Implementing Integrated Bio- Behavioral Surveys among Key Populations at Higher Risk of HIV Exposure with an Emphasis in Respondent Driven Sampling

Lessons learned from the field

2010-2012

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Acronyms

ACASI	Audio computer-assisted self-interview
ANC	Antenatal care
CDC	Centers for Disease Control and Prevention
DBS	Dried blood samples
FSWs	female sex workers
GAC	Ghana AIDS Commission
IBBS	Integrated Biological & Behavioral Survey
IDU	injecting drug user
IRB	Institutional Review Board
KAVI	Kenya AIDS Vaccine Initiative
MOUs	Memoranda of Understandings
MSM	men who have sex with men
NACC	National AIDS Control Council
NASCOP	Kenya National AIDS and STIs Control Programme
PEPFAR	The United States President's Emergency Plan for AIDS Relief
PI	Principal Investigator
QA	Quality assurance
QDS	Questionnaire Development System
RDS	Respondent Driven Sampling
RDSCM	RDS Coupon Manager
STI	sexually transmitted infections
TWG	Technical Working Group
UCSF	University of California, San Francisco

Introduction

What follows is a description of the constructive lessons learned by University of California San Francisco (UCSF) staff and partners while conducting Integrated Biological & Behavioral Surveillance (IBBS) Surveys among key populations at higher risk of HIV exposure in Africa, with special emphasis on RDS. This document is intended for university and ministry of health staff, public and private public health researchers, and surveillance officers who will be involved in planning, organizing, monitoring, implementing or analyzing IBBS on HIV and AIDS and associated risk factors of populations that may be at higher risk for HIV infection.

Behavioral surveillance is the ongoing systematic collection, analysis, interpretation, and dissemination of information on behaviors that relate to one or more public health conditions.[1] Behavioral surveillance is used for public health action to reduce morbidity and mortality and to improve health.[2] Most behavioral surveillance is now integrated and focuses on gathering data on HIV and STI prevalence and the associated risk factors. The purpose of behavioral surveillance is to assess trends in an epidemic and identify factors that impact a public health condition specific to the geographic area and population being studied.

Respondent Driven Sampling (RDS) was first used in 1994 to study Intravenous Drug Users (IDUs) in the United States.[3] Today, this sampling method is utilized worldwide to study hard-to-reach populations when traditional probability sampling methods are infeasible. The RDS sampling method is meant to reduce bias associated with chain referral sampling by using social network theory which attempts to map relationships and characteristics shared by groups. Information about the social networks of persons recruited into an RDS study are used during analysis to weigh the probability of each recruit's selection and adjust for biases associated with non-random sampling.

[1] Lansky A. et al. HIV Behavioral Surveillance in the U.S.: A Conceptual Framework. 2007. Public Health Report; 122(Suppl 1): 16-23.
[2] MMWR **July 27, 2001 / 50(RR13);1-35**
[3]Heckathorn DD. (1997). Respondent driven sampling: a new approach to the study of hidden populations. *Social Problems*. 44(2):174-99.

PAST STUDIES CONDUCTED BY UCSF

UCSF has collaborated on three recent RDS studies: Kenya, Ghana, and Mozambique. The objective of these studies was to initiate periodic routine Integrated Biological & Behavioral Surveillance (IBBS) of these groups. Although there were some variations in the planning and implementation in each of these studies, consistent features included:

1) Formative research to assess RDS feasibility and planning;

2) Consent process whereby participants could consent to or decline any part of the study (e.g., questionnaire, rapid testing, blood draw, and storage of blood for future testing).

3) Face-to-face risk behavior questionnaire interview format;

3) HIV/STI risk assessment and disclosure counseling;

4) Rapid HIV testing with confirmatory testing of positive specimens;

5) Pre and post test counseling;

6) Referral to collaborating MSM/SW/IDU -friendly care and support services for persons testing HIV-positive on rapid testing and those with reactive STI tests were referred to;

7) Population size estimations using the distribution of a unique object;

8) Dissemination of findings to stakeholders in order to advocate for needed services, to develop appropriate prevention and care interventions, to guide future research, and to assess the impact of the response to the HIV epidemic over time.

