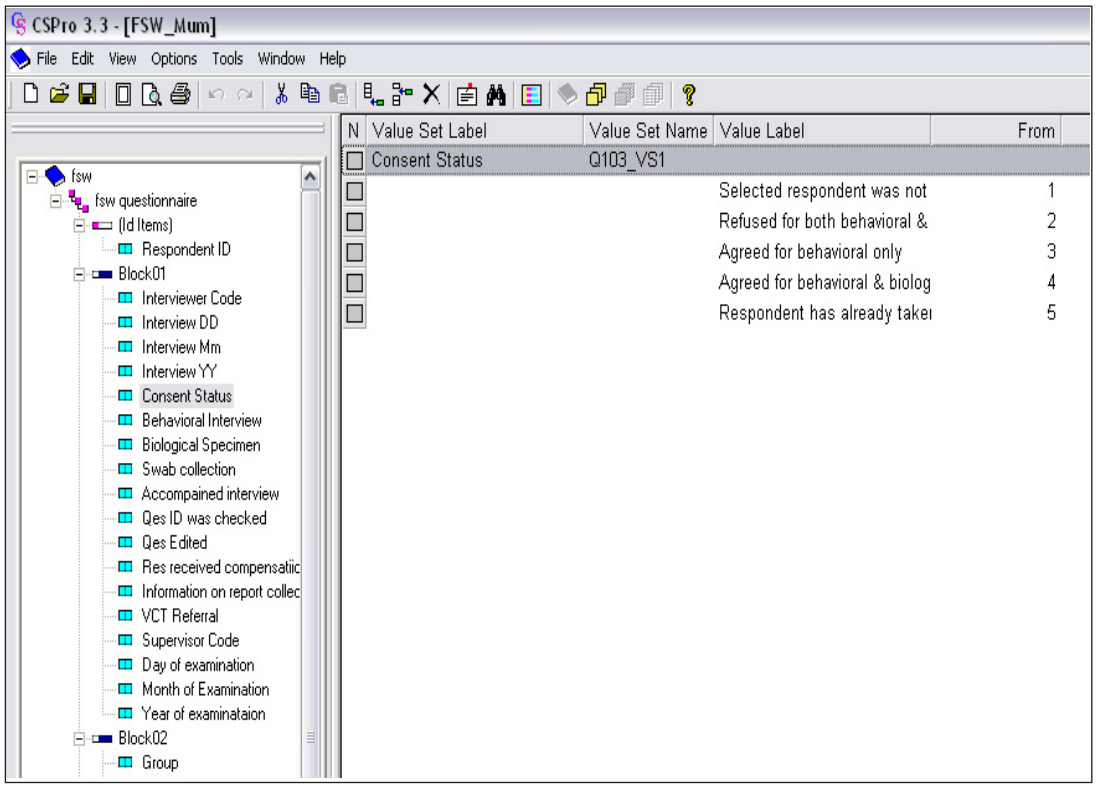
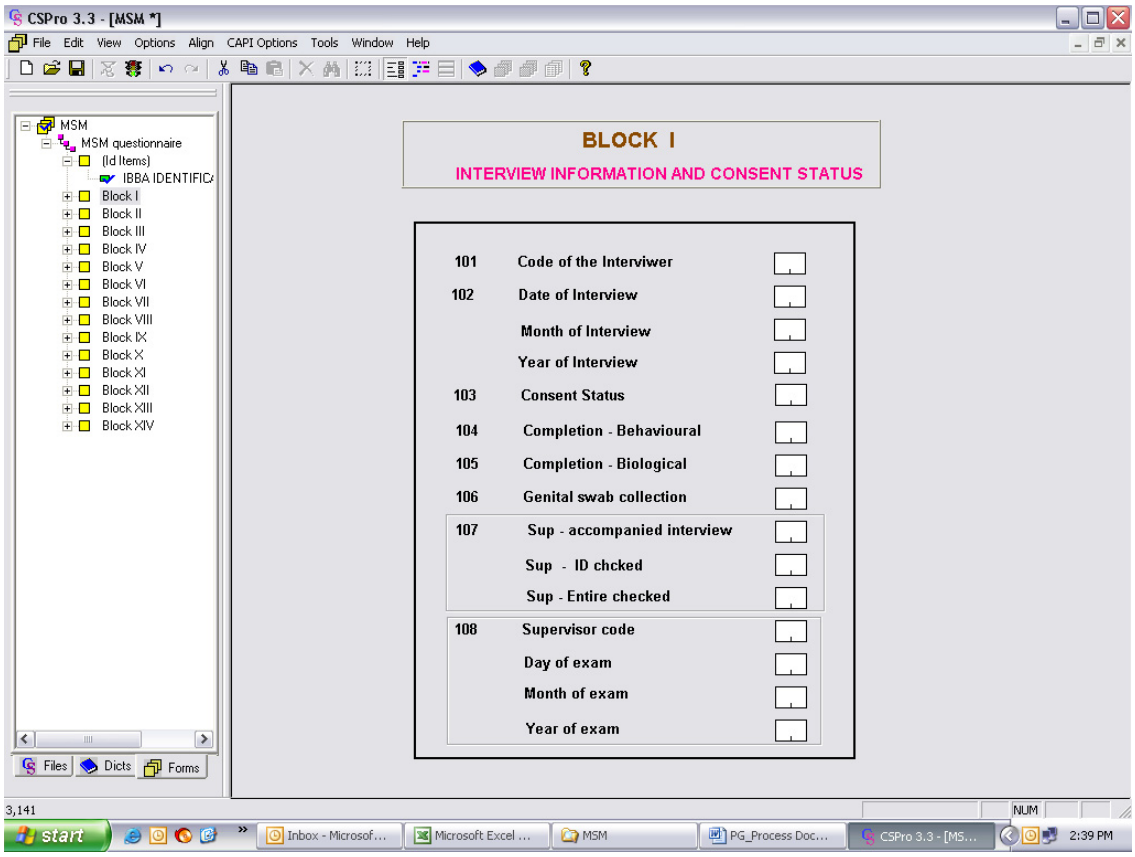


Figure 13. Typical CSPro data entry screen



Manage and edit questionnaires

When questionnaires arrive from the field, the data manager checks the documents received against those listed on the form that accompanies the shipment and notes on the form any discrepancies. The data manager then signs the form, as does the courier. Discrepancies are reported to the field supervisor, who initiates a trace to find the missing documents. It is advisable to arrange the questionnaires by ascending identification numbers. All the forms relating to a given person should bear that person's identification number and be stored with the questionnaire bearing the same number. This helps maintain order and simplifies the data entry process.

Data editing takes place prior to first-level data entry. Data editing has the following steps:

1. **Coding.** The data editor transfers all the responses to the code boxes. For any open-ended questions, the data editor starts post-coding by maintaining a list of all possible answers and developing a coding scheme. The data manager should add these codes to the data entry program and maintain them in a separate document for reference. When the editing is complete the data editor signs and dates the questionnaire in the appropriate places.

2. **Checking for inconsistencies.** Whenever a batch of questionnaires is received, the data manager goes through each document to verify that all relevant questions and the code boxes are complete and legible. Editing of the filled-in questionnaire to weed out inconsistencies is important, because data entry operators cannot proceed until inconsistencies are resolved. Handling inconsistencies prior to data entry helps with management of the workload. Also, if a pattern of errors emerges in the information recorded on the questionnaires, the data manager can alert the field staff to correct the errors.

For example, if the age of an FSW is entered as 25, and the age at first sex is entered as a number greater than 25, the program generates an error message: "Age at first sex cannot be more than the current age… please check." Correcting such errors prior to initiating data entry reduces their number and speeds up the data entry process.

The data manager investigates and resolves such inconsistencies, some of which may be complex. Where the data manager cannot sort out a problem, the field supervisor and, if needed, the coordinator can help. All the editing on the questionnaire is completed using a distinctly identifiable color pen to show that the changes have been made by the data management team. When the questionnaire check is completed, the data manager signs and dates the questionnaire in the appropriate places.

Enter data (first level)

Hire people with prior data entry experience as data entry operators. In addition, before the operators begin their work, they should receive two to three days of training to orient them to the questionnaire, the data entry program, the data processing system, and data confidentiality. The training should first- and second-level include hands-on practice entering data and checking for errors.

By the end of the training, the data entry operators should be comfortable with the data entry program and aware of their daily responsibilities under the supervision of the data manager. The data entry operators must not apply their own logic when they encounter inconsistencies during data entry; the data manager should sort out any issues before the operator proceeds. The data manager maintains a master list of the questionnaires that have been entered and by whom. Furthermore, the data manager makes sure that duplicate entries on different computers of the answers on a questionnaire do not occur.

The data entry application minimizes data entry errors by performing checks as the data are entered. If a value entered for a question is outside the range of values on the questionnaire or if some other basic inconsistency is detected, the application displays an error message requiring the data entry operator to resolve the inconsistency before advancing. For example, the program would signal an error if the operator entered a value of six on the application when the range of values was one to five.

Also, the data entry application should follow the skip pattern used within the questionnaire. That is, it will only ask for the responses to questions that should have been asked, given the responses to previous questions. For example, if a respondent reports that he has not heard of HIV/AIDS, the data entry application will skip all questions relevant to respondents who say they have heard of HIV/AIDS. These patterns are pre-set in the questionnaires and are locked in the data entry program. If the data entry operators face any problems, they should report these to the data manager.

Data from the CIS can be entered in Excel, which is used for weight calculation during data analysis.

Data can be saved only after answers to all of the relevant questions on a given questionnaire have been entered. Operators should not leave their computers to take a break or to stop for the day until they reach a point where they can save their work. Every evening, the data manager copies the data entered by all of the operators onto a secondary storage device, so information can be recovered if a computer crashes. All data entry should be password-secured so that only the data manager has access. Further, at the end of the day the data manager collects the questionnaires from each data entry operator and returns them to locked storage.

When the operators finish entering data for a given survey group, the data manager verifies that the data base captures the responses on each of the questionnaires. It is best to enter the data files in batches. For example, entering the files for 50 questionnaires at a time makes data entry and cleaning easier. It would be useful to clean the data in a phased manner, focusing on a specific district or study group at a time.

When all of the survey data are entered and cleaned, the data manager merges all of the clean data files into one. The set of questionnaires, the data entry program, the data file, and the list of post-coding are then submitted for second-level entry, verification, and cleaning of data.

Enter data (second level)

Depending on how and where second-level data entry occurs, the raw data, code list, data files, and soft copy of first-level data entry may have to be transferred to the secondary data processing unit. In any case, second-level data entry is entirely separate from first-level data entry. The data manager must ensure that no operator who handled first-level entry of responses to a questionnaire receives that questionnaire for second-level data entry. Although two levels of data entry cost more, this practice reduces the number of errors in the database and ensures that the data are thoroughly cleaned prior to analysis.

The second-level data processing team may consist of a data manager and three or four data entry operators. The responsibilities of this team differ slightly from those of the first-level team; some activities are the same for both groups. Members of the first- and second-level teams should be familiar with all the stages of data management and data confidentiality.

Prior to second-level data entry, the data manager makes sure that all the questionnaires for the survey group and associated files are available, quickly reviews the questionnaires for proper editing and entry (checking the signatures, for example), and distributes the questionnaires to the data entry operators. Data editing is handled during first-level entry so the second-level manager will not need to do it again.

Second-level data entry can begin immediately under the supervision of the data manager. The process of second-level data entry is initially the same as that of first-level data entry. The data manager verifies that data from all of the questionnaires are entered properly and merges the files into one. If any inconsistencies emerge during second-level entry, the first-level data manager is asked to clarify them.

The second-level team members clean the data after completing the data entry operation. Then the first-level and second-level sets of data are compared. If the CSPro software detects differences between them, it generates and displays an error file. This output must be given to the data entry operator responsible for correcting or cleaning the data. For example, let us say (see Figure 14) that comparison of the first- and second-level data sets for a questionnaire whose identification number is [0311401] shows that different TE codes—347 and 847—have been entered. The operator must locate the original paper version of the questionnaire to discover which code is right and correct the error in the appropriate data file. If 347 is the code entered on the questionnaire, then the operator must correct the reference file (B.dat) for that identification number. This process is carried out for the two sets of data that the first- and second-level teams generated for each questionnaire. Once the revisions have been made, the comparison is run again to ensure that the data in the two files match.

The data entry operators refer to the questionnaires to determine the correct value for every discrepancy, correcting the files as they go. This is an iterative process. Once the operators have fixed the data, the data manager compares the files again. The process should be repeated until no differences between the two files appear. At this point the first-level and second-level files are in effect the same file.

Figure 14. Typical error list

Input File	Path Name\A.dat	Reference File: Path Name\ B.dat
Case ID/ Item [0311401]	Input File	Reference File
TE code	347	847
TLC/PSU Code	987	981
Q301	34	43
[0311419]		
TLC/PSU Code	324	234
Q402	5	6
Q515B2	6	7

Comparison of data must be thorough. For example, suppose that first-level entry of a particular group has been entered into the file "A" and the second-level entry of the same group is entered into the file "B." *The comparison should be from both sides.* That is, file A should be compared with file B, and file B should be compared with file A. For example, suppose for a particular question code 2 is entered in A and code 3 is entered in B. This error will come to light in a comparison of A with B or B with A. But if file B captures data from an entire questionnaire that file A misses, the oversight can only be detected in a comparison of dataset B with A—not dataset A with B. To correct errors, record the identification number with the error and return to the questionnaire to check the correct response before updating the data entry programs. A similar process is followed for all the flagged variables in the error list.

The original raw data files "A" and "B," prior to comparison, are kept in a separate folder. All the hard copies of the error lists generated during the iterative comparison process must be stored properly, for future reference and to allow for cross-checking to confirm that the cleaning was done properly.

When the two data files—which can be termed first-level and second-level, or A and B, or input and reference—are identical, then either one can be considered "final." The final data file along with the code list for open-ended questions are sent to the data analysis team for further cleaning and editing prior to analysis.

Biological data entry. In IBBA, fewer biological indicators (variables) than behavioral variables are entered. For example, in the India IBBA, the biological indicators were HIV sero-positive, NG (gonorrhoea), CT (chlamydia), syphilis (RPR test), syphilis (TPHA test with titer), HSV-2 (10 percent of cases), Hepatitis B, and Hepatitis C.

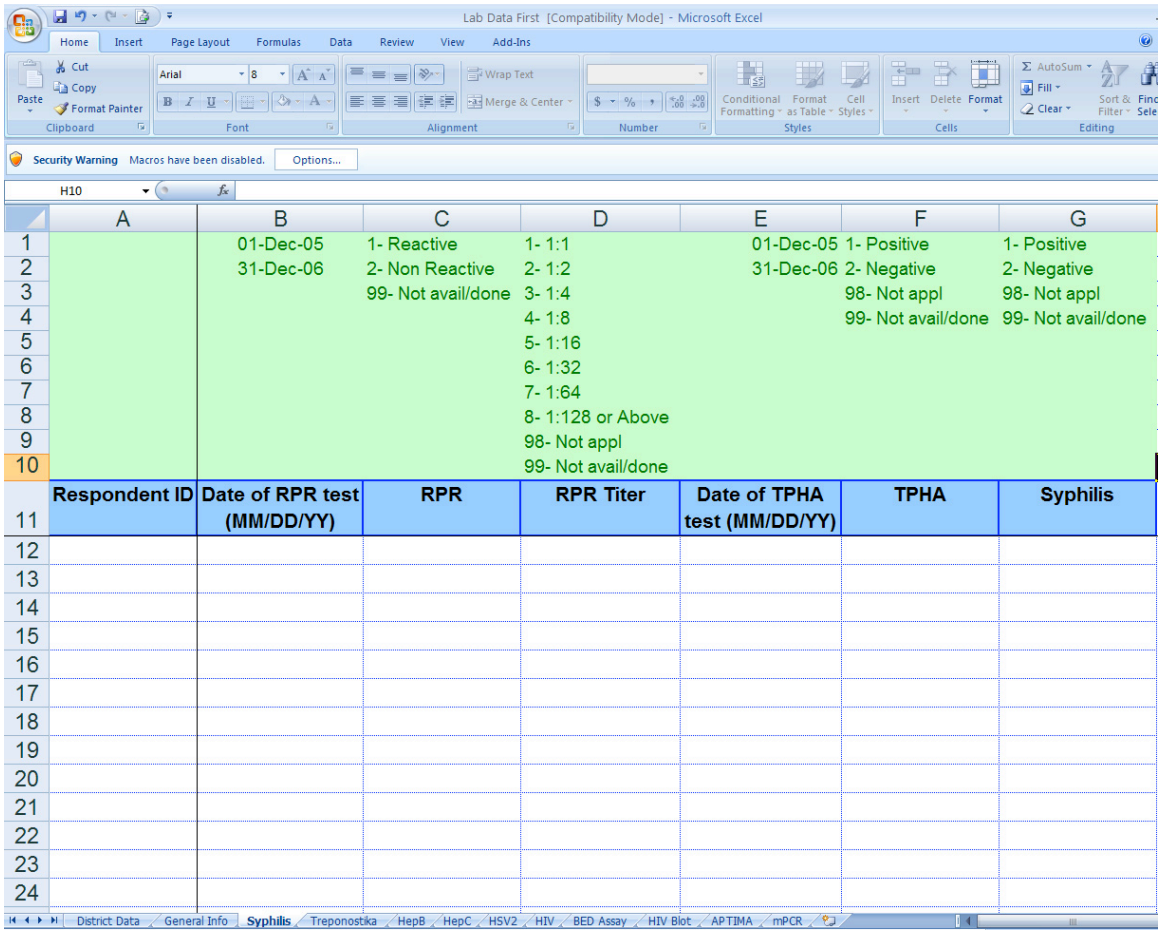
As for behavioral data, biological data require first-level and second-level phases of entry. In the IBBA in India, the national implementing agency—the Indian Council of Medical Research—was responsible for both levels, in order to maintain the confidentiality of test results. Because fewer variables are involved, biological data entry can be done using Microsoft Excel software, with consistency and range checks. A separate spreadsheet should be created for each biological indicator—syphilis, HIV, HBV, and so forth—and the key variable will be the identification number of the respondent/participant. Given the low volume of data, one team can handle first- and second-level entry and sort out the discrepancies. Data should be entered as it becomes available. Figure 15 shows a sample format, which can be used for both levels of data entry.

Important considerations for the entry of biological data follow:

- Enter the data for each biological test on a separate worksheet, which should provide space for the sampling domain, survey group, and sample information such as identification number and test results.

- For biological data collected for every study population, two Excel files should be created: one file (Lab Data First.xls) for first-level data entry and the other (Lab Data Second.xls) for second-level data entry.
- Data should be entered first in the Lab Data First.xls file and then in the Lab Data Second.xls file.
- When data entry begins, a separate worksheet should be completed showing information about the study population—survey group, sampling domain, and range of identification numbers.
- Valid ranges for data should appear at the top of each field (column) restricting entries to numbers within those ranges.
- Second-level data entry should be done separately, in the same manner as second-level entry of behavioral data. Upon completion, the first- and second-level entry files should be opened. A third Excel file will then be created using the function "Comparison first and second"; discrepancies will appear in red. The data manager will make corrections in the first- and second-level files to reflect the information recorded on the hard copy of the clinical forms.
- A standard directory structure should be used to name the files. For example, in India, the following was used: State/region▶district▶group▶first-level or second-level data entry.

Figure 15. Example of a biological data entry form



Coupon entries for respondent-driven sampling groups. For all study groups where RDS is adopted, data entry for coupon numbers is required. This includes coupons received by a respondent and coupons given to that respondent for distribution. This helps the RDS analysis tool (RDSAT) trace the network chains that are used for analysis. The coupon a respondent takes to an interview is called the primary coupon and the three given to the respondent for distribution are called secondary coupons. The RDSAT will not run unless primary and secondary coupon numbers are entered in the data file for each respondent. Microsoft Excel can be used for entering the coupon numbers. (See Figure 16.)

Figure 16. Example of a coupon data entry form

Col A	Col B	Col C	Col D	Col E
Resp ID	Primary	Secondary_1	Secondary_2	Secondary_3
3110001	1	11	12	13
3110002	2	21	22	23
3110003	22	221	222	223
3110004	11	111	112	113
3110005	8	81	82	83
3110006	82	821	822	823
3110007	81	811	812	813
3110008	83	831	832	833
3110009	21	211	212	213
3110010	13	131	132	133
3110011	12	121	122	123
3110012	112	1121	1122	1123

In Figure 16, the first column is the unique identification number of the respondent, the second column is the primary coupon number, and next three columns are the secondary coupon numbers. The respondents whose primary coupon numbers (second column) are a single digit are the seeds. (If more than nine seeds are used, then some double-digit numbers may also represent seeds.) For example, identification number 311005— seed number 8—is given secondary coupons numbered 81, 82, and 83. The person who comes for an interview with (say) coupon number 83 is given three coupons numbered 831, 832, and 833. All coupon numbers given out in the survey are listed, even if the receiver of a coupon does not participate in the survey.

In entering coupon numbers, mistakes occur, because the numbers are mostly combinations of 1s, 2s, and 3s and the string of digits lengthens as a seed's chain of respondents grows. Therefore, it is especially important to clean the data before they are merged with behavioral and biological data. Checking RDS coupon data manually becomes impossible. Instead, the coupon numbers should be checked by applying a formula in the Excel sheet. The formula checks (1) whether each primary coupon number (Column B) is present within

the corresponding set of secondary coupons (Columns C, D, or E); (2) that no duplicate coupon numbers appear as primary (Column B); (3) that no duplicate coupon numbers occur across the columns of secondary coupons (C, D, and E); and (4) that the secondary coupon numbers (Columns C, D, and E) appear in the list of primary coupon numbers (Column B) either once or not at all. A coupon may not appear in Column B if the respondent did not participate in the survey.

Conduct secondary editing of cleaned data

When primary processing of behavioral data is complete, the yield is a clean data file for each study population. Although primary data processing is done using CSPro, secondary data processing is done primarily using a statistical package for social sciences software (SPSS). Therefore, the first step in secondary data processing is to convert the data from the CSPro data format to the SPSS data format. This is done using the "Export the data to SPSS" command in the CSPro tool menu.

When this option is selected, the data file is then exported to SPSS by the *export.bch* application. This application creates an ASCII data file and a syntax file. Although the SPSS data description files read the ASCII data files into SPSS, the files are not saved. To get the data description files to save the data in SPSS format, the SPSS command *save outfile = `filename.sav'* must be added to the end of each data description (syntax) file. The word 'filename' should be replaced by a name (following a standard scheme) depending on the type of data file. Once this command has been suitably modified and added to each data description file, executing the SPSS data description files creates the SPSS data files *filename.sav*.

Simultaneously the biological data sets and the coupon numbering data sets (wherever applicable) are also converted into separate SPSS files. Biological data sets are converted into a number of individual SPSS data files depending on the indicators applicable for the study population (HIV test, NG, CT, etc.). The key variable of each data set should be the identification number.

Merge behavioral and biological data

Merging behavioral, clinical, and biological data files for a specific study population (as well as RDS coupon numbering wherever applicable) in SPSS is an important step. Great care should be taken to avoid mistakes. The steps to merge these data are as follows:

- The SPSS file for all of the HIV tests is designated as the master file for merging.
- All records with biological test results are kept intact. Records that show no results (i.e., biological tests not given) are removed from the file.
- Then the file is sorted according to its identification number and saved.
- All other individual SPSS files to be merged are also sorted according to their identification numbers and saved.

Using the HIV file as the master file, all other biological indicator files and the behavioral files for a given study population are merged, using the identification number as the key variable. When RDS is employed, coupon numbers are also merged with the behavioral and biological data.

After the biological and behavioral data are merged, some individual data records in the merged file should be compared with individual SPSS files to verify that the merging of the data has been successful.

Chapter 11

11

Data analysis

- Analysis in RDS surveys and cluster-based surveys
- Analysis software programs
- Weights for cluster sampling surveys
- Triangulation and trend analysis

IBBA data should be analyzed within a sampling domain to provide insight into behavioral and biological data, and after repeated surveys, trends over time. The data can be used to provide insight into survey group behavior within sampling domains, by triangulating data with program data and other research studies. IBBA data will also be useful at state or national levels to indicate regions of higher risk, program and policy needs, and progress in combatting the spread of HIV.

This chapter presents guidelines on statistical analysis of data from IBBA surveys. It describes which statistical tests are most appropriate, and provides formulas and examples for the most common tests. Basic analysis is covered in detail, while data triangulation and trend analysis are discussed at an introductory level. A list of suggested readings is offered for those who seek more detailed insight.

Preparation for analysis

Analysis in RDS surveys and cluster-based surveys

Conducting analysis in surveys that used RDS sampling and cluster sampling differs. RDS requires the use of the RDSAT program; analysis is dependent on incorporating the recruitment or network chains between respondents. Cluster sampling surveys analyze data by applying weights based on probabilities of inclusion in the survey; various analysis programs can be used, including SPSS and SAS. In India, SPSS was used. Table 28 lists key data management and analysis processes according to sampling method, in the order in which the processes should be performed.

Table 28. Data management and analysis in IBBA for cluster-based and RDS surveys

Cluster-based survey	RDS survey
Data entry of cluster information sheet in Excel	Data entry of coupon numbers in Excel
Double data entry of behavioral questionnaires in CSPro	Double data entry of behavioral questionnaires in CSPro
Double data entry of biological data in Excel	Double data entry of biological data in Excel
Data cleaning	Data cleaning
Export behavioral and biological data sets from CSPro to SPSS	Export behavioral, biological and coupon number data sets from CSPro to SPSS
Merge behavioral and biological data sets in SPSS	Merge behavioral, biological, and coupon number data sets in SPSS
Code and recode variables in SPSS	Code and recode variables in SPSS
Weight calculation	Prepare and export final text data (.txt) file to RDSAT
Analysis in SPSS	Analysis in RDSAT
**Although SPSS, CSPro, and Excel are referred to in the above table, the researchers should select data entry and analysis programs to suit their convenience. For RDS, RDSAT must be used to analyze data.*	

Analysis programs

Numerous statistical analysis computer packages such as EPI-INFO, SPSS, SAS, and STATA can be used to analyze IBBA data. These packages are useful in managing datasets and applying standardized formulas to analysis. However, they should be used by researchers who fully understand the assumptions and limitations of these analytical tests.

