Voluntary Counseling and Testing
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

Voluntary Counseling and Testing (VCT)

UCSF Intervention Core
Version 1.4
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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 VCT 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 VCT 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 VCT SOP manual that details implementation procedures for the VCT component.
2.1.2 Manuals
The VCT SOP 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 this manual for delivery of VCT.

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
VCT Coordinators have at least a Masters degree in the field of social sciences and Supervision experience and training. Team Leaders, who will be primarily responsible for QC activities, have a minimum qualification of a high-school diploma, basic counseling training based on each local site’s national standards including HIV/AIDS counseling, and are trained phlebotomists. 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, staff also 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 VCT

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, and (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 of their teams 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 VCT Team Leaders are responsible for QC of the VCT component at their site. The Coordinator will also make occasional evaluations at their discretion to ensure compliance and provide inter-rater reliability (see section 3.2.4.3). It is the responsibility of the Coordinator to ensure timely and accurate QC activities and discuss session ratings.
for feedback to staff with the Team Leaders. The VCT Team Leader will sit in as an observer during the session and rate the session using the form titled:

- **VCT Quality Control Evaluation Form**

### 3.2.1. Rating Criteria

Standardized criteria are used for evaluating VCT. The criteria are based on two broad categories of qualities: (1) general counselor skills consonant with the counseling style recommended for use with the intervention and (2) skill and adherence to required elements. General counselor skills include being empathic, non-judgmental, maintaining appropriate boundaries, relaying the objectives of the voluntary testing & counseling session, 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**

For example, suppose the session is to contain a problem-solving exercise, which has a specific structure and procedure. Although the problem-solving element is tailored to each participant's needs in each specific session, the problem-solving technique should be recognizable as such.

#### 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. The average score for each group of items should be recorded on the appropriate line at the end of that section. At the end of the form there’s a space to write in the overall 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 1-5:** 10% of sessions delivered in the first month of VCT will be evaluated with a minimum of 2 evaluations per counselor, per month.

**Ongoing:** 5% of sessions delivered per month will be evaluated with a minimum of 1 evaluation per counselor per month.

**Note:** One QC evaluation consists of monitoring one counselor complete the entire pre- and post-test counseling services provided to one participant. In the instance where a participant receives pre-test counseling but does not return for post test counseling, the pre-test session evaluation will serve as 1 complete evaluation. The evaluator should calculate totals and averages for the sections completed, fill out the summary sheet as usual, and make note that the participant did not return for post-test counseling. A participant may decide to discontinue participation at any time. If a session is ended before completion at the wish of the participant, the evaluator will still count this as 1 complete evaluation, record total and averages on the summary sheet, and record that the session was ended at the request of the participant.

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 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.

3.2.4.4 Inter-Rater Reliability
The Coordinator conducts an independent rating of 25% of the VCT 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.
3.3 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/Definition of a Month
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
3.4 Quality Control in Standard VCT (SVCT) Sites
Sites without existing SVCT facilities will have created their own SVCT sites as part of the study. Quality assurance and supervision procedures in these newly created SVCT venues will reflect, as closely as possible, procedures at the CBVCT venues.

Study-controlled quality assurance and supervision cannot be guaranteed at sites relying on existing SVCT facilities. These sites will work closely with the SVCT venues to determine what is feasible and the site will provide training and recommendations as needed. The type of QC and supervision provided at existing SVCT venues will be carefully documented.

3.5 External Evaluation by Intervention Core

3.5.1 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, counseling techniques, 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.

3.5.2. 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.

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

4.1 VCT Hours Worksheet (Completed by Team Leader)

**Team Leader Responsibilities**
Fill out the VCT Hours Log Worksheet each day.
Turn VCT Hours Worksheet in to the Coordinator weekly.

**Filling out the form:**
**Header:** Write in the date and location/venue

**Line A:** Time Service Set Up Began. This is the time of day that the mobile service begins set up today. Depending on site, this will either be the time that the caravan set up began or the time that the staff began their set up at the local venue.
**Line B:** Time Service Set Up Completed. This is the time of day that the set up is finished and the team is ready to begin greeting participants. Even if no participants show up until long after you’ve completed set up, record the time your team was ready, not the time that the first participant arrived.

**Line C:** Personnel. Record the number of staff members with the team today.

**Line D:** Time Break Down Began. This is the time of day that the team began to put away materials and disassemble the caravan. This is not the time that the last participant showed up, but rather the time that your mobile service was “closed for business” so that breakdown of the mobile site could begin.

**Line E:** Time Break Down Completed.

**Line F:** Total number of hours/minutes that mobile unit was completely set up and operational (this should be the elapsed time between item B and item D). This is the number of hours/minutes that the mobile service was “open” to receive participants. Please be sure to not record amount of time that participants were seen, but rather the amount of time that the service was available.

**Line G:** Notes. Please note any conditions such as weather or situations that may have affected the mobile unit or participant turn out.

### 4.2 VCT Hours Log (Coordinator)

#### Coordinator Responsibilities

Fill out the VCT Hours Log each week and turn in completed form to Project Director after 4 weeks. The form has space to record 4 week’s worth of information.

Use the VCT Hours Log Worksheets to compute the number of hours/minutes that VCT was available at each venue during the past week. This is determined by adding up all of the Line F entries collected for a particular week. Using the dose log, write in the name of each community/venue followed by the number of hours/minutes the mobile unit was operational at that venue in the past week. This is the total of all Line F (worksheet) entries for each venue. Double check that the elapsed time computed to determine Line F is correct, and make corrections as necessary. At the end of 4 weeks, add up the hours/minutes across each community, and write in the total monthly hours/minutes available in the Monthly Total box.

### 5.0 Contact Information

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