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I. Introduction

A. Purpose of This Manual

The purpose of this manual is to describe the strategy for providing post-test support services (PTSS) in Project Accept's five sites (Soweto and Vulindlela in South Africa; Kisarawe, Tanzania; Mutoko, Zimbabwe; and Chiang Mai, Thailand). Provision of PTSS is the third of the project's community-based intervention components; the other two are (1) conduct of community mobilization activities and (2) provision of mobile/community-based VCT.

The three intervention components are designed to function interdependently, as described throughout the manual. Therefore, this manual should be read together with the manuals that describe the community mobilization and community-based VCT (CBVCT) components of the intervention.

As a multisite study, it is crucial that all sites implement intervention activities that conform to common standards, procedures, and guiding principles. 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 Core at UCSF and the Steering Committee 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. 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. Post-Test Support Services Component

A. Definition of Project Accept Post-Test Support Services

Post Test Support Services (PTSS) are the third component of the intervention. This component is based on a social action model and is designed to build psychosocial support to improve the quality of life for individuals diagnosed with HIV. The expected outcomes include a reduction in social harm, an increase in social support through disclosure to those most likely to provide support, and a reduction in internalized stigma. Social support should also decrease the behavioral risk of further transmission. Our objective in providing post-test support services is to create a culturally appropriate support system for community members following their decision to take part in CBVCT.

In establishing Project Accept PTSS, the overarching aim is to ensure that services are accessible to and meet the needs of intervention communities. The Study Site Project Director; Community Mobilization, VCT, and PTSS coordinators; and intervention communities will work together to identify post-test service needs, map existing community social services, and develop the optimal method of establishing Project Accept PTSS. The UCSF Intervention Core recommends a standard PTSS delivery plan as outlined in this manual. Each research site may make local adaptations to the curriculum manuals to meet cultural and site specific needs. The Intervention Core and the Steering Committee must approve these adaptations. Dose calculations, discussed later in this manual, indicate the number of each type of service to be provided based on population calculations. The Intervention Core has provided a guidance document to each site regarding dose.

PTSS staff will report to the PTSS coordinator. The PTSS Coordinator will oversee all PTSS centers in the intervention communities. Working in concert with the Study Site Project Director and Community Mobilization and VCT coordinators, the PTSS coordinator will negotiate with communities to set up PTSS centers, identify post-test service needs, and map existing community social services (see the Community Preparedness and Involvement Manual for more detail on the needs assessment and mapping processes). The PTSS coordinator will be responsible for monitoring the functioning of PTSS centers and conducting quality assurance of PTSS. The PTSS coordinator will report to the Study Site Project Director. Each intervention community will be staffed for 20 hours a week for PTS Services. The staff will include 2 PTSS team leaders and 4 counselors. Each team will be composed of 1 team leader, and 2 counselors. The Thailand site will develop a plan to accomplish these goals with staffing appropriate to their configuration of seven smaller villages randomized to the intervention.

PTSS offers 5 core services:

1. Coping Effectiveness Training workshops (CET)
2. Stigma Reduction Skills Building Workshops
3. Large Information sharing groups
4. Ongoing psychosocial support groups
5. Crisis counseling for individuals or couples
Additional services may also include recreational/social activities and referrals to non-Project Accept health and social services.

PTSS members will be closely involved in determining PTSS activities and in facilitating many of these activities.

**B. Goals of PTSS**

Project Accept is a randomized controlled trial to evaluate the effect of the intervention at the community-level, rather than at the individual level. Therefore, the *primary goal* of PTSS is to encourage and support both HIV-negative and HIV-positive PTSS participants to become effective community change agents so that:

1. HIV testing is more of a norm.
2. Knowledge of one’s HIV status is more of a norm.
3. Opportunities for safe and thoughtful disclosure of one’s HIV status increase.
5. General information about HIV increases.
6. HIV/AIDS-related stigma is reduced.
7. Social harm and discrimination are reduced.
8. Refer possible community-based outreach volunteer candidates to work with the Community Mobilization component of the intervention.

The *secondary goal* of PTSS is to create a locally appropriate support system to meet a carefully defined range of needs for community members following their decision to take part in CBVCT—regardless of their HIV test result—so that PTSS becomes part of the fabric of communities. This support system will include the following services:

1. Coping effectiveness workshops
2. Ongoing psychosocial support groups
3. Informational and group recreational activities
4. Limited individual and couples counseling
5. Referral of participants to existing health and social services, including those related to basic/primary health care; treatment of opportunistic infections, STIs, and TB; and antiretroviral therapy. Through this service, we will respond to our ethical obligation to provide the best available link to services in the local area, including the highest standard of HIV care and social support.

