Post-Test Support Services
Quality Assurance and Quality Control Guidelines
United States National Institute of Mental Health
(HIV Prevention Trials Network 043)

NIMH PROJECT ACCEPT
Quality Assurance and Quality Control Guidelines

Post Test Support Services (PTSS)

UCSF Intervention Core
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1.0 Introduction and Overview

The Intervention Core at University of California, San Francisco oversees quality assurance and quality control of NIMH Project Accept intervention components. There are several mechanisms by which the quality of intervention sessions will be ensured. These mechanisms are summarized in this overview, and are described in more detail throughout this document.

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. Supervision is carried out by the Coordinators and Project Directors. 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.

2.0 Quality Assurance Procedures for PTSS 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, which are described in this section.

2.1 Development of Intervention Protocol Manuals

The Intervention Core, with assistance from the Intervention Sub-committee, developed the PTSS SOP and component manuals that detail implementation procedures for Coping Effectiveness Training (CET), Stigma Reduction Skills Training, Facilitation of Information Sharing Groups and Support Groups, and Crisis Counseling Sessions.
2.1.2 Manuals
The PTSS SOP and each component manual details step-by-step implementation procedures including goals, materials required, and general timelines. Exercises and examples are provided in each manual. Each staff member uses and refers to these manuals for delivery of PTSS components.

2.2 Training
- All Team Leaders and Counselors have received the 5-day counselor training outlined in the Counselor Training Manual.
- All Coordinators and Project Directors also participated in an 8-day Training of Trainers (TOT) course in preparation for training site staff. The first 2 days included an orientation to Project Accept, an overview of HIV/AIDS including ART, an overview of ethics, and training on adverse event reporting and IRB requirements. The 3rd day included introduction sessions to the Intervention Component Groups and an overview of ethics for community members. The remaining 5 days were devoted to intervention specific training (Community Mobilization, VCT, and Post Test Support Services).
- All Counselors are trained by the Coordinators using the materials and skills from the TOT.
- All Team Leaders are trained in QA/QC procedures and use of the rating instruments by the Coordinator.

2.2.1 Qualifications
PTSS Coordinators have at least a Masters degree in the field of social sciences as well as supervision experience and training. Team Leaders, who will be primarily responsible for QC activities, have a minimum qualification of a high-school diploma and basic counseling training based on each local site’s national standards including HIV/AIDS counseling. They also received the Project Accept Counselor Training.

2.2.2 Competency
Upon completion of TOT training, Coordinators and Project Directors are considered proficient to train and supervise staff in their respective areas of specialty (i.e. VCT, PTSS, & CM). After training, Team Leaders are considered proficient to supervise their staff and ensure quality of procedures. At a later date, all staff received training in “Good Clinical Practice” (GCP), provided by HPTN.

Counselors will be considered proficient and qualified to implant the intervention upon completion of training by the Coordinator and upon completion of satisfactory or higher role plays evaluated using the tools described below for ongoing QC procedures.
2.2.3 New Staff
Should the originally trained staff members no longer be available, new Coordinators will be selected and trained by the site project director or a designated senior staff trainer. New counselors will be trained by the project coordinator or a designated counselor trainer. Trainee candidates will be selected based on qualifications and relevant experience.

2.3 Staff Member Quality Assurance Activities

2.3.1 Session Review
Staff are expected to review component or session protocols, session checklists, and any relevant participant information in advance of each session.

3.0 Quality Control Procedures for PTSS

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.

3.1 Supervision
Team Leaders, who are responsible for all Quality Control evaluations at their site, will be supervised and monitored by the Coordinators and Coordinators responsible for inter-rater reliability, will be supervised and monitored by the Project Director. Staff supervision may occur on a variety of levels. It is encouraged that arising QA/QC issues be discussed at component specific staff meetings, study-wide staff meetings, as well as in one-on-one meetings. The frequency and structure of these meetings is left at the discretion of the Team Leaders and Coordinators who have the best assessment of staff needs based on regular QC evaluations.