Statistical package for social sciences (SPSS) is one of the most commonly used, less expensive, and user-friendly analysis software available. SPSS does not require any advanced knowledge of programming for the analysis to be performed. Although statistical analysis software (SAS) is a more robust analysis software, it is relatively expensive and requires some amount of programming knowledge. EPI-INFO, developed by the United States Centers for Disease Control and Prevention (CDC) and available free on the CDC website, can also be used for analysis. Respondent-driven sampling analysis tool (RDSAT) is specially designed, free software for the analysis of data collected through RDS. For more information, see Resource and References.

Field experience: Data entry

In IBBA in India, CSPro was used for data entry of cluster-based surveys (all behavioral and clinical questionnaires) and analysis was done in SPSS. Biological data and sampling data were entered in Excel. For RDS surveys, data entry (coupon numbers, biological data) was done in Excel and merged. New variables were created in SPSS, converted to RDSAT data format, and analyzed in RDSAT.

Weights for cluster sampling surveys

To analyze cluster sampling surveys, weights are applied to the dataset. The weight calculation will not be necessary where RDS or the take-all approach is adopted for sampling the study population. For more information about the take-all approach, see Chapter 5.

For clusters selected using PPS, weighting addresses the differential probabilities of selection (as larger clusters are more likely to be selected in the survey through PPS). Information for calculating weights is collected from the CIS and sampling frame. The weighting calculation should be documented for future reference. Using programs (e.g., Microsoft Excel) to calculate the weights is the simplest method once all the CIS data is entered into the same program.

Assumptions used in weighing IBBA cluster sampling survey data:

- Clusters are selected by systematically using probability proportionate to size (PPS) sampling
- Samples from each selected cluster are drawn by simple random sampling.

Weights are calculated in the following steps: (1) prepare for weight calculation; (2) calculate probabilities of selecting clusters and individuals; (3) calculate sampling weights; (4) calculate standardized weights; and (5) adjust for take-all sampling. It is recommended that calculations be done in Microsoft Excel using formulas to reduce the chance of errors.

Prepare for weight calculation. To calculate the weights, the following information is required (table 29):

1). The sampling frame should be retained, including the measure of size for all clusters selected for the survey and the cumulative measure of size for all the clusters in the sampling frame (those that were selected and those that were not).

   If two sampling techniques were applied in one survey domain (i.e., combined sampling), then the information should be kept on separate Excel worksheets for each of the sampling methods. There will be two worksheets—each containing a sampling frame, MoS, and a separate CMOS.

2). Each CIS should be entered on a separate Excel worksheet. All of the data on the CIS should be entered.

3). Review the dataset for the following:

- Check if $N_i \geq a_i$ (that is, eligible number of respondents ≥ eligible number of respondents selected for participation in the survey). If this condition is violated, the data should be cross-checked with the hardcopies of the CIS and field notes. If it is not possible to correct this, then a_1 should be equated to N_i[1]— provided the adjustment is not very large.
- If any discrepancies occur in n_i (number of respondents who completed behavioral and biological components of the survey) and the information available in the database (that is, questionnaires entered in the database) on the number of interviews at a selected cluster, this data needs to be cross-checked with the CIS, questionnaires, and then field teams. This must be resolved before proceeding.
- Check if $a_i \geq n_i$ (that is, eligible number of respondents selected at a cluster ≥ number of respondents who completed behavioral and biological components of the survey). If this condition is violated, the CIS and field notes should be cross-checked. If it cannot be resolved, then a_i should be equated to n_i.
- If $n_i = 0$, then that cluster is not used at all for weight calculation.

The information can be listed in one Excel spreadsheet. If two different sampling methods are used, then two Excel spreadsheets should be made—one per sampling method.

Note. *If two or more rounds of cluster selection occur for the survey because the sample size was not completed after the first round of selection, the clusters selected in Round I and in Round II and so on should be noted in Table 30 to ensure that the appropriate weights are given.*

[1] The corrections suggested above should be made only if the discrepancies are within an acceptable level. Otherwise the best possible estimates should be made using the information available. For example, 'a_i's may be estimated from the mean ratio of 'n_i' to 'a_i' of available data.

Table 29. Sample format for weight calculation

Survey group: **Survey dates:** **Survey domain:** **Sampling method:** **CMOS:**				
Cluster ID	MoS (M_i)	Number of eligible respondents (N_i)	Number selected for interview (a_i)	Number completed (Beh.+Bio) (n_i)
1	45	40	14	12
2	38	36	12	9
3	28	24	11	9
4	28	25	11	9
5	48	42	14	12
6	38	33	12	9
7	48	44	18	12

Calculating probabilities of selecting clusters and individuals. The probability of selecting individuals through simple random sampling that accounts for the probability of selecting a cluster (through PPS)—that is, two-stage sampling—is as follows:

$$P_i = (m \times \frac{M_i}{M} \times \frac{a_i}{N_i}) \qquad \text{Formula (1)}$$

Where i = a specific cluster

m = number of clusters selected for the IBBA survey (from the sampling frame),

M = cumulative measure of size of the survey group (selected and non-selected clusters) (from the sampling frame)

M_i = the measure of size of the specified cluster (sampling frame)

N_i = the estimated number of individuals eligible to participate in the survey (from CIS)

a_i= the number of individuals selected for interview (from CIS)

Notes:

- M_i may be equal to, more than, or less than N_i
- This formula should be applied to each cluster selected for the IBBA survey. The weights for each individual selected within a given cluster will be the same.
- If combined sampling was done within the sampling domain, the weight calculation should be applied separately for TLC and CCS sampling methods.
- The total number of individuals participating in the survey is not required for the weight calculation.
- If more than two stages of sampling were done, then Formula (1) will be modified. For example, in a large city in India, three stages of sampling were done.

  Stage 1: selection of segments (for mapping)—equal probability

  Stage 2: selection of clusters (after mapping)—PPS

Stage 3: selection of individuals—simple random sampling

If S = total number of segments, and

C = total number of selected segments, then

the formula for probability of selection of individuals is modified to[2]

$$P_i = (m \times \frac{M_i}{M} \times \frac{a_i}{N_i}) \times \frac{C}{S} \qquad \text{(Formula 2)}$$

Calculating sampling weights. The sampling weight for selecting individuals from a cluster (i) is given by:

$$w_i = 1/P_i \qquad \text{(Formula 3)}$$

Where P_i = is the inclusion probability of selection for individuals in the ith cluster

The sampling weights need to be applied to the data. Analyzing data without using sampling weights assumes that each individual, cluster, and so forth had the same probability of being selected into the survey, which does not hold true. Analyzing data without weights leads to misleading and incorrect results.

Calculating standardized weights. An adjusting factor needs to be applied to the dataset after applying sampling weights. Without applying the adjusting factor, the number of observations for the weighted analysis (that is, the total number of survey respondents) will be inflated or deflated from the actual number. The standardized weight is the adjusting factor that is applied to the survey data. The standardized weight is calculated taking into account the total survey sample size.

The standardized weight should be calculated for each cluster. Formula 4, given below, is the general formula for standardized weight calculation:

$$w_i' = \frac{w_i \times \sum n_i}{\sum (w_i \times n_i)} \qquad \text{(Formula 4)}$$

n_i = number of completed interviews at cluster i

Calculations should be done separately for different sampling methods when combined sampling is used.

Adjustments for take-all surveys. The following adjustments can be made to the weight calculation for take-all surveys:

- If N_i was not available, corresponding MoSi (M_i) was used and vice versa for N_i ; and
- If a_i was not available, response rate, $n_i \div a_i$ was calculated from the available data, and a_i was estimated by using n_i and the average response rate. If the estimated a_i was more than N_i ,then the value of a_i was equated to N_i; and
- If MoSi, N_i, and a_i were not available for a cluster, then all these three values are equated to n_i,

The cumulative measure of size (CMOS) of the universe was not changed.

Spreadsheet for weight calculation—cluster sampling. Table 30 is a spreadsheet that can be used for weight calculations. The type of cluster, cluster identification number, M_i, N_i, n_i, and a_i are copied from the data sheet referred to in Table 29 and pasted accordingly into Table 30. CMOS values for TLC and conventional clusters are typed into the appropriate cells.

[2] It is possible that some probabilities of selecting an individual (P_i) will be > 1. This could happen when M_i (measure of size of a selected cluster) is greater than the sampling interval. If such events are few, then P_i should be equated to "1," implying that the larger clusters were selected with certainty.

W_i is the standardized weight for the respective clusters. When these weights are applied during data analysis, they will not inflate or deflate the sample size. The last two columns on the spreadsheet are used to cross-check and verify the sample size to ensure that the formulas were applied correctly. The totals in the cross-check column should match the total number of respondents surveyed.

While applying weight, it is always advisable to take the maximum number of digits (5 to 6) after the decimal point for accuracy of the sample size to be maintained. It can be noted that the mean of the sample weights when all respondents are considered is 1. The standardized weights are inserted in the respective data files through the SPSS (or whichever program is used) syntax files and saved as the final file for data analysis.

These weights should be applied whenever data analysis is done.

Preparing data for analysis

Coding and recoding of variables. The questionnaire has been designed to simplify interviewing as much as possible. Answer categories were mostly precoded and few of them were open-ended and multiple-choice. Some key indicators required recoding of variables to analyze data.

When entering data, numbers rather than words are often used as codes, in order to simplify data entry and reduce errors. For example, instead of entering "Always used condoms," the code may be "01." When analyzing data, however, "01" will not be as helpful as "Always used condoms," so the codes will need to be labeled to facilitate analysis and interpretation. Indicators are entered according to their sequence in the questionnaire, but they should also be labeled. This makes analysis easier and more efficient, and reduces the likelihood of mistakes. This task is known as creating new variables, renaming variables, and categorizing variables in the data file based on the analysis plan. For example, if we analyze a continuous variable, "Current age," which lists each age reported (e.g., 18, 19, 20, 21, 22), will be difficult to interpret. A new variable—"Age cat," with the categories 18 to 21 years, 22 to 25 years, and 25 & above—would be more useful and can be accomplished by recoding. We can also combine two or more variables into a single variable depending on the requirements.

For example, a new variable "FSWs who have both regular and occasional clients and also are married" is a combination of three variables. This iterative process varies with the analysis plans.

Maintaining syntax and definitions of new variables. Syntax is the list of data analysis commands that can be stored and used for analysis at any time. Syntax helps, because it maintains a record of analysis that has been conducted, shows how variables were created, and lists basic analysis that may be needed time and again. Keeping copies of the syntax (and labeling specific analysis throughout) saves time and increases accuracy, particularly when the surveys are repeated over time or conducted across study populations. For example, if syntax is stored, age categories of respondents can be retained consistently across survey populations and repeated surveys.

Often new variables are created from the existing variables for ease of analysis. For example, in the IBBA conducted in India, the duration of sex work was calculated by deducting the age at first paid sex from the current age. Maintaining the syntax of these calculations ensures consistency.

Univariate and bivariate analysis

Univariate analysis. Most of the indicators in the IBBA are calculated through univariate analysis. Univariate analysis involves a single variable. Its purpose is to describe the variable by calculating central tendency (mean, median, mode); dispersion (range, variance, maximum, minimum, standard deviation); and also the frequency distribution and the confidence intervals. Calculating the proportion of FSWs having occasional clients or the proportion of IDUs sharing needles and syringes and the corresponding confidence interval would be examples of univariate analysis. Line, bar, and pie graphs are also generated from the univariate analysis results.

Table 30. Sample weight calculation sheet

Type of cluster	Number of clusters selected (Nc)	CMOS	Completed interviews (Sum of ni)	cum Wi*ni	Selection problem of segmention case of 3 stage sampling (S)								
Conv	34	2059	34	469	1.00								
TLC	49	3030	33	475									
Type	Cluster no	MoSi = expected measure of size for cluster i	ni = no of completed interviews at the cluster i	Ni=total no of eligible respondents at the cluster i	Number of eligible respondents approached for interview at cluster i (ai)	PM = (MoSi/CMoS)*Nc (Selection probability of i-th cluster–Stage 1)	PN = ni/Ni (Selection probability of a respondent within the i-th cluster–Stage 2)	Xi = PM*PN*S	Response rate (Ri) = (ai/ni)	Pi = Xi*Ri (Selection probability of respondent after combining Stage 1 & 2)	Wi = 1/Pi (unstandardized weight)	Wi*ni	Wi (standardized weight)	Cross-check
TLC	1	7	4	6	5	0.1132	0.67	0.08	0.8	0.060374	16.56	66.25	1.15	4.605
TLC	2	11	4	11	7	0.1779	0.36	0.06	0.57143	0.0369637	27.05	108.21	1.88	7.521
TLC	3	20	15	20	7	0.3153	0.75	0.24	2.14286	0.5068069	1.97	29.60	0.14	2.057
TLC	4	9	5	11	6	0.1375	0.45	0.06	0.83333	0.0520677	19.21	96.03	1.33	6.674
TLC	5	4	2	4	3	0.0566	0.50	0.03	0.66667	0.0188669	53.00	106.01	3.68	7.368
TLC	6	5	3	5	3	0.0728	0.60	0.04	1	0.0436634	22.90	68.71	1.59	4.775
C	50	5	3	5	4	0.0826	0.60	0.05	0.75	0.037154	26.92	80.75	1.95	5.854
C	51	7	4	9	5	0.1156	0.44	0.05	0.8	0.0410987	24.33	97.33	1.76	7.056
C	52	8	3	5	4	0.1238	0.60	0.07	0.75	0.0557309	17.94	53.83	1.30	3.902
C	53	13	5	9	8	0.2064	0.56	0.11	0.625	0.0716704	13.95	69.76	1.01	5.057
C	54	9	5	8	5	0.1486	0.63	0.09	1	0.0928849	10.77	53.83	0.78	3.902
C	55	13	7	10	8	0.2064	0.70	0.14	0.875	0.1264267	7.91	55.37	0.57	4.014
C	56	13	7	12	7	0.2064	0.58	0.12	1	0.1204063	8.31	58.14	0.60	4.215

A frequency table in univariate analysis is done on indicators which are categorical, which are defined according to certain categories (for example, literate/illiterate, yes/no), and which may not be very useful for continuous variables. Most IBBA indicators are categorical—for example, the proportion of people reporting that they used a condom during last sex with their paid female partner. An example of univariate data from the IBBA in India is presented in Table 31.

Table 31. Proportion of female sex workers using condoms with different male sexual partners, in Maharashtra, India

Indicator	%	N	95% confidence interval (lower estimate, upper estimate)
Used a condom during last sex with an occasional client	93	326	90.2, 96.4
Used a condom consistently with occasional clients	88	311	83.9, 92.8
Used a condom during last sex with a regular client	91	245	85.5, 96.5
Used a condom consistently with regular clients	84	231	75.7, 90.5
Used a condom during last sex with regular (main) male partner	49	96	40.2, 57.9
Used a condom consistently with regular (main) male partner	39	75	27.9, 48.1

Univariate analysis for continuous variables also includes calculating the mean, median, and range of variables. For example, age is a continuous variable. The mean, median, and range will help interpret the data. Fewer indicators like this occur in the IBBA. When a variable is skewed (that is, the median and the mean differ substantially), both should be reported. When they are quite similar it is sufficient to report either of them (though the mean is the most frequently reported).

Bivariate analysis. Bivariate analyses involve two variables. The major purpose of bivariate analysis is to explain the association between the two variables and typically look for the influence of one variable (also known as an independent variable) over other variables (dependent variables).

For example, age may be related to the number of clients that sex workers have. Statistical tests in bivariate analysis determine whether any observed difference reflects a true difference or may be due to chance. Calculation of p-values using chi-squared tests shows the association between two categorical variables. An example of bivariate analysis is presented in Table 32.

Bivariate analysis may include analysis by breaking down indicators and comparing them—for example, Is age related to the client load? Is sex worker type (for example, street or brothel) related to condom use?. To illustrate, if a female sex worker group is covered, subgroups may be brothel-based, street-based, bar-based, and so forth. While bivariate data is interesting and appealing, it should be interpreted cautiously. Small sample sizes (<30) within the subgroup (especially when there are multiple subgroups such as age category (for example, 18 to 25, 25 to 34, 35 to 44, 45to 54, 55+) should not be analyzed. Also, a large variation in confidence

Bivariate analyses should be interpreted cautiously, because the IBBA is a cross-sectional study. The data found in the IBBA may be indicative of some interesting trends, but it cannot describe or show causality: the data capture only a unit in time. Over-interpreting the data can be misleading and lead to poor data use.

intervals indicates that the estimate is not too precise. Further, when comparing estimates, if the confidence intervals overlap, the estimates may not be as different as they seem. Statistical tests using chi-square test for comparison of categorical variables or the Student t-test when comparing two means should also be done, to learn whether the difference is significant.

Table 32. Condom source and marital status among female sex workers in Kolhapur district, Maharashtra, India

	Source of condom			
	Peer	Client	Other	N
Never married	0.0	0.0	100.0	17
Currently married	5.7	4.3	90.0	70
Widowed/divorced/separated	3.7	7.4	88.9	27
p-value	0.638			

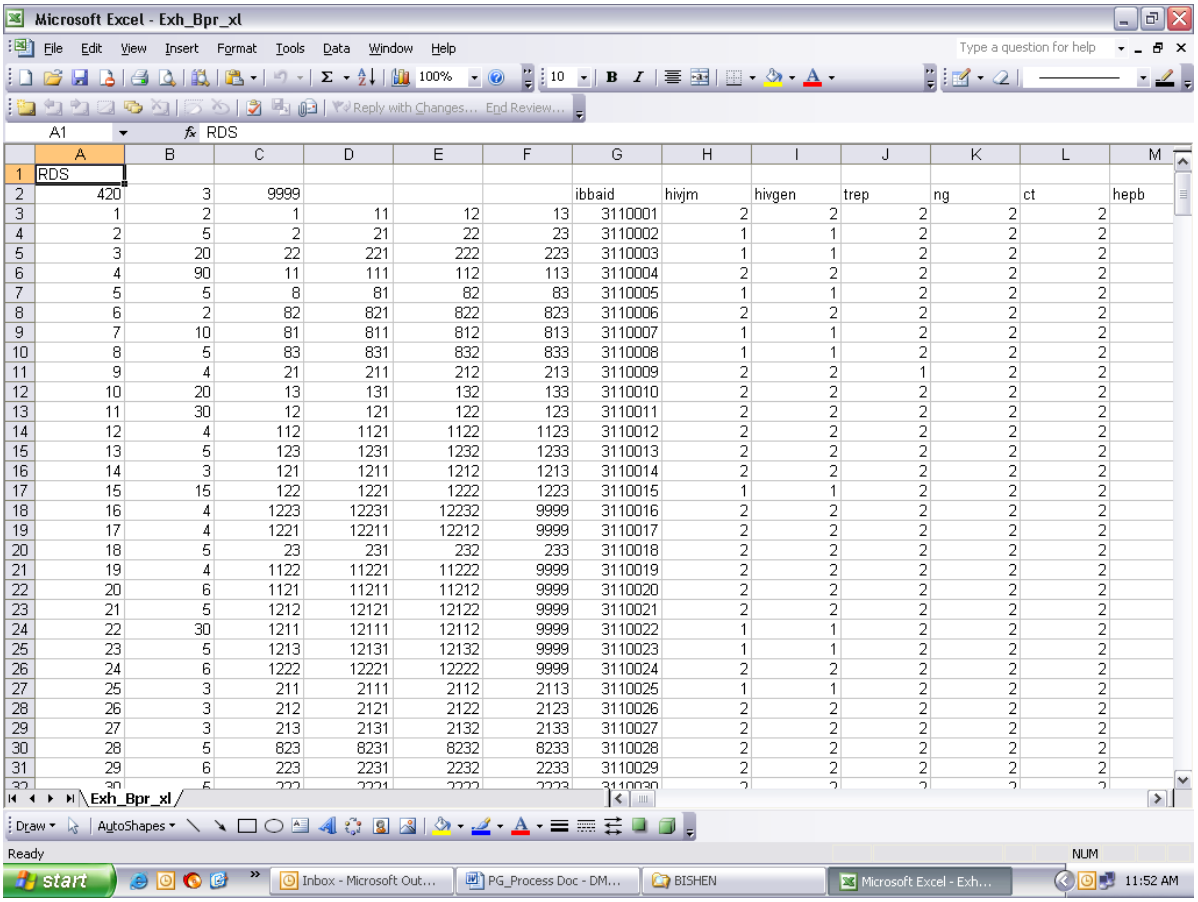
Analysis in RDSAT

Analysis in RDSAT requires preparatory work before data is analyzed. The data must be converted into text form before RDSAT can be used to generate estimates. The text form follows a specific format. Before converting the data entry to a text file, the following should be done:

1. Create new variables and recode variables in SPSS *before* converting the data into the text form used in RDSAT. Returning to do this after initiation of analysis is more complicated in RDSAT and requires repetition of previous steps.

2. The SPSS file should be brought into Excel to prepare the definite format for RDSAT. Figure 17 is an example of the format of the Excel file.

Figure 17. Example of an SPSS file imported into Excel for conversion into RDSAT format



	A	B	C	D	E	F	G	H	I	J	K	L	M
1	RDS												
2	420	3	9999				ibbaid	hivjm	hivgen	trep	ng	ct	hepb
3	1	2	1	11	12	13	3110001	2	2	2	2	2	
4	2	5	2	21	22	23	3110002	1	1	2	2	2	
5	3	20	22	221	222	223	3110003	1	1	2	2	2	
6	4	90	11	111	112	113	3110004	2	2	2	2	2	
7	5	5	8	81	82	83	3110005	1	1	2	2	2	
8	6	2	82	821	822	823	3110006	2	2	2	2	2	
9	7	10	81	811	812	813	3110007	1	1	2	2	2	
10	8	5	83	831	832	833	3110008	1	1	2	2	2	
11	9	4	21	211	212	213	3110009	2	2	1	2	2	
12	10	20	13	131	132	133	3110010	2	2	2	2	2	
13	11	30	12	121	122	123	3110011	2	2	2	2	2	
14	12	4	112	1121	1122	1123	3110012	2	2	2	2	2	
15	13	5	123	1231	1232	1233	3110013	2	2	2	2	2	
16	14	3	121	1211	1212	1213	3110014	2	2	2	2	2	
17	15	15	122	1221	1222	1223	3110015	1	1	2	2	2	
18	16	4	1223	12231	12232	9999	3110016	2	2	2	2	2	
19	17	4	1221	12211	12212	9999	3110017	2	2	2	2	2	
20	18	5	23	231	232	233	3110018	2	2	2	2	2	
21	19	4	1122	11221	11222	9999	3110019	2	2	2	2	2	
22	20	6	1121	11211	11212	9999	3110020	2	2	2	2	2	
23	21	5	1212	12121	12122	9999	3110021	2	2	2	2	2	
24	22	30	1211	12111	12112	9999	3110022	1	1	2	2	2	
25	23	5	1213	12131	12132	9999	3110023	1	1	2	2	2	
26	24	6	1222	12221	12222	9999	3110024	2	2	2	2	2	
27	25	3	211	2111	2112	2113	3110025	1	1	2	2	2	
28	26	3	212	2121	2122	2123	3110026	2	2	2	2	2	
29	27	3	213	2131	2132	2133	3110027	2	2	2	2	2	
30	28	5	823	8231	8232	8233	3110028	2	2	2	2	2	
31	29	6	223	2231	2232	2233	3110029	2	2	2	2	2	

To make the Excel spreadsheet (as shown in Figure 17), follow these steps:

- The first cell of the topmost row should have the word 'RDS'
- In the second row, the first cell indicates the number of respondents
- In the second row, the second cell cites the maximum number of coupons that were distributed (regardless of the number of people who participated)
- The third cell is the code used in the data entry program for missing responses due to skips in the questionnaire or for any other reasons
- None of the cells in the file may be empty
- The respondent's data start from the third row (From the third row, the first column is the default serial number of the respondent; the second column is the network size of the respondent—pulled from the RDS section in the questionnaire. Ensure that the network size is at least equal to the number of recruits. If the network size is inferior to the number of recruits, it should be recoded. A maximum plausible network size is decided by data managers according to the distribution of the reported network size. All outliers will be replaced by the maximum plausible network size. The third, fourth, fifth, and sixth columns are the primary coupon number and the secondary coupon number for the corresponding respondents.)
- The rest of the columns show the responses to the questionnaire or recoded/created variables.

Once the spreadsheet is done, the file should be converted into a text file. Any deviations from this fixed format will make RDSAT unusable for analysis. Another limitation with RDSAT is that it does not generate tables in a printable format. Thus, manual imputation from the estimates generated in RDSAT is required to generate tables.

Debugging the syntax is an iterative process done after reviewing the tables generated. Cross-tabulations are generally not done in RDS surveys, because the software cannot calculate percents by rows or columns, or produce statistical tests. Future software versions may address these needs.

Planning and interpretation

Analysis plans

Data analysis plans should be developed when the questionnaire and key indicators are developed. These plans are important to:

- Ensure that all significant variables for analysis are included in the data collection instruments
- Ensure that key indicators are easy to obtain from the data collection instruments and are collected well
- Know that the information in the instrument has a clear purpose or a plan for using it
- Identify at an early stage other sources of information useful for triangulating data
- Identify the correct denominators used for analysis

Developing analysis plans early ensures that consensus on the purpose and expected outputs can be achieved by the many partners involved in the IBBA. Nevertheless, these analysis plans are unlikely to be perfect; adjustments and additions to may be made as data are analyzed.

Analysis plans may be implemented in different phases, depending on the amount of data and the number of surveys conducted. Releasing topline findings (key indicator results) soon after the survey's completion will be most useful to partner agencies and those intending to use the data. More detailed analysis can be conducted on an ongoing basis, with clear timelines.

In IBBA in India, three standard types of analysis were carried out:

- Topline analysis—frequency outputs of the key indicators
- Descriptive analysis—frequency outputs for all indicators in the IBBA, including means, where appropriate
- Exhaustive analysis—bivariate tables (cross tabulation) with key information areas and potential descriptors, including p values using chi-square tests

Interpret cross-tabulations cautiously. The data found in an IBBA may suggest some interesting trends, but they cannot describe or show direct relationships, because they capture only a unit of time.

Key indicators of an IBBA

When the questionnaire is developed, it will be necessary to identify key behavioral indicators. Key indicators are those used to understand more about the potential for and control of HIV epidemics. Sound analysis hinges on clear formulation of key indicators and anticipation of how the indicators will be calculated within the questionnaire. The online resource Behavioral Surveillance Surveys: Guidelines for Repeated Behavioral Surveys in Populations at Risk of HIV[3] has a very good section on key indicators for each survey group, including the purpose and definition.