Ghana

Background: Following a formative assessment, the Ghana Men's Health Study collected biological and behavioral data from men who have sex with men (MSM) in 6 cities: Accra, Tema, Cape Coast, Takoradi, Kumasi, Koforidua. To facilitate better recruitment and geographic representation, the cities of Accra/Tema and Cape Coast/Takoradi were paired making a total of four sites that were paired with a study office in a different site. A sample size of 500 MSM per location was based on providing 80% power to detect a significant ($p<0.05$) 10% change in condom use between the proposed study and future rounds of IBBS studies with MSM using a chi-square test and assuming a design effect of 2.0. Data collection started in mid April 2011 in the first set of sites: Accra/Tema and Cape Coast/Takoradi. Nine weeks into the study, the target sample size was revised to 300 in each of the four sites based on multiple factors. Data collection in the first set of sites spanned 12-14 weeks in time to reach a sample of 300-500 MSM.

Objectives: The goal of the Ghana Men's Health Study was to measure HIV prevalence, STI, related risk behaviors, and access to prevention and care services among adult MSM in RDS sites across Ghana.

Funding and partners: The Ghana AIDS Commission (GAC) commissioned the study with funding from CDC and provided coordination support and oversight while CDC and UCSF provided technical assistance and oversight. The study was also conducted through subcontracts with the following two institutes at the University of Ghana for in-country implementation: 1) the Noguchi Memorial Institute for Medical Research (NMIMR) who was responsible for all the laboratory aspects of the study including testing, pre/post test counseling, and quality assurance (QA) at the central NMIMR lab, and 2) the Regional Institute for Population Studies (RIPS) who was responsible for implementing all other study components.

Testing: Consenting respondents received rapid HIV testing using dried blood spot; blood test for markers of syphilis, HBV, and herpes simplex type 2 (HSV-2) infection

Kenya

Background: The Kenya IBBS was conducted from 2009-2010 among MSM, injecting drug users (IDUs), and female sex workers (FSW) in Nairobi and Kisumu, Kenya. The target sample size was 600 per group and was calculated to provide sufficient power to detect within a ±5 percentage point of the hypothesized true HIV prevalences of the target populations. The MSM study took place between July to mid-October, 2009, with a final recruitment of 563. The FSW study was performed from mid-October 2009 to early-Jan, 2010 with 593 recruited. Finally, the IDU study began in early January 2010 and completed by the end of March 2010 with 263 IDUs recruited for the study.

Objectives: The project objectives included 1) the identification and recruitment of members of these vulnerable populations, 2) monitoring prevalence of HIV and other selected STIs,3) identifying and describing key characteristics of these populations which place them at risk, and 4) identifying how the most vulnerable subgroups of these populations may be identified, reached, and served by various health programs. Instruments provided estimates for the

MARPS' HIV knowledge, attitudes, and risk and prevention behaviors. Information elicited from the questionnaire informed and guided population size estimation, particularly information on service enrollment which was entered into a modified capture-recapture formula.

Funding and partners: This surveillance activity was funded through The United States President's Emergency Plan for AIDS Relief (PEPFAR) and was conducted in collaboration with Population Council, NASCOP, the National AIDS Control Council (NACC), CDC Kenya, CDC Atlanta, University of California at San Francisco, the Nyanza Reproductive Health Society, University of Illinois at Chicago, the Institute of Tropical and Infectious Diseases, University of Nairobi, the University of Manitoba, the Gay and Lesbian Coalition of Kenya, and the Kenya AIDS Vaccine Initiative (KAVI). Kisumu (Nyanza Province), the study covered MSM only (415 recruited) and was implemented by Nyanza Reproductive Health Society/University of Illinois, Chicago through a subcontract from Population Council.

Testing: Consenting respondents were tested for STIs and asked to provide a specimen for rapid HIV testing.

Mozambique

Background: Mozambique conducted two IBBS studies: the Mozambique Men's Study among MSM starting in March 2011 followed by the Woman's Health Monitoring Survey among FSW in September 2011. The studies were rolled out in Maputo, Nampula/Nacala, and Beira. The proposed sample size for the MSM study was for 500 men in each of the three study sites based on providing 80% power to detect a significant ($p<0.05$) 10% change in condom use between the proposed study and future rounds of IBBS with MSM. MSM aged 18 and over who reside in Mozambique were eligible to participate. The proposed sample size for the FWS study was 400 females per location based on providing 80% power to detect a significant ($p<0.05$) 15% absolute change in self reported condom use between the proposed study and future rounds of IBBS among FSW at each site. Eligible participants for this study were females, who exchanged sex for money in the last 6 months, aged 15 years and over who reside, work, or socialize in one of the selected study areas. Both studies used a chi-square test and assumed a design effect of 2.0

Objectives: To measure HIV prevalence, STIs, related risk behaviors, and access to prevention and care services among MSM and FSW in Mozambique.

