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Project Accept Standard Operating Procedures Manual:
Community-based Voluntary Counseling and Testing

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I. Introduction

A. Purpose of This Manual

The purpose of this manual is to describe the strategy for providing mobile voluntary counseling and testing (VCT) in the communities\(^1\) randomized to receive the Project Accept intervention. Provision of mobile, easy-to-access VCT (referred to as community-based VCT or CBVCT) is the second of the intervention's three components; the first component is the conduct of community mobilization activities and the third is provision of post-test support services (PTSS).

Note that we refer to communities that have been randomized to receive these three components as intervention communities. Control communities are those that have been randomized to receive only VCT that is delivered in a standard, stationary (clinic-based) format (SVCT).

The three intervention components above are designed to function interdependently, as seen in section II.B below. Therefore, this manual should be read together with the operational manuals that describe the Community Mobilization and PTSS components of the intervention. A training manual for community-based VCT has also been developed and should be viewed as a companion to this SOP manual.

As a multisite study, it is crucial that all sites implement intervention activities that conform to common standards and procedures. We do recognize, however, that the local context in each site is unique and may require adaptations of what is presented in this manual. In those cases, adaptations are welcome; however, they should be submitted to and approved by the Project Accept Intervention Subcommittee prior to implementation.

B. Project Accept Intervention Subcommittee

The Intervention Subcommittee is tasked with overseeing all aspects of the Project Accept intervention. The subcommittee is chaired by Stephen F. Morin, PhD, of the University of California San Francisco (UCSF), and comprises members from each of the five project sites. The duties of the subcommittee are to:

1. Develop the intervention concept
2. Coordinate the conceptualization and writing of operational manuals that guide the conduct of the intervention
3. Coordinate the conceptualization and writing of training manuals for each intervention component

C. UCSF Intervention Core

The intervention core at UCSF oversees quality assurance and quality control of the intervention components. This includes:

\(^1\) Spanning the five study sites: Soweto and Vulindlela in South Africa; Kisarawe, Tanzania; Mutoko, Zimbabwe; and Chiang Mai, Thailand.
1. Monitor the implementation of the intervention to ensure that all sites are carrying out the intervention according to common standards and procedures set out in the operational manuals
2. Develop and conduct regular quality assurance activities
II. Overview of Project Accept's CBVCT Component

Communities randomized to the CBCVT arm of the intervention will receive deployment of a mobile VCT unit staffed by counselors, nurse-counselor/phlebotomists, and an outreach worker/driver (note that outreach worker/drivers are supervised by the Community Mobilization coordinator; their roles and responsibilities are discussed in depth in the Community Mobilization Standard Operating Procedures Manual.) The counselors and outreach worker/driver will provide information on HIV/AIDS and the VCT process upon the mobile unit's arrival at a given location to encourage people to consider undergoing HIV testing. Counselors will refer participants who have undergone VCT, regardless of their test results, to Project Accept post-test support services (PTSS), which are discussed in depth in the PTSS Standard Operating Procedures Manual.

A. Goals of Project Accept CBVCT

The overarching goal of CBVCT is to remove practical barriers (fees, inconvenience, waiting times for results) and enhance VCT through confidentiality, high-quality counseling, detailed procedures to minimize negative HIV-related life events, and referral to post-test support services. This ease of access is anticipated to:

1. Increase rates of HIV testing
2. Increase accurate HIV knowledge
3. Increase accurate assessment of personal risk
4. Change social norms about testing
5. Increase the frequency of discussions about HIV in communities
6. Decrease behavioral risk for HIV

B. How CBVCT Relates to Project Accept's Innovation

Project Accept encourages individuals to become aware of their HIV status, a feature that is also common to standard, facility-based VCT. However, Project Accept’s innovation is that it goes beyond individual awareness of one’s HIV status to facilitate a process that:

1. Makes HIV testing a community norm
2. Creates an enabling environment for disclosure of one’s HIV status
3. Reduces HIV/AIDS-related stigma
4. Increases acceptance of people living with HIV/AIDS

To achieve these four objectives, the disclosure process occurs at three key levels that continually reinforce one another:

1. During community mobilization, early adopters of VCT are trained to disclose that they have been tested for HIV
2. During PTSS, individuals who have tested positive for HIV are taught to safely disclose their status to their family and friends.

3. PTSS also provides training to early adopters of PTSS so that they become community change agents, some of whom may disclose their HIV status publicly. For further elaboration, please refer to the Community Mobilization Standard Operating Procedures Manual.

C. Counseling Standard

The counseling standard for Project Accept VCT (both CBVCT and SVCT) is based on that utilized in the Voluntary HIV-1 Counseling and Testing Efficacy Study (often referred to as VCT-1), a randomized controlled trial conducted in Dar es Salaam, Nairobi, and Port of Spain (Trinidad). The study tested whether an HIV VCT intervention was more efficacious in promoting sexual behavior change than a health information and condoms intervention.

VCT-1's HIV VCT intervention was modeled on the client-centered, personalized risk reduction model recommended by the U.S. Centers for Disease Control and Prevention (CDC) and World Health Organization (WHO). This counseling model is grounded in a personalized risk assessment and the development of a realistic, personalized risk reduction plan for each study participant.

VCT-1 found that its client-centered, personalized risk reduction VCT intervention was more effective in promoting sexual behavior change than was the health information and condoms intervention. The VCT-1 counseling model is now considered the "standard of care," and it is therefore our ethical obligation to provide it to all our study participants, both in the CBVCT and SVCT arms. (The client-centered approach and personalized risk reduction model are discussed in depth in section V below. More information on the VCT-1 study is provided in the Project Accept Staff Orientation Manual.)