3.2 Evaluation of Sessions
The PTSS Team Leaders are responsible for QC of their PTSS team members. The Coordinator will also conduct evaluations for inter-rater reliability (see section 3.2.4.3). The Coordinator will also make occasional evaluations at their discretion to ensure
compliance and provide inter-rater reliability. It is the responsibility of the Coordinator to ensure the timely and accurate QC activities and discuss session ratings for feedback to staff with the Team Leaders. The PTSS Team Leader will sit in as an observer during the session and rate the session using the appropriate evaluation form:

- CET Quality Control Evaluation Form
- Stigma Reduction Quality Control Evaluation Form
- Information Sharing/Support Group Quality Control Evaluation Form
- Crisis Counseling

3.2.1. Rating Criteria
Standardized criteria are used for each intervention component. The criteria are based on two broad categories of qualities: (1) general counseling skills consonant with the counseling style recommended for use with each of the PTSS components (group vs individual) of the intervention and (2) skill and adherence to required elements of each session or component. General counselor skills include being empathic, non-judgmental, maintaining appropriate boundaries, maintaining session cohesion, etc.

Consistent with current recommendations for quality control review of behavioral and psychological interventions (Waltz, Addis, Koerner, & Jacobsen, 1993, JCCP, 61, 620-630), ratings are made for both adherence to protocol and competence at conducting specific elements of the intervention.

3.2.1.1 Adherence to Protocol Rating
For specific manualized intervention elements, the rater indicates the extent to which an element is present or absent on a scale of 1-5 where a score of 5 indicates 100% adherence, 4 indicates 95% adherence, and 3 indicates 90% adherence. Scores below 3 are considered unsatisfactory and warrant immediate action including retraining and additional supervision.

5= Excellent/ Very Strong (100% adherence)
4= Satisfactory/ Strong (95% adherence)
3= Satisfactory (90% adherence)
2= Poor: Needs additional supervision
1= Unacceptable: Needs intensive supervision/ training

3.2.1.2 Competence Rating
In addition to adherence to manualized guidelines, each observed session is also rated, using the same scale, on the skill with which the staff member delivered the session. Again, each element is rated on a scale of 1-5 based on the operational
definitions listed above. The rating form used for adherence and competence ratings is included at the end of this document.

3.2.1.3 Making Ratings
Raters should record a score for each item on the QC form. Items on the QC form are grouped based on type of element being rated. For instance, there’s a group of items regarding technique, a group of items on adherence to the manual, etc. At the end of the form there’s a space to write in the overall average score for the entire session rated. This score is the average of all items and should reflect your assessment of the staff member’s entire performance of the session rated.

3.2.2 Rater Training
To ensure that each rater is applying the rating criteria consistently, two steps were taken. First, Team Leaders and Coordinators have a minimum basic counseling skills background (see 2.2.1). Second, sessions on QA/QC were held during the 8-day Training of Trainers meeting where it was assured that Coordinators understood the theoretical underpinnings of the intervention, a detailed review of the quality assurance and quality control procedures, review of the rating criteria and operational definitions, and practice review and discussion. Coordinators trained Team Leaders at their site using the curriculum they learned at the TOT.

3.2.3 Sampling Strategy

Month 1: All CET, Stigma Reduction sessions, Two Information Sharing Sessions; 20% of all Support Sessions; and 15% of all Crisis Counseling hours will be evaluated.

Month 2-6: One CET, Stigma Reduction session, and Information Sharing Sessions; 10% of monthly Support Sessions; and 10% of all Crisis Counseling hours will be evaluated.

Ongoing: One CET, Stigma Reduction and 4 Information Sharing Sessions; 5% of Support Sessions will be evaluated every quarter (3 months); and 5% of all Crisis Counseling hours will be evaluated.