Funding and partners: Implementing partners for the FSW study included INS, Pathfinder, and I-TECH. The MSM study included the same implementing partners along with PSI. CDC provided funding and technical assistance in the implementation of the studies.

Testing: Both studies conducted rapid HIV testing with confirmatory testing of positive specimens; collected dried blood spots (DBS) and tested samples with ELISA for HIV surveillance purposes at the National Institute of Health (national laboratory); stored DBS specimens for future HIV-related tests (pending protocol approval); performed rapid syphilis testing (Maputo only); and performed external quality assurance for HIV and Syphilis testing.

LESSONS LEARNED FROM PAST STUDIES

1. Administrative preparation

1.1. Institutional commitment

- Develop Memoranda of Understandings (MOUs) between participating institutions for each study. This may help to clarify roles and responsibilities of each participating institution, especially those not monetarily contracted to work on the study.
- Assemble an overall Technical Working Group (TWG) of study investigators and other interested parties that meet at least once a month. This helps to keep everyone informed about overall study activities.
- Ensure that there is a data sharing agreement in place or an understanding of where and when data will be analyzed and who will write reports/publications. It may be difficult to find a time when all members can meet or to make concrete decisions if the group is larger than 15-20 members.

1.2. Managing Study Documents across multiple users

- Develop and follow a pre-implementation checklist for planning and preparation prior to launching the study.
- As a policy for all study documents, task one person with addressing comments and approving new versions of the same document. Save these files with a descriptive name, followed by the date that the version was last saved and the initials of the person making the most recent changes. Also embed dates into the headers or footers within the document.
- Use a file sharing program (e.g., www.dropbox.com) to facilitate the sharing of study documents. Send document versions by email and also mention which folder the document is available in the program. Maintain order among shared files by assigning one person to be in charge of deleting shared items.
- Identify one person to batch, zip, and send the updated version of all relevant documents for each phase of the study to everyone on a weekly basis (e.g., every Friday). That person should also keep track of all edited versions and be copied on all related correspondence to make sure their edits are captured in the official zip file of current documents.

1.3. IRB

- Identify a lead point person to be the only person that communicates with each Institutional Review Board (IRB).
- Avoid submitting one protocol to different IRBs in parallel. The added confusion of harmonizing the submission of amendments to different IRBs can become overwhelming.
- Submit formative research and quantitative study protocols together to avoid unnecessary delays.

2. Study planning and pre-implementation

2.1. Formative Assessment Activities

- Explore participant comfort using different types of electronic data collection devices such as Netbook computers and tablets during the formative assessment to see if these would be a useful mechanism for data collection.
- Use mapping during the formative assessment to identify landmarks that can be used when designing the map and directions to the study site for the coupons.
- Have the same team conduct formative assessment and partake in the implementation of IBBS. This can help ensure that the results from the formative assessment will actually be used to improve the study design. This also reduces the amount of time needed to explain RDS theory to staff during the implementation stage of the study.

2.2. Site Selection, Acquisition, and Considerations

- When selecting a site, find a balance between access to and/or visibility of your site and the value of anonymity and stigma reduction.
- Select a site with a room where staff can spend time while not working with participants so that rooms needed for work (i.e., the laboratory room and/or reception) do not become overcrowded with idle staff members.
- Health clinics tend to be good sites because they are:
    - central and easy to get to;
    - often located on major bus routes;
    - busy so anonymity is preserved; and,
    - less expensive to set up.
- If your study includes multiple cities with both single and paired sites, then launch the single sites first since paired sites are logistically more difficult to organize, operate, and monitor.
- If a city is very large warranting multiple sites, ensure that they are far enough apart that it is not worth someone's time and energy to travel from one site to another just to get the incentive, but still close enough so networks overlap.