D. SVCT Communities

Communities randomized to the SVCT arm of the study will receive the installment of clinic-based VCT services in existing district hospitals, community-based health care centers, or other local health delivery facilities (a version of VCT consistent with the study protocol may be integrated into existing VCT services). Training for the CBVCT and SVCT counselors will be the same, where possible; however, no study-sponsored active community mobilization, mobile VCT services, or special post-test support services will be provided in the SVCT arm beyond the standard procedures of each clinic for informing patients of services (for example, informing individual patients that VCT is available, posting a flyer in the clinic announcing VCT availability). The SVCT arm will run for two and one-half years, simultaneous with the intervention arm.
Existing SVCT

In establishing SVCT in existing district hospitals, VCT clinics, community-based health care centers, or other local health delivery facilities, each SVCT venue will develop a Memorandum of Understanding with the host facility. The MoU should include:

- The ethical framework under which SVCT will be conducted, including confidentiality and informed consent procedures
- Lines of reporting, including supervision and support, debriefing schedules, and professional relationship between study and clinic/"regular" staff
- Explanation of the procedures at the local SVCT unit

When using existing SVCT facilities, study-determined quality assurance and supervision cannot be guaranteed. These sites will work closely with the SVCT venues to determine what is feasible, and the site will provide training and recommendations in this regard. Sites will carefully document the type of QA and supervision provided at the SVCT venues, whether or not it ultimately follows the recommendations made by the Project Accept site.
III. History of Development of CBVCT Component of Project Accept

Project Accept was planned in the context of recognized ethical principles for protecting human participants in international research. The project also involves numerous strategies to ensure that the trial reflects the needs and concerns of the participating communities and countries. Among them is ensuring that participants who test positive for HIV are linked to the highest quality care available.

To this end, Project Accept formed a Cofactors Subcommittee with the following objectives:

1. Describe antiretroviral program models as they develop
2. Track the implementation of antiretroviral therapy (ART) distribution programs
3. Track the implementation of other interventions that may influence VCT uptake and risk behaviors
4. Develop a referral process from VCT services to HIV/AIDS clinical care services
5. Develop an evaluation framework to measure the impact of ART availability on HIV incidence, VCT uptake, and risk behaviors

Project Accept is tracking the availability, accessibility, cost, use, and planned rollout of ART, opportunistic infection (OI) management (including tuberculosis [TB]), isoniazid preventive therapy, cotrimoxazole prophylaxis, prevention of mother-to-child transmission (PMTCT), STI diagnosis and treatment, home care, and other interventions in study communities. The project will work with the institutions providing this care to construct effective referral mechanisms. It will also monitor how care services affect study participation, behavior, and VCT uptake.

The resource information on institutions providing care and treatment to participants who test HIV positive will also be made available to counsellors for use in referring participants needing such care and treatment. Counsellors will be trained on how to discuss care and treatment (ART) with participants. (See the Project Accept HIV/AIDS Treatment for People Living with HIV/AIDS Training Manual, designed for inclusion in all staff training manuals.) Training in referral options and provision of referrals will also be provided.

During community mapping (see the Project Accept Community Preparedness and Involvement Manual for detail), existing HIV care and related services were documented. Both the Cofactors and Intervention subcommittees utilized findings from this mapping, as well as the community baseline sample, to determine current usage of care and related services. Where there were few or no care services in the community to which participants can be referred, the Cofactors and Intervention Subcommittees strategized to address this gap.

To track access to these services, each study site project director listed all health facilities (public, nongovernmental, commercial) in each community and determined which types of HIV-related prevention and treatment interventions were available in each facility by interviewing facility managers at baseline; this list will be updated annually.

The goal in each component (community mobilization, VCT, and PTSS) is to raise awareness of the potential for treatment. In those components of the intervention where there is contact with participants (VCT and PTSS), individuals will be directly linked to treatment.
At the end of the study, Project Accept will assess whether the availability of ART, and the proportion of eligible individuals receiving it, was associated with VCT uptake, HIV risk behaviors, and HIV incidence across sites.

Site study teams coordinated with local health authorities and other key actors to enhance access to existing treatment and care services. However, because this trial is designed to determine the impact of an intervention comprising community mobilization, community-based VCT, and post-test support service components, it will not take primary responsibility for providing treatment services for HIV-positive participants. VCT is a widely accepted HIV prevention intervention in all of the study sites, and national governments at the study sites have been encouraged to provide it. It is recognized that VCT, even in the absence of advanced HIV treatment regimens, does provide benefits to individuals, and large numbers of individuals in these settings wish to know their HIV infection status.
IV. Theoretical Foundations of CBVCT Tipping Point Theory

A number of theories guide the conceptualization and development of the Project Accept CBVCT component. A brief outline of each theory followed by how the theory informed the development of the CBVCT component is described below.

A. Tipping Point Theory
See also the detailed discussion of Diffusion of Innovation Theory in the Project Accept Community Mobilization Standard Operating Procedures Manual.

A “tipping point” occurs when a critical mass of adoption occurs in a social network. It is affected by three factors:

1. The “law of the few”
2. The “stickiness” of the behavior
3. The context of the innovation

The “law of the few” refers to the role that a few core transmitters can have in the diffusion of key factors (such as microbes, behaviors, or beliefs) across a social network. We believe that behavior change among a core of HIV-infected individuals, as well as a change in beliefs among community leaders, will significantly slow the epidemic.

The “stickiness” of a behavior refers to the social salience of the behavior, or how important it is deemed to be to the collective community. We believe that increasing the proportion of individuals in a community who are aware of their HIV status will increase the collective awareness that HIV is a real threat and that many HIV-infected people are in the social network.

The context of the innovation refers to the physical and social context where behaviors occur; the context of innovations has a strong impact on the readiness to adopt them. We believe that providing VCT in the context of where people live will change social norms around HIV testing, increase the frequency of discussions about HIV in communities, and ultimately decrease behavioral risk.

B. Client-Centered Counseling Approach and Personalized Risk Reduction Model

As previously discussed, Project Accept utilizes a client-centered, personalized risk reduction VCT model, based on that proven to be efficacious in the VCT-1 study and recommended by CDC and WHO, among others. This model is now considered the "standard of care" for HIV VCT, and it is therefore our ethical obligation to provide it to all our study participants, in both the SVCT and CBVCT arms.

The model decreases the emphasis on education, persuasion, and test results in favor of personalized risk assessment and the development of a realistic, personalized risk reduction plan for each participant. It is built on the development of a risk reduction plan for each participant.
that considers his/her emotional reactions, interpersonal situation, specific risk behaviors, and readiness to change.