3.2.4 Corrective Action to Address Deviation from Protocol

3.2.4.1 Feedback to Staff Member
After completing ratings for specific criteria, raters write an explanation for both unsatisfactory and satisfactory ratings in the notes section of the QC form. While the goal of QC is to identify and correct non-adherence to the study protocol, it’s also important to acknowledge elements that were performed particularly well and to include these in the summaries. It’s important that staff be given positive reinforcement in the areas where they are doing well and to be acknowledged for
their valuable contribution to the project and to the team. These summaries, including corrective feedback and reinforcement of good performance, should be discussed with the individual during individual supervision. Issues that are re-occurring for a number of staff members should be addressed in staff meetings for correction and retraining as needed. In addition, “incidents” that are observed during quality control reviews are noted and reported to UCLA, the site Project Director, and the Intervention Core. (For more information on “Adverse events and Incidents” refer to Section 8.3 in Protocol V2: 2005).

3.2.4.2 Minimum Requirement of Adherence
A score below 3 on any item or an average score below 3 on any group of items (below 90% adherence) will be discussed with the staff member for correction. At the discretion of the Team Leader, Coordinator, or Project Director, this may include additional training, supervision, or temporary reduction in responsibility.

3.2.4.3 Inter-Rater Reliability
The Coordinator conducts an independent rating of 25% of the PTSS sessions evaluated. The Coordinator participated in initial training at the TOT, taught the QC procedures to the Team Leaders, and supervises the Team Leaders. Discrepancies in these ratings are discussed and resolved with the original rater so that his or her ratings are consistent with the independent ratings of the Coordinator.

3.2.4.4 Retraining/Booster Sessions for Particular Staff Members
Staff demonstrating an Overall Rating of 2 or 1 (below 90% adherence) will be pulled from the project for intensive retraining. This may include assuming a secondary observational role in subsequent sessions observing a senior staff member’s work, retraining, role plays, or other activities. The staff member will be allowed to resume their role after conducting 2 observed and evaluated sessions rated at 90% adherence or higher. Action for a score of 2 or below on any of the sub-sections is at the discretion of the site. In some instances the Team Leader or Coordinator may determine that a one-on-one meeting to review the topic area is sufficient to correct the problem while in other instances it may determined that more formal training is needed. Depending on the severity of the non-compliance or inability to receive a satisfactory score after retraining, the Project Director (in consultation with the Coordinator) may release the staff member from their role on the project.

3.3 Reports and Documentation
Each month, the Coordinator will collect and review all QC evaluation forms with the Team Leader. The evaluations will then be reviewed with the Project Director. In instances where below satisfactory performance is noted, the Project Director will consult with the Intervention Core and work with the Coordinator to design a plan to correct the issue and bring performance up to standard.
Each month, the Project Director will write a “Monthly Site QC Report” based on that month’s evaluations. This will be in the form of a narrative that includes:

- Overall ratings of adherence to elements
- Less than satisfactory performance and how it was corrected
- Site trends off protocol and how they were corrected
- Challenges
- Accomplishments
- Plans and recommendations for moving forward

### 3.3.1 Timelines

QC reports and documentation will be tracked on a monthly basis. For the purposes of this study, a month will be measured in 4-week increments. Because of the staggered start across sites, each site will be on their own individual timeline. For instance, a site might enter the field on the 15th of the month. In this case, their 4-week month starts on the 15th. Also, the work week might run from Monday through Friday at some sites, while it might run from Wednesday to Sunday at another site. For this reason, each site will receive an individualized reporting schedule from the Intervention Core. This schedule will list the dates that the site QC report is due to the Intervention Core.

In general, the QC report is due to the Intervention Core 10 days after the end of each site’s “month.” For instance, if the end of your month is the 13th, your report would be due on the 23rd.