**C. Guiding Principles**

This manual provides guidelines for delivering Project Accept PTSS services. While standardized manuals have been created for each component, the components also allow for sites to make cultural appropriate adaptations as necessary. The principles listed below are meant to
guide sites as they undertake that process. The following guiding principles will be carried out at all sites:

1. Disclosure of HIV status will ALWAYS be voluntary; no participant will ever be pressured to disclose his/her HIV test result.

2. Each PTSS coordinator will consult with the site’s Community Mobilization and CBVCT coordinators in establishing days and hours of operation so that PTSS venues are open and available to maximize opportunities for coordination and increase accessibility to services.

3. In selecting a community locale for PTSS, the need to protect participant privacy should be considered.

4. Provision of PTSS must be responsive to and accommodate the daily lives of participants (e.g., their hours of work, religious holidays, weather, seasonality). Flexible hours for PTSS operations are crucial; sites should also ensure that PTSS maximizes opportunities to reach community members through community events.

5. Although fixed PTSS is desirable, some sites may use mobile services or a combination of mobile and stationary services. PTSS may also be offered through existing community structures (see section VI.A below).

6. Staffing issues such as whether local hires are recruited will depend on the needs of the community as well as consideration of how local hiring may affect participants’ privacy.

**D. How PTSS Relates to Project Accept's Innovation**

The Community Mobilization Operations Manual discusses Project Accept's innovation, that is, what makes Project Accept unique. This definition is helpful for us to review to better understand how PTSS contributes to the project'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 provided with skills to disclose that they have been tested for HIV.

2. During PTSS, individuals (both HIV-negative and HIV-positive) are equipped with skills to safely and thoughtfully disclose their status to their family and friends (what we refer to as “private disclosure”).

3. PTSS also provides a venue for providing stigma reduction skills (including safe and appropriate disclosure) to HIV-negative and HIV-positive participants, some of whom may choose to disclose their HIV status in community venues (a process we refer to as “public disclosure”).

We will look at how levels 2 and 3 are put into practice throughout the sections below.

III. Theoretical Foundations of PTSS

Two theories guide the conceptualization and development of Project Accept's post-test support services. These theories, Social-Contextual Action Theory and Coping Effectiveness Theory and how these theories informed the development of our PTSS services is described below.

A. Social-Contextual Action Theory

Psychologist Craig Ewart, PhD, formerly of Johns Hopkins University and now with Syracuse University, examined the evolution of behavior change theories and how they had been utilized to design prevention interventions. Through the 1980s, these theories could generally be characterized as "self-change" or "self-regulation," wherein individuals overcome destructive behavior patterns and strengthen self-protective capabilities. Ewart believed that although theories grounded in self-regulation help us understand personal change, they fall short as public health strategies for several reasons, notably because they focus solely on an individual's actions and ignore the individual's interpersonal relationships as well as the larger societal environment and influences that can hinder or facilitate one's self-regulatory mechanisms.[1]

To improve public health prevention strategies, Ewart proposed a new conceptual model in 1991—social-contextual action theory. Social-contextual action theory explains health protective behavior as an interaction among three domains:

1. individual: the self-regulatory capabilities and habits of the individual; internal processes
2. interpersonal/social interaction: the link between self-change processes and interpersonal relationships
3. societal/community/environmental: the larger systems or contextual influences that determine how personal change mechanisms operate[1]

This model goes beyond the simple conception of biological susceptibility to a health hazard (for example, lung cancer risk in workers exposed to airborne asbestos fibers). Although such biological models are useful in explaining many public health risks, social-contextual action theory offers a more dynamic approach.[1] Such an approach is well suited to HIV/AIDS.
because of the extensive research that has demonstrated how HIV transmission is shaped by numerous nonbiological factors, including those that are interpersonal, such as sexual relationship power dynamics. Research has also shown us that the broader societal and community context—including functioning of and access to governmental and NGO services, stigma & discrimination, macroeconomic policy, civil conflict, poverty, and mobility—also influence HIV transmission as well as individuals' ability to access HIV/AIDS care and treatment.[2-8] Ewart stresses that:

"When it is not feasible to remove health threats from human environments, prevention must strive to promote individual self-protective activity by altering laws and policies, rendering environments conducive to personal action, and educating the public."[1]

As we will see in the next section, social-contextual action theory helps us pinpoint the personal, interpersonal, and societal/community factors and norms that can be changed to encourage self-protective activities.