2.3. Supplies Acquisition

- Assess the amount of time needed for the procurement of supplies and start procurement as early as possible especially for laboratory supplies and supplies being procured internationally. Some countries require up to three months to procure laboratory supplies internationally.
- Divide procurements up into batches dependent on when you need the supplies in order to manage storage, shelf life, expiration dates, etc.

- Prepare detailed lists of office supplies including cleaning/kitchen/bathroom items so as to avoid last minute procurement.
- Consider purchasing a generator if power outages are frequent.

2.4. Coupons, consent form & forms

- Avoid designing coupons and result appointment cards to look the same since participants may get confused.
- Reduce the length and simplify the comprehension level (max 6th grade reading level) of the consent form. Field test the most simplified version and then consider shortening and simplifying it again.
- Prior to printing, ask the printing company to provide several samples of what the final study documents/materials (i.e. coupons, appointment cards, labels, questionnaire booklets) will look like prior to printing.

2.5. Incentives

- Incentives for the second visit (if necessary) can be helpful in getting people to return for their test results.
- In conjunction with national standards, decide when writing the protocol whether you can split primary incentives between those participants who complete only the questionnaire and those who complete the questionnaire AND provide a blood/specimen sample.
- Consider dividing the prevention materials so half are provided at the 1st visit and the other half at the 2nd visit. For example, provide 5 condoms and lube after the 1st visit and 5 of each after the second visit.
- The provision of gynecological exams or make-up/hygiene kits at the interview site can be a useful incentive, especially for FSW.
- Budget for extra transport reimbursements in case lab results are not ready by a participant's second visit and that participant has to make an extra trip.

2.6. Testing, treatment and referral preparations

- Take the study setting into consideration when determining whether testing should be a part of the protocol. For example, a clinic setting may facilitate more comfortable and successful testing than a bar-based setting.
- Be sure that appropriate follow-up care and/or treatment are available for all infections tested.
- Research the caliber of providers/clinics available for referral and determine whether or not participants feel motivated to follow through with referrals prior to providing them.
- Consider ways to motivate hospital staff to collect referral visit cards when participants present for follow up. This will help to track referrals.

- Create a referral voucher with the participant's coupon number on it. Ask the referral clinics to collect the vouchers to determine the percentage of persons seeking follow-up care and treatment.
- Work with care and treatment centers to provide some transportation cost or small incentive so people do seek follow up care and treatment if needed.
- If possible, provide on-site treatment for syphilis or other STIs.
- Consider the following points when determining which tests should be run at the site versus at the central lab:
    - The amount of training lab technicians at the study office would need
    - Whether an onsite lab technician would become overburdened with the participant volume and conducting numerous tests on site
    - The amount of time the participant would have to wait until his test results are ready.

3. Questionnaire Development

3.1. Questionnaire design

- Utilize the UCSF standard questionnaire as a guide for determining which questions should be included or excluded in the questionnaire
- Involve people who have worked extensively with the key population being studied prior to definitively removing/including questions.
- Consider ranking questions as a mechanism for quantifying which questions should be included in the questionnaire. For example, identify questions as '1' if their inclusion is a stakeholder/funding requirement or if the response is something the ministry must know; identify questions as '2' if they should be included but may not be a requirement or as beneficial; identify questions as '3' if the results would be interesting but may not be useful in forming conclusions about the study population.
- Avoid asking questions just because "we've always asked them" and instead ask questions based on an analysis plan
- Balance the length of the questionnaire between what the respondents will tolerate and the information that is necessary to ascertain for this study. The questionnaire should take less than 45 minutes.
- Consider including a mechanism for determining and recording why someone declines a specific component of the study. For example, if someone declines an HIV test and participation in the interview, probe as to why someone declines HIV testing and then probe as to why they decline the interview. At the end of the questionnaire, consider re-asking participants who initially opted out of the testing component if they would now like to do the testing. This may occur once the participant has developed a rapport with the interviewer. Update consent form to changes as necessary.
- Consider adding a follow-up question on secondary visit questionnaires to track whether participants went to a health facility for a referral and if they did, to which health facility.
- Decide ahead of time which variables need checks and the mechanism for checking them.
- When working with multiple languages, create one Excel file of the the questionnaire in English in one column and any other study languages in the adjoining columns.
- Allow plenty of time (weeks) to program the questionnaire, test it, and make edits.