[3] Family Health International. Behavioral Surveillance Surveys: Guidelines for Repeated Behavioral Surveys in Populations at Risk for HIV (2000). Research Triangle Park, NC: Available at www.fhi.org/en/hivaids/pub/guide/bssguidelines.htm.

Generally, prevalence of HIV and STIs, key risk behaviors, and knowledge of prevention methods are key indicators in an IBBA. Other areas of inquiry add depth to these data, by describing the population group surveyed (for example, demographic information) and specific behaviors (for example, places to obtain condoms), which can be useful for programs.

Areas of inquiry in an IBBA can be demographic characteristics, migration patterns, sexual behavior, condom use, types of sexual partners, knowledge about HIV and AIDS, and exposure to intervention. For the biological assessment, prevalence of STIs, including HIV, can be estimated for all the respondents/participants surveyed. In addition, prevalence of hepatitis B and C can be estimated among IDUs (see Table 33).

Table 33. Behavioral and biological indicators of IBBA in India

Behavioral indicators	Biological indicators
Number and types of sexual partners	All participants
Condom use with different types of partners	Syphilis serology
Practices related to condom use and safe sex	N. gonorrhea NAT
Knowledge of STIs and STI care-seeking behavior	C. trachomatis NAT
Knowledge and attitudes toward HIV and AIDS	Herpes simplex virus types 2 (HSV-2) serology (10% sample)
Drug and substance abuse	HIV serology
Mobility and migration patterns influencing risk	BED assay for early HIV infection
Perception of HIV and STI risk	Hepatitis B virus (HBV) surface antigen (IDU only)
Exposure to intervention	Hepatitis C virus (HCV) antibody (IDU only)

Trend data

IBBA data are useful when surveys are done among the same survey group, in the same geographic areas, and over time. Data from repeated surveys can be analyzed to understand current scenarios and changes in the epidemic's patterns. This information is especially useful when analyzed together with statistical testing for significant differences, because it can reveal new areas in need of programming and intervention strategies and policies in need of revision.

Before analyzing data from IBBA and BSS surveys together, the data analysis team should be clear about the methodological differences:

- All data sources come from the same sampling domain
- Differences in eligibility and exclusion criteria
- Differences in sampling method
- Sampling method employed
- Key environmental changes that may describe changes in the local scenario
- Changes in sample size calculation or sampling methodologies
- Differences in weighting data or other analytical procedures
- Changes in the questionnaire

Even if the survey definitions are different, if the data have been collected in a different manner, they can still be viewed together to gain some information about the local scenario. Interpretation should be cautious, because the data may reveal more about the methodology than the epidemic. If the data analysis team has a good understanding of the local situation, they can still interpret and compare data, because they will have some idea of expected changes. Triangulation with other data sources also helps to confirm results observed in the dataset.

Data triangulation

Triangulation uses multiple sources of data to understand more about specific questions and to describe local situations. Data triangulation is not an exact science. For example, within the IBBA, a lot of information is available on the key indicators, including HIV prevalence and STI prevalence. Intervention programs can provide a wealth of information: when the programs started, what type of services they provide, where they work, trends in people visiting program sites over time, feedback, and qualitative research done with the community. Intervention program data provide more context on the local situation, explain changes in data, and are an aid in planning.

Using multiple data sources adds to knowledge, by pooling together all types of data (intervention, quantitative and qualitative research studies, and so forth). Data triangulation can be used to:

- Explain changes in data that are troubling and not explainable from information gathered within one dataset
- Explain or verify positive trends observed in one dataset
- Explain observations, trends, and outcomes, by adding depth to data analysis and interpretation
- Provide information on underlying or contributing factors to observations that may not be contained within one dataset
- Improve the quality of programs and strategies
- Guide program and policy development
- Include environmental and external influences, which may affect observations, explain data, and project future needs

Data triangulation is complex. Before conducting analysis and interpretation, the data analysis team must understand the context, strengths, and limitations of each of the datasets. The team considers different methodologies, research purposes, periods of time, definitions, data collection methods, data quality, and coverage areas. Incomplete documentation of the data during the collection phase will limit its use later.

Although triangulation adds depth to the data, it does have limitations. It is easy to over-interpret data, especially when we are looking for certain trends or expected outcomes. Keep in mind that the data being compared were not collected for this purpose. Apparent trends may reflect differences in methodology rather reality. Data triangulation cannot show causality. It can indicate a relationship, but it cannot assert how factors interact or whether a relationship is true.

Data interpretation

Data sharing and interpretation start soon after completion of the survey. Involving multiple partners in interpreting the data will be useful, because different perspectives and experiences add to mutual understanding of the datasets.

When interpreting and sharing data, be mindful of the following points:

- Did we capture who we thought we were going to capture? Sometimes a methodology changes when it is implemented in the field; this may affect how the survey is done and who is included.
- Small samples or subgroups should not be analyzed, because the data are likely too few to be valid for interpretation.
- Did the survey implementation follow the original design, or are there indications that changes in the survey methodology may affect the data?
- Do not read more into the data than they support.
- Because we do not know when an infectious disease occurred, observed current behaviors may be unrelated to the infection. Therefore, cross-sectional studies such as IBBA cannot show causality. They can only indicate that a relationship between variables may exist.
- Subgroup analyses are always dangerous, because restricting the analysis to a small group can make a behavior that has a minor effect on the epidemic appear to have a major effect.

Chapter 12

12

Dissemination of findings

- Potential audiences for IBBA findings
- Forms of dissemination
- Presentation of the data

IBBA data are important to many people—policy makers, health professionals, NGO staff, and community members. The data are useful for monitoring HIV epidemic trends, highlighting areas of concern and success in intervention programs, indicating particular needs for more resources, estimating the size of risk populations, and discovering trends in the epidemic.

IBBA data contain a wealth of information; presenting all of it can be confusing and even misleading. Often such epidemiological data fail to elicit response due to poor communication. When audiences are not clear about the main themes, they are not likely to use the data well. It is essential to share information selectively with specific audiences, so that they can interpret it in terms of their particular interests and use it effectively.

Disseminating the data is also important to achieve consensus among the survey developers on the results and strategies that are needed. By sharing the data with community members, the developers may understand better how to interpret the data and how to tackle any issues that arise. This chapter discusses how to define the intended audiences and disseminate the data to them. It also reviews different ways to communicate the data.

For information to be communicated and used effectively, it is essential to tailor it to the interests of specific audiences.

IBBA's diverse audiences

When sharing data with different groups, consider the needs and interest of each one and tailor a dissemination plan that takes into account who the audience is, how they typically receive information, and what information will be most compelling. Ensure that the key points of concern for each audience are clearly highlighted and not lost in a preponderance of details. Potential audiences for IBBA findings and their areas of interest are described in Table 34, which offers a generic list that can be adapted to local scenarios.

For the India IBBA, a written report of the results was provided to the Ministry of Health; the National AIDS Control Organisation; State AIDS Control Society; the India AIDS Initiative, or Avahan (a program of the Bill & Melinda Gates Foundation); Avahan partners; and other NGOs and agencies in the country working on STI and HIV issues. Attention was given in the preparation of reports to the sensitivities attached to the social risk of the groups included in the IBBA. At the end of the IBBA, one-day workshops were held in each of the five states to disseminate the assessment's findings. Workshops were also held to disseminate the findings of the IBBA to those along the national highway corridors.

An oral debriefing was done with key interested parties: relevant ministries, other donors, and key NGOs. Specific disseminations were carried out for the population subgroups surveyed in the IBBA.

Results from this assessment were also presented at national, regional, and international meetings and published in international peer-reviewed journals.

Table 34. Potential audiences for IBBA findings

Type of audience	IBBA data areas of interest	Other
Community members	Trends in the biological data and in key indicator data Discussion/exploration of areas of concern revealed by the IBBA data Identification of strategies to address and improve areas of concern Experience in implementing the survey and the effect of the survey on the community	Triangulate data with: • Information on types and coverage of existing programs • Qualitative information • Validation of IBBA results • Feedback on interventions Dissemination approach: • Group discussion
NGO program managers, influential leaders, and local health officials	Trends in behavioral and biological data Groups showing higher and lower risk of HIV Size estimations by group Program coverage (e.g., are the most at-risk groups covered by interventions?)	Triangulate data with: • Program information from NGOs • Other studies Dissemination approach: • Bring together different NGOs to discuss more broadly
NGO technical leaders	Categories of information according to technical area (for example, clinic staff may be more interested in coverage, STI prevalence, knowledge of STIs, and treatment-seeking behavior)	Triangulate data with: • Program information from NGOs • NGO studies Dissemination approach: • Bring together different NGOs to discuss more broadly
Donor agencies	Trends in behavior and biological data Coverage by interventions Areas and groups at increased risk How IBBA data informs country/state information about trends	Triangulate data with: • Program information from NGOs • Other studies • Data on health policy • Program evaluation information Dissemination approach: • Bring together different NGOs and donors to discuss explanations and needs more broadly
Government agencies	Trends in behavior and biological data Coverage by interventions Areas and groups at increased risk How IBBA data informs country/state information about trends	Health policy information Health needs assessments NGO coverage data

IBBA data can supplement program-monitoring data to reveal trends in the community and areas of program strengthening and achievements. Information on trends in sexual behavior, health-seeking behavior, awareness, prevalence of HIV and STIs, and coverage by interventions would all be useful to the monitoring and evaluation of programs. Further, repeated surveys among the same subpopulations would provide trend data, which can be used to guide programs and to identify areas of epidemic potential, as well as program gaps and successes. IBBA data can also be triangulated with data from other existing epidemiological surveys and the results disseminated to improve programs and policies in a state or district.

Joint dissemination (with different groups and types of representatives) would also be useful, to ensure that multisectoral lessons are incorporated into strategic planning efforts. This also allows for larger discussions, interpretation of results, and planning. For example, disseminating key indicator data to NGOs, government partners, and donors simultaneously may generate a discussion about the direction in which projects need to move. Although the IBBA data may show certain trends, information at different levels can supplement the findings with key information on existing programs, coverage data, strategy information, and insight into key behaviors.

Although the media can reach a large audience with anecdotal, human-interest stories pertaining to HIV and AIDS, care has to be taken to avoid stigmatizing any of the at-risk subgroups as a result of misrepresentation of the findings of IBBAs. Any interaction—or decision to avoid interacting—with the media should be considered carefully. On the one hand, the media can play a positive role when they push government and donors to work with groups at risk for HIV and advocate for policy changes. On the other hand, misunderstandings about the data can further stigmatize these at-risk groups and create negativity in the community. If the media are involved in using IBBA data, the program should consider providing clear, short written briefs about the meaning of the data. A sensitization session could also be held with the media prior to releasing such briefs.

Types of dissemination

Methods of data dissemination can take place in many forms. For example, reports and publications can be developed for wider circulation. Group discussions with government partners, NGOs, and community members may provide insight on trends in the data, a context for understanding community needs and concerns, and enlightenment about how these needs and concerns can be addressed. Oral presentations can be used to reach a range of audiences through strategic use of graphs, maps, and fact sheets. It is important to use appropriate local language in communicating the findings of IBBA with these groups.

Respondents/participants in the IBBA surveys should be asked to take action based on the findings so that the risk of HIV/AIDS is reduced. Any feedback provided by the survey participants should be passed along to program managers so they can refine survey instruments, conduct analysis as required, and modify survey implementation and dissemination strategies.

Key dissemination materials could be made more widely available by placing them on the Web sites of the organizations. Web sites are a relatively low-cost means of sharing the findings of IBBA with a large audience. Although the presentations on a Web site are a passive way to reach out to audiences, the cost of such communication is negligible. Dissemination through written materials may be accomplished with fact sheets, summary reports, detailed survey reports, and presentations. Although fact sheets and summary reports help reach a large audience at relatively low cost, detailed reports make all the findings of the survey available to program managers and policy makers.

Fact Sheets. Fact sheets are an easy means to reach a large audience at low cost. Fact sheets generally focus on a specific topic and illustrate it with graphic representations. They are short, so that the reader is not overwhelmed by details. The highlights of survey findings can be described. Fact sheets are a useful way to share IBBA data widely. They can be distributed at dissemination meetings. Although higher level government officials should receive the summary report, they should be given a fact sheet, as well.

Summary reports. Summary reports are an easy-to-follow format with fewer technical details than the full-length report or a set of topical reports will contain. In India, one national summary report was produced, which contained an overview of the results for each group/study domain. More detailed results were presented in state reports. Summary reports are useful for people looking for a an overview of IBBA data.

Detailed survey reports. All the information gathered through the IBBA survey can be contained in detailed survey reports. Although these reports can be used by all agencies working on preventing HIV and AIDS, such reports are also helpful for program managers who need data in great detail—for all the sites, and for the study population. These reports would contain in-depth analyses of data of each sample population by their subgroups and background details. Although important indicators are discussed in the main body of the report, additional data can be appended. Detailed reports should contain references and appendices to support the findings. Such reports follow the formatting norms of research publications. The report should provide some contextual information and may include some triangulation of data to facilitate interpretation.

Presentations. The findings of IBBA can be prepared and shared with a large audience in presentations. Although these are designed to suit a particular audience, an overview presentation would be useful to have ready for last-minute requests. In face-to-face dissemination, the presenter and the team need to answer questions raised by the audience. It is important that the presenter take observations and questions from the key stakeholders seriously and respond with utmost sincerity. Further, the presenter should be careful and sincere in addressing difficult and controversial questions, including the limitations of the study.

Academic and scientific publications. Sharing key findings through specialist publications helps disseminate the data nationally and internationally. This can lead to identification of national, regional, and global trends. It can also identify new areas for research, inform both donors and programs, and support advocacy for policy change. Target publications with a clear area of focus. Developing a paper for publication is time-consuming given the required analysis and background reviews. The task is nonetheless necessary to ensure that the data are widely shared.

Field experience: Fact sheets for the IBBA in India

In the IBBA conducted in India, a fact sheet with tables and graphs was produced to cover each study population in a state. For each district, data were presented that included sample details, indicators measured, definitions of terms used, background characteristics of the respondents, the number of different types of sex partners, condom use, knowledge and experience of STIs, exposure to intervention, as well as STI and HIV prevalence.

Presentation of data

Data presentation is a critical part of sharing data. Present the data as clearly as possible, using narration, tables, and graphs. Some valuable points to remember are:

- Contextualize data by giving a background to the local scenario and triangulating data with other available information.
- Include information on the methodology, such as defining the group that was covered and the geographic domain to which the data are applicable. For a narrative report, this can be done in more detail, but for summary reports, presentations, and group discussions, this can be covered briefly.
- Use simple language. A pitfall in explaining and interpreting data is to do so in a longwinded and complicated way. This will intimidate people and make them less likely to use the survey data. Instead, simple language in presentations and publications makes the data accessible and helps to ensure that it will be used more widely.

- Share data using different types of disseminations. Design disseminations through consultations with community groups, research groups, and government partners that may yield suggestions on where and how to disseminate data. Different forums include discussions within the community, journal publications, dissemination reports, and summary fact sheets.
- Label the data. The data are not self-explanatory. For example, a graph should have a clear title, both axes should be labeled, and the units should be indicated.
- Share data as percentages, because they are not valid as whole numbers. Percentages can be discussed in many ways to help people grasp their meaning. Use pictures to show the proportion of people affected (see "Example: Showing data as percentages" on the next page.)

Field experience: Disseminating findings in India

In India, data was disseminated in the following ways:

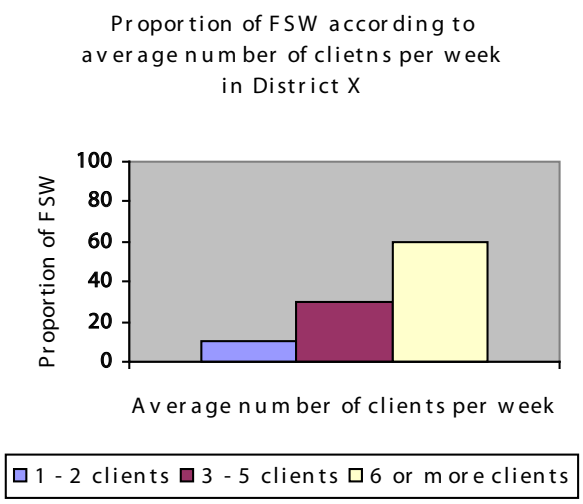
- National summary report
- State report (one report per study group within a state)
- Fact sheets
- Top-line findings (key indicator)
- Descriptive tables (cross tabs with key indicators)
- Presentations to government, NGOs, etc.
- Journal publications
- Online data dissemination
- Further data analysis as partners request it

- Too much data can overwhelm the key points. Select the data appropriate for the presentation (narrative, discussions, and oral) and take care to highlight the important information. Similarly, select data for graphs and tables wisely.
- Look at the confidence intervals – wider confidence intervals indicate that the data point is less reliable. For example, if seventy percent of FSWs use condoms consistently with their clients, but the confidence interval is fifty to ninety percent, we know that the information was not captured very precisely. Further, in a comparison of two different datasets, overlapping intervals may indicate that the proportions are more similar than they appear.
- Check the denominator:
  - There are many skips in the questionnaire. The denominator may become much smaller as a result.
  - If the denominator for a percentage is very small, the data will not be valid for interpretation and should not be presented.
  - If a subset of the group is represented, then this should be specified when the data are presented.

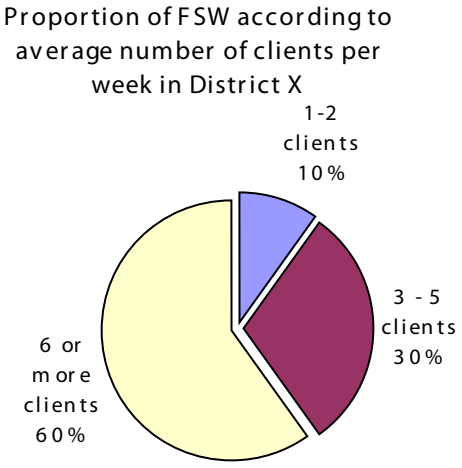
Example: Showing data as percentages

If the IBBA data show that 10 percent of female sex workers have one to two clients per week, 30 percent have three to five partners per week, and 60 percent have six or more partners per week, there are at least three ways to show this.

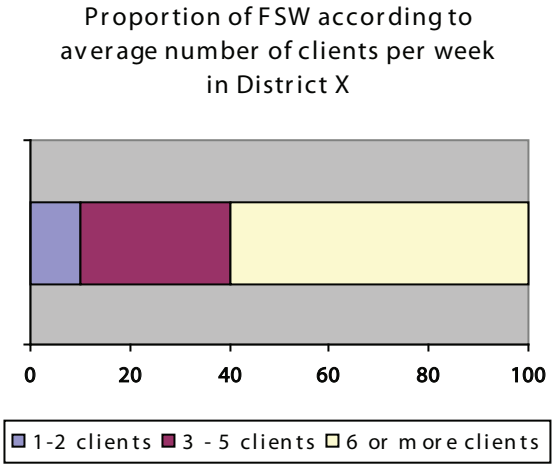
Option 1



Option 2



Option 3



Appendix 1

IBBA survey protocol

1

Mapping, size estimation, and integrated behavioral and biological assessment (IBBA) in high HIV prevalence settings in India

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Indian Council of Medical Research
National AIDS Research Institute
in partnership with
FHI

1.0 Background and rationale

In India, sentinel surveillance is used annually to estimate the prevalence of human immunodeficiency virus (HIV) infection in the country and to monitor trends in the epidemic. Sentinel surveillance for HIV in India began in 1994, at 55 sentinel sites, under the National AIDS Control Program-I (1992–1999). The population groups and sites for HIV sentinel surveillance are selected based on information about various groups whose behavior increases their risk of HIV infection. The high-risk groups of the population include patients attending sexually transmitted disease (STD) clinics, female sex workers (FSWs), injecting drug users (IDUs), and men who have sex with men (MSM). An example of a low-risk group of the population is women attending antenatal clinics. The rationale for selecting sentinel sites in the clinics attended by these subgroups of the population is that blood samples are collected from the people who attend the clinics for various purposes, and the samples can be tested for HIV in an unlinked anonymous manner. Since 1994, the number of sites in the sentinel surveillance system has been increasing. In 2002, sentinel surveillance was conducted at 384 sites and in 2003, at 455 sites.

Despite the HIV, sexually transmitted infection (STI), and risk behavior surveillance activities currently underway in India, there are considerable gaps in the information available to understand both the course of the epidemic as well as the STI correlates and behavioral risks that fuel it. To measure the major outcomes and impacts of the interventions funded by the Bill & Melinda Gates Foundation under the Avahan India AIDS Initiative (Avahan), the existing surveillance system must be strengthened and expanded. A robust surveillance system will allow the foundation and its governmental and nongovernmental partners not only to follow key trends in HIV, STIs, and risk behaviors, but also to use the data to project trends into the future.

The purpose of this assessment is to gather data for impact monitoring and evaluation of the Avahan India AIDS Initiative in 71 districts of six states and five highway sites. The proposed mapping, size estimation, and integrated behavioral and biological assessment (IBBA) will provide some of the key data needed to assess major outcomes and impacts of the interventions funded by the Bill & Melinda Gates Foundation. This is the first independent impact-level evaluation of this scale of targeted interventions with sex workers and clients, high risk men and IDUs on HIV/AIDS. The project will be implemented in close collaboration with National AIDS Control Organisation (NACO) and State AIDS Control Societies (SACS) and will provide valuable information to feed back into and strengthen the National AIDS Control Program in India.

The IBBA will be conducted two times during the seven-year project period of Avahan. The baseline assessment will be undertaken in 2005 and the endline assessment in 2009. This protocol aims to cover the baseline and endline assessments.

2.0 Objectives

The overall objective of the IBBA is to collect necessary information for assessing the outcomes and the impact of HIV interventions in Avahan project districts. In addition, conduct of the IBBA will strengthen the capacity of national and state level institutes including the Indian Council of Medical Research (ICMR), the National AIDS Research Initiative (NARI), the National Institute of Epidemiology (NIE), the National Institute of Nutrition (NIN), the Regional Medical Research Council (RMRC), and the National Institute of Medical Statistics (NIMS).

The specific objectives of the IBBA are to collect the following data in selected districts of the Avahan project states of Andhra Pradesh, Maharashtra, Tamil Nadu, Manipur, and Nagaland and along the National Highways:

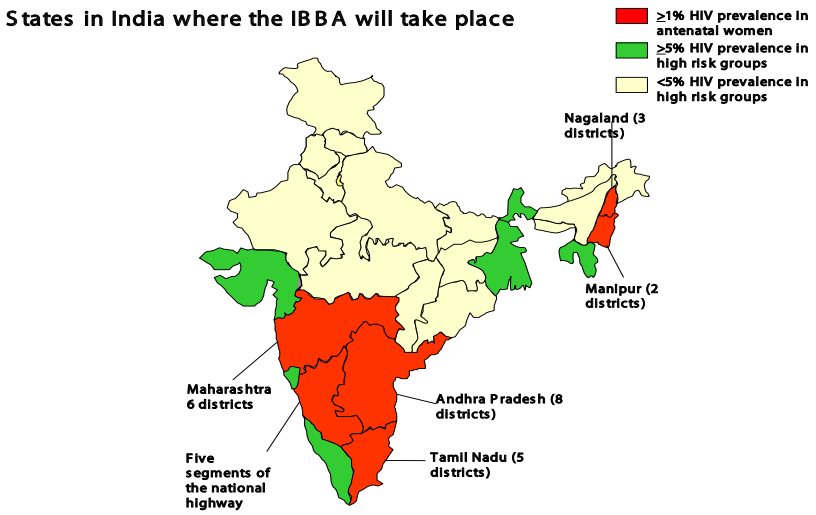
1. To measure the major outcomes and impacts of the interventions funded by the Bill & Melinda Gates Foundation under the Avahan India AIDS Initiative, by collecting behavioral and biological trend data in populations targeted by the interventions

2. To make available data that will be used for estimating sizes of populations targeted by the project
3. To make information available to a partner organization under Avahan for modeling the impact of the intervention

3.0 Methods

3.1 IBBA populations:

The populations that will be included for mapping, size estimation, and IBBA are shown below.



3.1.1 Operational definitions of IBBA populations

Female Sex Workers: (Definitions will vary by state/district to match the Avahan program)

a. **Female Sex Workers (FSW):** Females ages 18 years or older, either brothel- or non-brothel-based, who sold sex in exchange for cash at least once in the past one month

b. **Female Sex Workers, Brothel-Based (FSW-BB):** Females ages 18 years or older working/living/operating in brothels in red light/brothel areas (to be specified for each district) who have been paid cash in exchange for sex at least once in the past month

c. **Female Sex Workers, Non-Brothel-Based (FSW-NBB):** Females ages 18 years or older soliciting male clients on the street or in other non-brothel settings and who sold sex in exchange for cash at least once in the past one month

d. **Service Bar-Based Female Sex Workers (FSW-SBB):** Females ages 18 years or older, soliciting clients in service ("free service") bars, who sold sex in exchange for cash at least once in the past one month

Clients of FSWs: Men ages 18 years or older recruited from red light districts and other commercial sex access points who have paid cash in exchange for sex with a female at least once in the past one month

Injecting Drug Users: Males ages 18 years or older who have injected drugs for nonmedical reasons any time during the past six months.

Men Who Have Sex with Men (Definitions will vary by state/district to match Avahan definitions)

a. **Male Sex Workers:** Males 18 years or older who sold sex to other males in exchange for cash (cash/kind in some places) at least once in the past three months. (*Hijras*/transgenders to be sampled separately)

b. **Men Who Have Sex with Men:** Males ages 18 years or older who exchanged (bought or sold) sex in exchange for cash (or cash/kind) at least once in the past three months

Long Distance Truck Drivers: Men ages 18 years or older driving trucks along interstate transport routes

3.1.2 Protection of vulnerable subjects

Recruitment of these high-risk populations requires addressing the clandestine, socially marginalized nature of these groups and the behaviors that they engage in. To protect participants who may be vulnerable to coercion or undue influence, the following general procedures will be adhered to. These procedures will have added specificity as this protocol is contextualized for each site.

- Access to these groups may require going through various gatekeepers such as employers, brothel owners, or police. Discussions with employers will clarify the purpose of the IBBA: e.g., STI detection and treatment, STI counseling, condom distribution, and obtaining information to guide improved implementation of ongoing projects. Employers will be made aware that no data forms will have names, with except the consent form, which will not be linkable to any of the behavioral or biological data, and that participation by all individuals will be voluntary and through random recruitment. While these employers might be used to gain access, they will not be used for any component of recruitment and no information regarding recruitment will be given to these intermediaries. Sites where employers appear to be coercive will be excluded from the IBBA.