The personalized risk reduction plan requires that the participant's individual risk situation be assessed. The participant and counselor form an alliance to undertake this risk assessment, which includes gathering information about the participant's sexual and other risk behavior as well as his/her interpersonal, social, and resource situation. After the participant and counselor have identified the former's risk behaviors, the counselor works with the participant to develop strategies to reduce his/her risk. For each risk reduction behavior, internal and external barriers to change, perceived efficacy to enact the new behavior, readiness to change, and the availability of resources to change are assessed. In supporting the participant's enactment of the personalized risk reduction plan, the counselor acknowledges and supports the participant's strengths (for example, previous success in changing behavior) and works with the participant to problem solve regarding anticipated difficulty in enacting the plan.

The Project Accept CBVCT Training Manual demonstrates how the client-centered, personalized risk reduction VCT model is put into practice in a detailed, step-by-step fashion. The core skill that counselors will be trained in to conduct this type of counseling is motivational interviewing, which we examine in depth below.

C. Motivational Interviewing

When we discuss motivational interviewing, we must note what we are not referring to motivation as a personality trait, but rather as a state of readiness for change. Motivation may fluctuate over time or from one situation to another, and can be influenced to change in a particular direction. Lack of motivation (or resistance to change), therefore, is not a set individual characteristic but rather open to change.

This conceptualization of motivation as a state that is open to change contrasts with traditional approaches that view motivation as a personality trait, and denial or resistance as something to be dealt with through aggressive confrontation. When an individual's motivation is mixed, we call this ambivalence, which is often voiced through the expression of both the positive and negative aspects of the behavior, for example “I know using condoms is safer, but it’s hard to do in the heat of the moment." A basic premise of motivational interviewing is that ambivalence is normal—not a character flaw—when a person is considering changing a behavior that is problematic.

Motivational interviewing is a client-centered, directive style of counseling designed to assist individuals in resolving ambivalence and increasing their commitment for change. Compared with nondirective counseling, motivational interviewing is more focused and goal-directed. The main goal of motivational interviewing is to examine and resolve the participant's ambivalence about behavior change. The counselor is intentionally directive in pursuing this goal. The counselor-study participant relationship is more like a partnership than expert/recipient roles. The counselor respects the participant's autonomy and freedom of choice (and consequences) regarding his/her own behavior.
Motivational interviewing evolved from the experience of William Miller, PhD, of the University of New Mexico with the treatment of alcohol addiction; it was later elaborated by Miller and Stephen Rollnick, PhD, of Cardiff University. It draws from social psychology, including theories of cognitive dissonance and self-efficacy, as well as empathic processes. A brief overview of each is presented below.

Theoretical Underpinnings

Cognitive Dissonance

Cognitive dissonance is the feeling of psychological discomfort produced by the combined presence of two thoughts that do not follow from one another. The existence of dissonance, being psychologically uncomfortable, motivates the person to reduce the dissonance and leads to avoidance of information likely to increase the dissonance. The greater the discomfort, the greater the desire to reduce the dissonance of the two cognitive elements. The techniques of motivational interviewing function to arouse cognitive dissonance.

Motivational interviewing produces a dissonant state (by focusing on ambivalence or inconsistencies) and then controls the direction chosen for the dissonance resolution through the skilled use of motivational interviewing techniques. Ambivalence is key and is resolved by focusing on the study participant's desires, expectations, beliefs, fears, and hopes, with particular emphasis on the inconsistencies between these and the problematic behavior. Counselors should therefore view ambivalence not as a barrier but rather as a crucial entry point into the personalized risk reduction counseling model.

Self-Efficacy

Beliefs of personal efficacy play a central role in personal change. This focal belief is the foundation of human motivation and action. Unless people believe they can produce desired effects by their actions, they have little incentive to act or to persevere in the face of difficulties. Self-efficacy is a person’s belief that he/she can carry out — and succeed at — a specific change strategy. A person’s belief in his/her ability to change a specific behavior strongly predicts his/her ability to make that change. Self-efficacy is a relatively good predictor of behavior change.

Self-efficacy beliefs shape the outcomes people expect their efforts to produce:

- People with high efficacy expect to succeed, realize favorable outcomes.
- People with low efficacy expect their efforts to fail, bring poor outcomes.

Self-efficacy beliefs also determine how obstacles and impediments are viewed:
- People with high efficacy believe that they can overcome obstacles by persevering and by improving self-management skills. They do not give up, but rather "stay the course" in the face of difficulties.
- People with low efficacy believe that their efforts in the face of difficulties will fail and would therefore be a waste of time to undertake. They quickly give up trying.

Strategies that increase self-efficacy are powerful tools to foster behavioral change. Actively supporting the participant's own belief in his/her ability to alter a behavior is intended to increase the likelihood that the participant will change the behavior. Counselors also model self-efficacy with their own optimistic views concerning the participant's abilities. The counselor actively looks for and reinforces the strengths of a participant back to the participant. Motivation is enhanced by helping participants to see how their behavior change is in their own self-interest and the broader goals they value highly.

**Accurate Empathy**

When we talk about empathizing with people, we usually mean that we "feel for" them or that we know "what they are going through." Within the context of motivational interviewing, however, we use the term "accurate empathy," which is defined as skillful reflective listening that clarifies and amplifies the participant's own experience and meaning, without imposing the counselor's own material. In this context, the counselor listens carefully to what the participant is saying, and then reflects it back to the participant, often in a slightly modified or reframed form. Acknowledgment of the participant's expressed or implicit feeling state may also be included. Note that accurate empathy does not mean identification with the participant or having had similar past experiences.

Accurate empathy:

- Is unlikely to evoke participant resistance
- Encourages the participant to keep talking and exploring the topic
- Communicates respect and caring, and builds a working alliance between counselor and participant
- Clarifies for the counselor exactly what the participant means
- Can be used to reinforce ideas expressed by the participant

The counselor demonstrates his/her understanding of the participant's perspective through reflection, with the assumption that listening in a nonjudgmental and accepting way facilitates relationship building and, ultimately, change. Accurate empathy focuses heavily on the exploration of ambivalence concerning behavior change. Reflective listening facilitates the participant's understanding of his/her ambivalent attitudes, with the expectation that this greater understanding will lead to increased motivation for change.