### 3.3.2 What is due to the intervention core each month?

Materials due are outlined in the chart at the end of this manual. In brief, these are:

- QC report by the Project Director
- Summary pages only from QC evaluations
- Hours Log

### 3.3.3 Where to send material

All sites have confirmed they have scan/e-fax capacity to email QC materials to the Intervention Core. Please forward to both Gertrude and Joanne at the following email addresses:

Gertrude.sakutukwa@ucsf.edu

AND

Joanne.mickalian@ucsf.edu

### 3.4 External Evaluation by Intervention Core
3.4.1 Review of Monthly Site QC
The Intervention Core will review the monthly QC reports and consult with the site Project Directors in cases where corrective action is needed or where problems with adherence show signs of beginning to emerge. Using these monthly reports and QC forms, the Intervention Core will produce a quarterly report back to the sites. These reports will summarize the QC activities reported by the site in the previous 3 months including a summary of rating scores, and noting areas of satisfactory performance, areas for improvement, and recommendations for correction. The reports will also describe issues that are emerging from the QC that relate to more than one site, such as protocol adherence, etc. The sites will use these reports as a training tool to focus attention, provide early feedback, and foster preventive intervention so that problems do not develop.

3.4.2. Biannual Monitoring by the Intervention Core
The Intervention Director from the Intervention Core at UCSF will conduct in-person quality control monitoring visits every six months (biannually). The purpose of these monitoring visits will be to maintain staff competent performance and adherence to the protocol by:

- Observing sessions and rating performance using the QC evaluation form
- Reviewing files and forms for completeness and accuracy
- Observing daily operations
- Ensuring that the intervention is available for the duration prescribed in the SOP and according to SOP guidelines
- Meeting with the Project Director and Coordinators to provide direct supervision, feedback and answer questions.

** Note that visits may be more frequent in the early phases of the intervention, for example, a visit after month 1, after month 3, and every six months thereafter. These early visits are particularly intended to assess implementation of SOPs—particularly regarding informed consent, confidentiality, avoidance of negative HIV-related life events, and manualized procedures—and recommend needed revisions.

3.4.3. Start-Up Conference Calls with the Intervention Core
To assist with facilitation of start-up, the Intervention Core will hold monthly consulting conference calls with the leadership of each site. This will include the site PI, Project Director, Coordinators, Team Leaders, and U.S. PI. The goal of these consultations is to provide assistance, review goals and plans, and address any emerging issues as the team gets ready to enter the field. The scheduling of these calls is flexible to allow for more or less frequency as needs change over time. These calls will remain on-going as needed throughout the entire course of the intervention.

4.0 Quality Control of Hours of Availability (Dose)
The purpose of the QC evaluations of the sessions and staff described above is to ensure that the identical procedures and content are delivered to every participant regardless of which study site they’re seen at or which staff member they’re seen by.

In addition, we must ensure that the amount of time that PTSS services are available in a community is consistent with the time prescribed in the PTSS SOP. To evaluate compliance with the number of hours PTSS is available, the Team Leader will fill out the “PTSS Hours Log Worksheet” each day. The Coordinator will collect these worksheets and use them to calculate the number of hours the PTSS service was open and available to receive participants in each community during the past week. This information will be recorded on the Excel spreadsheet “PTSS Hours Log” and emailed to UCSF Intervention Core once per month with the other QC materials.

### 4.1 PTSS Hours Log Worksheet (Team Leader)

**Counselor Responsibilities:**

- Fill out the VCT Hours Worksheet each day.
- Turn in VCT Hours Worksheets to the Coordinator weekly.
- Write in the date and location/venue.

**Filling out the VCT Hours Worksheet**

- Write in name of each intervention community on the “Community Name” line.
- Use a separate table grid for each community.
- Make as many copies of this form as needed.

Each day write in the date and the number of hours/minutes that each PTSS activity was AVAILABLE for each community – this is the amount of time that each activity was open and prepared to see participants. Even if no participants showed up, you must record the amount of time this service was available and staff were prepared to see participants, should someone show up. Report time of actual usage on the PTSS Activity Log (Utilization Committee form).