- Specific efforts will be undertaken to inform the nongovernmental organizations (NGOs) working with the populations targeted by the IBBA, as well as community leaders, about the purpose, risks, and benefits of the IBBA. Prior to recruitment, information about the IBBA will be shared through educational sessions with NGOs and other partners. At these educational sessions the IBBA will be explained and questions answered. These educational sessions will stress the voluntary nature of the IBBA and its importance in tracking progress in reducing HIV transmission.

- IBBA participants will be protected through a voluntary written consent process, with the option of witnessed verbal consent for those who are not comfortable with written consent. All IBBA documents and specimens will be labeled with only a unique respondent number, with the exception of the consent form, which will not be linkable to any of the other IBBA documents or data. Prior to recruitment, two IBBA staff members will explain the IBBA procedures in detail to potential participants in a private room and answer all questions. They will emphasize that participation is voluntary and should participants decide not to participate or withdraw from the IBBA at any time, their decision would not affect any services from the NGO or the clinic that they would normally receive. The IBBA staff will administer written or witnessed verbal informed consent, depending on the preference of the participant.

- The IBBA is anonymous. The participant's signature on the consent form is in no way linked to the person's behavioral and biological data, because the unique respondent number does not appear on the consent form. No names or personal identifiers will be recorded. All questionnaires and biological specimens will be labeled with the respondent number. The assessment participant will be given a card with his/her unique respondent number as a way to return for syphilis results and free syphilis treatment (with the exception of those referred to the Avahan-supported Population Services International [PSI] clinics). As there are no identifiers there is no way to trace any positive laboratory tests or to determine who chose to participate or not participate in the assessment.

- The IBBA project staff, India Council of Medical Research (ICMR), FHI, and community monitoring boards will closely monitor the consent procedure.

- Discussions will be held between ICMR, National AIDS Research Institute (NARI), FHI, IBBA, and Avahan project staff and community leaders on the potential impact of data and appropriate release of the data when the IBBA is complete.

3.1.3 Key behavioral and biological indicators

Behavioral Indicators

- Sexual risk behavior including number and type of sex partners ("commercial," "regular," and "non-regular")
- Condom use with different types of sex partners
- Other practices related to condom use and safe sex
- Knowledge of STIs and STI care-seeking behaviors
- Knowledge and attitudes toward HIV/AIDS
- Drug and substance use (including injecting and equipment sharing)
- Mobility and migration patterns influencing sexual behavior and risk
- Perception of HIV and STI risk
- Exposure to Avahan and other HIV/AIDS prevention interventions

Biological Indicators

- STI prevalence: syphilis serology, N. gonorrhoea (Ng), C. trachomatis (Ct), herpes simplex virus (HSV) 2 serology, HBC and HCV in IDUs, and for those reporting ulcers T. pallidum (Tp), H. ducreyi (Hd), and HSV-2 antigen detection
- HIV prevalence
- HIV incidence (BED-CEIA validated for Indian sub-type C)

3.2 Site and respondent selection

3.2.1 Selecting project districts for mapping, size estimation, and IBBA

At present Avahan is working in approximately 75 districts across six states of India, 19 districts in Andhra Pradesh, 20 in Karnataka, 16 in Maharashtra, 4 in Manipur, four in Nagaland, and 12 in Tamil Nadu. Based on the recommendation of the WHO M&E Advisory Group for the IBBA, it was decided that the IBBA would be carried out in approximately 24 project districts: eight in Andhra Pradesh, six in Maharashtra, two in Manipur, three in Nagaland, and five in Tamil Nadu. In addition, four segments of the National Highway would also be part of the IBBA.

For selecting the IBBA districts within states, two key criteria were considered: (1) socio-cultural region (SCR); and (2) size of the female sex worker (FSW) population, or, in the case of Manipur and Nagaland, size of the injecting drug user (IDU) population. Specifically, the requirement was to have representation from each of the different SCRs within a state to ensure heterogeneity in terms of social, economic, and cultural characteristics. Then within each SCR, the criterion was to select the districts with the highest number of people at high risk (FSWs and IDUs). A third criterion—prevalence of antenatal clinic (ANC) attendees in the district—was originally proposed to fulfill the objective of obtaining a mix of higher and lower prevalence districts. However, in the end, this criterion did not play a role, because there were only a handful of cases where more then one district was selected within an SCR, and in those cases, after considering the size of the

risk population, there was not much significant difference in terms of ANC prevalence. It is recognized that the size of the risk populations (FSW and IDUs) is fluid and that attempts to enumerate these populations at any given time will yield different results. However, since a probability-based method was not being used to select districts, the primary concern was to try to select the districts with the highest concentrations of at-risk populations. The proposed method adequately addresses this need.

3.2.2 Selecting individual respondents for the IBBA

Sampling sub-populations of the type of interest for Avahan presents significant challenges. First, lists (or sampling frames) of sub-population members rarely if ever exist. Second, because sub-populations often represent a small proportion of the general population, obtaining statistically reliable data for them through conventional household surveys would require prohibitively large household samples. Third, many of the types of dwellings in which they live (for example, brothels, migrant hostels, prisons, or unconventional dwellings) might not be included in typical household survey sampling frames. Finally, because they engage in behaviors that are illegal or at least stigmatized in many settings, members of such sub-populations are often reluctant to participate in household surveys and risk revealing their behaviors to others who may be present at the time of a survey.

In recent years, a number of sampling approaches have been developed for hard-to-reach and hidden populations that appear to produce survey estimates with acceptable levels of accuracy. Such methods will be used for the IBBA.

The choice of sampling method for individual sub-population members will depend upon the specific group being assessed. Two alternative sampling approaches will be used for the sub-groups included in the IBBA: time-location sampling and respondent driven sampling. (In a few rare situations, conventional cluster sampling will be used for some types of sex workers.)

In time-location sampling (TLS), a sampling frame will be obtained through a listing exercise conducted by the IBBA research agency. The listing exercise will use existing information from all existing sources and add to it. From the geographical sites identified during mapping/listing, a time-location sampling frame consisting of venue/time slots will be constructed. Subsequently a random or systematic sample of primary sampling units (i.e. venue/time slots) will be chosen and data on behavioral and biological indicators will be gathered from a random or systematic sample of population sub-group members appearing at those venues during fixed-length observation periods (e.g., three-hour time segments, entire days or nights). Examples of sites used in TLS for population sub-groups included in the IBBA are brothels; service bars (Mumbai only); street sites where sex workers congregate to solicit clients; and truck stops, border crossings, and bars/restaurants along major highways. Cluster sampling will be used for sex workers and truckers. The specific types of sites to be listed will be finalized after the pre-survey assessment. For MSM/MSW the sampling method will vary by state, and will depend on how the groups are defined in each state, which is related to the way the Avahan program defines and targets them. For clients of sex workers, field trials will help determine which sampling method works best. For IDUs it is proposed to use RDS.

In general RDS will be used for sub-populations for whom significant proportions do not congregate at identifiable sites. RDS is an elaboration of chain-referral sampling (CRS) designed to overcome the major biases associated with CRS methods, such as snowball sampling. This is accomplished by, among other things: (1) restricting the number of recruits per recruiter and weighting the data inversely to personal network size to prevent the sample from being dominated by "seeds" and recruits with large personal networks; and (2) providing incentives to reduce non-response bias. We anticipate using this method for sampling IDUs and possibly other groups such as male sex workers or MSM.

3.3 Sample sizes

3.3.1 Measuring changes in behaviors and documenting STI prevalence

Sample sizes for each population sub-group included in the IBBA have been calculated on the basis of the following factors typically used in surveys with probability samples:

- The expected baseline value of key behavioral indicators (e.g., consistent condom use with various partner types)
- The magnitude of change it is desired to be able to detect
- The confidence level
- Statistical power
- Design effect

The following formula was used to determine the sample size for target groups for the IBBA:

Where: $$n = D\,\frac{\left[\sqrt{2P(1-P)}Z_{1-\alpha} + \sqrt{P_1(1-P_1)+P_2(1-P_2)}Z_{1-\beta}\right]}{\Delta^2}$$

D = design effect;

P1 = the estimated proportion at the time of the first survey;

P2 = the proportion at some future date, such that the quantity (P2–P1) is the size of the magnitude of change it is desired to be able to detect;

P = (P1 + P2) / 2;

Δ^2 = (P2 – P1)2

$Z_{1-\alpha}$ = the z-score corresponding to the probability with which it is desired to be able to conclude that an observed change of size (P2–P1) would not have occurred by chance;

$Z_{1-\beta}$ = the z-score corresponding to the degree of confidence with which it is desired to be certain of detecting a change of size (P2–P1) if one actually occurred.

For the IBBA, the following assumptions have been made regarding these parameters:

- Expected baseline value: 50 percent. Measurements require the highest sample size to detect change when the baseline is 50 percent; hence this figure was used. If it can be safely assumed that baseline values of all indicators are significantly lower or higher, then sample sizes could be lowered.
- Desired change to detect: 10 to 15 percent. This refers to the amount of change that can be detected between two survey rounds. For example, if condom use changed by an absolute 10 to 15 percent, this would be detected as a statistically significant change. A lower absolute change would not be detected as statistically significant. Smaller differences require larger sample sizes.
- The alpha level has been set at 0.05, corresponding to 95 percent confidence in the observed estimates.
- The beta level has been set at 0.10, corresponding to 90 percent power.

- Design effect: 1.7 for time-location sampling and 1.5 for RDS. This adjusts for the use of sampling designs that are not simple random methods: e.g., cluster sampling.

Minimum sample size requirements per sub-population per district to measure both differences between groups and changes over time at the levels of significance and power indicated above are summarized in the table below. These numbers will be adjusted upward after the pilot test to account for anticipated non-response (refusal and duplication).

Justification for IBBA sample sizes for key sub-populations

IBBA population	Indicator	Expected baseline value	Change to detect	% in denominator	Design effect	Required sample size	Sample size (rounded off) required for the IBBA
1. FSW/ brothel-based	Consistent condom use with clients	50%	15%	ALL	1.7 TLS	385	400
2. FSW/ non-brothel-based	Consistent condom use with clients	50%	15%	ALL	1.7 TLS	385	400
3. Male sex worker/MSM	Consistent condom use with clients	50%	15%	ALL	1.5 RDS	339	400
4. Injecting drug user	Consistent use of safe injecting equipment	50%	15%	ALL	1.5 RDS	339	400
5. Clients of FSW (male bridge group)	Consistent condom use with FSW	50%	15%	ALL	1.7 TLS	385	400
6. Long distance truck drivers	Consistent condom use with FSW	50%	15%	75%	1.7 TLS	592	500

3.3.2 Measuring changes in HIV incidence

Based on the BED Incidence EIA testing procedure, individuals tested are classified into three groups:

- Those who are HIV seronegative (Nneg)
- Those who were infected within the last W days (i.e., 153 days) preceding the test (Ninc)
- Those who were infected more than W days preceding the test (Nprevalent at day –W = Ntested–Nneg – Ninc)

For the analysis of incidence, one ignores those in category 3 above, since as they sero-converted longer in the past than the "window" period for the BED-CEIA, they are "non-informative" for the purpose of measuring HIV incidence. Thus, the number of 'informative' participants for the incidence analysis is Nneg plus Ninc.

The recommended approach for estimating the "incidence (density) rate" (IDR per 100 person-years; that is, events per 100 years of risk) and a 95-percent confidence interval for the incidence rate treats the number of recent infections as a Poisson random variable with total time at risk equal to the time at risk among the sero-negatives (Nneg* 153 days), plus average time at risk among the incident cases (Ninc * 153 days /2). An alternative measure for summarizing incidence is the "cumulative incidence" (Pt), which is the probability of becoming infected by the end of some time period t (for example, t=1 year or t=153 days). When the risk of experiencing the event of interest during the exposure period of interest is constant (as is assumed when the Poisson model is applied as above) there is a convenient 1 to 1 relationship between P and IDR as shown below:

Pt years = 1-exp (-IDRt years) or IDRt years= -ln (1–Pt years)

For example, if the IDR1 year = .05 events per person-year (or 5 events per 100 person-years) then the probability that a person who is followed for one year experiences the event within that year (P1 year) is .0488. Alternatively, if IDR1 year = .05 this implies that IDR153 days =.02096 and P153 days=.02074.

Using the BED-IEIA test results, we can estimate P153 days directly for a cross-sectional sample using the observed proportion Ninc / (Nneg + Ninc). Thus, if our goal is to test whether two independent groups have the same risk of HIV incidence, we can simply compare the observed proportions of participants with an infection within the past 153 days (among the informative participants) for the two groups using standard approaches for dichotomous variables (e.g., a chi-square test for a two by two table). Note that the two groups being compared can be samples from two separate populations, or two independent samples from a given population taken at two different points in time. The latter scenario would apply in the case of measuring changes in incidence over time for the sub-populations of interest for Avahan.

A sizeable number of calculations were run with different combinations of parameters, including underlying annual infection probabilities of between 1 percent and 25 percent. These calculations reveal that on the order of 1,200 to 1,500 subjects per sub-population per round of IBBA would be needed to measure declines in incidence of 5 percentage points. Thus, measuring changes in incidence for individual sub-populations within IBBA domains (i.e., districts) is not feasible, but is feasible for most groups when aggregate estimates at the state or overall Avahan project level are desired.

3.4 IBBA teams

There will be state specific IBBA teams for each of the six states and one team for the National Highway sites. Each team will have the following constitution.

3.4.1 Pre-survey assessment

FHI will hire three consultants who will:

- Gather and review all the available mapping information, for the selected districts and national highway segments, available from various sources including Avahan partners, NACO, SACS, NGOs/CBOs, and different donor agencies. Based on a thorough and critical review of methodologies and the coverage and quality of the existing mapping information, the gaps in developing a comprehensive sampling frame for different respondent groups will be identified and filled through a rapid listing exercise coordinated by ICMR and its partners.
- In addition, the consultants will gather information to guide methodological decisions related to the fieldwork for the main assessment.

3.4.2 IBBA

3.4.2.1 Core team

ICMR will be charged with implementation of the project, with technical support and assistance from FHI. The principal investigator will assemble a core team who will direct the IBBA. This team will consist of one principal investigator with senior level medical epidemiological skills and experience, one research coordinator and one research associate with strong knowledge of quantitative research, one senior microbiologist who will supervise the specimen collection and transport procedures as well as the laboratory procedures of the IBBA, and one data analyst who will oversee the data management process in the various states. The number and cadre of the logistic and financial support team will be decided at a later date.

3.4.2.2 State and highway teams

There will be six state-wide teams and one highway team. These teams will have overall responsibility for the activities within the state or highway. They will be headed by a program manger with a core team consisting of a field coordinator and a laboratory manager. They will report to the core team regularly and on request. The activities will follow the protocol of the overall IBBA, and the results will be capable of both "standing alone" and being aggregated into the overall program data.

3.4.2.3 District and highway sector teams

There will be multiple field teams in each state and on the highway. The teams will be overseen by district level field coordinators. The composition and responsibilities of the team members are described below.

Supervisor: There will be one supervisor for each field team. The supervisor will be responsible for the overall management of the field team. The responsibilities include ensuring IBBA procedures are properly followed including sampling (with appropriate documentation), accurately completed questionnaires, consent forms signed by the participant or the person obtaining consent and properly witnessed, forms being stored in a secure storage space, and data entry being accurately done. The supervisor will also ensure that the collection and transport of biologic specimens is being conducted correctly and that appropriate syndromic treatment for STIs, consistent with that provided by the Avahan program, is made available to the participants. The supervisor will have experience in quantitative research.

Community liaison staff will be attached to each sub-population data collection site. These staff will be recruited locally, and use their local knowledge to assist the IBBA team to select the sample according to the methodology laid out in the protocol. They will also be able to provide information on the studies and reassurance to potential respondents that the principles of confidentiality and anonymity will be strictly adhered to. It is likely that these liaison staff will have been previously working with the community, but current employees of an NGO being evaluated by the IBBA will be excluded. The community liaison staff will have no access to the data and will not handle completed questionnaires.

Interviewers: There will be three to four interviewers on each field team. For populations where time-location sampling is used, a sampler/counter will be responsible for recruiting eligible respondents into the IBBA according to the sampling plan, assigning each respondent to an interviewer, counting eligible respondents throughout the pre-determined time interval, maintaining the sampling flow with random recruitment of respondents, and completing the required documentation for the cluster. He/she will need to remain at the site the entire time to count respondents, even if the data collection is complete before the end of the sampling period.

The interviewers will be responsible for ensuring that respondents understand the IBBA procedures, risks and benefits; obtaining informed consent for both the behavioral and biologic components; and administering the questionnaire. The interviewer will sign on the informed consent form if the participant gives consent

to participate in the IBBA and an additional member of the staff will witness the consent process and sign the form to confirm that the process has been followed in full. The interviewers will be higher secondary literate, with prior participation in large-scale quantitative surveys. All interviewers will receive training in interviewing techniques, including how to protect confidentiality and the rights of participants.

Medical staff: There will be one medical professional on each IBBA team who will provide syndromic treatment in a manner consistent with the Avahan program, and who will take ulcer swabs on those respondents reporting symptoms of genital ulcers, if such ulcers are visible upon external exam. A trained medical person will be made available at a nearby referral site where participants will be able to retrieve their syphilis test results approximately a week to 10 days after data collection.

VCT: Results of the HIV test from the IBBA will not be made available to respondents or anyone else at any point (apart from those anonymously analyzing the data from the IBBA). Respondents wishing to know their HIV status will be accompanied to pre-selected VCT sites by an individual specifically trained to accompany them. There they can undergo counseling and testing for HIV (using a separate test and separate blood-draw from the IBBA).

Laboratory technician: There will be one laboratory technician on each IBBA team who will be responsible for drawing blood and collecting urine samples from the participant. The technician will ensure that the specimen tubes/bottles are labeled accurately, stored in a cold box, and transported safely to the testing laboratory.

Data entry operators: Due to the large volume of data that will be collected each day as a part of the IBBA, it will be necessary to enter data on a daily basis from the behavioral and biological IBBA procedures. Therefore, a data entry operator will be attached to every district to enable daily data entry that can be consolidated from all field locations into a centralized database.

Once the core research teams and the field teams are identified, there will be extensive training at all levels starting with a project orientation meeting for the core team of investigators, followed by training for field teams (including separate trainings for supervisors, interviewers, phlebotomists, team doctors, community liaison staff, VCT staff, district-level data entry staff, and district-level and state-level laboratory staff. Core team members will also receive ethics training based on FHI's research ethics training curriculum.

3.4.3 Field monitoring

There will be several layers of monitoring to ensure that the IBBA is being conducted correctly and informed consent is being obtained according to the approved protocol.

FHI, NARI, and the ICMR State Institutes will have ultimate responsibility for ensuring that the protocol is being followed accurately and that ethical standards are maintained. In this aspect the core staff at the district level will be accountable to the senior staff at the state level, and the senior staff at the state level will be accountable to NARI and FHI. The program managers and state-level field coordinators will be responsible for close monitoring of the components of the IBBA. They will make frequent site visits during the fieldwork, ensure adherence to IBBA protocols, and maintain ethical standards. The district field coordinators and supervisors of the field teams will form the last layer of monitoring. They will be responsible for day-to-day monitoring of the IBBA activities, including proper adherence to sampling procedures, completion of consent forms and questionnaires, specimen collection and handling, medical treatment, and data entry. They will be expected to take appropriate actions in the case of any breaches. ICMR, NARI, and FHI staff will make at least three field visits to each district in each round of the IBBA.

A community monitoring board will be established in each district (or smaller areas as necessary) to serve as a liaison between the IBBA sub-populations and the researchers. This group will be composed of individuals accepted and esteemed by their peers (i.e. the sub-population being assessed). Their function will be to monitor and provide feedback to the IBBA staff if procedures are not being handled appropriately.

3.4.4 Follow-up of participants

Follow-up of IBBA participants will be done through the unique respondent number. Following the interview and collection of biological specimens, the participants will be given a specific date after which they will be able to collect syphilis test results. They will be encouraged to go to specific referral clinics to collect their syphilis results. The benefits of returning for these results include free treatment in case of a positive syphilis test and further counseling and education for a safer and healthier life. Results of syphilis tests and treatment for those who are infected will be dispensed at participating Avahan clinics where possible, and other clinics where Avahan clinics are not in close proximity to the IBBA sites. Respondents who wish to be tested for HIV will be accompanied by NGO staff or other persons identified and trained for this purpose to previously identified VCT sites, where they can receive pre-test counseling, repeat HIV testing (results from the IBBA HIV test will not be made available for this purpose), and post-test counseling and referrals for further HIV/STI prevention and care and support services. The NGO (or other) staff will facilitate access to the VCT sites and serve as advocates for the participants. Post-test counseling for HIV will be done for every participant who goes to the VCT site, regardless of the test result.

Training on STI counseling will be provided to participating NGO (and other) clinic staff. The VCT services to be used during the IBBA will be identified and strengthened as part of the IBBA preparatory work and will be monitored throughout the assessment.

4.0 IBBA procedures

4.1 Sampling frame development

A list of primary sampling units (PSUs) will be needed for those sub-populations for which time-location cluster sampling is used. This is anticipated for all sub-populations with the exception of IDUs and MSM. The sampling frame will consist of physical locations where sub-population members congregate. The sampling frame must be complete, meaning that all such locations must be included and the list of locations should be up-to-date and reflect the current configuration of venues where the sub-population can be accessed. An incomplete or out-of-date sampling frame would increase the risk of obtaining a biased sample and should therefore be avoided. In addition, the types of sites to be included in the sampling frame will need to be specified in advance. For example, if the pre-survey assessment suggests that female sex workers can be found in brothels, bars, discos, hotels, lodges, parks, street corners, hair salons, bus stations, and train stations, a decision will have to made whether to include ALL such types of sites in the sampling frame or only a subset. This delineation will be documented and maintained over subsequent rounds of the IBBA to ensure consistency over time.

In some instances it will be decided to have multiple categories of sex worker, for either stratified sampling or separate sampling domains. It is recognized that sex workers often "cross over" different types of sex work (e.g., brothel-based, street-based, residence-based, etc). Information about this will be obtained in the questionnaire so it can be accounted for in the analysis.

In addition to the list of sites, information concerning important characteristics of each site will be needed to guide the sampling design. These characteristics include: times of day when sub-population members can be accessed at that site; any distinctive differences in the sub-population members frequenting the site at different times of the day or days of the week; information regarding whether the same sub-population members tend to frequent the site every day or whether there is turnover; information regarding whether sub-populations frequenting this site also frequent other sites; and an approximation of the number of sub-population members who can be expected to be present at the site at different times of the day, week, or month. Any seasonal patterns will be noted as well.

Developing such a list will require participation and collaboration by individuals and/or organizations that are close to the sub-population or part of the sub-population. This may include organizations that are

conducting programs or providing services for the population. In fact, such a list or partial list may already be available and usable as a starting point for a sampling frame. But disclosure of such lists can be sensitive, just as facilitating access to the community can be sensitive, which is why it is so important to build a trusting relationship with the community ahead of time.

Gathering information to construct the sampling frame will be one of the first encounters between the research team and the sub-population members. In parallel to this step a series of community preparation activities will take place to share information with key partners and gatekeepers about the purpose of the IBBA. The activities will include discussions about what the IBBA will entail, its risks and benefits to the community, and measures to protect the privacy of those who participate in the IBBA. The researchers will be prepared to respond to inquiries about the details of the IBBA and to receive input on how to ensure its success.

4.1.1 Size estimation

Size estimates will be done in the 29 districts selected for the IBBA plus the national highways. The groups for which size estimates will be done are:

- Female sex workers, brothel-based (FSW-BB)
- Male sex workers (MSW) or men who have sex with men (MSM)
- Injecting drug users (IDUs)
- Truck drivers and helpers (TD/H)

Note: Size estimates for clients of sex workers will have to come from household surveys conducted outside of the IBBA—for example, from the National Behavioral Surveillance Survey by NACO and the National Family Health Survey by the Ministry of Health and Family Welfare.

A combination of methods will be used for size estimates. It is generally advisable to use multiple methods because of the limitations of any one method. The choice of methods will depend on the population and the local situation and will be guided by the findings of the pre-survey assessment.

- **Enumeration –** In populations where a large proportion of the "members" can be found at sites or venues that are relatively stable—that is, (1) not too much movement of sub-population members between sites; and (2) sub-population members are present at the sites most of the time—then an enumeration (headcount or census) can be done. Such a count would involve visiting all sites/venues where sub-population members congregate for several days in a row and counting the number of sub-population members present. This information can be supplemented by key informants. If this method is selected the enumeration can be done during sampling frame development for the IBBA.
- **Multiplier –** This method uses IBBA data (whether by RDS or TLS) combined with service delivery or program statistics. The ability to use this method will depend on the quality of the data obtainable from local NGOs or service providers. The method will be possible only if NGOs (for example, Avahan projects or other service providers) collect data on the number of clients participating in their programs/interventions over specific periods; if the clients are identifiable by type (e.g., FSW-BB, FSW-NBB, MSW, etc.); and if the data are recorded/classified by type of client. If data are collected on visits or number of contacts as opposed to individuals, they will not be usable for size estimation. These issues are being investigated in detail during the pre-survey assessment. If the multiplier method is used then questions in the IBBA will have to be carefully constructed to capture whether respondents access the services being used to obtain the multiplier.

Note: An alternate method of obtaining the multiplier might be possible if high quality service statistics are not available. This alternate method would involve tagging potential respondents ahead of time (by giving them a

"gift" that they will remember, such as a key chain or an armband), and then documenting the proportion who report having received the gift as part of the IBBA. This would then serve as a multiplier.

- **Direct survey estimate with RDS adjustment –** This method would entail direct size estimation based on IBBA data collected using venue-based sampling. The limitation would be that it would not capture sub-population members who do not frequent the types of venues included in the IBBA sampling frame. To address this limitation, a separate abbreviated RDS assessment could be conducted for the purpose of finding out what proportion of sub-population members do not access the types of venues included in the IBBA sampling frame. This would provide a multiplier that would allow for an adjustment to the direct size estimate. This method would require that two IBBAs be done: the TLS sample for the behavioral and biological data and the RDS for the multiplier. Reduced sample sizes for the RDS assessment might be possible. Given the excess time and resources required, this approach might be used in a limited number of sites on a trial basis to see whether it is useful enough to consider for size estimation in other sites.