**How Social-Contextual Action Theory Informs the Design and Implementation of PTSS**

Social-contextual action theory involves three interdependent levels:

1. individual/self-regulatory
2. interpersonal/social interaction
3. societal/community

Let us now examine how each level is relevant to PTSS.

**Self-Regulatory Capabilities**

Research has found that improvements in self-regulatory capabilities can reduce the likelihood of sexual transmission of HIV.[9-12] Project Accept's PTSS coping workshops, support groups, and other activities (see section VI below) will provide opportunities for HIV-positive and HIV-negative individuals to build and/or improve their self-regulatory capabilities by gaining:

1. problem-solving skills
2. social skills, such as negotiation and partner communication
3. technical skills, for example, condom use

**Interpersonal/Social Interaction**

As we discussed above, social-contextual action theory views an individual's change capabilities not just as a function of his/her self-regulation, but also as a function of an individual's close personal relationships. For example, a study found that in an urban clinic serving low-income outpatients, including a family member in brief, focused counseling and regimen planning increased the patient's long-term compliance with antihypertensive medications, resulting in improved blood pressure control and reduced mortality. Other studies have shown that
cooperation of a spouse enhances compliance with diet, smoking, and exercise interventions and with substance abuse treatment. Research on social support indicates that the availability of a trusted confidant (a spouse, other family member, or friend) is a critical factor in determining whether people feel they have adequate support to cope with difficult situations.[1]

As mentioned above (and as will be discussed in depth below), provision of social support is the core of Project Accept PTSS. PTSS support groups for those who are HIV-positive will provide safe venues where participants will be given tools to help them identify a trusted person to whom they can safely disclose their HIV status. Groups will also be a venue for learning effective coping and problem-solving skills related to living positively. We envision that participants in support groups will have reduced behavioral risk of transmitting HIV and less internalized stigma.

For those who are HIV-negative, PTSS support groups will offer the opportunity to problem solve around how to stay negative, for example, by discussing sexual relationship dynamics and practicing/role playing how to talk to one's sex partner about using condoms or encouraging him/her to be tested for HIV.

Societal/Community Context

Social-contextual action theory helps us understand the link between societal and community structures and personal health behavior. Recalling that the expected outcomes of PTSS are reduction of HIV/AIDS-related stigma, discrimination, and social harm, we need to look at a model of social-contextual action theory that has been applied to HIV/AIDS-related stigma. We find such a model in the work of Dr. Richard Parker of Columbia University and Dr. Peter Aggleton of the University of London, who have utilized elements of social-contextual action theory—specifically the third component relating to societal/environmental influences—and applied them to HIV/AIDS-related stigma and discrimination.

Parker and Aggleton have documented that stigma and discrimination are usually viewed as individual processes—what some individuals do to other individuals—rather than as social processes. This conception of stigma as a static, individual feature or characteristic ignores that stigma is socially constructed and limits understanding of the underlying causes and possible responses to HIV/AIDS-related stigma and discrimination.[13]

Thus, if stigma and discrimination are understood as the products of social rather than individual processes, it follows that effectively addressing stigma and discrimination requires social action—rather than just individual psychological approaches—to change the context within which individuals and communities respond to HIV/AIDS. Parker and Aggleton propose that to create a climate in which stigma and discrimination are no longer tolerated requires environmental interventions—in particular, social and community mobilization and empowerment of marginalized groups to resist stigma and discrimination—and structural interventions, particularly laws and policies that protect the rights of people living with and affected by HIV/AIDS. They note that:
"Empirical evidence indicates that some of the most effective responses to the HIV/AIDS epidemic have been those where affected communities have mobilized themselves to fight stigma, discrimination, and oppression."[13]

Drawing on community mobilization, empowerment, and social transformation, Parker and Aggleton offer a conceptual model that engages both communities and those who experience stigma and discrimination. Their model aims to achieve social and community change rather than just individual behavior change, with particular attention to learning lessons from the experience of community organization and of empowering stigmatized populations and communities.[13]

Let us recall the primary goal of PTSS: to encourage community members to become change agents who educate and mobilize communities so that HIV/AIDS-related stigma is reduced. To achieve this goal, Project Accept PTSS focuses on support groups because in such groups potential change agents are likely to be identified; PTSS offered only through a drop-in center would not be sufficient to identify those with the potential to become community change agents.

Those who are so identified will be considered candidates to become Project Accept community-based outreach volunteers (CBOVs, which are discussed in depth in the Community Mobilization Manual). These CBOVs will be intensively trained to educate communities about HIV/AIDS and encourage community members to be tested for HIV. In addition, a small pool of HIV-negative and HIV-positive PTSS participants will be referred to stigma reduction skills building courses; oversight of course graduates will be the responsibility of the Community Mobilization coordinator.