After 7 days have passed, add up the number of hours/minutes in boxes “Day 1” through “Day 7” for each activity and write the total in the “Weekly Total” column.

**Notes.** Record any local conditions that may have affected participant flow, staff, or PTSS set up.

Fill out a new form every seven days.
PTSS Hours Log (Coordinator)
The Coordinator fills out the “PTSS Hours Log” weekly and emails the sheets to the Intervention Core at the end of each month.

Write in name of each intervention community on the Community Name line.

Use a separate table grid for each community.

Make as many copies of this form as needed.

Each week write in the date and the number of hours that each PTSS activity was AVAILABLE for each community (refer to the PTSS Hours Worksheet to determine number of hour/minutes).

After 4 weeks have passed, add up the number of hours/minutes in boxes “Week 1” through “Week 4” for each activity and write in the total in the “Monthly Total” column.

Fill out a new form every 4 weeks.

Turn in completed Logs to the Project Director for inclusion in the monthly QC report to the Intervention Core.

5.0 Contact Information

Forward all materials by the 10th of each month.

- Site QC Report
- QC Evaluation Forms
- Hours Log

Send to:
Gertrude Khumalo-Sakutukwa and Joanne Mickalian

Gertrude.sakutukwa@ucsf.edu

And

Joanne.mickalian@ucsf.edu

Additional Comments: All Project Accept site personnel are required to allow UCSF Intervention Coordinating Center and designated NIMH staff access to inspect study facilities and documentation as well as observe the performance of study procedures. Site personnel are
encouraged to share information on study implementation successes, issues, and problems with UCSF Intervention Coordinating Center staff to help ensure the highest quality of study conduct.

This Quality Assurance/Quality Control plan has been approved by the Steering Committee and all modifications to the plan will be approved by the Steering Committee before implementation.

PTSS: Quality Control Procedures Flowchart

<table>
<thead>
<tr>
<th>Staff Member</th>
<th>Responsibility</th>
<th>Frequency</th>
<th>Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>Counselor</td>
<td>Deliver PTSS</td>
<td>See SOP guidelines for your community</td>
<td></td>
</tr>
</tbody>
</table>
| Team Leader               | Asses staff performance and complete QC evaluation  | Month 1: 15%  
|                           |                                                     | Month 2-5: 10%  
|                           |                                                     | Month 6+: 5%                  | PTSS Quality Control Evaluation Form for appropriate component |
|                           | Assure that PTSS services are available for the prescribed hours per day and week | Fill out Hours Worksheet Daily  
|                           |                                                     | Turn in to Coordinator weekly | PTSS Hours Worksheet |
| Team Leader & Coordinator | Discuss positive performance and areas for improvement with staff members | At staff meeting or schedule an individual meeting sooner if performance below satisfactory level |                                                        |
| Coordinator               | Turn in all forms to Project Director               | Last day of the month         |                                                        |
|                           | Asses staff performance and supervises Team Leader  | Ongoing                      |                                                        |
|                           | Collect PTSS hours worksheet, complete hours log, and email log to UCSF | Fill out weekly  
|                           |                                                     | Send in monthly               | PTSS Hours Log |
| Project Director          | Synthesize QC report forms, write site report, review hours log and turn all in to Intervention Coordinating center | 10th of each month           | Monthly Site QC Report (narrative) |
|                           | Work with Coordinator to address below satisfactory | As needed                    |                                                        |
| **Intervention Coordinating Center** | Review monthly site reports and produce reports back to the sites based on their monthly narratives and forms | Quarterly  
May be done more frequently at the start of the intervention and taper as adherence maintains at 95% (satisfactory) level, but will not fall below quarterly reporting |
| | | |
| | Provide feedback and available for questions/consultation to Project Directors, Coordinators, and study staff | Ongoing as needed |
| | Site visits and meetings with Coordinators and Project Director | Quarterly |