- **Capture-recapture –** This method involves "tagging" members of a sub-population at given locations during specific periods and then repeating the exercise later. Based on the overlap (people who are tagged and retagged) and those not retagged, the size of the population can be estimated. The method relies on a number of assumptions: (1) samples taken at time one and time two must be independent of one another (that is, not correlated); (2) each member of the population should have an equal, non-zero probability of being captured; (3) the individuals identified in both captures must be correctly identified as recaptures, and no one else should be identified as a recapture; and (4) there should be no major in-migration or out-migration from the population between the initial and the second capture. Given the difficulties of not violating these assumptions, this method is likely to be of limited use. However, it may also be subjected to trial in a limited number of sites.

Based on the information currently available, the table below indicates the proposed method of size estimation for each population, subject to change after the pre-survey information is available.

Population	Sampling method for IBBA	Proposed size estimation method	Alternate method (If good service statistics not available)
FSW-BB	TLS	Enumeration plus multiplier using IBBA data and service statistics	Direct estimation
FSW–NBB	TLS	Multiplier using IBBA data and service statistics	Direct estimation
MSW/MSM	RDS	Multiplier using IBBA data and service statistics	Direct estimation coupled with RDS
IDU	RDS	Multiplier using IBBA data (from RDS sample) and service statistics	
LDTD	TLS	Multiplier using IBBA data and service statistics or truck company data	

4.2 IBBA procedures

4.2.1 The behavioral assessment

For the behavioral assessment, standardized behavioral questionnaires for the different sub-groups included in the IBBA will be used. Care will be taken to ensure that the data needed for impact modeling are also gathered in the IBBA. The information that will be obtained using the behavioral questionnaire will include:

- Socio-demographic characteristics
- Sexual history and practices (penile-vaginal, oral, anal)
- Types of sex partners
- Condom use with different type of sex partners
- Knowledge of STIs and STI care-seeking behaviors
- Knowledge and attitudes toward HIV/AIDS
- Sex purchasing and selling behaviors among males with other males
- Needle, syringe, and drug-sharing practices among IDUs (and other groups who may inject, such as FSWs)
- Questions related to mobility
- Exposure to Avahan and other HIV/AIDS prevention interventions

The questionnaires will be adapted to local needs (language; terminology) and will be pre-tested in all IBBA areas. Before pre-testing, the questionnaires will be checked for appropriate sequencing and skip patterns, translated to the local language(s) of each state, and back-translated to check the accuracy of the translation. Pre-testing the questionnaires will include checking to make sure that the questions are interpretable in a commonly understood manner and that the original meaning of the questions have been kept intact in the process of adapting them. An instruction manual will be developed for interviewers and supervisors that will cover the questionnaire one question at a time, explaining in full each question's rationale and intended meaning.

4.2.2 Clinical procedures

IBBA procedures for STI testing and treatment and HIV testing and counseling are outlined in the table below.

Venous blood draw on FSW, MSW, MSM, clients of FSW HIV (prevalence/incidence) Syphilis (RPR≥ 1:8, TPHA) HSV2 on subset Dry blood spot IDUs HIV (prevalence/incidence), HBV, HCV, syphilis (Treponostika)
First catch 20 ml urine–prepare and store for Ng/Ct testing using nucleic acid amplification tests (NAATs) Self administered vaginal swab – prepare and store for Ng/Ct using NAAT
Ulcer swab mPCR for TP/HD/HSV2 if report external clinical ulcer

Treatment and follow-up
Syndromic management for STIs consistent with Avahan guidelines
Refer to Avahan clinic if report symptom of ulcer which cannot be identified by external examination
STI and HIV education
Provision of syphilis serology test results and free treatment if positive
Escort to VCT center for retesting (for those who so desire)

The decision to obtain urine for a self-administered vaginal swab will depend on the final decision regarding which NAATs test kit is chosen for the study sites and the willingness of the participants to take a self-administered swab. There is extensive experience globally with self-administered vaginal swabs as a well accepted, easy method to obtain specimens for NAAT testing.

4.2.2.1 Rationale for STI/HIV testing

As part of the IBBA participants will be tested for STIs and HIV. Following consent procedures (see details below), a venous blood sample and a urine specimen or self-administered vaginal swab will be collected. For IDUs a dry blood spot will be obtained in the place of venous blood. All testing will be linked anonymous testing, whereby all specimens are linked only to a unique respondent number.

Participants will be given this number and told that they need to keep the number in order to obtain their syphilis test results, if they so desire. This number system will be supplemented with a personal password/code word system as recourse for participants who lose their numbers.

After completion of the behavioral questionnaire and collection of specimens, sex workers (both male and female) will be provided with syndromic STI treatment in a manner consistent with the Avahan program. Ulcer swabs will be taken from all who both report ulcer symptoms and are found upon external examination to have a genital ulcer. Treatment will be given and ulcer swabs transported with the urine and blood samples. Participants whose symptoms are more complex (who have internal ulcers, for example) will be accompanied, if they agree, to NGO clinics for more comprehensive evaluation and treatment. Results of syphilis serologic testing will be available at the NGO clinics at a specified time after recruitment. Because results will be labeled only with the identification number, participants will need to present with their numbered cards to obtain syphilis results. NGO outreach and peer educators will enforce the importance of returning for syphilis test results and treatment. All participants will know through the consent process that their blood is being drawn for syphilis and HIV testing and that it will be stored for potential future research on HIV infection.

IBBA respondents wishing to know their HIV status will be aided by an individual specifically trained to accompany IBBA respondents who so desire to pre-selected VCT sites, where they can undergo counseling and testing for HIV (using a separate test and separate blood-draw from the IBBA). This facilitation will include accompanying the participant to the VCT site and paying transport costs and user fees if necessary. The NGO outreach worker/peer educator will act as an advocate for the participant at the VCT site as well as reporting back on the quality of the service with respect to accessibility.

The VCT services to be used during the IBBA will be identified, strengthened and monitored as part of the IBBA preparatory work. During the pre-survey assessment for the IBBA sites, existing VCT services – both government and private, will be identified. In sites where there are no readily accessible VCT sites, a temporary VCT site will be set up. Based on key informant interviews with health providers and others in the community, the ones providing the best quality of services will be identified from multiple sites. These VCT services will be approached and asked to participate as referral counseling sites. Those that agree to participate will undergo refresher training in HIV counseling as well as sensitivity training for issues of the

target populations (including IDUs, MSWs, and FSWs). Community representatives will be part of this training. As part of site preparation, clear referral networks will be documented for HIV-infected persons for referral from the VCT site and NGOs will also document service referrals at their sites if they are at significant distance from the VCT site.

Strengthening the existing VCT sites to provide results to IBBA participants increases costs and management complexity for the IBBA but has several advantages:

- It uses and strengthens existing infrastructure that is likely to be sustainable.
- It will make subsequent rounds of IBBA easier to implement.
- It will build relationships with government sectors.
- It will enhance the services of the government sites to make them more accessible to marginalized populations.

In addition, use of independent VCT sites addresses the expressed preference of members of the community not to have the NGOS working with them know their HIV status.

The monitoring will be done by the NGO staff accompanying the participants (for those participants who want to be accompanied) and periodic assessment visits by ICMR and FHI.

Details of specimen collection and clinical procedures

The clinical procedures involved in STI prevalence studies are standard medical procedures for clinical examination and clinical specimen collection. Everyone involved in clinical procedures will be medical personnel.

- Collection of 20 ml of first-catch urine, at least two hours since last void, or self-administered vaginal swab for nucleic acid amplification testing for N. gonorrhoea and C. trachomatis.
- Collection of up to 10 ml (generally 7 ml in a vacutainer) of venous blood to test for HIV and syphilis serology. A subset will have stored serum tested for HIV incidence (BED-CEIA) and HSV2. Remaining sera will be stored for quality control testing for a short term or (if participants have consented) for a long term.
- For patients reporting GUD symptoms, an external examination will be performed, including inspection of genital and anal areas and local lymph nodes, to identify any local changes: erythema, warts, abrasions, ulcers, swelling, and discharge. All genital and anal ulcers identified will be sampled with a Dacron swab for T pallidum, HSV-2, and H ducreyi using multiplex PCR.

At the conclusion of the IBBA activities, the participants will receive group education on STIs and HIV, be provided with IEC material and information about NGOs/CBOs in the district, and be directed to condom outlet points and other service providers such as providers of health care and legal aid.

4.2.2.2 Consent procedures

A detailed and standardized consent process will be conducted for each respondent. Respondents will be asked for written consent to participate in the IBBA with an option of oral witnessed consent if they prefer. The purpose of the IBBA and the IBBA procedures will be explained in simple and understandable terms, in the local language. The potential participants will be informed that all information and discussions will remain confidential, that their participation is voluntary, that they may refuse to answer any questions, and that they may leave the IBBA at any time. They will also be informed that their non-participation will not affect medical treatment if they seek it. The prospective participant will be asked to explain the activities of the IBBA back to the interviewer and witness to confirm an understanding of the procedure. The potential

respondent will be asked to give written consent for the behavioral questionnaire and the biologic samples separately. If the prospective participant does not wish to give written consent, he/she may also give oral witnessed consent to participate in the IBBA. In the case of oral consent, once the members receiving the oral consent are convinced that the participant understands what has been agreed upon, the interviewer and the witness will sign the consent form, which declares:

> *I have read and explained this informed consent form to the IBBA participant in* (name of local language). *The participant has explained the IBBA activities back to me and I am convinced that the participant understands the activities that will occur. The participant has not been coerced to participate and has given oral consent to participate in all aspects of this IBBA.*

If the participant refuses to participate, the IBBA staff will respect the respondent's rights and thank them for their time.

4.2.3 Field data flow

Forms for each respondent will be kept in a folder. Each respondent will be given a unique respondent number. All forms for a given respondent will contain that number with the exception of the consent form. The questionnaire will contain information on location, time and date of interview, the name of the consent staff member, interviewer, doctor, supervisor, and data entry clerk(s). The folder will contain:

- The consent form (signed and witnessed)
- The completed questionnaire

The supervisor will sign the cover of the folder after checking the forms for accuracy and completeness. Immediately thereafter, the consent form and the completed questionnaire will be separated. All folders will be taken to a secure location each night.

4.2.4 Field collection, transport, and storage of biological specimens

Approximately 10 milliliters of venous blood will be collected in red top vacutainer tubes and labeled with the participant's unique number and date of collection. This will be placed in a cold box that will be transported to the district laboratory at the end of each IBBA session each day. At the district laboratory, the specimen will be centrifuged and the serum aliquoted into four tubes and labeled with the IBBA respondent number and date of collection. After performing the syphilis tests, the serum will be retained for confirmation and quality control. All samples will be frozen for transport to the state laboratory.

First catch urine samples (20 milliliters) will be transported to the district laboratory, where they will be aliquoted into three 1-milliliter tubes and then frozen for transportation to the state laboratory.

4.3 Laboratory procedures

Blood, swabs, and urine specimens will be picked up by the laboratory technicians for laboratory tests.

- HIV: Screening for HIV will be done using enzyme-linked immunosorbent assay (ELISA). A positive HIV screening test will be confirmed with a second ELISA and then undergo the BED-CEIA test (see below).
- Syphilis serologic testing performed on sera using a quantitative rapid plasma regain (RPR) screening test with a qualitative treponema pallidum hemagglutination assay (TPHA) confirmation test.
- Polymerase chain reaction (PCR) for N. gonorrhoea, C. trachomatis. First catch of 20 milliliters of urine will be stored in a cold box until it is transported for processing to laboratories with capacity to perform PCR tests.

- Multiplex Swab on reported and clinically identified genital or anal ulcers. Dacron swab stored dry at -70°C. Subject batched specimens to multiplex testing for T pallidum, H ducreyi, and Herpes simplex Type 2.
- HSV-2 serology.
- HIV incidence testing: The newly developed BED-CEIA (HIV-1 subtypes B, E, and D, IgG-Capture Enzyme ImmunoAssay) that has also been validated with the Indian sub-type C assay will be used for measuring incidence of HIV.

4.3.1 Laboratory sample allocation and management

At the district laboratory, the specimen will be centrifuged and divided into four aliquots of serum. One of the aliquots of serum will be used for syphilis testing locally, and the remaining aliquots stored frozen in preparation for transport to the state level laboratory.

The state laboratory will carry out the activities outlined and act as a staging station for frozen samples destined for the central laboratory.

The central laboratory (NARI in Pune) will receive and store all samples from the state laboratories, and carry out HIV incidence testing. All quality assurance activities will be managed from the central laboratory.

Long term storage of specimens: A protocol will be developed by ICMR and NARI on long-term storage of specimens so that specimens could be used for additional testing at a later time.

4.3.2 External quality assurance

The standard operating procedures and basic minimum standards will be agreed with NARI, who will draw up an implementing laboratory supervision and quality assurance schedule. Ten per cent of all samples will be re-tested in a different laboratory according to an agreed quality assurance panel construction.

4.4 Data analysis

The questionnaires for the IBBA will be checked daily for completeness and accuracy by the field team supervisors and transported daily to a central location. At this center, the questionnaires will be stored in a secure place. Data on the questionnaires will be entered into CSPro (or other appropriate data entry program) on a daily basis. Cluster information (needed for analysis) will also be entered into an appropriate database on a daily basis. All biological specimens will also be labeled with the corresponding unique identification number. Results of the laboratory tests will be entered into the database as and when the test results are available. Checks will be built into the data entry software to avoid data entry errors. Double data entry will be done to maximize accuracy. Analysis of the IBBA data will be done in SPSS for the TLS samples and with RDSAT for the RDS samples.

4.5 Pilot test

Subsequent to pre-testing and finalizing questionnaires, a full pilot test will be conducted in one of the IBBA districts of each state. The pilot test is meant to be a “dry-run” of the entire process prior to the main survey. Its purpose is to test the process (focusing on sampling and operational procedures) before going to scale. The pilot will:

- Be done in one IBBA Avahan district in each state and will be staggered so that sex workers (female, male, transgender) are done first (It is anticipated that the first pilot will take place in Andhra Pradesh.)
- Include 25 respondents per group (in each state)
- Allow for testing the sampling strategies for different groups

- Allow for testing the specimen collection and transport procedure
- Allow an estimation of the refusal and duplication rate to guide required sample size inflation for the main IBBA where necessary
- Allow testing of the consent procedure
- Include information (lessons learned) that can be incorporated into the field guidelines for the main IBBA

Note: ***In populations where RDS sampling is used, a full pilot of the sampling process will not be possible. However, the rest of the IBBA process can be piloted.***

5.0 Potential risks and benefits

5.1 Potential risks

All efforts will be made to minimize the risks to the participants.

There will be no physical risks involved for any of the participants during the data collection process (pre-survey activities, construction of sampling frame, collection of behavioral data). There are no physical risks that are more than any risk of a routine STI examination and venipuncture. There are minimal risks of bleeding and bruising related to venipuncture. Physical risks involved in collecting blood by venipuncture and while obtaining swabs specimens will be minimized by the use of medically trained personnel to draw blood and collect biological samples. The IBBA will also ensure adequate supply of new, sterile disposable needles. Puncture-proof containers will be used for needle disposal and biological waste will be disposed of in an appropriate manner.

The interviews conducted during the pre-survey activities and development of the sampling frame will focus mainly on group and location characteristics. Therefore, there is no perceivable individual harm done to individuals of the sub-population during this phase of the project. However, the exercise might result in the group or the locations mapped becoming more conspicuous, leading to stigmatization or harassment of the group by law enforcement agencies and others. There is a possible psychological risk due to the sensitive nature of the questions in the behavioral and biological questionnaire. The questionnaire will be administered in a private setting, it will not contain identifiers, and the participants will be told that they can refuse to answer any questions. There are also some psychological risks from learning that one is infected with an STI or HIV. These will be handled by providing counseling about STIs/HIV and about reduction in HIV-related risk behavior.

There may be social risks of being diagnosed with an STI. In general the psychological and social risks of being diagnosed with HIV infection are more severe than the risks of being diagnosed with other STIs. The IBBA protocol will pay particular attention to confidentiality procedures and will ensure high quality training of IBBA staff and HIV counselors. Participants will be assigned a unique respondent number at the time of enrollment. No identifiers will link STI results with IBBA participants.

5.2 Potential benefits

At an individual level, the participants will be treated syndromically on the day of the IBBA for STIs in accordance with the Avahan STI Clinic Operating Guidelines and Standards. The IBBA will contribute to the improvement of the health of the individuals and their health seeking behavior through counseling by the IBBA team doctors. Participants will be referred for retrieval of syphilis test with free treatment as necessary.

By providing enhanced access to HIV voluntary counseling and testing services to those who so desire, the IBBA can contribute to the positive living of people who test positive for HIV and enable HIV secondary prevention efforts. Those who test negative will be counseled to eliminate their risk of HIV infection by

adopting safe behaviors. The information obtained from the IBBA will be used to design HIV prevention interventions for the population sub-group and also to provide care and support services for those infected and/or affected by HIV.

6.0 Ethical review

The protocol and draft questionnaires will be reviewed for approval for the two rounds of the IBBA—baseline in 2005 and endline in 2009—by the institutional ethics committee of each partner institute that will implement the IBBA in different locations. In addition, the protocol will be submitted to the Health Ministry Screening Committee of the Ministry of Health and Family Welfare and to the Protection of Human Subjects Committee (PHSC) of FHI. In addition to the protocol, the consent forms and the draft questionnaires will also be submitted for approval to the PHSC. Approval will be obtained from all the above-mentioned review bodies prior to subject recruitment.

7.0 Monitoring plan

Explicit monitoring plans will be developed to ensure that the IBBA teams adhere to all provisions designed to protect the rights of voluntary participants during the assessment. ICMR and FHI will be responsible for the overall monitoring of the IBBA. This will include:

- Review IBBA procedures to ensure that the protocol guidelines are followed and any amendments if required are approved by the appropriate committee
- Verify that informed consent was correctly administered for all participants by reviewing signed copies of the consent forms
- Ensure adverse event reporting and that any participants experiencing adverse events have been appropriately treated and referred for further care if necessary
- Conduct monitoring visits during the fieldwork
- To preserve confidentiality of participants, ensure that the IBBA data collection instruments and biological samples are being stored properly and that only the necessary staff have access to that data
- Ensure data entry is being done appropriately
- Oversee the process of data analysis and report writing

8.0 Ethical issues

Keeping in mind the sensitive nature of the IBBA, topmost priority will be assigned to the protection of participants at all phases of the assessment and during dissemination of the results. The IBBA has been designed to maximally protect the participants balanced with the individual benefit and community benefits from this IBBA. Specifically:

- Participation will be voluntary, with subjects free to withdraw at any time. Withdrawal will not affect services they would normally receive.
- Informed consent is written, with the option of oral witnessed consent. The consent form will be translated and pilot-tested. This consent will be translated into the local language. Participants will be offered a written statement regarding the research. The ethical committee of the ICMR in India felt that written consent is the preferred method to obtain consent for IBBA. They realized, however, that signed consent might deter participation, given the clandestine and potentially illegal nature of some of the behaviors of the study participants. As such, the committee also wanted the option of a witnessed oral consent. Use of oral consent is appropriate as per 45 CFR 46, 46.117(c).

- No names will be recorded except on the signed consent form, which will be stored separately from all other project documents (e.g., completed questionnaires, laborarory results, etc.). All documentation is anonymous, linked only by a unique respondent number.
- IBBA staff will be trained in discussing sensitive issues and protecting participants' confidentiality and human rights.
- Specific procedures have been developed to ensure that there is maximum anonymity and that there are no reprisals by employers for non-participation.

8.1 Security policy for protecting IBBA population confidentiality

A uniform security and confidentiality policy for protecting study populations should be followed throughout the IBBA process. This includes information related to the protocol and methodological guidelines, mapping of sites, sampling frame, selected clusters, consent forms with personal identifiers, interview schedules including sexual and behavioral information of respondents, and biological specimens. Security and confidentiality will be ensured at all steps by the following measures:

- ICMR Institutes that subcontract research agencies for implementation of any IBBA activity including mapping, sampling frame preparation, sampling, interviewing, and specimen collection will sign an agreement with the ICMR Institutes. The research agency will follow the agreement and the ICMR Institutes will ensure implementation of the agreement. Any breach in agreement will be reported to the ICMR ethical review committee and FHI PHSC.
- The research agency will inform each and every employee regarding the confidentiality policy and each employee will sign an oath of confidentiality.
- Operational guidelines on data and specimen security for protecting IBBA populations confidentiality have been developed. This includes data and specimen safety procedures during and after data collection at field level, at district laboratory and district offices of research agencies, and at ICMR institutes and ICMR laboratories. ICMR will ensure the implementation of the guideline at all levels.
- The operational guidelines state that use of public computers is allowed ONLY under exceptional circumstances where no other communication method is available. The following precautions should be followed in such situations: prior approval from the NARI director before using public computers; use of public computers to send IBBA-related information should be done no more than once a week by a senior-level staff member in presence of a supervisor; and files should not be loaded on the hard disk of the computer, but rather transmitted directly using an extended drive, USB device, or a diskette.

9.0 Dissemination plans

A written report of the results of the IBBA will be provided to the Ministry of Health, the National AIDS Control Organisation, SACS, Bill & Melinda Gates Foundation: Avahan India AIDS Initiative, Avahan partners, and other NGOs and agencies in the country working on STI and HIV issues. Attention will be given to the sensitivities attached to the social risk of those groups included in the IBBA when preparing reports. At the end of the IBBA, a one-day workshop will be held in each of the five states to disseminate the findings from the assessments. Workshops will also be held to disseminate the findings from IBBA on the National Highways. An oral debriefing will be done with key interested parties including relevant ministries, other donors and key NGOs, and specific disseminations will be done for the population sub-groups included in the IBBA. Results from this assessment will be presented at national, regional, and international meetings and published in international peer-reviewed journals.

Dissemination of HIV prevalence levels from the various populations at the district level will not be made publicly available. Circulation of these district-specific data will be limited to Avahan, FHI, ICMR, NARI, and selected State Government partners. Only data aggregated at the state level on HIV will be disseminated publicly.

10.0 Project outputs

10.1 IBBA outputs

- A measure of size of each sub-population in each district included in the IBBA will be obtained. This information will feed into the models to gain estimates of number of infections averted.
- Key HIV, STI, and drug-injecting risk behavior indicators and related knowledge and intervention exposure indicators, as outlined in section 4.2.1, will be identified.
- HIV prevalence and incidence data will be obtained.
- STI prevalence data will be obtained.

This data will be critical to the construction of the models that will yield the overall impact numbers, in terms of infections averted.

Appendix 2

2

Community liaison

This guideline is adapted from the field manual for the IBBA for FSWs, their clients, MSM, and *hijra* (transgenders). This document guides the supervisor in identifying the community liaison (CL) and details the responsibilities and activities of the CL.

Part I: Identification of a community liaison (CL)

Who can be a community liaison?

The CL is a member of the survey team and acts as an interface between the team and the community at all stages of the fieldwork. The CL reports to the field team supervisor.

A CL can be (1) an individual from the survey group in the district where the IBBA survey will take place, or (2) in the case of a survey of clients of FSWs the CL can be drawn from stakeholders or others who have positive relationships with the survey group.

CLs do not include people who are power holders who can force or coerce individuals into participating in the survey.

Examples of community liaisons for the various IBBA surveys are:

- FSW survey – FSW
- MSM survey – MSM
- Hijra survey – *Hijra*
- Intravenous drug users (IDU) survey – former IDU
- Client's survey – individuals having relationships with clients, such as brothel madams, pimps, paan wallahs, tea shop owners, and regular partners of FSWs

Roles of the community liaison

- Community preparation
- Building rapport with stakeholders, gatekeeper, and community members during fieldwork
- Identifying members of the survey group
- Rapport building with selected respondents
- Being a witness for consent (when needed) and screening (for RDS)

- Clarifying or assisting with participation (when needed)
- Addressing concerns of respondents and community members and ensuring adherence to harm minimization guidelines

How is a community liaison identified?

Local NGO's, including their peer educators, may be helpful in identifying community liaisons. The survey team may also have built relationships with the community during mapping activities. Talk to several people before selecting a community liaison, so that the selected individual is well-respected by the community. For the clients' survey, speak with clients, regular partners, and FSW to find out who the community trusts.

How many community liaisons are required for a survey?

Each field team will have one CL. In a cluster sampling survey, the team may choose several CL team members, depending on areas being covered by the survey. For example, urban brothel areas may be covered by a brothel-based FSW from that town, and urban street-based sites covered by street-based FSWs from that town, etc. Selecting CL based on type of group (e.g., brothel-based, street-based, etc) and geographic locality ensures that the CL is familiar with the locality. The supervisor should *not* involve a specific CL in sites where she/he is actively involved (e.g., by soliciting or cruising at the site).

What are the important qualities of a community liaison?

The community liaison should be

- a person from within the community but not from the same area where the survey is happening;
- able to converse in the local language;
- able to access and have rapport with members of the community;
- a good communicator;
- able to identify with the community;
- respected by community members and have good relationships with them;
- willing to be associated with the project for the duration of the IBBA fieldwork, including the training period; and
- willing to work in unstructured situations and at odd hours, and to travel extensively.

Does the community liaison need training?

The supervisor orients the CL to the IBBA, including discussing the purpose of the survey, its benefits and risks, and harm minimization procedures. The supervisor also discusses the role of the CL and ensures that the CL accompanies the team during the mock fieldwork (during training) so they start to understand their role in fieldwork. Training on the role of the CL is also part of the field teams' training.

Part II: Specific responsibilities of a community liaison

1. Community preparation

Community preparation builds relationships in the survey community, to help the team understand the community's concerns about the survey and to strategize on how to conduct the IBBA. Along with the supervisor (and possible other team members), the community liaison:

- explains the survey's purpose, benefits, and harm minimization in simple terms;
- builds relationships and gains the support of stakeholders, gatekeepers, and survey group members;
- ensures that key persons are aware that an IBBA survey will take place in their area;
- helps understand and address community concerns about the survey;
- helps identify venues for conducting the survey;
- discusses with the supervisor the site dynamics and issues that should be addressed; and
- helps prepare the survey team to work with the community by addressing the survey team's concerns and apprehensions.

2. Building rapport with stakeholders, gatekeepers, and community members on the day of the survey (cluster sampling surveys)

A key role for the CL is to help gain cooperation at the survey site when the survey team initially arrives. The following steps occur (under the guidance of the supervisor) before sampling starts:

- With the field supervisor, approach and talk to the key gatekeeper(s) at the site.
- Briefly explain that the survey team is there to conduct a health survey and that they will be asking community members to participate, and gain their support for this.
- Explain that participation in the survey is voluntary, and that no personal identifying information will be collected.
- Provide reassurance that all information collected will be absolutely confidential and not shared with anyone.