B. Coping Effectiveness Theory

In 1984, Dr. Richard Lazarus of UC Berkeley and Dr. Susan Folkman of UCSF defined psychological stress as:

"a particular relationship between the person and the environment that is appraised by the person as taxing or exceeding his or her resources and endangering his or her well being."[14]

Coping refers to what individuals do in response to situations that they appraise or evaluate as personally stressful. Coping can be internal, taking the form of thoughts, or external, taking the form of actions.[15]

The strategy used in a particular situation depends on how a person assesses the stressful situation: Can it be effectively changed by the individual? Or must she/he live with it and find other ways of reducing stress?[16]

Lazarus and Folkman define coping strategies as either:
1. Altering the source of stress, changing problematic aspects of stressful situations
2. Changing the emotional response to stressful situations when the source of stress cannot be changed[14, 17]
These two strategies are referred to as problem-focused and emotion-focused coping, respectively (see table 1). Problem-focused coping is based on problem solving, changing the situation in some way, whereas emotion-focused coping is directed at changing one's emotional response to it.[16]

Table 1. Characteristics of Problem-Focused and Emotion-Focused Forms of Coping

<table>
<thead>
<tr>
<th>Problem-Focused Forms of Coping</th>
<th>Emotion-Focused Forms of Coping</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cognitive processes directed at altering the nature or circumstances of the stressful situation. These include deciding how to use available resources to effect concrete change.</td>
<td>Cognitive processes directed at lessening emotional distress; these strategies include avoidance, minimization, distancing, selective attention, positive comparisons, and wresting positive value from negative events.</td>
</tr>
<tr>
<td>Problem-focused coping embraces a wider array of problem-oriented strategies than problem solving alone.</td>
<td>Cognitive strategies can also be directed at increasing emotional distress for some individuals who need to feel worse before they can feel better; these strategies include the need to experience distress acutely, engage in self-blame or some other form of self-punishment.</td>
</tr>
<tr>
<td>Problem solving implies an objective, analytic process that is focused primarily on the environment, but this style of coping also includes strategies that are inwardly directed.</td>
<td>This process can play out in a way that is similar to an athlete who is “psyching” up for a competition.</td>
</tr>
<tr>
<td>Problem-oriented strategies can be directed at the environment (such as altering environmental pressures, barriers, resources, procedures, etc.) and/or directed at the self (which includes strategies directed at motivational or cognitive changes such as shifting the level of aspiration, reducing ego involvement, finding alternative channels of gratification, developing new standards of behavior, or learning new skills and procedures).</td>
<td>All of these emotion-focused forms of coping involve a reappraisal of the stressful situation, which in turn diminishes the threat by changing the meaning of the situation to the individual.</td>
</tr>
</tbody>
</table>


How someone copes with stress depends on the resources she/he has available, including:

1. Personal resources, for instance, material savings
2. Interpersonal resources, such as supportive family and friends
3. Societal resources, for example, supportive community structures and attitudes[16, 18]
In the above list, we can see parallels with social-contextual action theory, which views personal health behavior in the context of individual, interpersonal, and societal/community factors.

Effective coping occurs when there is a "fit" between coping strategy selected (problem- vs. emotion-focused) and the "changeability" of the stressful situation. Ineffective coping occurs when people respond to changeable stressors with emotion-focused coping strategies or when people respond to unchangeable stressors with problem-focused coping strategies.[17]

Using coping effectiveness theory to develop interventions involves matching coping skills with the nature of the stressor. For example, an emotion-focused coping strategy can lessen the effects of dealing with the AIDS-related death of a partner (an unchangeable situation), whereas a problem-solving approach can be effective in coping with how and to whom to disclose one's HIV status (a situation that can be managed and made less stressful).[14, 16]

**How Coping Effectiveness Theory Informs the Design and Implementation of PTSS**

HIV/AIDS provides a good test of coping effectiveness theory because some HIV-related stressors are changeable (for example, learning to negotiate condom use with a sex partner), whereas others are unchangeable (receiving an HIV-positive test result, for instance). Several randomized controlled trials have found that interventions based on coping effectiveness theory can manage psychological distress and improve positive psychological states in patients confronting chronic illness such as spinal cord injuries or HIV/AIDS. One trial conducted in the U.S. found that building the coping skills of HIV-positive individuals was more effective in reducing psychological distress than providing them only with informational material.[17, 19]

Elements of coping effectiveness theory are adapted into the design of PTSS services:

1. Coping effectiveness workshops (for HIV-positive participants)
2. Ongoing psychosocial support groups (for both HIV-positive and HIV-negative participants)