Accurate empathy communicates an acceptance of participants as they are, while also supporting them in the process of change. Research has found that counselor empathy can be a significant determinant of a participant's behavior. Conversely, confrontational counseling has been associated with a high dropout rate and relatively poor outcomes.
How Motivational Interviewing Informs the Design and Implementation of CBVCT

The following key principles of motivational interviewing guide the conduct of Project Accept VCT:

1. *The counselor and study participant become partners in the latter's health care.* Counselors view themselves as having expertise and knowledge about HIV, while viewing participants as being the experts on their own lives who know if and how change will work for them and the best methods for achieving their personal goals. The counselor and participant work together to explore the participant's behavior and risk, motivation to change these behaviors, and options for risk reduction.

2. *Motivational interviewing views participants as possessing the necessary capacities to alter their behavior.* The counselor's role is to elicit the participant's ideas, evoke confidence, and draw out the participant's own internal reasons for change. Open-ended questions and reflective listening facilitate this process (see below). The intention is that the participant—rather than the counselor—will generate his/her own arguments for change.

3. *Motivational interviewing has respect for the participant's autonomy.* The counselor acknowledges that the decision to change lies within the participant's control.

4. *Motivation to change is elicited from the participant, and not imposed from without.* Motivational interviewing relies upon identifying and mobilizing the participant's intrinsic values and goals to stimulate behavior change.

5. *It is the participant's task—not the counselor's—to articulate and resolve his/her ambivalence.* As discussed above, ambivalence takes the form of a conflict between two courses of action, each of which has perceived benefits and costs associated with it. Many participants have never had the opportunity of expressing the often confusing, contradictory, and uniquely personal elements of this conflict. The counselor's task is to facilitate expression of both sides of the ambivalence and guide the participant toward an acceptable resolution that triggers change. In the face of ambivalence, resistance is likely. When the counselor reacts to resistance with confrontation or persuasion, the participant is likely to continue arguing against change. In contrast, a participant's resistance is likely to weaken when the counselor accurately acknowledges and understands it.

6. *Direct persuasion is not an effective method for resolving ambivalence.* It is tempting to try to be "helpful" by persuading the participant of the urgency of the problem and the benefits of change. However, this approach usually increases client resistance and diminishes the probability of change.

7. *The counseling style should generally be calm and eliciting.* Direct persuasion, aggressive confrontation, and argumentation are the conceptual *opposite* of motivational interviewing. To a counselor accustomed to confronting and giving advice, motivational
Characteristics of a motivational interviewing style DO include:

- Helping the participant to develop and verbalize arguments for change increases the likelihood of change
- Helping the participant when ready to develop a specific change plan also increases the likelihood of change
- Seeking to understand the participant's frame of reference, particularly through reflective listening
- Expressing acceptance and affirmation
- Eliciting and selectively reinforcing the participant's own self-motivational statements, expressions of problem recognition, concerns, desire and intention to change, and ability to change
- Monitoring the participant's degree of readiness to change, and ensuring that resistance is not generated by jumping ahead of the participant
- Affirming the participant's freedom of choice and self-direction

Characteristics of a motivational interviewing style DO NOT include:

- Arguing that the participant has a problem and needs to change
- Offering direct advice or prescribing solutions to the problem without actively encouraging the participant to make his/her own choices
- Using an authoritative/expert stance, leaving the participant in a passive role
- Doing most of the talking
- Behaving in a punitive or coercive manner

To put the above principles into practice, the CBVCT training manual includes exercises to build counselors' skills in:

1. *Expressing empathy and using reflective listening.* An empathic style is fundamental to motivational interviewing. The counselor's underlying attitude must be one of acceptance and belief that ambivalence is normal. Reflective listening facilitates the process of understanding the participant's experience for both the counselor and the participant.

2. *Asking open-ended questions.* Open-ended questions evoke the participant's thoughts and perspectives on his/her behaviors. Skillful motivational interviewing enables the participant to do most of the talking, as the counselor uses open-ended questions to provide a structure and framework for the discussion and directs discussion around resolving ambivalence.

3. *Eliciting "Change Talk."* Eliciting "change talk" is a key example of motivational interviewing's directive nature, which distinguishes it from other forms of empathic counseling. Change talk involves statements made by participants that express need ("I
4. **Developing discrepancy.** Within this empathic style, it is the counselor's task to create and amplify any discrepancy between the participant's present behavior and his/her behavior change goals, so that the participant him/herself presents the argument(s) for change. One can also think of this as the degree of discrepancy between status and goal, between what is happening at present and what one values for the future. When discrepancy becomes large enough and change seems important, a search for possible methods for change is initiated. Given sufficient importance, if people find an avenue for change that they believe will work (general efficacy) and that they believe they can do (self-efficacy), they will often pursue it through behavior change.

5. **Supporting self-efficacy.** The participant is seen as the key to finding solutions to his/her problems. He/she is responsible for choosing and carrying out personal change, while simultaneously believing in his or her ability to change.

6. **Offering affirmations.** The genuine affirmation of positive characteristics and behaviors is particularly important when discussing sensitive issues such as one's sexual behavior. By acknowledging a participant's strengths, counselors are able to develop rapport and trust, and facilitate an objective and honest discussion of behavior by easing a participant's fear of being judged or criticized.

7. **Rolling with resistance.** A participant's resistance should not be opposed, as it signals a change strategy. Rather, it should be acknowledged and explored, with the view to shifting the participant's perceptions.

8. **Avoiding argumentation.** Argumentation or direct persuasion is counterproductive and should be avoided, as it is likely to produce defensiveness or resistance in the client. Instead, the counseling style should generally be calm and facilitative so that the relationship between the counselor and participant is more like a partnership than an expert/recipient one.
V. VCT Procedures- Set Up

The sections below draw heavily from the standard operating procedures manual created for the Zimbabwe CBVCT pilot (June 2002). They should be read along with the CBVCT Training Manual. Each site will then tailor the SOPs to its local context.