3.2. Domains to be included in RDS questionnaires

Always include	Include if appropriate
•Recruiter and coupon info •Demographics •Marriage and family •Sexual history •Condom Access &use •Lubricant Access & use •STI/HIV/AIDS Knowledge •HIV testing •HIV Care and Treatment •Stigma •Health services utilization •Program coverage •Social networks & Size Estimate	•Alcohol + Drug use/abuse •Mobility questions •Mental Health questions •Concurrency •Migration/integration

4. Lab Logistics and Testing and Counseling Activities

4.1. Lab supplies inventory management

- Designate a focal person for lab supplies who can keep track of inventory, expiration dates, procurement, and which sites are in need of supplies.
- Site supervisors should fill out weekly inventories of the supplies that remain at week's end. Subtract this number from the number of supplies received initially to determine which materials are running low and need to be reordered before they have actually run out.
- Consider maintaining a supplies calendar (covering the next three months) that identifies which supplies need to/should be ordered and when and always plan for extra supplies.
- Conduct a thorough literature review of test kits to determine what is most appropriate in terms of specificity, cost, and ability of labs to do confirmatory testing.

4.2. Handling and labeling of samples

- Maintain very strict quality control of samples.
- Set a clear Lab quality assurance (QA) plan that describes whether samples will be tested for QA at the study lab or sent to another lab and when QA will be conducted (e.g. at the end of the study but before data analysis versus ongoing).
- Have site supervisors do weekly checks of all codes on samples prior to sending them out.
- Consider utilizing two coolers so that one cooler remain at the lab while the other is used to transport samples
- Train lab staff in the proper handling and labeling of samples.
- Develop a lab transport schedule that identifies when samples will be collected from each site.
- Designate a person on the receiving end who will sign paperwork and is responsible for making sure the samples have been picked up/dropped off prior to closing down for the day.
- Develop a rotating schedule so that every weekend (or observed holiday) a person from the study team comes to the study site and puts away the dried blood spots (DBS) samples left to dry from the day before.
- Ensure the lab partner in-country where samples will be sent has a high level of expertise.
- Follow everything up with documentation forms, signed by the appropriate persons.

4.3. Recording, reporting, and protecting test results

- Have counselors involved early in discussions about storage of test results at sites and who has access to that information. Site

supervisors should have access to results for study monitoring purposes.

- Write test results on two separate forms so that mistakes can be more easily corrected. Counselors may forget to write down the test result which can be corrected if written twice.
- Write down the return date of the participant's second visit on the test results form that goes to the lab so the lab is aware.
- Think through all the rules and exceptions you would be willing to make in terms of timing of test results disclosure. For example, consider: Who is eligible to get money and for which situations?; Who is eligible to recruit and under which circumstances?; What happens when a recruit changes his/her mind about getting tested?; How much time will you give them to change their mind?
- Regularly update counselors about the testing algorithm paying particular attention to how discrepant results (e.g., initial test is positive and confirmatory test is negative) should be handled.
- Be sure that the counselors emphasize to the participant the importance of the confirmatory test in discrepant cases and the need for referral services in the case of a confirmed positive result.
- Counselors should be reminded to notify site supervisors, counseling supervisors on site, and study investigators of discrepant results.

4.4. Lab Databases

- Lab databases (e.g, Excel, CSPro, or EpiData) should have a testing algorithm that breaks down test results by individual test performed for each infection for each participant and not just positive or negative.
- For reference testing, budget extra time to create system, forms, and standard operating procedures (SOPs) for managing the specimens and results at the lab.
- Consider budgeting for data entry staff at the lab.

- EpiInfo is a free alternative to QDS for questionnaire design. While EpiInfo is easy to program, it cannot accommodate validity checks or complex skip patterns.

5.1. *Questionnaire Design Studio (QDS)*[4]

- Train a few key staff locally (ie: Data Manager(s) who oversee all the sites) in the operation and programming of QDS.
- Staff members who are thoroughly trained in QDS can walk other staff members through the process of updating QDS and other minor software glitches.
- Local capacity building in the use and programming of QDS allows staff to make real-time changes in the local language.
- When training staff in programming in QDS, provide examples from other studies.
- Only install the CAPI QDS program onto the computers being used for data collection and install the warehouse and design studio QDS software onto the data manager(s) computers. If too many programs are installed on the machines used for data collection, they may experience frequent crashes.