Because interventions based on coping effectiveness have been proved to be effective in industrialized countries, we need to examine carefully how elements of this theory might be adapted to respond to the daily lives and realities of Project Accept participants and to the socio-cultural and economic contexts in which they live. To that end, sites are encouraged to adapt the manual for cultural appropriateness with final sign off from the Intervention Core.
IV. Pre-Intervention PTSS Activities

A. Preparatory Activities

In establishing Project Accept PTSS, the overarching aim was to ensure that services are accessible to and meet the needs of intervention communities. To achieve this aim, the UCSF Intervention core led a team of Project Accept site investigators on a study tour of post-test support centers in Uganda, Kenya and Zimbabwe. The objectives of the tour were (1) to understand how PTSS has evolved in Africa, (2) to inform the design and operation of PTSS best practices, (3) to understand how PTSS evolved to meet the needs of both positive and negative clients and, (4) to better understand the linkage between prevention and care, including ARVs. It was evident from this tour that post-test support services in these three African countries put emphasis on stress management and coping; that PTSS evolved to meet the needs of both positive and negative clients; that a small group of stigma reduction advocates could be identified and given communication skills and; that while both individual and group approaches were found, groups were more linked to community level change. In light of these findings, Project Accept will adopt the following PTSS model:

B. Establishment of Project Accept PTSS

The study site project director; Community Mobilization, VCT, and PTSS coordinators; and intervention communities will work together to identify post-test service needs, map existing community social services, and develop the optimal method of establishing Project Accept PTSS. Each research site will develop a plan for PTSS that will be sent to the Intervention Core and Steering Committee for approval. This plan will include documentation of existing, accessible community services.

Step 1: Conduct an inventory of existing community-based services in intervention communities through ethnographic mapping and needs assessments. (See the Project Accept Community Preparedness and Involvement Manual for more detail on these processes.)

Step 2: Determine the optimal method for establishing Project Accept PTSS; options may include one or a combination of the following:

   a. Creating a stand-alone, stationary PTSS center in the community. (Ideally, the center will have at least four rooms [team leader’s office, private counseling room, activity/meeting room, and resource room] and a reception area.)
   b. Setting up PTSS in temporary venues (mobile PTSS).
   c. Establishing PTSS in an existing governmental, nongovernmental, or community-based organization, including development of criteria for selecting partners/subcontractors and with the proviso that a related Memorandum of Understanding between the partner and Project Accept be approved by the Intervention Core and Steering Committee. MoUs must address QC/QA; staff roles, responsibilities, and supervision; and all SOPs, within the context of conducting a randomized controlled trial and meeting NIMH requirements.
V. Project Accept Enrollment Procedures

A. PTSS Eligibility Criteria and Membership Categories

Individuals who have undergone HIV testing at Project Accept or other HIV testing venues will be eligible to access the full range of PTSS services, and will be designated as “members”. Those who have not been tested for HIV will be designated as “guests”, and will have access to a more limited range of services. Both members and guests will go through a verbal informed consent process the first time that they come for services. Those who have not tested will be allowed to access the large informational groups offered at PTSS sites, but will not be able to access other PTSS services until they have been tested. Persons interested in testing will be referred to Project Accept VCT.

Because this is a research study, persons who meet any of the following criteria will not be eligible to participate in PTSS (and will be referred to existing alternate services):

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

B. Registration/Sign-In

Counselors will register members upon their first visit to PTSS and will sign them in on subsequent visits, using the registration logs developed by the Utilization Subcommittee. At the initial visit, counselors will also administer verbal informed consent to members and guests. To document that verbal informed consent has been administered, the intake counselor will fill out the PTSS consent log. This log includes the participant’s ID number generated from that day’s intake log, membership status (member or guest), and the counselor’s initials. This consent log will be stored in a binder along with that day’s intake log.

Counselors will also note whether members were accompanied by family members or friends. During members’ first visit to PTSS, counselors will ask them, as well as accompanying family and friends, to discuss their service needs and expectations. PTSS staff will use the findings from this needs assessment to design PTSS activities and ensure that they are responsive to participants' needs. This process will also help to demarcate the difference between (a) the services delivered by Project Accept PTSS and (b) those delivered by non-Project Accept organizations/agencies, thus clarifying where secondary referrals will be necessary. In addition, PTSS staff, working with the Intervention Subcommittee, will conduct ongoing, periodic participant needs assessments through the duration of the research period to ensure responsiveness to participants' needs as well as to facilitate sustainability of PTSS post-Project Accept.
C Referrals to Non-Project Accept Organizations/Agencies

Because 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. As discussed above, PTSS staff will identify and map a core of community-based health and social service providers to which participants will be referred. The PTSS coordinator and team leader will negotiate with the relevant service organization about the nature of services to be provided to PTSS participants.