A. Overview

Mobile vans or temporary units set up at local community venues will provide free, anonymous VCT in specifically selected venues where people gather, such as market areas, shopping centers and community centers. In the case of mobile vans, identification of suitable venues will be a joint effort between the research staff and the community mobilization personnel. Permission will be sought from community leaders, local authorities and entrepreneurs at business centers to park the van and set up a temporary unit in the vicinity. The van will visit each testing venue on a rotating basis. For VCT set up at existing community venues, the research team will visit each venue on a similar rotating basis. The fieldwork days will be any combination of weekdays and weekends to ensure that the mobile unit is accessible even to those community members who are employed. A schedule of visits to the mobile testing venues will be kept in the van or testing venue, and copies will be distributed to community working groups, community-based outreach volunteers, local police stations, local health centers, and other community centers deemed appropriate by the study team. (See the Community Mobilization Standard Operational Procedures Manual for more detail.) The schedules will be distributed by outreach workers in advance of the mobile VCT unit visit. Each research site will submit a plan for how to operate the mobile VCT component of the study to the Intervention Subcommittee and Steering Committee for approval. The mobile VCT component of the study is scheduled to operate for two and one-half years following the baseline assessment.

B. Equipment

The caravan or community venue will be equipped for counseling and HIV test laboratory work. The space will have a seating area for counseling, HIV testing counter-space, a refrigerator, and a washbasin area. In addition, it will have numerous cabinets for storage of mobile VCT supplies and outreach materials.

Study sites will purchase vehicles suitable for their terrain. Those sites providing VCT from a mobile van should purchase a vehicle that is capable of towing a caravan. Each vehicle should also be large enough to carry six to seven staff members, including the outreach worker/driver.

C. Testing Venue Set-Up and Break-Down

At the beginning of each day, the research team will set up their testing venues and make sure that they have adequate materials and supplies for the anticipated total number of participants for the day.
Set up time and exact procedures are based on location and type of set up (mobile or stationary/ fixed site). Staff should be versed in set-up and breakdown of mobile site and allow for sufficient set-up/ breakdown time each day. Please refer to site-specific venue set manuals for complete set-up instructions.

D. Materials

These are guidelines for mobile units. Sites should adapt site-specific material protocols as needed.

General Materials for Mobile Venue

- 20-liter jerry can with water
- Basin
- Two coolers for staff snacks and tea during fieldwork
- Cleaning supplies: bleach, multipurpose countertop cleaner, dust pan and small broom, hand-washing soap, hand sanitizer
- Collapsible chairs and tables

Information, Education, and Communication (IEC) Materials in Waiting Area

- Project Accept leaflet
- General HIV/VCT brochure
- Male and female condoms
- Pamphlets on male and female condom use
- Other IEC materials (site specific)

Pre- and Post-Test Counseling Supplies

- Informed Consent Information Sheet
- Staff schedule
- Prepared packet containing one laboratory form, two HIV test labels, and all other materials needed for use with each participant
- CBVCT Service Utilization Form
- Male and female condoms available in waiting area
- Pamphlets on male and female condom use
- Envelopes to carry condoms and information
- Model penis
- Model pelvis/vagina
- Laboratory forms
- Box of tissues, pens, pencils, paper
- Other (site specific)

Rapid Test Kits and Supplies

Refer to Site Specific Laboratory SOP manuals.
Referral Materials

- Information sheets about Project Accept PTSS
- CBVCT Referral Log (for referring participants to non-Project Accept services)
- VCT-PTSS referral cards
- Negative Life Events Card (Palm Card)
- Information referral sheets for non-Project Accept community resources

E. Rapid HIV Testing Algorithm

All sites will use tests that have been validated locally and approved by their ministry (or department) of health. The standard algorithm for Project Accept intervention sites will be simultaneous/parallel running of two rapid tests in the mobile laboratory, with a third test (either a third rapid test or an ELISA EIA) used as a tiebreaker for discordant results. Sites may, however, propose a serial testing algorithm if required by local standards, regulations, pilot findings, or other local considerations. All sites must submit their rapid testing algorithm and specific choice of test(s) to the Project Accept Laboratory Subcommittee. The subcommittee will ensure that all rapid tests chosen by sites are sufficiently sensitive and that rapid testing QA is standardized across all sites. All study sites will adhere to the SOPs elaborated by the subcommittee regarding laboratory practices, biohazard containment, and PEP guidelines.

F. Staff Incidents

If staff members experience occupational exposure to HIV, the incident will be reported and a protocol will be followed to minimize their risk of being infected with HIV that includes the provision of postexposure prophylaxis with antiretrovirals when indicated. All staff at risk for occupational exposure to HIV will be trained on universal precautions and on the postexposure prophylaxis protocol. All staff performing HIV tests will require training and certification on performing the test and on quality assurance. Refer to PEP Policy Guidelines.
Figure 2. Parallel HIV Rapid Testing Algorithm

- Both tests negative
  - STOP: Report as HIV negative

START:
Rapid Test #1
&
Rapid Test #2

+/
Discordant Results

STOP: Report as HIV positive

RUN 2nd TIME:
Rapid Test #1
&
Rapid Test #2

+/
Discordant Results

STOP: Report as HIV positive

- Both tests negative
  - STOP: Report as HIV negative

RUN:
Rapid Test #3

STOP: Report as HIV negative

- Negative
  - STOP: Report as HIV negative

- Both tests positive
  - STOP: Report as HIV positive

- Both tests positive
  - STOP: Report as HIV positive

- Positive
  - STOP: Report as HIV positive

- Negative
  - STOP: Report as HIV negative

+/
- Ne
VI. CBVCT Procedures- Eligibility & Enrollment

A. Participant Recruitment

At the mobile testing site, participant recruitment is the responsibility of the outreach worker/driver and is discussed in depth in the Project Accept Community Mobilization Standard Operating Procedures Manual.

Those who agree to participate will be invited into the van or community venue where the study counselor will receive them. The counselor will perform the following list of procedures:

- Pull out a packet with study forms and documents (consent document, lab form, CBVCT Service Utilization Form, etc.)
- Administer verbal informed consent in the participant’s choice of language (local language or English/Thai).
- Explain to the participant the advantages and disadvantages of taking an HIV test and give the participant an opportunity to ask questions.
- Ensure that the individual meets the participant eligibility requirements outlined in section VII.A above.
- Assign a unique personal code to individuals who agree to participate in the study and have given informed consent. (As previously mentioned, we recommend that sites that are not currently doing so consider the inclusion of non-identifying verifiers such as sex and approximate age along with client ID numbers.)
- Provide pretest counseling to participants.

To verify that verbal informed consent has been given, the counselor will record the counselor’s initials, the date/time of consent, the language of verbal consent, and other participant information on the CBVCT Service Utilization Form, along with the standard demographic/utilization information collected for each CBVCT participant.