5.2. *Coupon Management and RDSCM 3.0 (CDC NHBS version)*

- Hire staff with basic knowledge of English to work with RDS Coupon Manager (RDSCM).
- Determine ahead of time who will review the coupon manager and how frequently.
- Have the site supervisor monitor the data entered into RDSCM daily to avert issues with the coupon manager entering incorrect coupon numbers and/or forgetting to register coupons distributed in the system.
- Ensure the RDSCM database is backed-up/exported to somewhere routinely.

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[4] QDS System Requirements for QDS v2.6.1.
Operating System: Desktop—Windows XP, Tablet, Vista*, or Windows 7*; Pocket PC—Windows Mobile 2003, Windows Mobile 2003 SE, Windows Mobile 5**, Windows Mobile 6 (Classic/Professional)**, Windows Mobile 6.5 (Professional)**
RAM: 32MB Minimum, 64MB Recommended.
Disk Space: 20 MB for installation (additional space required for questionnaires).

If intending to use audio, a sound card is also required.

* When installing HAPI under Vista or Windows 7, the setup program does not install the QAD File Filter program. This change is due to the fact that the Windows Mobile Device Center does not support the file conversion feature provided by Microsoft ActiveSync under Windows XP.
**The QDS functions DBVALUE, DBCOUNT, and DBSTATUS do not work on the Windows Mobile 5 or Windows Mobile 6 platform.

- Train on the delete coupon function. This function (under administrative tasks menu) is really helpful for eliminating the problematic coupons in the system. (Delete → Re-start RDSCM →Then do a fresh re-enter).
- Always have at least two other paper-based (manual) methods to track coupon information. Therefore, install cloud drives that run XP if planning to use RDSCM on Netbooks. As a caution, the cloud drives make the Netbooks run very slow.
- Currently, Netbooks do not run on Windows XP. In order to get version of RDSCM CDC v3.0 to run in Windows 7, run it in compatibility mode for Vista SP2 by following the steps below:

1. Right click on the RDSCM program's shortcut link
2. Click on Properties
3. Go to the Compatibility tab
4. Click on "Run this program in compatibility mode for:"
5. Select "Vista (Service Pack 2)"

5.3. Data collection

- If electronic data collection will be used, procure devices that are compatible with Windows since some mobile devices will soon no longer support Windows and in turn will not be compatible with QDS.
- Keep paper questionnaires available for backup in the case that electronic data collection tools fail, the power goes out, or the participant is not comfortable with digital collection.
- Some participants may fear the electronic data collection devices (e.g., netbook, laptop, PDA) can take their pictures or record their voice so have interviewers address participant concerns about tablets by explaining the function of the tablet prior to conducting the interviews.
- Always ask the personal social network size question (i.e. how many people do you know, they know you, who are…) face-to-face if using Audio computer-assisted self-interview (ACASI).
- Conduct thorough piloting of all electronic questionnaires including testing multiple response scenarios to verify that all skip patterns work accurately (e.g., partner matrix).
- If using ACASI, re-record ACASI interviews in the local language as opposed to programming in the default 'American' voice.

5.4. Data Management

- Create a data management SOP from the start and identify priority forms and the order in which they will be processed.
- Be sure to hire someone who's conversant with data management/data backup.

- Ensure proper and secure data storage by electronically sending study files from each site to the centrally located data manager at the end of every work day.
- Encrypt the files and require a password for access.
- To help protect data and prevent viruses 1) provide each site supervisor with a portable USB modem to facilitate the sending of files; 2) only allow the supervisor USB to be used with these devices, 3) disable internet on all netbooks or tablets containing QDS, and 4) after launch, avoid deleting any files to ensure secure data management
- Wait until the near final or final version of forms and questionnaires are developed before starting to develop a database. However, complete the database before the study starts so that it can be tested.

5.5. Data Analysis

- Start thinking early about narrowing the scope of your study and the tables you wish to create from this data but take caution in mentioning any raw estimates of prevalence prior to RDS adjustment.
- Consider creating a "publications panel" to help guide the development of Guidelines for Publication and eventual peer-reviewed manuscripts and conference presentations.