Participants may need referrals for various health and social services such as treatment of opportunistic infections, ART, PMTCT, violence, food, housing, etc. To record these referrals, PTSS staff will complete the PTSS referral log developed by the utilization sub-committee. Please refer to Utilization SOP “Appendix 11 Type of Referral Organizations” for a complete list and the referral log.

D. Protocol for Identifying Early Adopters of PTSS as Candidates to Become Community-based Outreach Volunteers (CBOVs)

Please refer to the Community Mobilization SOP for detailed information.
VI. PTSS Services

A. Types of Services Offered
See training manuals for each component for in-depth background and detailed instruction on how to deliver each type of service. Staff will fill out utilization forms both to record hours that services are available and to record usage by participants. These forms will be filled out each day. Refer to the Utilization SOP for full instructions.

a) Coping Effectiveness Training (CET)
PTSS members and guests will be offered the opportunity to participate in a one-day CET workshop. Each workshop will be comprised of 8-10 participants.

The objectives of the workshops are to:
1. Optimize mental health outcomes, including ability to manage stress and cope with one’s HIV results.
2. Build a core of community members with effective coping skills

The workshops are designed to build skills in:
1. Managing stress
2. Coping effectiveness
3. Identification of post-test social support

We anticipate that the dynamics of the workshop and the interpersonal bonds that are likely to develop among participants will result in a small pool of workshop graduates identified for further skills building in mobilizing their communities around HIV and HIV testing through:
1. Referral to Project Accept’s Community Mobilization component as possible candidates to become community-based outreach volunteers
2. Participation in stigma reduction skills building

b) Stigma Reduction Workshops
We anticipate that the dynamics of the CET and the psychosocial support groups, and the interpersonal bonds that are likely to develop among participants, will result in a small pool of graduates/participants, both HIV-negative and HIV-positive, who go on to attend a skills-building course that offers them stigma reduction tools (participants from the Community Mobilization and CBVCT components will also be referred to the course). The main objective of the course will be to prepare individuals and communities for public disclosure of HIV status (no one will ever be pressured to disclose his/her HIV status, either privately or publicly.)

The content of the course will focus on building skills in:

- Accurate knowledge of HIV/AIDS and of HIV testing
- Music, dance, and drama for presentations in community venues
- Safe and appropriate public disclosure of HIV status
• Public speaking, including giving testimonials and dealing with radio, newspaper, television, and other media
• Advocacy, covering national laws and policies regarding the rights of PLWHA, access to antiretroviral treatment, and community resources designed for PLWHA
• Problem solving to deal with stress and burnout

Graduates of the skills-building course will be referred to the Community Mobilization Coordinator, who will be responsible for monitoring their activities.

c) Information Sharing
Information sharing groups are larger group meetings formed around specific age groups, serostatus, or other characteristics/topics. PTSS staff, a non-Project Accept guest lecturer, or PTSS participants may facilitate these groups. Possible group topics may include:

- Nontesters: preparing to take an HIV test
- How to use condoms and negotiate their use
- Health and nutrition for PLWHA, including OIs
- Physical exercise
- Relationships, including sexual relationships
- Life planning
- Legal issues and policies related to HIV infection
- Spiritual issues
- Resources for family members and friends
- Communication for development (writing grant proposals, securing funding, developing and sustaining community PTSS)
- Health and social services offered in the community (presented by representatives of community organizations)

Facilitation methods may include lectures, i.e., formal talks given on a specific topic or participant led discussion. Participants may identify a topic of interest relevant to their situation and the PTSS team leader will invite a guest speaker with expertise in that area. Another method will be group discussion, wherein participants share information, ideas, and opinions under the guidance of a facilitator. (Note that all sites will also aim to have a resource area with Information-Education-Communication [IEC] materials available for participants' use.)

d) Psycho-social Groups
Psychosocial support groups, comprise of 8-10 participants, will meet two to four times a month. These groups will provide an opportunity for participants to meet other people in similar circumstances and to make friends. Group topics will be flexible and based on the expressed preferences of participants as well as staffing availability. Groups may be formed around topics such as:
For those who are HIV-negative: avoiding HIV acquisition
• Coping with negative or positive HIV test results
• Identifying social support
• Stress management
• Safe and thoughtful disclosure of HIV serostatus to family and friends
• Emotion and feelings
• Serodiscordant couples
• Positive/healthy living
• Adherence to ART
• Gender- and age-specific support groups
• Coping with an HIV-positive family member or friend

Selected support groups members will be trained in support group facilitation so that support groups are led by both PTSS staff and by peers. Such training will also seek to sustain PTSS activities after Project Accept has ended.

e) Crisis Counseling and Psychosocial Support
PTSS counselors will provide counseling sessions to individuals and couples by appointment or when requested for by an individual attending any of the PTSS activities offered at the PTSS center. Given our staffing limitations, individual and couples counseling will primarily be geared toward crisis management.