* In South Africa, written informed consent is required for HIV VCT. No identifying information will be retained other than the signed consent form, which will not be linked to the participant's HIV test result.

These documents will all be stored in the requisite regulatory binder/file, and will be available for review by GCP monitors. If verbal informed consent is not documented, this would constitute a protocol violation and data on such participants would not be included in analysis.

Each study site is responsible for developing consent forms for local use according to site IRB, and to provide translations and back translations as appropriate.

B. Eligibility

Individuals may participate in CBVCT (or SVCT) if they meet both the following criteria:
- ≥16 years of age
- Able and willing to provide verbal informed consent

Persons will be excluded from participation and will be referred to existing alternate services if they meet either of the following criteria:

- <16 years of age
- Have an obvious psychological/psychiatric disorder as determined by the research team that would invalidate the informed consent process or otherwise contraindicate participation

C. Informed Consent

Project Accept's informed consent procedures have been developed by the UCLA Operational Coordinating Center (and are outlined in the Project Accept Protocol, version 2.1. October 1, 2005). All Project Accept intervention staff and volunteers, including those implementing the VCT component of the study, will receive HPTN and site-specific ethics training, which will include training in informed consent.

The HIV test administered in Project Accept will be voluntary and will take place only after the participant has provided his/her verbal informed consent. (Note that in South Africa, written informed consent is required for all HIV testing regardless of whether it is offered as a service or as part of a research study. Thus, South African Project Accept sites will need to document that their informed consent procedures are an exception to the standard outlined in this manual because of local requirements. Moreover, written informed consent forms for HIV testing will not be linked to Project Accept research records.)

Each study site is responsible for developing a VCT informed consent form/information sheet for local use and for translating it into local languages (as well as verifying the accuracy of the translation by performing an independent back-translation). These forms must be submitted to the UCLA Operational Coordinating Center and Intervention Subcommittee for review and approval.

D. Client Confidentiality

It is required that all study participant information be kept confidential and private. All study personnel will be trained in the concept of confidentiality to ensure participant privacy. Participants in the study will be reassured repeatedly that all information that they provide about themselves and their participation in the study will be kept in the strictest confidence. Counseling will be conducted in private where the conversation between the participant and the counselor cannot be overheard.

Because HIV and AIDS are highly sensitive and emotionally charged issues, information about the participants’ HIV serostatus and his/her sexual partners must be considered the most confidential of information and must be protected at all times. All study personnel are bound by
strict ethical procedures that prevent them from revealing any study participant information—including what study participants say or do during the community mobilization, VCT, and post-test support services interventions—outside of supervisory meetings or in consultation with one another for the purposes of quality assurance or assistance in providing counseling services. Discussions between counselors and counseling team leaders, including case discussions in supervision, will protect the privacy of participants. Participants’ confidentiality will be protected in conversations between counselors and other study staff. Study personnel are not to discuss participants (through non-name identifiers/descriptors) in public places or with anyone not employed by the study. Breeches in participant confidentiality may be grounds for dismissal of counselors and other staff.

E. Oath of Confidentiality- Staff

Staff members sign the Project Accept Oath of Confidentiality as well as any confidentiality oath required by their institution. Signing of the oath indicates that the staff member agrees to uphold the confidentiality specific to their work, that all participant information is confidential and shall not be divulged or made known to unauthorized persons, and that a breach of confidentiality may be grounds for disciplinary action or termination of employment. The signed oath is kept in personnel files.

F. Women and Disclosure

Women potentially face gender-related negative consequences following disclosure of HIV status. The VCT Counselors will attend the core Project Accept Counselor Training. This training includes modules on counseling special groups such as women. This module includes a pre-test counseling component designed for all female participants that outlines physical risks that may be associated with disclosure. In addition, given that a history of prior domestic violence is the best predictor of future violence, counselors will be equipped with tools to help them identify women with such a history so that these participants may assess potential risks before testing and be counseled about referrals to minimize this risk.

G. Negative Life Events

Negative life events are detrimental social interactions experienced by study participants. During counseling, participants, particularly women, may report negative events associated with participating in the study. These may include breakup of a marriage or sexual relationship, physical abuse by a sexual partner, neglect by family, being disowned by family, rejection by peers, and being discriminated by health care providers or employers. We will also provide participants with a palm card containing information on how to contact the local research staff to report such events. Participants will be asked to return to the research site or otherwise contact research staff in order to make such reports as well as receive referrals to mitigate potential harm.
Palm cards will not include identifying information about the study or references to HIV or HIV testing, so that the cards will not have the potential to jeopardize the confidentiality of participants.

H. Adverse Events and Incidents

Adverse Events, Serious Adverse Events, and Incidents are categories of occurrences that can occur during the course of the research. Broadly defined

- **An adverse event (AE)** is any undesirable, unintended reaction or event (whether expected or unexpected) that results from study procedures or study interventions.
- **A serious adverse event (SAEs)** will be defined as a subset of AEs that are fatal, life threatening, require hospitalization or prolong existing hospitalization, or result in persistent or significant disability.
- **Incidents** are defined as a problem involving the conduct of the trial. Examples of incidents would include protocol violations (i.e., enrolling a participant who did not meet eligibility criteria), and other events (such as harassment of study staff) that do not qualify as AEs.

Detailed information on the documenting and reporting procedures for AEs, SAEs, and Incident can be found on the Administrative Forms section of the Project Accept website.
VII. Content of Counseling and Testing Intervention

The detailed content and step-by-step procedures for the counseling and testing intervention are found in the CBVCT Training Manuals and are summarized below.

The counseling and testing intervention includes one pretest counseling session and one post-test counseling session. It is anticipated that counseling sessions will last at least 30 minutes each, depending on the individual participant’s situation. Pre- and post-test counseling is separated by the length of time required to generate test results (approximately 20 minutes).

**Pre-Test Counseling**

The first meeting between the counselor and the participant will begin by confirming that informed consent has been obtained and assuring the participant that his/her confidentiality will be protected. The counselor will review any HIV knowledge the participant is unsure of and correct any misperceptions about the transmission of HIV.