6. Data Quality Assurance

6.1. Data Entry for paper-based questionnaires

- Start inputting data early during data collection so data quality can be assessed and data availability ensured.
- Create a contingency plan for how and where data will be backed up. Diligently back up data every day to ensure no data goes missing.
- If using Editors or position similar to Editors for QA, develop a Job AID that highlights the following three elements requiring special attention: key variables, consistency checks across variables, and complex skip patterns.
- Assess capacity for data entry in order to monitor data (i.e., how many forms can the entrants enter per day?).
- Strongly supervise data entry especially the comparison of double entry and be sure that any discordant results are assessed using the original files.
- Set up a schedule for when data can be checked (e.g., every 100 records or monthly) to assess the quality of the database and data entry.

6.2. Coupons and lab numbers

- Interviewers or counselors may write down the coupon or lab number incorrectly on one form and then correctly on another form or sometimes not at all. Therefore, have at least two different places where staff must write down study codes and test results, especially rapid test results, and have the site supervisor check these at the end of each day to allow for the correction of these mistakes.
- Have the site supervisor flip through each folder at the end of the day to make sure everything is filled out correctly.

6.3. Questionnaires and Forms

- Thoroughly review skip patterns and questions for acquiring required data (network size, age, etc) before implementing the study and thoroughly check data forms before they leave the site.
- Check files and forms daily for at least the first 2 weeks or until all forms are being completed correctly. Have interviewers sit next to their peers as their completed questionnaires are reviewed so feedback can be given.
- For paper questionnaires, have the site supervisor review completed questionnaires while the participant is still in the interview site. Resolve any discrepancies before the participant leaves. If this is not possible, flag discrepancies for the participant to resolve when he or she returns for their second visit.
- Decide how hard copies will be filed. It is important to keep them in a predetermined order for ease of reference in the future.

- If you have multiple sites, then ensure to schedule 2nd visit appointments only when the team will be back in the same study office as the 1st visit to prevent having to remove participant folders from sites.

7. Study Monitoring

7.1. Call Log

- Record the coupon ID number on the call log if using a call log to track the calls coming in to the study (e.g., people seeking directions, study hours, or an appointment). This log can track how many unique participants express interest in participating in the study. This type of information may be helpful to identify bottlenecks and barriers to recruitment if coupon return rates are low.

7.2. Monitoring Scamming: Coupon trading and "faking"

- Work with community outreach workers to develop a list of additional "filter" non-standardized questions that coupon managers can ask potential participants.
- The coupon manager should select randomly from the list of filter questions and avoid asking the same questions in the same order every time. This prevents participants from memorizing the questions and answers and coaching their friends on how to answer.
- Include "confidence" scales after the screening and behavioral interview.
- Have community outreach workers stand outside of the study site to learn about any coupon trading or bribing.

7.3. Weekly Monitoring Reports

- Plan in advance what types of indicators the core team want to monitor regularly – it may be more than what the RDS monitoring tool is capable of.
- Accompany RDS monitoring tools with a narrative that explains at a minimum the specific situations the study team encountered. These can be valuable learning experiences.
- Monitor study data using weekly recruitment monitoring reports.
- Send weekly recruitment monitoring reports back to site supervisors to help staff understand the importance of the study and to show that all activities are being closely monitored.

7.4. Site Flow and Capacity

- Conduct weekly phone calls with the full investigator team and make sample size decisions as a team.
- Decide who will determine when to cut or increase coupons and how that will be communicated.
- Assess where participants are coming from using weekly monitoring reports. This also allows for participants to be geographically pruned and trimmed.
- Set expectations so staff members understand and agree on the number of people the site can accommodate each day. This sets a concrete number for when people should be turned away and not asked to wait.

- Conduct dry runs of the entire study process and make sure all field staff understand the flow.
- It is important to help staff understand how they can be flexible in the case of bottle necks.
- Consider the benefits and challenges of having a scheduled appointment versus walk-ins. Participants rarely make and/or keep appointments.
- Accept the number of participants that can complete the study in a day and then begin a waiting list of those who will be given priority the next day in the case that participants line up before study opening hours.
- Keep as little cash/incentives as possible in the study site office for security reasons.
- If using cash to pay out transportation reimbursements for participants, be sure to take into account fluctuations in participant flow when determining the minimum amount necessary.
- Have small bills on hand for change.