3. Identifying members of the survey group (cluster sampling surveys)

In many sites that are public place (e.g., bus stops and beaches), it may be difficult for the team's counter to identify and list all members of the community. The CL works with the supervisor and counter at the selected site to help identify members of the survey group. The CL needs to be familiar with the eligibility criteria and site boundaries to do this.

4. Rapport building with selected respondents

In a cluster sampling survey, once the supervisor has gone through the sampling protocol and selected respondents, the CL (with the supervisor) approaches the respondent and interacts with them briefly. At this time the liaison engages the respondent in a conversation about general matters to build rapport. Then the liaison asks the respondent if he or she is willing to participate in a health survey and can spare the time to speak to the supervisor. Together, the supervisor and CL briefly explain the IBBA survey, and if the individual agrees, the CL (or other field team member) accompanies that person to the IBBA venue.

With an RDS survey, the CL is involved in greeting individuals as they come to the RDS venue and making them comfortable before inviting them for screening in the survey.

5. Being a witness for consent (when needed) and screening (for RDS)

The CL can be present, if requested by the interviewer or respondent, when the consent form is administered. At this time the liaison clarifies any doubts the respondent has about the survey, if the interviewer is not able to do so. The CL's role is a supporting one, to assist the interviewer by helping to address the respondents' concerns. The CL does not (by himself or herself) talk to respondents about the IBBA or administer the consent. When in doubt, the liaison provide assurances to the respondent that the principles of confidentiality and anonymity will be strictly adhered to.

When the respondent consents to the interview, the liaison is present as a witness and signs the consent form as such, if the respondent does not want to sign the consent himself or herself.

After witnessing the consent, the liaison leaves the respondent with the interviewer and moves to talk to the next selected respondent.

With an RDS survey, the CL may be involved in screening to ensure that the individuals understand the purpose of the survey, their rights, and to confirm that they are members of the survey group. This is helpful for the screener, because the CL is more familiar with common terms that community members use. For example, a drug user may be asked to describe how he or she injects and a CL would be able to assess if the individual is an injecting drug user better than the screener.

6. Clarifying or assisting with participation if needed

There may be some terms or questions during the interview that the respondent is unfamiliar with and use of local terminology would help in explaining the question. Although many of these concerns will be addressed during pre-testing of the questionnaire, the CL may help with this when needed during the interview. The CL should not be involved in the entire interview, as this may bias results. Instead, the CL helps with specific questions if needed.

The CL may accompany respondents to the laboratory technician site where biological samples are collected. The CL helps put respondents at ease if they are agitated, or concerned about the collection of blood. The liaison does not ask them about or talk about the behavioral questionnaire, or ask them if they have consented to giving samples. The CL only responds to respondents' questions or concerns.

If a respondent asks the CL if he or she should give biological samples, the CL should clarify any doubts the respondent has but state that providing samples is the respondent's choice. No staff member should coerce or pressure the respondent to consent to giving biological samples. Staff members may be present at the time of the sample collection, if the respondents requests them to stay.

7. Addressing concerns of respondents/community members and ensuring adherence to harm minimization guidelines

Measures will be in place throughout the survey process to reduce any potential harm to respondents. Throughout the survey a key role of the CL is to respond to the concerns of the community members and or respondents at the survey site. When respondents or community members at the survey site have questions about the IBBA, the CL assists the survey team in clarifying the doubts or concerns. Since it is very likely that community members and respondents will identify with the liaison on the team, the liaison is key to addressing problems at the survey site along with the supervisor.

Adverse events can happen in the field for many reasons: a respondent may become upset or madams or police or local community members may cause problems. The CL works together with the supervisor to address the situation at the site (in accord with guidance from the project manager) and also assists with completing an adverse event report.

Appendix 3

3

Adverse event report format

1. Participant ID number _____

2. Date the adverse event reported _____

3. Type of adverse event: (circle one)

a. Grade 1: Mild adverse event

b. Grade 2: Moderate adverse event

c. Grade 3: Severe adverse event

4. Name of state _____ 5. District _____

6. Date when the adverse event occurred _____

7. Where did it occur? (Circle one)

a. on the streets b. in brothel c. at home

d. at lodge e. in clinic f. at cruising spot

g. any other (specify) _____

8. Describe the nature of the adverse event.

a. Site _____ b. Type of sub-population _____

c. Date (DD/MM/YYYY) when this occurred _____

d. Time _____

e. Description (Attach a separate sheet, if necessary.)

_____

_____

_____

_____

_____

9. In addition to the study participants, who reacted against it?

1. Others from risk category

2. NGO

3. Press/electronic media

4. Police

5. Social activists

6. Any other

10. Category (outcome) of the serious adverse event:

a. at individual-level (circle one)

1.Attempt to commit suicide/death

2. Incapacity secondary to physical violence

3. Separation from the partner

4.Isolation in the brothel

5. Required intervention to prevent permanent impairment

6. Any other (specify):

b. at community-level (circle one)

1. Police raid

2. Negative story about IBBA in press

3. Reported drop-in clients

4. Any other (please specify)

11. Relationship of serious adverse event to IBBA implementation: _____

1 = Unrelated

2 = Possibly related

3 = Definitely related

12. In your district have similar adverse events occurred in the past while implementing IBBA?

(Circle one): 1. Yes 2. No

If "Yes," how often? (Provide the participant ID numbers of other reports.)

13. Did it occur while this investigator was involved? 1. Yes 2. No

14. Please describe remedial actions taken in the past.

15. What immediate steps were taken in response to the adverse event?

16. What steps do you propose to take as a result of the adverse event reported above?

Provide documentation to the IRB (local ethical committee) for review and approval of any of the steps checked below.

1. No action required
2. Propose amendment to study protocol
3. Amend informed consent document
4. Terminate or suspend protocol
5. Any other (describe):

17. Please write the current status of the adverse event?

a. Unresolved

b. Persistent

c. Partially resolved

d. Completely resolved

Signature of principal investigator: _____

Date: _____

Appendix 4

4

Adverse event resolution form

Female Sex Workers
Integrated Behavioral & Biological Assessment

1. Participant's ID number _____ (Fill in the same number from the adverse event report)

2. Date adverse event reported _____ 3. Date of resolution _____

4. Type of adverse event: (circle one)

   1: Mild adverse event

   2: Moderate adverse event

   3: Severe adverse event

5. State _____ 6. District _____

7. Briefly describe the method of resolution that was chosen, why, and who is responsible for overseeing its implementation.

_____

_____

_____

_____

_____

8. Who was involved in making the decision?

_____

_____

_____

_____

_____

Signature of principal investigator: _____

Date: _____

Appendix 5

5

Laboratory assessment tool

Name of the laboratory_____

Name of the director_____

Address _____

City/town_____District_____ _____

Telephone _____ Mobile _____

1.Laboratory operations

	Primary health center/area hospital/private lab	District hospital lab/private lab	Medical college lab/ specialist lab
a Is the lab building in good condition with adequate space?	Yes No	Yes No	Yes No
b. Is the laboratory connected to hospital?	Yes No	Yes No	Yes No
c. Is electricity available in the lab >90% per day or is there a back-up generator?	Yes No	Yes No	Yes No
d. Is running water available >90% per day?	Yes No	Yes No	Yes No
e. Is there a computer with Internet?	Yes No	Yes No	Yes No

2. Specimen collection, labeling, and handling

	Primary health center/area hospital/private lab	District hospital lab/private lab	Medical college lab/ specialist labs
a. Do physicians use standard lab forms to order tests that contain patient information: contact address, specimen source, date and time of collection, type of test requested?	Yes No	Yes No	Yes No
b. Are specimens that are received/ collected in the lab labeled with the patient's name/unique identifiers?	Yes No	Yes No	Yes No
c. Does the laboratory have a log book/electronic record of all specimens sent for diagnostic testing?	Yes No	Yes No	Yes No
d. Does the lab have a specimen storage and discard policy?	Yes No	Yes No	Yes No
e. Are standard acceptance and rejection criteria used for specimens with prolonged transit times/hemolysed serum etc. (time of collection to time of processing in lab)?	Yes No	Yes No	Yes No

3. Volume of tests performed in the laboratory

Name of the test	Primary health center/ area hospital/private lab # per month	District hospital lab/ private lab # per month	Medical college lab/ specialist labs # per month
a. Gram stain Urethral swabs Vaginal swabs Rectal swabs			
b. Wet mount			
c. KOH			
d. VDRL			
e. RPR			
f. TPHA			
g. Culture and sensitivity			
h. Chlamydia antigen			
i. TV culture			
j. BV Nugent score			
k. HIV rapid test (Name)			
l. HIV ELISA			
m. HBV antigen.			
n. Others			

4. Human resources (laboratory directors/supervisors/technicians/assistants)

	Primary health center/area hospital/ private lab	District hospital lab/private lab	Medical college lab/ specialist labs
a. Does a qualified lab director supervise the laboratory?	Yes No	Yes No	Yes No
b. Does the lab employ qualified supervisors?	Yes No	Yes No	Yes No
c. Do qualified medical technologists always perform tests?	Yes No	Yes No	Yes No
d. Are continuous training and mentoring of technologists conducted?	Yes No	Yes No	Yes No
e. Does the supervisor/director review reports before sending?	Yes No	Yes No	Yes No

5. Laboratory quality assurance systems

	Primary health center/area hospital/private lab	District hospital lab/private lab	Medical college lab/ specialist labs
a. Is a written, organized standard operating procedure and quality control (QC) program in place?	Yes No	Yes No	Yes No
b. Does the laboratory use internal QC in each test run?	Yes No	Yes No	Yes No
c. Is the performance of internal QC recorded and monitored?	Yes No	Yes No	Yes No
d. Does the laboratory participate in EQAS?	Yes No	Yes No	Yes No
e. EQAS VDRL/RPR/TPHA?	Yes No	Yes No	Yes No
f. Is there any process for documentation of remedial action when QC is not valid?	Yes No	Yes No	Yes No
g. Is there any process for monitoring and making corrective action?	Yes No	Yes No	Yes No
h. Is there an equipment preventive maintenance system?	Yes No	Yes No	Yes No
i. Does the lab have a system for regularly monitoring quantities for reagents and supplies so that no stock shortages occur?	Yes No	Yes No	Yes No
j. Are EQAS reports available?	Yes No	Yes No	Yes No
k. Is calibration of equipment conducted once a year?	Yes No	Yes No	Yes No

6. Infection control and safe waste disposal

	Primary health center/area hospital/private lab	District hospital lab/private lab	Medical college lab/ specialist labs
a. Do the laboratory staff receive training on universal precautions and laboratory safety?	Yes No	Yes No	Yes No
b. Is a safety manual easily accessible to the laboratory staff?	Yes No	Yes No	Yes No
c. Are standard methods used in infectious waste disposal (autoclave, disinfection, etc)	Yes No	Yes No	Yes No
d. Are protective clothing/equipment available for laboratory staff.?	Yes No	Yes No	Yes No
e. Is universal precaution observed while handling blood and body fluids?	Yes No	Yes No	Yes No
f. Are sharps disposed in puncture proof container/destroyed?	Yes No	Yes No	Yes No
g. Is infectious waste segregated?	Yes No	Yes No	Yes No
h. Do staff receive 3 doses of HBV vaccination?	Yes No	Yes No	Yes No
i. Are PEP protocol and drugs available?	Yes No	Yes No	Yes No
j. Are 1% bleach and needle destroyer available?	Yes No	Yes No	Yes No

7. Reporting procedure

	Primary health center/area hospital/private lab	District hospital lab/private lab
a. Are records available on patient test results?	Yes No	Yes No
b. Are clear polices available on turn-around time and error detection for each test?	Yes No	Yes No
c. Are STAT test results and report available while the patient is in the clinic?	Yes No	Yes No
d. Are reports submitted in a standardized format with normal ranges?	Yes No	Yes No
e. Does policy exist on confidentiality and sharing of results?	Yes No	Yes No

Actions needed to strengthen the laboratory in order to participate in IBBA:

1.

2.

3.

4.

5.

6.

Signature of IBBA state laboratory manager:

Suitable for IBBA laboratory activity

Not suitable for IBBA activity

Appendix 6

6

Minimum equipment for network laboratories

A. Field laboratory

Infrastructure	Lab supplies
1. Chairs (participant, medical officer, and laboratory technician)	1. Vacutainer tubes
2. Working table	2. Needles and needle holders
3. Examination table/cot	3. Tourniquet
4. Privacy (curtain)	4. Alcohol swabs
5. Examination light	5. Containers for collection of urine (50ml)
6. Running water	6. Urine transport tubes with disposable pipettes
7. Soap	7. Dacron swabs and tubes for Dacron swabs
8. Waste disposal bins (three-color-coded, if possible)	8. Sterile cotton balls
9. Needle destroyer	9. Sterile normal saline (0.9%)
10. Cabinets for keeping stocks of supplies and stationery	10. Thermacol boxes with sponges and thermometer
11. Small desk for thermocol box for transport of specimen	11. Lab forms
	12. Scissors, cello tape, and package tape
	13. Permanent markers
	14. Tissue roll for specimen packing
	15. Gel packs (frozen)
	16. Zip lock bags (small and big)
	17. Disposable gloves
	18. Labels with participants' ID numbers.
	19. Disposable bags and autoclave bags
	20. Puncture-proof container for needle disposal
	21. DBS paper (Number 903, Schleicher and Schuell) with envelopes
	22. Lancets
	23. Large low-gas-permeable zip lock bags
	24. Desiccant pouches
	25. Humidity indicator card

B. District laboratory

1. Refrigerator (4°C)
2. Deep freezer (-20°C)
3. RPR shaker
4. Bio-safety cabinet, class 2
5. Autoclave
6. Serum separation centrifuge
7. Micropipette
8. Small oven in sites collecting dried blood spots (DBS)—a subset of IBBA sites where blood was not collected

C. State laboratory

1. Refrigerator (4°C)
2. Deep Freezers (-20°C and -70°C)
3. RPR shaker
4. Bio-safety cabinet Class 2
5. Autoclave
6. Serum separation centrifuge
7. Micropipettes (variable and fixed volume)
8. ELISA washer and plate/strip reader
9. Incubators (37°C)
10. Water bath (56°C and 100°C)
11. PCR thermocycler
12. Commercial test equipment (Gen APTIMA, Roche COBAS, etc.) for the dedicated laboratories conducting molecular-based diagnostic/reference tests

Appendix 7

7

Consent form

This sample two-part consent form was used for some of the IBBAs in India. Part A covers a behavioral and clinical investigation. Part B covers permission to use blood samples in future research.

Participant ID

Behavioral & Clinical Investigation Consent Form – PART A

Integrated Behavioral and Biological Assessment (IBBA)

Sponsor:

Implementing Partners:

Principal Investigator:

Co-principal Investigators:

Date of Ethics Committee Approval: _____

Introduction: My name is _____(name), and I work in a collaborative project with _____ (research agency) and _____(state-level institute). We are collecting sexual health data for a project called Integrated Behavioral and Biological Assessment (IBBA), which is supported by _____. The round-I of IBBA was conducted during 2005-07 and we are currently doing round-II of IBBA to evaluate and measure changes in behavioral and biological indicators. The findings of IBBA round-I have been widely disseminated to the community through the implementing agencies. You are being chosen to request participation by chance and not for any other reason. This consent form gives you information about IBBA Round-II. You are being requested to think about your participation in this study through this consent form. It is necessary for you to receive complete information about this study to participate in it. Therefore, you have to read this form or somebody will read it out loud to you. If you are willing to participate in this study, you will put today's date and sign this consent form. If you cannot or do not wish to sign, a witness will sign it.

Purpose of study

Comprehensive interventions to reduce the spread of HIV infection among different vulnerable population groups have been accorded high priority in India. Many nongovernmental organizations are implementing comprehensive focused interventions among various "at risk" populations in India. However, limited information is available about the impact of such programs. This study proposes to assess the impact of these interventions, especially those sponsored by Avahan.

Your participation in this study

If you agree to participate in this study, we will ask you some personal questions about you, your migration history, sexual behavior, substance use, and sexually transmitted infections, etc. The interview is likely to last for about forty-five minutes. We will also request you to permit us to collect blood and urine samples. Our study doctor will perform an external physical examination and if you have certain symptoms, you will be requested to permit us to collect vaginal secretions or secretions from an ulcer on the external genitals. At the end of this form, we will request you to give consent for each of these procedures. You may participate, only if you are willing to. You may choose not to answer certain questions, if you do not want to. There is no right or wrong answer to any of the questions. After that, your 10 ml (approximately 2 teaspoonfuls) of blood will be taken. Your blood sample will be tested for syphilis, HIV, and HSV2 antibodies. If it is found that you are having symptoms suggestive of sexually transmitted infections, our study doctor will provide you with appropriate medicines for treatment. Also, you will be referred to a clinic where you can get the result of your syphilis test and if you are found to be infected you will receive medicines against it. The results of the HIV test will not be revealed to you. If you wish to know HIV test results, you will be referred to a nearby Integrated Counseling and Confidential Testing Center (ICCTC). This study cannot provide you with treatment for HIV, but the study staff will refer you to other available sources of care.

Who is eligible?

You should be above the age of eighteen years and willing to participate in this survey

Risks and benefits of participating in the study

You may feel discomfort when your blood is drawn. Some may feel dizzy or faint. You may have a bruise or a swelling where the needle goes into your arm. You may become embarrassed when discussing sexual behaviors. You will talk with a trained staff member who will help you deal with any feelings or questions you have.

We will make every effort to protect your privacy and confidentiality in IBBA. However, it is possible that others who learn of your participation may treat you unfairly or discriminate against you. In very rare situations your family or community may not accept you.

This study may be of no direct benefit to you. However, you and other community members may benefit in the future from information learned from this study. If you have symptoms, the doctor will offer you medicine for some STDs that are treatable. If you wish, you will be referred for a pelvic exam and additional STD treatment if needed. You will also be referred for counseling and testing for HIV. This study cannot provide you with other medical care, but study staff will refer you to other available sources of care.

If you decide not to participate in this study

You may decide not to take part or to withdraw from the study at any time. You will continue to receive the services from your local intervention program (if you were receiving them), along with your routine medical care.

Confidentiality

The study staff will keep your personal information confidential. In all other forms other than this consent form, and on all the samples, instead of name, only a code number will be mentioned. The forms linking your name and the assigned code number will be kept under lock and key. This information will not be given to anybody else without your permission.

Compensation for your participation

There is no cost to you to participate in the study. You will be compensated for your time and effort: (_____). Additionally, the cost of travel for going to the referred STI treatment and HIV counseling center (_____) will be reimbursed. No other compensation will be provided to you.

Problems related to the study

If you ever have any questions about this study, or in case of research-related injuries, you should contact _____(name of investigator), _____(designation), _____(state-level institute), _____(address) at _____(phone), or if you have questions about your rights as a research participant, you can call _____(name), Chair, Ethical Committee,_____ (state-level institute) at _____(phone).

Statement to be made by a woman willing to participate in the study

I have read this consent form completely/this consent form has been read out loud to me. All my doubts have been cleared. I can withdraw my participation any time if I choose to. I have understood this. I have received and understood the information about my rights and have been promised that my personal information will be kept confidential.

I want to participate in this study myself by my own free will and am willing to (circle number/s that are accepted):

1. Answer the questionnaire.
2. Consult the study doctor.
3. Provide blood, urine, and if necessary, swabs from genital ulcer bases.
4. All (1+2+3).

I have been offered a copy of my consent form and (circle number that is accepted):

1. I want a copy of my consent form.
2. I don't want a copy of my consent form.

Ethics Committee Stamp of Certification Date of Expiry of Consent Validity

Please do not sign after date of expiration.

Date _____

Name of participant _____ Signature of participant _____

Name of witness _____ Signature of witness _____

Consent Form: Permission to use blood samples in future research–Part B

Introduction

Of the blood sample that is going to be collected, a small quantity of blood may be left over. In such circumstances, we would request you to permit us to keep this leftover blood for future research instead of discarding it. We may be able to use this leftover sample to undertake newer tests as the technology develops or to study genetic and immunologic factors influencing the risk of acquiring the HIV infection or disease progression. It will be only used for research and not for any commercial gain. If you agree to this, it means that you also give us permission to do such studies on this blood sample. These results will not be used to identify participants individually.

Sample identification

Your leftover blood sample will have a unique number only and not your name. Though we would be able to link the test result with the other data that we have collected, we will not be able to get back to you with the test results as we will not be recording your address.

Risks

There are no risks to you from future use of your specimens. Reports about research done with your sample will only be presented in publications and meetings and shall not have your name or any other personal identifier.

Freedom to refuse

You can decide not to allow use of your samples for future research or you may change your mind at any time about allowing your samples to be used for future research. If you wish to change your mind, you can contact _____ (name of investigator), _____ (designation), _____ (state-level institute), _____ (address); _____(phone) and let that person know. To do so, if you provide the number on the paper we give you today, it will help us best. We will find your specimen and destroy it so that it will not be available for future research.

Your decision to allow us to use your specimens in future research will not have any effect on your taking part in this assessment, or on your ability to obtain services from the project. Even if you refuse to permit use of blood samples in future, you can take part in IBBA and also receive services from any intervention project.

Voluntary consent

I certify that all my questions and concerns have been answered and I willingly agree that samples can be used for future research. I give permission for the use of my leftover blood sample in future research for the purposes described above. (Please check one)

_____ YES
_____ NO (If NO, my specimens will be destroyed.)
I have been offered a copy of my consent form and (circle number that is accepted):

I want a copy of my consent form.

I don't want a copy of my consent form.

Date _____

Name of participant _____ Signature of participant _____

Name of witness _____ Signature of witness _____

Appendix 8

8

IBBA questionnaire

This Integrated Behavioral and Biological Assessment (IBBA) was designed for interviews with High Risk Groups as part of Avahan—the India AIDS Initiative, with support from the Bill & Melinda Gates Foundation.

Place participant ID sticker here

Questionnaire ID

Introduction

1. Greetings (for example: good morning/good afternoon/good evening).

2. Introduce yourself and name the organization you are with.

3. Emphasize the confidentiality and importance of the responses, and let people know that the names of respondents are not recorded.

4. Thank the person for having agreed to participate.

Note to interviewers:

1. Set up a private atmosphere in which to conduct the interview, and makes sure no one else is present while the interview takes place

2. Blocks 1 and 2 must be completed in full for all respondents selected for the study, regardless of whether they refuse to participate (refusals). The interviewer should fill in the code column and the editor will fill in the code boxes.

3. Block I, questions 101 to 110 and 114 are completed by the interviewer.

4. Block I, questions 111, 112, 113, 115, and 201 are completed by the supervisor after the completion of both behavioral and biological interview of the participant.

5. Data management team completes Q 202 to Q205.

Block 1. Interview information and consent status					
#	**Question**	**Answers**	**Codes**	**Skip to**	**Code Boxes**
101	Name and code of locale (cluster #)	Name:_____			
102	Name of state	Andhra Pradesh Maharashtra Nagaland Tamil Nadu Karnataka	1 2 4 5 6		
103	Name of district	Name:_____			
104	Name of city/town/village	Name:_____			
105	Group	FSW combined FSW brothel based FSW nonbrothel based FSW service bar based	01 02 03 04		
106	Type of locale	brothel service bar lodge street home other:_____	01 02 03 04 05 97		
107	Date of interview	Date: _____	Day	Month	Year
108	Name and code number of interviewer	Name: _____			
109	Did you participate in IBBA in 2005/2006/2007?	No Yes Don't know/don't remember	00 01 98		
110	Consent status	Refused for both behavioral & biological Agreed to behavioral only Agreed to behavioral and biological Respondent has already taken part in this round of IBBA (IBBA Round 2)	01 02 03 04	►**End** ►**End**	
Stop, do not continue with the interview if the respondent already participated in IBBA Round 2 survey. (Refer to block I, Q110.) Continue with interview if the respondent has given consent for behavioral only or for behavioral and biological. Interviewer to skip to Q114. Q111, Q112, Q113, Q115 AND Q201 will be filled by the supervisor after participation in the survey is complete]					
111	Completion status–behavioral	Completed interview Did not complete interview	1 2		
112	Completion status–biological	Only blood sample collected Only urine sample collected Both blood and urine sample collected Gave none of the samples	01 02 03 04		
113	Genital swab collection	Swab taken Swab not taken	1 2		

#	Question	Answers	Codes	Skip to	Code Boxes
114	Language of the interview [For the interviewer: if the respondent has consented and completed the consent forms, start the interview.]	Bengali English Hindi Kannada Marathi Tamil Telugu Nagamese Others (specify) _____	01 02 03 04 05 06 07 08 97	▶301	
115	Respondent follow–up	a. Respondent received compensation b. Respondent was explained where she will receive syphilis test results and received card with respondent number	No: 00 Yes: 01 No: 00 Yes: 01		a. b.