However, counselors may also provide counseling to PTSS members and guests who may be experiencing other psychosocial problems which may not necessarily require crisis management.

Counselors will be encouraged to focus on channeling participants to other, less resource-intense PTSS activities, including our coping effectiveness workshops, psychosocial support groups, informational groups, and recreational activities. Counselors will also provide referrals to non-Project Accept health and social services within the community.

f) Participant Initiated Activities

PTSS staff or participants may facilitate these group recreational or social activities. Facilitation methods may include:

- Brainstorming: Facilitator takes spontaneous responses from participants without evaluating the responses.
- Group Work: This is a structured group activity. The facilitator prepares an activity related to the participants’ needs and asks participants to work in small groups to generate a solution for the problem. Groups report back in a plenary session for further discussion (5-10 participants in each group).
Interactive games to help identify and mitigate HIV/STI risks in sexual relationships.
- Role-plays: Participants simulate a real-life situation.
- Drama: Participants act out roles and problems faced in everyday life and generate solutions. Unlike role-play, drama is rehearsed.
- Case Studies: Facilitator presents facts about a relevant situation that participants analyze and discuss.
- Storytelling.
- Demonstrations and return demonstrations: Facilitator demonstrates an activity or skill to participants who repeat the procedure while facilitator observes. Participants learn by doing.

B. Negative Life Events, Adverse Events, and Incidents

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.

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 (ie, 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.

All the above activities will be characterized by flexibility and responsiveness to participants' needs. To that end, activities may be modified over the research period. In addition, other site-specific activities may be introduced to meet participant and community needs.
VII. Intervention Dose

As part of a well characterized intervention it is vital that Project Accept be as uniform as possible across intervention sites. One means of achieving this is by standardizing the number of hours, referred to as dose, for VCT, PTSS, and CM. It is important to note that the dose figures refer to the number of hours offered not the number of hours that the intervention components are used. The QA/QC documents measure the amount of time that the intervention is made available to communities; whereas the Utilization documents measure how much the intervention is used by communities. See the QA/QC chapter for more information.

PTSS:
PTSS dose was originally proportionate to community size for all five of the PTSS sub-components, as summarized in Table 1 below.

Table 1: Original PTSS Sessions Frequency Projections 60 weekly PTSS hours per population size of 10,000 persons

<table>
<thead>
<tr>
<th></th>
<th>CET</th>
<th>Stigma Reduction</th>
<th>Information Sharing Groups</th>
<th>Support Sessions</th>
<th>Counseling</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monthly hours</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>10</td>
<td>38</td>
<td>60</td>
</tr>
<tr>
<td>%</td>
<td>6.66%</td>
<td>6.66%</td>
<td>6.66%</td>
<td>16.66%</td>
<td>63.33%</td>
<td>100%</td>
</tr>
</tbody>
</table>

The hourly breakdown for each component of PTSS was based on previous PTSS experience. However, when projected for CET, Stigma Reduction, and Information Sharing Groups, the above dose calculations yielded an insufficiently low frequency for these components of PTSS. Instead, the number of monthly CET, Stigma Reduction, and Information Sharing Groups sessions are standardized across all sites irrespective of community size as listed in Table 2.

Table 2: Modified PTSS Session Frequency Projections

<table>
<thead>
<tr>
<th>Monthly Sessions</th>
<th>CET (8 hours each)</th>
<th>Stigma Reduction (8 hours each)</th>
<th>Information Sharing Groups (2 hours each)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2</td>
<td>2</td>
<td>8</td>
</tr>
</tbody>
</table>

The number of monthly Support Group sessions and the number of monthly Counseling remain proportionate to community size.

The Intervention Core will provide 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:
\[
\frac{60 \text{ weekly hours}}{10,000 \text{ people}} = 0.006 \times (\text{population 16 and older}) \times 0.1666 = \text{weekly hours}
\]

Support Session.

\[
\frac{60 \text{ weekly hours}}{10,000 \text{ people}} = 0.006 \times (\text{population 16 and older}) \times 0.6333 = \text{weekly}
\]

Counseling Hours.
VIII. Roles and Responsibilities of PTSS Staff

Each site will have two PTSS teams; each PTSS team will comprise one team leader and two counselors. Each team will serve two intervention communities. The site PTSS coordinator will oversee both teams.