The counselor will then engage the participant in an assessment of his or her own HIV-related risk behavior and negotiating a realistic, personalized risk reduction plan. The participant and counselor form an alliance to undertake the risk assessment, which includes gathering information about the participant's sexual and other risk behavior as well as his/her interpersonal, social, and resource situation. After the participant and counselor have identified the former's risk behaviors, the counselor works with the participant to develop strategies to reduce his/her risk. For each risk reduction behavior, internal and external barriers to change, perceived efficacy to enact the new behavior, readiness to change, and the availability of resources to change are assessed. In supporting the participant's enactment of the personalized risk reduction plan, the counselor acknowledges and supports the participant's strengths (for example, previous success in changing behavior) and works with the participant to problem solve regarding anticipated difficulty in enacting the plan.

When appropriate, the risk reduction plan may be written and given to the participant to cue and reinforce behavior change.

**Preparation for Testing**

Pre-test counseling includes soliciting the participant's knowledge about the HIV antibody test and any previous testing experiences, providing information about the test as needed and correcting any misconceptions about testing and/or test results. The meaning of a negative test result and a positive test result is explicitly stated, and participants are asked to discuss a plan of action in the case of a negative test result or in the case of a positive test result. All participants will be provided with a sheet with contact information for crisis management in the event of negative HIV-related life events.

At the end of pre-test counseling, the counselor asks the individual participant if she/he would like to proceed with HIV testing. If the answer is no, the participant is thanked and escorted out of the caravan. If the answer is yes, the counselor fills out the laboratory form with the
participant's unique personal code. For those participants who wish to receive results on another
day, the counselor will record an additional unique identifier, for example, mother’s maiden
name, to enable verification that the participant ID and the test results attached to it belong to the
same person.

The nurse-counselor/phlebotomist will then prepare for the test using the SOPs elaborated by the
Project Accept Laboratory Subcommittee. She/he will explain the testing procedure to the
participant before pricking the participant’s finger to collect a blood sample.

**Disclosure of Results to Participant**

The participant is asked when he/she would like to receive test results. If he/she chooses a later
date, an appointment is scheduled for the participant to return to the caravan or community venue
at that time. Participants receiving test results the same day will be asked to wait outside the van
or in a waiting room/area at the testing venue while the nurse-counselor/phlebotomist runs the
HIV test. The waiting period will be approximately 15-20 minutes.

The test result will be given to the counselor by the nurse-counselor/phlebotomist. The counselor
will then invite the participant to return to the caravan or counseling room and will check with
the participant to determine if he/she is prepared to receive the test result and post-test
counseling. For continuity purposes, it is recommended that the same counselor offer both pre-
and post-test counseling to the participant.

As previously discussed in section VIII.B, all sites, except Zimbabwe, will give participants the
option of receiving written certificates of their HIV test results. In Thailand, this option will be
available if the client opts to receive a confidential VCT service.

**Post-Test Counseling**

Post-test counseling will begin with the disclosure of test results. The counselor will disclose the
test result in a direct, neutral tone of voice and wait for the participant's reaction before
proceeding. The counselor will assist the participant to understand the meaning of the test results,
cope with the emotional impact of the test result, and modify the risk reduction plan as needed.

Regardless of test result, all participants in the intervention communities (i.e., those receiving
CBVCT) will be referred to Project Accept Post-Test Support Services.

For participants who are HIV-positive, in addition to referral to PTSS, the counselor will assist in
making a safe disclosure plan and will provide appropriate referrals for health and social
services. Implications of the positive result for that participant will be discussed; the
individualized risk reduction plan will be reviewed with the goal of preventing reinfection and
protecting partners.

For participants who are HIV-negative, the implications of the negative test result will be
discussed and the individualized risk reduction plan reviewed with the goal of staying negative.
The participant will also be referred to PTSS.
If a participant so requests, one additional counseling session with the counselor may be permitted with the approval of the VCT counseling team leader. Because VCT and PTSS will not have the capacity to meet all participants' needs, counselors will make referrals to non-Project Accept organizations/agencies so that members can have immediate, practical needs met. Referrals to outside organizations will be recorded on the CBVCT Referral Log.

In the event that a participant returns to a Project Accept site for testing (because of the window period or because he/she simply wishes to be retested), the counselor will create a new unique identifying code for the participant and follow all the steps outlined above, as though the participant were new to the study. The participant's previous unique identifying code will not be used to ensure that there are no privacy breaches.
VIII. Intervention Dose

Project Accept provides a standard intervention across all study sites. This means all sites both offers the same VCT services and make the service available for the same amount of time each week, proportionally determined by community size. The Intervention Core developed dose guidelines for each site to assist in determining the number of hours that intervention should be available in each community based on the community size. These calculations in turn determine the number of staff needed in order to make VCT available for the prescribed number of hours. Please note that the dose figures refer to the number of hours that VCT is open and offered, not the number of hours that the service was used by participants. For example, suppose the dose guidelines indicate that VCT be made available for 8 hours a day. On a given day the staff set up the mobile clinic for 8 hours and participants utilize services for 6 out of those 8 hours. In this scenario the dose hours (hours of service availability) would be recorded as 8 and the utilization hours (hours the service was used by the participants) would be recorded as 6. The staff has met the required number of dose hours.

Team Leaders and Coordinators: please see the QA/QC Manual and Utilization SOP for instruction on filling out dose and utilization forms. Dose is tracked using the CBVCT Hours Worksheet and Hours Log. Utilization is tracked on the CBVCT Intake Log.

How Dose is Calculated
The VCT dose is determined by the number of people that would have to be seen each week in order to test all individuals aged 16 and over (all eligible Project Accept participants) during the two and a half years of the intervention. The results of calculation (1) are then multiplied by one and a half hours (90 minutes) the approximate amount of time needed to complete all VCT procedures for one individual (including consent, blood draw, counseling, and results disclosure). The results of calculation (2) yield the total number of weekly VCT hours. Note that VCT dose calculations are proportionate to each community size.

The Intervention Core provides the site intervention director with dose calculation figures for all intervention components. Sites should make every effort to achieve 100% of the dose hours listed. However, in certain circumstances it may be difficult to do so. Dose hours between 90% and 100% are permissible. Anticipated or actual dose hours less than 90% should be discussed with the Intervention Core.