Block 2: Editing and data entry					
#	Question	Answers	Codes	Skip to	Code Boxes
[Stop: Q201 is filled by the supervisor after the survey is complete.]					
201	These responses for questionnaire have been scrutinized for completeness and consistency by:				
	Name of supervisor _____ a. Code of Supervisor	Date of scrutiny Day Month Year	Signature		
[Stop: Q202 to Q205 is filled by members of the data management team.]					
202	Date of scrutinizing the questionnaire Name of scrutinizer: Organization	Date of examination Day Month Year	Signature		
203	Name, code and date of data entry person (1) Organization: _____	Name: Code: Signature:	Date Day Month Year		
204	Name, code and date of data entry person (2) Organization: _____	Name: Code: Signature:	Date Day Month Year		
205	Data entry checked by: Organization: _____	Name: Code: Signature	Date Day Month Year		

Block 3. Demographic characteristics					
#	**Question**	**Answers**	**Codes**	**Skip to**	**Code Boxes**
301	How old are you?	Age in completed years Don't know No answer	 98 99		
302	Can you read and write? [Enter 'No' if respondent 'cannot read and write' or 'can read' only.]	Yes No	01 00	 ►304	
303	What is the highest grade of school you have completed?	Highest grade completed			
304	Apart from sex work, what other work do you do to earn income? [Do not read these answers to the respondent. Circle only one answer.]	None Nonagricultural labor Petty business<<amplify?>> Maid servant Agricultural labor Artisan/handicrafts Others (specify)_____ No answer	01 02 03 04 05 06 97 99		
305	What is your current marital status? [Interviewer is to probe for the answer. Circle only one answer.]	Unmarried – living alone Unmarried – living with partner Married – living with husband Married – living with partner other than husband Married – living alone Divorced/separated – living alone Divorced/separated – living with partner Widowed – living alone Widowed – living with partner Other	01 02 03 04 05 06 07 08 09 97	►309 ►309	
306	Do you have children? If yes, how many?	Number of children_____ Does not have children No answer	00 99	►308 ►308	
307	What is the age of the youngest child? [If less than one year, code as '00']	Age of child in completed years _____ Don't know/don't remember No answer	98 99		
308	Have you attended a private or public antenatal clinic (ANC) in the past one year?	No Yes, public/government facility Yes, private facility Both, public/government and private facility Don't know No answer	00 01 02 03 98 99		
309	Are you currently in debt?	No Yes No answer	00 01 99		

Block 4. Sex work and migration					
401	Which city/village/district/state do you belong to? [In other words, Where were you born or where do you go when you go home? Probe and record the name of the city/village, district, sate and country (if not India).]	a. Village/city/town_____ b. District_____ c. State_____ d. Country_____ Same as current place of interview Don't know No answer	 995 998 999	 ▶404	a. b. c. d.
402	Where do you live now? [Probe and record the name of the city/village, district, sate, and country (if not India). This may be the same place where the interview is taking place.]	a. Village/city/town_____ b. District_____ c. State_____ d. Country_____ Same as current place of interview Same as place of home town (mentioned in Q401) Don't know No answer	 995 996 998 999	 ▶404	a. b. c. d.
403	How often do you return home (native place)?	More than once a year Less than once a year Don't return home Don't know No answer	01 02 00 98 99		
404	For how long have you been doing sex work in this city/town/village? [City/town/place refers to the place where the respondent is being interviewed. If <1 week, record in days. If >1 week and <1 month, record in weeks. If >1 month and <1 year, record in months. If >1 year, record in years.]	a. Days:_____ b. Weeks:_____ c. Months :_____ d. Years:_____ Don't know No answer	 98 99		a. b. c. d.
405	Have you ever practiced sex work anywhere other than this district (insert name of district)?_____	No Yes No answer	00 01 99	▶501 ▶501	
406	Please give me the names of the different places where you have done sex work during the last 6 months. [Probe and record up to 5 different places/destinations during the last 6 months. If fewer than 5 places in the last 6 months, then ask about the last 12 months.]				

City/town/village		District	State	Did you practice sex work there before the last six months but in the last one year?	
a				No Yes Don't know No answer	00 01 98 99
b				No Yes Don't know No answer	00 01 98 99
c				No Yes Don't know No answer	00 01 98 99
d				No Yes Don't know No answer	00 01 98 99
e				No Yes Don't know No answer	00 01 98 99
407	Have you ever practiced sex work in Mumbai?	No Yes Currently in Mumbai Don't know No answer		00 01 95 98 99	

Block 5. Condom and drug–injection practice					
#	Question	Answers	Codes	Skip to	Code Boxes
501	Do you currently carry a condom? [Ask the respondent to show it to you.]	No Reports yes, and can show a condom Reports yes, but cannot show a condom No answer	00 01 02 99		
502	The last time you obtained a condom, where did you get it? [Read all responses and circle the one selected by the respondent.]	Peer educator/outreach worker Paan shop Apothecary/drugstore/chemist Client Vending stall Health facility/dispensary/clinic/ Hospital Bar/guesthouse/hotel Friend Madam Mobile van from NGO or drop–in center NGO Never obtained a condom Other (specify) _____ Don't know/ don't remember	01 02 03 04 05 06 07 08 09 10 96 97 98		

503	In the past month, have you had the experience of a condom breaking while it was being used?	No Yes Did not use a condom in past one month Don't know /don't remember No answer	00 01 96 98 99		
504	The last time you used a condom, did the condom break while it was being used?	No Yes Never used a condom Don't know No answer	00 01 96 98 99		
505	In the past month was there a time when you wanted to use a condom with a client but did not use it?	No Yes Don't know /don't remember	00 01 98	►507 ►507	
506	What was the main reason for not using a condom? [Do not read the answers. Circle only one answer.]	Client did not want to Condom not available Condom costs too much Trust the clients Used other contraceptives Other (specify)_____ No answer	01 02 03 04 05 97 99		
507	During the past month, have you consumed drinks containing alcohol?	Every day At least once a week Less than once a week Not in past one month Never consumed alcohol No answer	01 02 03 04 00 99		
508	Some people consume drugs for non–medical reasons (like marijuana, heroin, amphetamines, etc.) to feel good, get high, fly, trip, or have fantasies. Have you ever consumed drugs like these, even one time?	No Yes Don't know No answer	00 01 98 99		
509	Have you ever injected drugs for non–medical reasons? [Explain that 'injected drugs' means drugs taken for intoxication.]	No Yes Don't know No answer	00 01 98 99	►512 ►512 ►512	

The following questions are on the use of injected drugs for nonmedical reasons (for intoxication]					
#	**Question**	**Answers**	**Codes**	**Skip to**	**Code Boxes**
510	In the past year have you ever injected drugs for non–medical reasons?	No Yes Don't know No answer	00 01 98 99	►512 ►512 ►512	
511	When you injected such drugs in the past year, did you always use a brand new needle (one that had never been used before)?	No Yes Don't know No answer	00 01 98 99		
512	Do you think or suspect that any of your sexual partners ever used or shared injection drugs for nonmedical reasons?	No Yes Don't know No answer	00 01 98 99		
The following questions refer to injections for medical reasons					
513	Have you ever received, in the last one year, an injection from a medical doctor, nurse, registered medical practitioner, or traditional medical practitioner?	No Yes Don't remember	00 01 98	►517 ►517	
514	How many such injections have you received in the last one year?	Number of injections _____ Don't remember No answer	 98 99		
514	How many such injections have you received in the last one year?	Number of injections _____ Don't remember No answer	 98 99		
515	What did you receive these injections for? [Do not read the answers. Multiple responses are possible. Probe for HIV/AIDS]	Weakness/anemia Heart disease Diabetes Other chronic illness Body ache Fever/infection HIV/AIDS Other (Specify) Don't know/don't remember No answer	01 02 03 04 05 06 07 97 98 99		

#	Question	Answers	Codes				Code Boxes
516	From which of these types of practitioners have you received these injections? [Read the answer categories and mark all that are mentioned.]	Answers	No	Yes	DK	NA	a. b. c. d. e.
		a. Medical doctor	00	01	98	99	
		b. Nurse	00	01	98	99	
		c. Registered medical practitioner	00	01	98	99	
		d. Traditional medical practitioner	00	01	98	99	
		e. Other (specify)	00	01	98	99	
517	Did you ever receive a blood transfusion in your lifetime, for any reason? For example, a surgery, or for treatment after an accident, or otherwise..	No Yes No answer	00 01 99				

Block 6. Sexual history and sex work

Now I would like to ask some questions about your sexual history and some general questions about your work. I once again assure you that all this information will be kept fully confidential.

#	Question	Answers	Codes	Skip to	Code Boxes
601	How old were you when you had sexual intercourse for the first time? [If the respondent gives the number of years ago, subtract this from the age given earlier (Q301) and confirm with the respondent.]	Age in completed years _____ Don't know No answer	 98 99		
602	How old were you when you started sex work? (Translator note: Use the local term for sex work.)	Age in completed years _____ Don't know No answer	 98 99		
603	Where do you generally solicit or pick up most of your clients? [Do not read responses. Circle only one response.]	Home Rented room Lodge Dhaba or roadside restaurant Brothel Bar/night club Vehicle Public places (park, street, cinema hall, bus stand, railway station, etc) Tamasha (drama hall) By phone Other (specify) No answer	01 02 03 04 05 06 07 08 09 10 97 99		

604	Where do you generally entertain most of your clients? [Do not read the answers. Circle only one response.]	Home Rented room Lodge Dhaba or road–side restaurant Brothel Bar/night club Vehicle Public places (park, street, cinema hall, bus stand, railway station, etc.) Tamasha (drama hall) Other (specify) No answer	01 02 03 04 05 06 07 08 09 97 99		
605	How many clients did you have sexual intercourse with on the last day you worked?	Number of clients_____ Don't know No answer	 98 99		
606	How many days did you have sexual intercourse with clients in the past week (7 days)?	Number of days_____ Don't know No answer	 98 99		
607	How many clients did you have sexual intercourse with in the past week (7 days)?	Number of clients_____ Don't know No answer	 98 99		
608	Are there certain weeks/months during the year when you entertain more or fewer clients than that?	Yes, more Yes, less Yes, both more and less No Don't know No answer	01 02 03 00 98 99		
609	Out of last 10 clients, how many were occasional clients? How many were regular clients? [By 'occasional,' I mean the clients who came to you only once or a few times more, but you do not remember their faces or you do not know them. By 'regular,' I mean those clients whom you recognize well, who come to you repeatedly and you know them.]	a. Number of occasional clients_____ b. Number of regular clients_____ "a" PLUS "b" SHOULD = 10 No answer	 99		a. b.
610	Out of the last 10 clients, how many would you say come from outside this city and live away from their home?	Number of clients_____ Don't know	 98		

Occasional male clients are clients who came to you only once or a few times, but you do not remember their faces or do not know them.					
#	**Question**	**Answers**	**Codes**	**Skip to**	**Code Boxes**
611	Do you have occasional clients?	No Yes	00 01	►6 16	
612	The last time you had sexual intercourse with an occasional client, did he use a condom?	No Yes Don't know/don't remember No answer	00 01 98 99		
613	How often do your occasional clients use condoms with you?	Every time Most of the time Sometimes Never Don't know No answer	01 02 03 04 98 99	 ►615a ►615a ►615a ►615a ►615a	
614	How long have your occasional clients been using condoms every time they have sexual intercourse with you? [If <1 week, record in days. If >1 week and <1 month, record in weeks. If >1month and <1 year, record in months. If >1 year, record in years.]	a. Days:_____ b. Weeks:_____ c. Months:_____ d. Years:_____ Don't know No answer	 98 99		a. b. c. d.
615 a	In the last one week, how often have you used condoms with your occasional clients?	Every time Most of the time Sometimes Never Did not have any occasional clients in the last week Don't know No answer	01 02 03 04 96 98 99		
615 b	In the last one month, how often have you used condoms with your occasional clients?	Every time Most of the time Sometimes Never Did not have any occasional clients in the last one month Don't know No answer	01 02 03 04 96 98 99		

Regular male clients are clients you recognize well, who come to you repeatedly, and whom you know well					
#	**Question**	**Answers**	**Codes**	**Skip to**	**Code Boxes**
616	Do you have regular clients?	No Yes	00 01	▶622	
617	In the past one week, how many times did you have sexual intercourse with any of your regular clients? [If the answer is no, record '00.'] [If the answer is yes, how many times?]	Number of times:_____ Did not have sex with regular client in the last one week	 00		
618	The last time you had sexual intercourse with a regular client, did he use a condom? …This does not need to be within the last week.	No Yes Don't know / don't remember	00 01 98		
619	How often do your regular clients use condoms with you? [Read all answers and circle the one selected by the respondent.]	Every time Most of the time Sometimes Never Don't know	01 02 03 04 98	 ▶621a ▶621a ▶621a ▶621a	
620	How long have your regular clients been using condoms every time they have sexual intercourse with you? [If <1 week, record in days. If >1 week and <1 month, record in weeks. If >1month and <1 year, record in months. If >1 year, record in years.]	a. Days:_____ b. Weeks:_____ c. Months:_____ d. Years:_____ Don't know No answer	 98 99		a. b. c. d.
621 a	In the last one week, how often have you used condoms with your regular clients?	Every time Most of the time Sometimes Never Did not have any regular clients in the last week Don't know No answer	01 02 03 04 96 98 99		
621 b	In the last one month, how often have you used condoms with your regular clients?	Every time Most of the time Sometimes Never Did not have any regular clients in the last one month Don't know No answer	01 02 03 04 96 98 99		

Occasional and regular clients These questions are for both types of clients, occasional and regular.					
#	**Question**	**Answers**	**Codes**	**Skip to**	**Code Boxes**
622	Did you have an instance in the last 30 days where you did not use condoms? Why? [Do not read the answers. Circle all answers that apply.]	I always used condoms with all of my clients in the last 30 days Client refused Client paid more for sex without a condom No condom available Was afraid of violence Too embarrassed to ask him to use a condom I do not like using condoms Other (specify) Don't know/don't remember No answer	01 02 03 04 05 06 07 97 98 99		
623	The last time you used a condom during sexual intercourse with any client, who put the condom on, yourself or the client?	Self Client Never used a condom No answer	00 01 96 99		
624	How much did your last client pay to have sex with you?	Amount in Rs. _____ Don't know No answer	 98 99		
Anal intercourse					
625	Have any of your clients ever asked you to have anal intercourse with them?	No Yes Don't know /don't remember No answer	00 01 98 99	▶627 ▶627 ▶627	
626	On average, how many clients per month ask for anal intercourse?	Number _____ Don't know / don't remember No answer	 98 99		
627	Have you ever had anal intercourse with a client?	No Yes No answer	00 01 99	▶701 ▶701	
628	In the past one week, did you have anal intercourse with any of your clients? [If the answer is no, record '00.' If the answer is yes, ask how many times?]	Number of times:_____ Don't know/don't remember No answer	 98 99		
629	The last time you had anal intercourse with a client did he use a condom?	No Yes Don't know /don't remember No answer	00 01 98 99		

Block 7. Noncommercial sexual partners Regular nonpaying male partner (husband, boyfriend, or live–in partner)					
#	**Question**	**Answers**	**Codes**	**Skip to**	**Code Boxes**
701	Do you have a main (regular) male sexual partner who does not pay to have sex with you? …By main, regular partner, I mean husband, boyfriend, or other live–in partner.	No Yes No answer	00 01 99	▶709 ▶709	
702	How long have you been having sexual relations with this partner? [The question is open–ended. Listen to the response.] If <1 week, record in days. If >1 week and <1 month, record in weeks. If >1month and <1 year, record in months. If >1 year, record in years.]	a. Days _____ b. Weeks _____ c. Months _____ d. Years _____ Don't know No answer	 98 99		a. b. c. d.
703	What is the age of this partner?	Age in years _____ Don't know No answer	 98 99		
704	During the past one week, how many times did you have sexual intercourse with your main/regular partner?	Number of times_____ None Don't know / don't remember No answer	 00 98 99		
705	The last time you had sexual intercourse with your main/regular partner, did he use a condom? …Does not have to be within the last one week.	No Yes Don't know No answer	00 01 98 99		
706	In general, how often does your main/regular partner use condoms with you? [Read all answers and circle the one selected by the respondent.]	Every time Most of the times Sometimes Never Don't know	01 02 03 04 98	 ▶708 ▶708 ▶708 ▶708	

707	How long have you and your main/ regular partner been using condoms every time you have sexual intercourse? [If <1 week, record in days. If >1 week and <1 month, record in weeks. If >1month and <1 year, record in months. If >1 year, record in years.]	a. Days:_____ b. Weeks:_____ c. Months:_____ d. Years:_____ Don't know No answer	 98 99		a. b. c. d.
708	In the past three months, how often have you used a condom with your main/regular partner?	Every time Most of the time Sometimes Never Don't know No answer	01 02 03 04 98 99		
Other nonpaying male partners					
709	Have you had any other partners who did not pay to have sex with you in the past year, other than the main partner we just talked about?	No Yes No answer	00 01 99	 ►715 ►715	
710	How many such partners have you had in the past one year?	# of other nonpaying partners _____ Don't know No answer	 98 99		
711	The last time you had sexual intercourse with one of these partners, did he use a condom?	No Yes Don't know / Don't remember No answer	00 01 98 99		
712	During the past one week, how many times did you have sexual intercourse with your nonpaying casual partner(s)?	Number of times_____ None Don't know / Don't remember No answer	 00 98 99		
713	In general, how often does your nonpaying casual partner(s) use condoms with you? [Read all the answers and circle the one selected by the respondent.]	Every time Most of the time Sometimes Never Don't know	01 02 03 04 98		
714	In the past three months, how often have you used a condom with your nonpaying casual partner(s)?	Every time Most of the time Sometimes Never Don't know No answer	01 02 03 04 98 99		

Now I would like to ask some questions about violence you have faced. **I once again assure you that all this information will be kept fully confidential.**					
#	**Question**	**Answers**	**Codes**	**Skip to**	**Code Boxes**
715	In the last six months, how many times would you say someone has beaten you (hurt, hit, slapped, pushed, kicked, punched, choked, burned but not used a weapon)?	Never Once 2 to 5 times 6 to 10 times 11 or more times Don't know/don't remember No answer	00 01 02 03 04 98 99	▶718 ▶718 ▶718	
716	Who did this to you? [Select all answers that apply.]	Stranger Madam or other broker Other sex worker Paying partner Nonpaying regular partner Police Pimp Other (specify) Don't know/don't remember No answer	01 02 03 04 05 06 07 97 98 99		
717	Did you tell others about this? Who did you tell? [Select all answers that apply]	Did not tell anyone Another sex worker(s) Friend/relative/family member who is not a sex worker Avahan project office (Interviewer to give name of local Avahan project _____) A different community–based organization or NGO Don't know/don't remember No answer	00 01 02 03 04 98 99		
718	In the past one year, were you ever physically forced to have sexual intercourse with someone even though you didn't want to?	No Yes No answer	00 01 99	▶801 ▶801	

719	In the past one year, who was the person (or people) who physically forced you to have sexual intercourse against your will? Anyone else? [Do not read answers. Record all answers that are mentioned.]		No	Yes	No answer		a. b. c. d. e.
		a. Police	00	01	99		
		b. Pimp	00	01	99		
		c. Client	00	01	99		
		d. Main (regular) nonpaying partner	00	01	99		
		e. Others_____	00	01	99		

Block 8. Self–reported sexually transmitted infections (STIs)						
Now I would like to ask about your health.						
#	**Question**	**Answers**	**Codes**		**Skip to**	**Code Boxes**
801	Have you ever heard of diseases that can be transmitted through sexual intercourse?	No Yes	00 01		►804	
802	Can you describe any symptoms of STIs in women? [Do not read answers. Circle '01' for all that are mentioned and '00' for all that are not mentioned.]	Answers	No	Yes		
		a. Lower abdominal pain	00	01		a.
		b. Foul–smelling vaginal discharge	00	01		b.
		c. Burning on urination	00	01		c.
		d. Genital ulcer or sore	00	01		d.
		e. Swelling in groin area	00	01		e.
		f. Itching in genital area	00	01		f.
		g. Other :_____	00	01		g.
803	Can you describe any symptoms of STIs in men? [Do not read answers. Circle '01' for all that are mentioned and '00' for all that are not mentioned.]	Answers	No	Yes		
		a. Urethral discharge	00	01		a.
		b. Burning or pain on urination	00	01		b.
		c. Genital ulcer / sore	00	01		c.
		d. Swelling in groin area	00	01		d.
		e. Can't retract foreskin	00	01		e.
		f. Other _____	00	01		f.
804	During the past 12 months have you suffered from vaginal discharge? [Translator note: Use the local term for 'vaginal discharge'.]	No Yes Don't know /don't remember No answer	00 01 98 99			
805	During the past 12 months have you suffered from lower abdominal pain without diarrhea or menses?	No Yes Don't know/don't remember No answer	00 01 98 99			

806	During the past 12 months have you suffered from genital ulcers or sores?	No Yes Don't know/don't remember No answer	00 01 98 99		
	[Interviewer should stop and check for the number of symptoms marked in response to Q804, Q805, and Q806 and mark here.]	Only one symptom More than one symptom No symptoms	01 02 03	►808 ►813	
807	What was the most recent of these you suffered from in the past 12 months? [Read responses and circle one answer only.]	Foul–smelling vaginal discharge Lower abdominal pain Genital ulcer/sore Don't know/don't remember No answer	01 02 03 98 99		
808	How long ago was this? [If <30 days, record response in days. If >30 days, record the response in months.]	a. Days _____ b. Months_____ Don't know / don't remember No answer	 98 99		a. b.
809	What did you do the last time you had a genital ulcer/sore, lower abdominal pain, or genital discharge? [This question has two kinds of responses: (a) Spontaneous response (b) Prompted response]				

First, allow the respondent to answer, then match her answers with the statements found in column (1) and circle the number in Column (2) for each appropriate answer. Then read out loud the answers that have not yet been mentioned and circle the respondent's answer in Column (3), (4) or (5) as appropriate.

	Spontaneous response	**Prompted response**			
	Yes	Yes	No	Don't know	
(1)	(2)	(3)	(4)	(5)	(6)
a. Sought advice/medicine from _____ (fill in name of Avahan clinic)?	01	02	00	98	a.
b. Sought advice/medicine from a government clinic or hospital?	01	02	00	98	b.
c. Sought advice/medicine from an NGO or charity–run clinic or hospital?	01	02	00	98	c.
d. Sought advice/medicine from a private clinic or hospital?	01	02	00	98	d.
e. Sought advice/medicine from a private pharmacy?	01	02	00	98	e.

f. Sought advice/medicine from a non–allopathic doctor (homoeopathic, herbal, other traditional)?	01	02	00	98	f.
g. Took medicine I had at home?	01	02	00	98	g.
h. Told my sexual partner about the STI?	01	02	00	98	h.
i. Stopped having sex during the time when I had the symptoms?	01	02	00	98	i.
j. Used condoms?	01	02	00	98	j.
k. Did nothing? go to ▶Q813	01	02	00	98	k.
z. Other _____	01		00		z.

#	Question	Answers	Codes	Skip to	Code Boxes
810	Of everything you listed in the previous question, what did you do first, the last time you had a genital ulcer/sore, lower abdominal pain, or genital discharge? [Do not read answers. Only one answer is possible.]	Sought advice/medicine from _____ (fill in name of Avahan clinic) Sought advice/medicine from a government clinic or hospital Sought advice/medicine from an NGO or charity–run clinic or hospital Sought advice/medicine from a private clinic or hospital Sought advice/medicine from a private pharmacy Sought advice/medicine from nonallopathic doctor Took medicine I had at home Told my sexual partner about the STI Stopped having sex when I had the symptoms Used condoms Other:_____ Don't know	01 02 03 04 05 06 07 08 09 10 97 98		
811	How long did you have this symptom before seeking treatment? [If <30 days, record answer in days. If >30 days, record the answer in months.]	a. Days :_____ b. Months:_____ Don't know/don't remember No answer	98 99		a. b.

#	Question	Answers	Codes			Skip to	Code Boxes
812	What type of medicine did you take? [Read answers. Multiple responses are possible. If a, b, c, d = 00, circle '01' for none.]	Answers	No	Yes	Don't remember		a.
		a. Injection	00	01	98		b.
		b. Tablets/capsules	00	01	98		c.
		c. Topical ointment/ cream/lotion	00	01	98		d.
		d. Other	00	01	98		e.
		e. None	00	01			
813	Do you have any of the following at present? [Read the symptoms aloud and record all mentioned.]	Answers	No	Yes			
		a. Burning on urination	00	01			a.
		b. Foul–smelling vaginal discharge	00	01			b.
		c. Genital ulcer / sore	00	01			c.
		d. Swelling in groin area	00	01			d.
		e. Lower abdominal pain	00	01			e.
		f. Others:_____	00	01			f.
814	Do you use antibiotic drugs (injection, tablets, or capsules) for preventing STIs?	No Yes Don't know No answer	00 01 98 99			▶901 ▶901 ▶901	
815	What antibiotic drugs do you use?	Specify a. _____ b. _____ c. _____ d. _____ Don't know No answer	 98 99				a. b. c. d.

Block 9. Knowledge of HIV/AIDS and its prevention					
#	Question	Answers	Codes	Skip to	Code Boxes
901	Have you ever heard of HIV/ AIDS before this interview?	No Yes	00 01	▶ 1001	
902	Can you know whether a person has HIV, the virus that causes AIDS, by looking at them?	No Yes Don't know	00 01 98		
903	Are there things a person can do to prevent getting infected with HIV/AIDS?	No Yes Don't know	00 01 98	▶ 905 ▶ 905	
904	What are the ways a person can prevent becoming infected with HIV/AIDS? [This question has two kinds of responses: (a) Spontaneous response (b) Prompted response]				

Let the respondent answer first, then match her answers with the statements found in Column (1) and circle the number in Column (2) for each appropriate answer. Then read out loud the answers that have not yet been stated and circle the respondent's answer in Column (3), (4) or (5) as appropriate.					
Methods to use	**Spontaneous response**	**Prompted response**			
	Yes	Yes	No	Don't know	
(1)	(2)	(3)	(4)	(5)	(6)
a. Take medicine/traditional herbal mixture before having sexual relations	01	02	00	98	a.
b. Always use a condom while engaging in sex	01	02	00	98	b.
c. Avoid the use of shared injection needles	01	02	00	98	c.
d. Avoid getting mosquito or other insect bites	01	02	00	98	d.
e. Don't use shared clothes or eating utensils	01	02	00	98	e.
f. Eat nutritious food	01	02	00	98	f.
g. Others	01		00		z.

[After completion of Q904, the interviewer should inform the respondent of the correct responses. Do not change the above answers.]