7.5. Community Mobilization Issues

- Have site supervisors do daily monitoring of community outreach workers and have them come to the study site on a daily basis for meetings.
- Implement a participant satisfaction survey to get direct, anonymous input on how participants perceive the way in which they were treated by different staff throughout the study.
- If they are dissatisfied, ask the site supervisor to talk with that person to see if any problems can be addressed before the participant leaves.
- Consider how the media, neighbors, authorities, or other community groups may negatively or positively affect study progress prior to the study and then develop a plan (e.g., SOP) for dealing with the media including designating a point person and talking points.

7.6. National supervision

- Develop a checklist of everything that a national supervisor should check for when conducting site supervisions. There is often so much happening during a visit that some important tasks can get overlooked. Having a checklist that can be used by all site supervisors will assure consistency in the supervision visits and also provides a record of areas of improvement found during supervision visits.
- Decide who is in charge of assessing data throughout the study and verify that they have access to the data.
- Determine who will communicate with technical experts about data monitoring outside the country

8. Human Resources

8.1. Training staff

- Consider developing a mentoring system in which each trainer is partnered with 3-4 trainees. This may help to individualize training and determine each staff's strengths and weakness.
- Establish prior to training if clinical staff are familiar with the STIs that will be screened and the treatment for these infections and then conduct a separate training for lab and clinical staff.
- Train more people than you actually need for your study but wait until after the training is completed to sign contracts for employment so that only those who performed best during the training period are actually hired. The remaining people who were trained but not hired can serve as replacements in case any staff quit or take leave during the study period.
- Cross-train team members, especially between receptionist, coupon manager, and site supervisor. That way if any team member is out sick or on leave, other team members can assist in taking over the duties.
- Be sure lab staff roles are explained and well understood. It is important that both central lab (those running the tests) and site lab (those taking the samples) are trained and understand how samples will be transported and how results will get back to the clinic.
- Provide basic laboratory and bio-safety training to ALL team members, including drivers and train all relevant staff in the use of necessary software.
- Strict rules need to be explained (and enforced) to field staff about their involvement in recruitment of study participants.
- Avoid using field staff to select seeds since this may be a conflict of interest in terms of field staff suggesting their friends rather than potential good seeds
- During training, reduce use of power point and theoretical discussions so to keep participants engaged.
- Focus training time on practicing exercises and simulations; consider leaving at least 2 full days for simulations.
- Have all SOPs, forms, etc in one single manual that everyone receives and continue to refer to the manual and the page numbers in the manual throughout the training.
    - Use this strategy when correcting mistakes so staff knows that changes are not new, they're in the manual. Also, this makes everyone aware of the roles and responsibilities of every member of the team.
- Allow plenty of time before Day 1 site launch for staff to become familiar with the computer, software and how to troubleshoot basic issues that arise.

- Conduct several rounds of role-playing, including utilization of netbooks, QDS/CAPI, RDS Coupon Manager and fingerprint software (if applicable).

8.2. Training SOPs

- Be sure that SOPs contain feasible instructions and tasks.
- For site supervisors, develop very detailed SOP's that specifically detail what they are expected to do on a daily/weekly basis.
- Site Supervisors should know the SOP's for all other site staff.
- Develop summary cards for SOP's that can be laminated and placed on a wall or desk for interviewers, counselors, etc.

8.3. Hiring staff

- Hire a mix of both members and non-members of the key population being studied as well as a mix of male and female interviewers since some respondents may be more comfortable talking with one gender over the other.
- Be aware that staff may know participants personally if the community is very small.
- Ensure that staff has strong communication and counseling skills especially when discussing specimen collection concerns and that they all have the same mentality about the importance of HIV testing

8.4. Managing staff work hours

- Inform teams that regardless of whether they reach sample size or not they will still be employed for the full time of the contract signed. This will avoid teams purposely keeping the number of participants per day low for job security.
- Balance formative research results, practical considerations, and staff morale when choosing hours of operation.
- Include a clause in the contract that people cannot quit from one day to the next and discount employee pay on days when a team member does not come to work.
- Include breaks when setting up staff schedules and consider national holidays and how they may affect field staff work schedules, national laboratory staff, and participant enrollment.

Additions, Corrections, Suggestions

If you have suggestions for improvements or your own lessons learned that you would like to share in this document, please write or email us using the information below. We will collect your letters and emails and consider your comments in the next update to this module.

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