Sample Calculation:
(1) Population 16 and older = number of participants seen each week
   125 (weeks of intervention)

(2) Number of participants seen each week x 1.5 hours = number of weekly hours of VCT
IX. Roles and Responsibilities of CBVCT Staff

Each Project Accept site will have 2 or 3 mobile VCT teams, which will be supervised by the site VCT coordinator. Together, these two mobile teams will comprise:

- 1 driver
- 1 Team Leader/ Counselor
- 3 Counselors
- 1 Phlebotomist
- 1 Phlebotomist floating between 2 teams

As previously mentioned, outreach workers/drivers will carry out their work at the mobile sites, but will be supervised by the Community Mobilization coordinator (see the Project Accept Community Mobilization Standard Operating Procedures Manual for detail).

A. VCT Coordinator

The VCT coordinator is responsible for overseeing all aspects of VCT at the site (both CBVCT and SVCT). The coordinator supervises the counseling team leader and assists him/her as needed in the field to accomplish his/her duties. The coordinator reports to the study site project director. Among the coordinator's specific responsibilities:

1. Negotiate with communities in setting up testing venues
2. Supervise and monitor all mobile VCT activities in the intervention communities
3. Monitor the functioning of mobile VCT activities
4. Work with the study site project director to install SVCT in control communities and to elaborate related memoranda of understanding
5. Oversee QA activities

The VCT coordinator will be trained by the study site project director. Centralized and/or outsourced training may also occur.

B. CBVCT Counseling Team Leader

One of the 4 counselors on each team will be designated the Team Leader. In addition to performing counseling duties, they will be responsible for:

1. Direct monitoring and supervision of all mobile VCT counselors, including nurse-counselors/phlebotomists
2. QC ratings and activities

As a result of these added responsibilities, it is anticipated that CBVCT team leaders will perform fewer counseling sessions than the other study counselors.
CBVCT counseling team leaders will report to and be trained by the VCT coordinator; centralized and/or outsourced training may also occur.

C. CBVCT Counselors

CBVCT counselors will conduct the HIV testing and counseling activities described in the procedures section. All Counselors will have a minimum qualification of a high-school diploma and basic counseling training based on each site’s national standards, including HIV/AIDS counseling. They must also successfully complete the CBVCT counselor training.

CBVCT counselors will be trained by the Project Coordinator and report to the counseling team leader.
## X. Core and Supplemental Training for CBVCT Staff

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<th>Supplemental</th>
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<td><strong>VCT Coordinator</strong></td>
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<tr>
<td>Overview of Project Accept (from Staff Orientation Manual)</td>
<td>General management/leadership</td>
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<td>HIV/AIDS basics, including ART</td>
<td>Refresher/advanced team building skills (on the assumption that coordinators bring basic team building skills with them when they are hired)</td>
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<td><strong>CBVCT Nurse-Counselors/Phlebotomists</strong></td>
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<td>Same as for CBVCT counselors above</td>
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<td>Must also possess relevant</td>
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certification/credential to perform rapid HIV tests, as required by site's MoH or other national regulatory agency

As determined by Project Accept Laboratory Subcommittee, in-service training in conduct of HIV rapid tests, biohazard containment, etc.

**Counselor Professional Development**

As part of QC activities, the study site project director and VCT coordinator will work with the Intervention Subcommittee to develop strategies to strengthen CBVCT staff capacity, recognize quality work, provide motivation, and support professional development with the objectives of:

- Updating and enhancing counseling skills and developing skills to respond to specific problems encountered at venues
- For counseling team leaders, updating and enhancing supervision skills
- Minimizing counselor burnout
- Maintaining morale and motivation for all site staff

Related tools will include:

- In-service training every six months
- To address counselor burnout, counseling staff from both arms of the study will be debriefed every two months by a mental health professional, such as a psychologist, who will allow counselors to discuss the stressful and difficult aspects of their work. Other tools may include stress management activities or retreats.
- Other opportunities for training updates and refresher courses (either on site or at another locale)
- Exchange visits between Project Accept sites
- Recognition of quality work through monetary and/or non-monetary means (for example, letter of recognition for service, “counselor of the year” awards, meal provision, time off, promotion opportunities)
XI. Quality Assurance/Quality Control

The Intervention Core at University of California, San Francisco oversees Quality Assurance and Quality Control activities for the entire intervention component. Quality Assurance (QA) is defined as the steps taken in advance to increase the quality and consistency with which an intervention is conducted. The quality assurance procedures for Project Accept fall into three broad categories: Development of Intervention Protocol Manuals, Training, and Activities.

Quality Control (QC) consists of activities conducted when the intervention is in the field in order to quickly identify and correct deviations from protocol as well as identify “less than optimal performance” (errors in staff judgment, participant problems, etc). The quality control procedures are designed to maintain the integrity of the components by assessing adherence and assisting staff in meeting these goals. Quality Control procedures consist of (1) weekly supervision of all staff at each site by the VCT Coordinator, VCT Team Leaders, and the Project Director, (2) weekly staff meetings at the site level (3) independent review and rating of sessions by the Team Leader, (4) regular feedback to individuals by the Team Leader, Coordinator and Project Director, (5) bi-annual visits by the Intervention Director, (6) monthly start-up conference calls with the Intervention Core, and (7) regular feedback from the Intervention Core to the sites based on these visits and reviews.

There are several mechanisms by which the quality of intervention sessions will be ensured. These mechanisms include:

1. A common set of qualifications necessary to successfully carry out the intervention were agreed upon and used by each site in their hiring decisions.

2. Standard Operating Procedures Manuals (SOP) were developed that define and describe each component of the intervention (Community Mobilization, VCT, and PTSS). Sites adapted each manual to meet their site-specific situations.

3. A comprehensive, centralized 8-day Training of the Trainers meeting was conducted with all Coordinators and Project Directors in preparation for training their staff before intervention implementation.

4. Each site conducts ongoing supervision of project staff in each component. The Coordinators and Project Directors carry out supervision. Team Leaders and Coordinators observe PTSS sessions in order to evaluate and provide immediate feedback on an individual and group basis. These reviews are discussed with the project director, who in turn shares with the Intervention Core.

5. All SOPs, site adaptations to the SOPs, and all QA/QC plans were approved by the Steering Committee and all modifications will be approved by the Steering Committee before implementation.

Please refer to the VCT Quality Assurance/Quality Control Guidelines Manual for detailed QA/QC procedures.
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