#	Question	Answers	Codes	Skip to	Code Boxes
905	Do you personally know someone (who also knows you) who is infected with HIV, suffers from AIDS, or has died of AIDS?	No Yes Don't know No answer	00 01 98 99		
906	Do you yourself feel you are at risk to be infected with HIV/AIDS?	No Yes Don't know No answer	00 01 98 99		
907	Have you ever taken an HIV/ AIDS test?	No Yes No answer	00 01 99	► 911 ► 911	
908	Did you take the test voluntarily? [Translator note: Voluntary here means did you go of your own choice, and not because it was required of you (ask for the last HIV test).]	No Yes Don't know No answer	00 01 98 99		
909	Did you collect the test result? [Explain that the interviewer does not want to know the test result]	No Yes No answer	00 01 99		
910	When did you last take an HIV/ AIDS test?	Less than a year ago More than a year ago Don't know No answer	01 02 98 99		

911	Are there are any drugs that can help treat people who have AIDS?	No Yes Dont know No answer	00 01 98 99		
912	Have you ever heard of antiretroviral therapy (ART)?	No Yes Dont know No answer	00 01 98 99	▶1001 ▶1001 ▶1001	
913	Do you know anyone who is currently taking ART? [Multiple responses possible. Interviewer to probe and record all responses.]	None Self Spouse Friend Regular client Other (Specify)_____ No answer	00 01 02 03 04 97 99		
914	Do you know where one can get ART treatment? [Multiple responses possible. Interviewer to probe and record all responses.]	Government hospital Private hospital/ clinic NGO Other _____ (Specify) Don't know No answer	01 02 03 97 98 99		
915	Do you think having ART will make other people be less careful about their sexual behavior? [Read answers and circle one.]	Much less careful Somewhat less careful A little less careful About the same Don't know No answer	01 02 03 04 98 99		

Block 10. Exposure to interventions

#	Question	Answers	Codes	Skip to	Code Boxes
1001	Now I would like to ask you a few questions regarding the HIV prevention program in _____ (name of district). I assure you of the confidentiality of the information provided. Please let me know if you do not want to answer any of these questions. Are you aware of any NGOs working with the prevention of HIV/AIDS among sex workers in _____ (name of district)?	No Yes	00 01	▶1003	
1002	When was the first time you received any service from these NGOs? [If <1 week, record in days. If >1 week and <1 month, record in weeks. If >1 month and <1 year, record in months. If >1 year, record in years.]	a. Days_____ b. Weeks_____ c. Months _____ d. Years_____ Never Don't know No answer	 95 98 99		

1003	Are you aware of the _____ (AVAHAN NGO name) working with the prevention of HIV/ AIDS among sex workers in _____ (name of district)? [Interviewer to show logo of NGO/Program to confirm]	No Yes	00 01	▶1026	
1004	Have you ever been contacted by peers/ staff of _____ (name of Avahan NGO)?	No Yes	00 01	▶1007	
1005	How long ago was the first time you were contacted by peers/staff from _____ (name of Avahan NGO)? [If <1 week, record in days. If >1 week and <1 month, record in weeks. If >1 month and <1 year, record in months. If >1 year, record in years.]	a. Days _____ b. Weeks _____ c. Months _____ d. Years _____ Don't know No answer	 98 99		
1006	How many times in the past one month were you contacted in the field by a peer/ worker from _____ (name of Avahan NGO) to give you information?	Number of times _____ Don't know	 98		
1007	Are you registered with the _____ _____(name of Avahan NGO) or given a registration number?	No Yes	00 01		
1008	Have you been given condoms by a peer worker from _____ (name of Avahan NGO)?	No Yes	00 01	▶1011	
1009	How often are you given condoms by a peer/worker from _____ (name of Avahan NGO)?	Every day More than once a week Once a week Fortnightly Once a month Other (specify) Don't know	01 02 03 04 05 97 98		
1010	How many condoms were you given the last (most recent) time you were given them by a peer/worker from _____ (name of Avahan NGO)?	Number of condoms _____ Don't know	 98		
1011	Have you ever seen a demonstration on correct condom use by a peer educator/ outreach worker from _____ (name of Avahan NGO)?	No Yes	00 01	▶1013	

1012	Have you seen a demonstration on correct condom use by a peer educator/outreach worker from _____(name of Avahan NGO) in the past one month?	No Yes Don't know	00 01 98		
1013	Have you ever visited the clinic(s) run by _____(name of Avahan NGO)?	No Yes	00 01	▶1020	
	For how long have you known about the clinics run by _____ (name of Avahan NGO)? [If <1 week, record in days. If >1 week and <1 month, record in weeks. If >1 month and <1 year, record in months. If >1 year, record in years.]				
1014		a. Days_____ b. Weeks_____ c. Months _____ d. Years_____ Don't know No answer	 98 99		
1015	How many times have you visited this clinic (these clinics) to see the doctor in the last six months OR since you first knew about the clinic (if less than six months)?	Number of times _____ Don't know	 98		
1016	How many times have you visited the Avahan clinic(s) for problems like abnormal/white vaginal discharge or genital ulcers or lower abdominal pain in the last six months OR since you first knew about it? (if less than six months)?	Number of times _____ Don't know	 98		
1017	Have you received this package with 4 tablets (show Avahan packet for presumptive, asymptomatic treatment) in the last six months OR since you first knew about it (if less than six months)?	No Yes	00 01	▶1019	
1018	How many times you have received this treatment (show Avahan packet for presumptive, asymptomatic treatment) in the last six months OR since you first knew about it (if less than six months)?	Number of times _____ Don't know	 98		
1019	Have you ever been tested for syphilis in this clinic (Avahan clinic)?	No Yes Don't know No answer	00 01 98 99		

1020	Have you visited the drop–in center run by _____(name of Avahan NGO)?	No Yes Don't know No answer	00 01 98 99		
1021	Have you attended meetings organized by_____(name of Avahan NGO)?	No Yes Don't know No answer	00 01 98 99		
1022	Are you a member of a self–help group formed with the help of _____ (name of Avahan NGO)?	No Yes Don't know No answer	00 01 98 99		
1023	Are you a peer worker/peer educator of _____(name of Avahan NGO)?	No Yes Don't know No answer	00 01 98 99		
1024	Are you a paid worker of _____ (name of Avahan NGO)?	No Yes Don't know No answer	00 01 98 99		
1025	Are you an unpaid volunteer for _____ (name of Avahan NGO)?	No Yes Don't know No answer	00 01 98 99		
1026	Apart from _____(name of Avahan NGO), do you know any NGO working for the prevention of HIV/AIDS in sex workers in _____(name of the district)?	No Yes Don't know No answer	00 01 98 99	▶1031 ▶1031 ▶1031	
1027	What are the names of these NGOs?	Name _____ Name _____ Name _____ Don't Know No answer	 98 99	 ▶1028	
	CHECK Q1027 and verify if the NGO is an Avahan or non–Avahan NGO. Names of Avahan NGO's: [If Avahan NGO is mentioned, ensure that Q1003 to Q1025 have been answered by respondent.]	Avahan Non-Avahan	01 02	▶1031	
1028	For how long have you known this (these) NGOs (marked in Q1027)? [If <1 week, record in days. If >1 week and <1 month, record in weeks If >1 month and <1 year, record in months If >1 year, record in years.]	a. Days_____ b. Weeks_____ c. Months _____ d. Years_____ Don't know No answer	 98 99		a. b. c. d.
1029	Have you received any type of services from this/these NGOs (NGO marked in Q1027) during the last six months OR since you first knew about it? (if LESS than six months)	No Yes No answer	00 01 99	▶1031 ▶1031	

1030	What are the services that you received from this/these NGOs/programs in the last six months OR since you first knew about it (If LESS than six months)? [Do not read the answers. Record all answers.]	Answers	No	Yes		
						a.
		a. Condoms	00	01		b.
		b. HIV education/ counseling	00	01		c.
		c. Health checkup	00	01		d.
		d. Free medicine for STIs	00	01		e.
		e. Free medicine for general health problems	00	01		f.
		f. Membership in self–help group	00	01		g.
		g. Training/meetings	00	01		h.
		h. Other (specify) _____	00	01		
		i. No answer	99			
1031	Are you currently taking any form of medication? If so, what?	No Name of medicine Don't know/don't remember	00 98			
1032	Have you ever been tested for TB in the (name of AVAHAN clinic) or elsewhere?	No Yes, in the Avahan clinic Yes in other clinics Don't know/don't remember	00 01 02 98			
1033	Are you a member of any sex worker collective?	No Yes Don't know No answer	00 01 98 99		▶1037 ▶1037 ▶1037	
1034	What is the name of the collective?	Name _____ Don't know	98			
1035	How long have you been a member of this collective? [If <1 week, record in days. If >1 week and <1 month, record in weeks. If >1 month and <1 year, record in months. If >1 year, record in years.]	a. Days _____ b. Weeks _____ c. Months _____ d. Years _____ Don't know No answer	 98 99			 c. d.

1036	What kind of services do you get from this sex worker collective? [Read responses. Multiple responses possible.]	Answers	No	Yes	Don't remember	
		No services	00	01	98	
		Condoms	00	01	98	
		HIV education	00	01	98	
		Health checkup	00	01	98	
		Free medicine for STI	00	01	98	
		Free medicine for general health problems	00	01	98	
		Membership in self–help group	00	01	98	
		Trainings/meetings	00	01	98	
		Referral to VCCTC	00	01	98	
		Others (specify)_____	00	01		

#	Question	Answers	Codes	Skip to	Code Boxes
1037	Do you now use any method of contraception, and if so, what?	No method Condoms Birth control pills IUD/Copper T Injections Female sterilization Other (specify) Don't know No answer	00 01 02 03 04 05 97 98 99		
1038	Have you received —this in the last 45 days? (show unique object distributed)	No Yes Don't know	00 01 98		

Block 11. Community mobilization					
#	**Question**	**Answers**	**Codes**	**Skip to**	**Code Boxes**
1101	Do you agree or disagree with the following statement: I feel a strong sense of unity with sex workers whom I do not know	Agree Disagree No answer	01 02 99		
1102	Are you a member of a community group (self–help group or community–based organization)? A community group is a formal group composed of and managed by members of the community. They meet at least once a month.	No Yes Don't know/don't remember No answer	00 01 98 99	▶1104 ▶1105 ▶1105	

1103	Why did you join this group? [Do not read answers. Circle all that are mentioned.]	The group provides useful services for my community NGO requested me to My other friends were a part of it Other (specify) No answer	01 02 03 97 99	▶1105 ▶1105 ▶1105 ▶1105 ▶1105	
1104	Why are you not a member of a community group? [Do not read answers. Circle all that are mentioned.]	Don't know of a group Scared to join Don't understand the advantages/ benefits of joining No time Not interested Other (specify) No answer	01 02 03 04 05 97 99		

#	Question	Answers	Codes			Skip to	Code Boxes
1105	In the last one year, have you negotiated with, or stood up against, the following in order to help a fellow sex worker? [Read all answers. Circle all that are mentioned.]	Answers	No	Yes	Don't remember		
		a. Police	00	01	98		
		b. Madam/brokers	00	01	98		
		c. Neighbors, landlords, and/ or local political leaders	00	01	98		
		d. Other sex workers	00	01	98		
1106	In the last 6 months, have you attended any public events (such as a rally or a gathering of sex workers) where you could be identified as a sex worker?	No Yes Don't know/don't remember No answer		00 01 98 99			
1107	Have you ever been arrested?	No Yes Don't know/don't remember No answer		00 01 98 99	▶1109 ▶1109 ▶1109		
1107 a	How long ago were you last arrested?	Less than a year ago More than a year ago Don't know No answer		01 02 98 99			
1107 b	What were the reasons for your arrest last time? [Do not read answers. Circle all that are mentioned.]	Soliciting clients on a public site Carrying a condom In routine police raid Other (specify) Don't know/don't remember No answer		01 02 03 97 98 99			

1108	In general, when you have been arrested, do any other sex workers help you?	Never Rarely Sometimes Usually Always Don't need help/not a problem for me Don't know No answer	00 01 02 03 04 05 98 99			
1109	At any time in the past 6 months, have you stopped carrying condoms with you because you were afraid the police would identify you as a sex worker?	No Yes Don't know/don't remember No answer	00 01 98 99			

Instructions for interviewer

- Carefully review the completeness of the contents of the questionnaire/respondent's answers.
- Clarify any doubts or questions the respondent has about HIV/AIDS.
- With the respondent, complete the biological component referral card. Ask the respondent if he/she is interested in a free consultation with the IBBA doctor. If the individual says yes, circle YES next to "Respondent wants consultation with doctor," otherwise circle NO.
- Interviewer to fill in his/her name at the bottom of the card.
- If there is at least one YES circled on the card, thank the respondent for participating in the survey and escort the individual to the community liaison, who will take her to the clinic or lab to complete the biological component of the survey. If there are two NOs circled, thank the respondent for participating in the assessment and refer the individual to the supervisor for compensation.
- Return the questionnaire to the supervisor.

Instructions for supervisor

- The supervisor should give the respondent information on HIV/AIDS, health facilities, and VCTC clinics if she does not want to meet the doctor.
- The supervisor should check the questionnaire and fill in Q111, Q112, Q113, Q115, and Q201.
- Provide compensation.

Biological component referral card

ID number: _____Date: _____

[To be filled in by the interviewer. After completion, tear off this card and send it with the ID stickers and the respondent to the IBBA doctor or laboratory technician. The community liaison escorts the respondent to the doctor or laboratory technician.]

To be filled in by the laboratory technician and doctor. Definitions for laboratory technician (LT):

- Respondent gave only blood sample – The LT checks this box if the respondent gave only a blood sample and not a urine sample.
- Respondent gave only urine sample – The LT checks this box if the respondent gave only a urine sample and not a blood sample.
- Respondent gave blood and urine samples – The LT checks this box if the respondent gave both blood and urine samples.
- Respondent did not give any samples – The LT checks this box if the respondent did not give blood or urine samples.

The laboratory technician and doctor complete the referral card, and at the end of the day it is sent to the supervisor.

Completed by laboratory technician (select appropriate category):

Respondent did not give any samples	
Respondent gave only blood sample	
Respondent gave only urine sample	
Respondent gave blood and urine samples	

Completed by doctor (select appropriate category):

Swab not taken	
Swab taken	
Syphilis follow–up card given	
VCTC referral card given	

Biological Component Referral Card

Consented for biological tests	**Yes**	**No**
Respondent wants consultation with doctor	**Yes**	**No**

Interviewer's name _____

Appendix 9

9

Primary sampling unit form

My name is _____ and I am working on a project with _____ (research agency) and _____ (associated organization). We are collecting necessary information to help us conduct a survey called the Integrated Behavioral and Biological Assessment (IBBA). The IBBA is being done to assess the outcomes and impact of the targeted interventions among female sex workers in _____ (state).

I request you to provide us with some information related to this particular location. You may choose not to talk to us. In any case your identity will always be kept confidential.

Section A. Site description

Site Code (Group–State–District–Town/Village) _____ ☐☐☐☐☐☐☐

A1. Site number _____ ☐☐☐

A2. Group name/Code: _____ ☐☐

A3. Name/Code of state: _____ ☐

A4. Name/Code of district: _____ ☐

A5. Name/Code of town/village: _____ ☐☐☐

A6. Name of the local area: _____

A7. Address or description of area where site is located (mention local landmarks to clarify description): _____

A8. Who did you speak to as key informants (FSWs and nonFSWs) at the site? Include their occupation/role and contact point.

1. _____

2. _____

3. _____

4. _____

A9. Location of the site.

Draw a detailed map of the site including:

- Landmarks, street names, intersections, and other identifying information
- Boundaries of the site (indicating the stretch that the site includes)
- Location where key informants were spoken to at the site
- Use arrows to indicate the direction of entry to the site.

  For example, if the site is a room in a building, be specific about which floor, which side of the hall the room is on, and which room is being discussed by showing all rooms on that floor in the drawing and highlighting the specific one(s) that make up the site.

  If the site is a stretch of a street, show the side(s) of the street where key population members are found. Provide details about intersections/landmarks to highlight the boundaries of the site.

Note: Use a full page to draw the detailed map.

Section B: Site characteristics

The information in this section is filled once a consensus is reached, after talking with at least one FSW and three non-FSW key informants at the site.

B1. Type of site (Please enter one): ☐☐

Bar	01
Truck halting point	02
Bus/taxi stand	03
Lodge/hotel	04
Street corner	05
Marketplace	06
Cinema hall	07
Brothel	08
Park/garden	09
Railway station	10
Home	11
Other (specify)	99

B2. Which days of the week do you find FSWs at this site (that is, operational days)? (Select all that apply.)

Monday ☐ Tuesday ☐ Wednesday ☐

Thursday ☐ Friday ☐

Saturday ☐ Sunday ☐

B3. What times of the day and night do you find FSWs at the site (that is, operational times)? Use railway (24-hour) clock to cite the hours.

☐☐:☐☐ to ☐☐:☐☐

B4. How many FSWs solicit at this site throughout the day?

Number _____

*If the site is fixed (where there is no variation in size), record the total number of FSWs attached to the site.

B5. What is the least number (minimum) of FSWs who are at this site at any given day/time? What is the most (maximum) number of FSWs who are at this site at any given day/time?

Minimum: _____ Maximum _____

*if the site is fixed (where there is no variation in size), record the same number in minimum and maximum.

**** Questions B6 – B8 are only for MOBILE groups, not fixed groups. For FIXED groups, proceed to C1.****

B6. For FSWs KI only: How many FSWs associated with this site also operate/solicit at other sites?

Number _____

B7. On which days of the week do you find the most FSWs at this site (i.e., peak days)? Select all that apply. Please probe if they say there is no variation to find out peak days

Monday ☐ Tuesday ☐ Wednesday ☐

Thursday ☐ Friday ☐

Saturday ☐ Sunday ☐

B8. At what times do you find the most FSWs at this site (peak time)?

Use railway (24–hour) clock to cite the hours.

Please probe if respondents say there is no variation to find out peak times.

☐☐ : ☐☐ to ☐☐ : ☐☐

C. Other information

C1. Is there any private place available for collecting biological specimens at or around this site? If yes, please observe and give details with respect to the following. Ensure that the space is large enough to conduct IBBA (i.e., space for three chairs, one table, two cabinets, and specimen storage).

	Place 1	Place 2
Name & address of the place		
Nearest landmark		
Contact person		
Number of rooms available		
Condition of the rooms		
Is a toilet available for collecting urine samples?		
Is running water available?		

C2. List all the dates that you visited the site to collect information, and the time and duration spent at the site.

Date (DD/MM/YY)	Day of week	Time/duration

C3. The interviewer should note any observations about the site including:

- Potential language barriers
- Problems at the site
- Thoughts on where the interview could take place
- Key informants who need to be met before starting the survey

C4. Name of the interviewer_____

Signature_____

C5. Supervisor to add any other observations.

_____

_____

_____

_____

C6. Name of the supervisor _____

Signature _____

D. Data entry

D1. Date of data entry (DD/MM/YYYY) _____

D2. Name and signature of data entry operator

Name _____

Signature _____

D3. Name and signature of data entry supervisor

Name _____

Signature _____

Appendix 10

10

Cluster information sheet

Place ID sticker here

Annexure 4.4

CLUSTER INFORMATION SHEET (CIS) - FSW

[CIS must be filled up for each and every selected Cluster)
IBBA Round 2

GENERAL INFORMATION

01 Name of the Sub-population
FSW **Combined** 01 FSW **Brothel** Based 02
FSW **Non-brothel** Based 03 FSW **Service Bar** Based 04

02 Name/Number of Cluster _____

03 Name of the District _____

04 Name of the State _____

05 Sampling Approach
1 Conventional Cluster Sampling
2 Time Location Cluster Sampling
3 Take All Selection

06 Type of Cluster
01 Peak day, Peak time 02 Peak day, Lean time
03 Lean day, Peak time 04 Lean day, Lean time
05 Repeated visits (take all) 06 Any day, Any time

07 Time Planned to Cover Cluster From ____ To ____

08 Time covered cluster (Actual) From ____ To ____

09 Date and Day of Visit Date (DD/MM/YYYY) __/__/____

Day of Visit _____

ACTUAL MEASURE OF SIZE (DENOMINATOR)

10 Number of **eligible respondents** at the selected cluster

DETAILS OF SELECTION

11 Total number of **eligible respondents selected** for interview

12 Total number of **selected respondents not available** to be approached

13 Total number of the **eligible respondents approached** for the interview

DETAILS OF SELECTION RESPONSES	
14 Total number of the eligible respondents **refused** to be interviewed	
15 Total number of eligible respondents who started but **could/did not complete** the interview	
16 Total number of eligible respondents who were **interviewed earlier** for IBBA	
17 Total number of **completed behavioral interviews**	

DETAILS OF BIOLOGICAL SPECIMEN COLLECTIONS	
18 Total number of eligible respondents who have given **only blood** sample	
19 Total number of eligible respondents who have given **only urine** sample	
20 Total number of eligible respondents who **refused** to give **both blood and urine**	
21 Total number of eligible respondents who have **given both blood and urine** sample	

TOTAL RESULTS AT CLUSTER	
22 Total number respondents planned to cover at the cluster	
23 Total number of **shortfalls** at the cluster	

Name of Supervisor _____ Date :

Appendix 11

11

RDS coupon design

IBBA Nagaland

Recruitment Coupon

Address:

Visit our IBBA centres at Hotel Senti (ground floor), Golaghat Road or Ellora Line (opposite Guardian Angels drop–in center) to participate in the study.

Our opening hours are from **Tuesday to Sunday, 10:00 AM to 3:00 PM**

(closed on Mondays)

Activation date: _____

Coupon number:_____ **Expiration date:**_____

Study ID# _____

IBBA Nagaland

Redemption Coupon

Coupon number: _____

You will receive compensation for each person you recruit and enroll into the study.

Note: You must present this coupon to claim your compensation.

Appendix 12

12

Field monitoring checklist

This document provides tools and a format for monitoring and supervision visits to IBBA survey sites made by project teams (in India, by FHI or the Indian Council of Medical Research) to ensure adherence to processes outlined in the IBBA protocol. The checklist includes sections on sampling methodology, preparedness at the clinic/interview site, processes during interviews, data quality monitoring, infection prevention at clinics, transport of specimen, and overall observations.

This monitoring and supervision form may be completed by members of project teams from implementing organizations or from the core team. Each form may be completed based on a field visit to one or more recruitment sites or one IBBA clinic location.

State		District	
Target group (e.g., FSW/MSM etc..)		Date of visit	
Duration of visit			

I. Sampling methodology

This section is used to document observations about how the sampling methodology was implemented in the field, based on observations and/or interactions with the team supervisor or Community Liaison Officer (CLO).

1. Type of PSU visited: Time–location cluster (TLC) or fixed site

2. Comment on field team's arrival time and departure time at/from site (if it is a TLC):

_____

3. Who besides the field supervisor was present at site during recruitment of respondents and what were their roles:_____

_____

4. Listing of all eligible respondents done at site (yes/no) _____

Comment, if any, on how eligible respondents were identified and listed:

_____

_____

5.Selection and recruitment of respondents were random (yes/no) _____

Comment, if any, on how respondents were selected and recruited in the field:

_____

_____

6.Comment, if any, on how denominator was counted at site:

_____

_____

7. Cluster Information Sheet (CIS) filled correctly and consistently (yes/no) _____

(Two to five filled–in CISs may be checked and compared with the respondent selection sheet)

Comments, if any, on filled–in CIS: _____

_____

II. Preparedness at the IBBA clinic/interview site

This section is completed based on observations during the visit to the field IBBA clinic location.

Name of IBBA clinic /interview site visited:

1. Distance of IBBA clinic from field recruitment site: less than 5 kms (yes /no) _____

2. Adequate space and lighting available at IBBA clinic (yes/ no) _____

3. Privacy for interview is ensured (yes/no) _____

4. Facilities for collection of urine samples available (toilets & water) (yes/no) _____

5. Community liaison person available at the site (yes/no) _____

6. Efforts made to make participant comfortable—greetings, offered chair, etc. (yes/no) _____

7. Procedures explained to the participant (yes/no) _____

8. Refreshments available (yes/no) _____

9. Drinking water available (yes/no) _____

10. Adequate lab consumables available to the LT (Compare with the number of participants expected at that site at that day.) (yes/no) _____

11. Two gel packs in ice–box present and in frozen state (yes/no) _____

12. Appropriate labels available for use (yes/no) _____

13. Interviewer guideline for survey population available to the interviewer (yes/no) _____

14. Supervisors guideline for survey population available (yes/no) _____

15. Laboratory guidelines available to the technician (yes/no) _____

16. Clinical guidelines available to the doctor (yes/no) _____

Other observations on the IBBA field clinic: _____

_____

III. Processes during interview

This section is competed based on observations and interviews with the supervisor or district coordinator during visit to field IBBA clinic or interview site.

1. Consent form filled and signature/consent (yes/no) _____
2. Consent form separated from the questionnaire after the interview (yes/no) _____
3. Questionnaire checked by team supervisor before the respondent left the survey site (yes/no) _____
4. Questionnaire stored properly (yes/no) _____
5. If a male doctor examined the FSWs, was a female attendant present (yes/no) _____
6. Was the clinical format complete (no blanks) (yes/no) _____
7. Respondent provided with referral for STI/Integrated Counseling and Testing Center (ICTC) (yes/ no) _____
8. Respondent provided compensation (yes/ no) _____

Comments on process of interviewing respondents: _____
_____

IV. Data quality monitoring

Five to ten filled questionnaires are reviewed at random and checked for completeness and consistency.

1. Have the filled questionnaires from previous day been scrutinized? (yes/no) _____
2. Questionnaire filled properly (yes/no) _____(one or more questionnaires filled out the day of the visit)
3. Is the data coding done at the field level? (yes/no) _____

Comments on how questionnaires have been filled (including legibility, completeness etc.) _____
_____

V. Infection prevention procedures

This section is completed based on observations and interviews of field lab technicians at the field IBBA clinic site:

1. Gloves used during blood collection and storage and urine storing. (yes/no) _____
2. Needles were crushed after blood collection (yes/no) _____
3. Syringe was destroyed and disposed (yes/no) _____
4. Left over urine was put in waste bin (yes/no) _____
5. All biological waste in is waste discard (yes/no) _____
6. Biological waste is sent to district for proper disposal (yes/no) _____

Comments on infection prevention procedures by field lab technician: _____
_____

VI. Transportation of specimen

This section is completed based on observations and checking the forms completed by the field laboratory technician at the IBBA clinic site:

1. Specimen was packed as per guideline (yes/no)____
2. Waste materials were packed as per guideline (yes/no)____
3. Specimen transport form signed by doctor (see previous day's office copy) (yes/no) ____
4. Specimen transport form signed by team supervisor (see previous day's office copy) (yes/no)____
5. Specimen receipt form from previous day available (yes/no) _____

Comments on process of transportation of specimen to district laboratory

_____

_____

Comments on efforts to make respondents comfortable at IBBA field clinic

(May be based on observations during visit to clinic, and through interactions with CLOs, supervisor, and field laboratory technician.)

_____

_____

VII. Overall observations and comments during field visit

_____

_____

_____

_____

VIII. Recommendations, if any

_____

_____

_____

_____

Appendix 13

13

Laboratory stock form

Date of order _____

Field team code _____

Signature _____

Name of the field supervisor _____

Name of the doctor _____

Name of the laboratory technician _____

Date the last supply was received _____

Article	Total quantity received until now	Total quantity consumed until now	Quantity on hand at present	Quantity requested	Quantity actually received*

Instructions for completing the form:

- Please write *nil* where required, instead of leaving the cell blank.
- At the time the drugs are requested leave the last column blank.
- Please complete the form in duplicate. Send one copy to the district when supplies are ordered and retain one copy for reference in the office.
- *After receiving the supplies, enter the quantity received on the office copy in the last column.