A. Coordinator

The PTSS coordinator is responsible for overseeing all aspects of PTSS within intervention communities. The coordinator supervises the 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 specific responsibilities:

1. Negotiate with communities to set up PTSS centers
2. Identify post-test service needs
3. Map existing community social services
4. Monitor the functioning of PTSS centers
5. Work with Community Mobilization staff to identify potential CBOVs
6. Ensure ongoing coordination with Community Mobilization and VCT coordinators
7. Oversee quality assurance of PTSS

The study site project director will train the PTSS coordinator; centralized and/or outsourced training may also occur.

B. Team Leader

The PTSS team leader is responsible for the day-to-day functioning of PTSS centers. The team leader supervises counselors. The team leader reports to the PTSS coordinator. Among specific responsibilities:

1. Describe PTSS services to interested participants
2. Design and implement activities based on those needs
3. Establish counselors’ work/duty schedules
4. Assume counseling duties as needed
5. Ensure that community referrals kept current
6. Quality control activities of their team members

The PTSS coordinator will train the PTSS team leader; centralized and/or outsourced training may also occur.

C. Counselors

PTSS counselors will:

1. Describe PTSS services to interested participants
2. Facilitate CET workshops
3. Train peers to facilitate psychosocial support groups
4. Facilitate stigma reduction skills-building courses
5. Provide counseling, primarily focused on crisis management, to individuals and couples
6. Provide referrals to non-Project Accept health and social services
7. Facilitate and/or assist PTSS members in facilitating other PTSS services
8. Assist the team leader in identifying participants' needs and designing responsive activities

Counselors will also be responsible for administrative and data collection tasks, including:

1. Obtain written informed consent from PTSS participants
2. Fill out PTSS activity logs
3. Ensure that every participant visit is recorded in the log
4. Schedule individual and group activities

The counselors report to the PTSS team leader. The PTSS counselors will attend the same training as the site's CBVCT counselors. They will then receive additional training from the PTSS coordinator and team leader with regard to PTSS-specific counseling needs, including coping effectiveness, crisis management, group facilitation, secondary referrals, PTSS-specific utilization forms, ensuring safety during counseling sessions, and in dealing with their own stress and avoiding burnout. (See section VIII for more detail on PTSS staff training).

D. Core and Supplemental Training for PTSS Staff

<table>
<thead>
<tr>
<th>Core Coordinator</th>
<th>Supplemental</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overview of Project Accept (from Staff Orientation Manual)</td>
<td>General management/leadership</td>
</tr>
<tr>
<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>
</tr>
<tr>
<td>HPTN and site-specific ethics training</td>
<td></td>
</tr>
<tr>
<td>HPTN and site-specific GCP training</td>
<td></td>
</tr>
<tr>
<td>Staff supervision and monitoring</td>
<td></td>
</tr>
<tr>
<td>Confidentiality</td>
<td></td>
</tr>
<tr>
<td>QA/QC</td>
<td></td>
</tr>
<tr>
<td>Utilization</td>
<td></td>
</tr>
<tr>
<td>Information and documentation systems</td>
<td></td>
</tr>
<tr>
<td>Data entry and management</td>
<td></td>
</tr>
<tr>
<td>Group facilitation</td>
<td></td>
</tr>
<tr>
<td>Coping effectiveness training</td>
<td></td>
</tr>
<tr>
<td>Crisis management/Suicide Risk Assessment</td>
<td></td>
</tr>
<tr>
<td>Stigma Reduction</td>
<td></td>
</tr>
</tbody>
</table>
The Intervention Subcommittee will strategize with the PTSS coordinator and team leader on professional development of PTSS staff. For example, many of the professional development activities/tools discussed for VCT counselors will also be applicable to PTSS personnel. For instance, opportunities for updating and enhancing skills in facilitation of psychosocial support groups will be crucial, as will ongoing training and refresher courses that strengthen PTSS personnel's ability to identify the counseling, care, and support needs of participants. Peer education and training of trainers will also be vital so that care and support skills are transferred to the community, thereby facilitating the sustainability of PTSS after the Project Accept research period ends.
IX. Quality Control and Assurance Procedures and Instruments

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 PTSS Coordinator, PTSS 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 PTSS Quality Assurance/ Quality Control Guidelines Manual for detailed QA/QC procedures.
References


   <http://www.caps.ucsf.edu/pdfs/CET%20Workbook.pdf>