Community Mobilization
Quality Assurance and Quality Control Guidelines
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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. 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 Community Mobilization 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 CM SOP and trainer’s manuals that detail implementation procedures for recruiting and training CBOVs, planning strategies for CM activities, facilitating support meetings, and documenting CM activities.
2.1.2 Manuals.
The CM 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 and CBOV uses and refers to these manuals for delivery of community mobilization outreach activities.

2.2 Training.
- 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 CM site staff are trained by the Coordinators using the materials and skills from the TOT.
- All CBOV’s received a 4 day structured training using materials and skills from the TOT.

2.2.1 Qualifications.
CM Coordinators have at least a Masters degree in the field of social sciences as well as supervision experience and training. CM staff have a minimum qualification of a high-school diploma and will receive the Project Accept CM Training. CBOVs are volunteers identified through the VCT component as early adopters or are identified through the Community Preparedness Phase.

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). At a later date, all staff received training in “Good Clinical Practice” (GCP), provided by HPTN.

Outreach staff 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 that the Coordinator evaluates using the tools described below for ongoing QC procedures.

CBOVs will enter the field after completion of the 4 day CBOV training.

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 CM staff will be trained by the project coordinator or a designated trainer. Trainee candidates will be selected based on qualifications and relevant experience.
2.2.4 New CBOV’s.
The recruitment of new CBOV’s will be ongoing throughout the trial, as potential candidates are identified by the study staff. CBOV’s may leave the project at any point in time they no longer wish to participate.

2.3 Staff Member Quality Assurance Activities

2.3.1 Session Review.
Outreach staff are expected to review protocols and any relevant information in advance of work each day. CBOV’s should refer back to training materials as needed.

3.0 Quality Control Procedures for CM

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) daily supervision of all staff at each site by the CM Coordinator and the Project Director who has been trained on the protocol, (2) weekly staff meetings at the site level (3) independent review and rating of structured outreach by the CM Coordinator, (4) regular feedback to individuals by the 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.
Coordinators, who are responsible for all Quality Control evaluations of their teams will be supervised and monitored by the Project Director.

3.2 Evaluation of CM Activities.
Community Mobilization: Staff and CBOV Evaluation

The CM Coordinator is trained to use the evaluation instruments, are responsible for QC of the entire CM component, including CBOV activity, at their site. CM is manifested through either formal outreach (at specific venues during scheduled times), and informal outreach (casual talks with friends and other members one’s social network). CM staff is responsible for supporting the CBOVs and conducting more formal outreach. CBOVs can choose the form of their outreach - either informal or formal. The Coordinator will observe both CM staff outreach at the mobile sites and formal outreach sessions held by CBOVs in the community, and evaluate performance using the appropriate evaluation form:

- Community Mobilization Staff Evaluation
- Community Mobilization: CBOV Evaluation
By nature of informal CBOV outreach, we will not be able to directly observe and evaluate delivery. Instead, emerging issues will be discussed at monthly support sessions meeting meetings and documented using the

- Community Mobilization: CBOV Outreach - Support Meetings
- Community Mobilization: Hours Log

The initial work of the CM staff in identifying the social networks and opinion leaders of the intervention communities will be documented using the

- Community Mobilization: Identifying Social Networks and Opinion Leaders
- CBOV Outreach – Support Session

Because the CM component is a very dynamic one and needs to be very responsive to on-the-ground realities as they take shape over the course of the intervention in the various sites, the QC is designed with 2 goals in mind. The first goal, is to assess the ongoing process of identifying social networks, performance and progress CBOV unstructured outreach, and setting goals for next steps in outreach. These evaluation forms will show us how this dynamic is working and ensure that mobilization activities stay focused to the task at hand and ensure that misinformation about the project or HIV/AIDS is corrected. The process of community mobilization lends itself more readily to qualitative rather than quantitative assessments. The form Outreach Support Sessions and the form Identifying Social Networks and Opinion Leaders use open-ended questions prompting respondents for short answer narrative answers. The CM Hours Log is used to document the number of hours that CM staff provide support to the CBOVs. The support can take a variety of forms and can include helping CBOVs tailor messages to members of their social network, or how to respond to difficult or challenging questions or situations.

3.2.1. Rating Criteria
The Staff Evaluation Form and CBOV Evaluation form are used to ensure that the manualized facilitation skills are adhered to by using standardized evaluation criteria. The criteria are based on two broad categories of qualities: (1) general facilitation skills consonant with the facilitation style recommended for use with the outreach (including such factors as empathy, non-judgmental, maintaining appropriate boundaries, maintaining session cohesion, etc.) and (2) skill in providing referrals. 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. 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, 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 site staff using the curriculum they learned at the TOT.

3.2.3 Sampling Strategy.

_Community Mobilization Staff Evaluation Community Mobilization: CBOV Evaluation_

Month 1: 15% of formal outreach sessions delivered in the first month conducted by both CM staff and CBOVs. Each CM staff will be evaluated a minimum 2 times.

Month 2-5: 10% of formal outreach sessions delivered per month conducted by both CM staff and CBOVs. Each CM staff will be evaluated a minimum of 2 times per month.

Ongoing: 5% of formal outreach sessions delivered per month conducted by both CM staff and CBOVs. Each CM staff will be evaluated a minimum of 1 time per month.
3.2.4 Filling out Forms.

Community Mobilization: CM Hours Log

**Ongoing**: The CM Coordinator uses this log to record the number of hours/minutes that CM staff outreach, CM staff support of CBOV’s, and CBOV outreach are provided. The coordinator is encouraged to develop a plan or method that best suits the conditions at their site to collect and keep track of this information on a daily basis. From this method as well as information gathered in the group sessions, the coordinator will fill out the CM Hours Log each week. The hours log is designed to capture 4 weeks of information.

Instructions: Write in the name of each intervention community on the “Community Name” line. Each week write in the total number of hours that CM staff outreach, CM staff support of CBOVs, and CBOV outreach was provided. After 4 weeks have passed, add the number of hours in each row and write the total in the “Monthly Total” column. Complete one table for each intervention Community and make additional copies of this page as necessary. Use a new form for each community every 4 weeks. Turn in completed forms to the Project Director for inclusion in the monthly QC report to the Intervention Core.

Community Mobilization: CBOV Outreach- Support Session

**Ongoing**: Coordinator Completes form each month following CBOV Support Sessions. These are open-ended questions regarding issues such as typical outreach activities, frequent topics, how messages were tailored, challenges and resolutions, as well as an estimate of time spent by CBOV’s in outreach/mobilization activities.

Community Mobilization: Identifying Social Networks and Opinion Leaders

**Ongoing**: Completed each month at CM staff meeting by all CM staff and CM Coordinator.

Identifying Social Networks and Opinion Leaders form will be filled out by the CM Coordinator at the completion of each monthly meeting with CM staff. The rater will answer questions describing how and why social networks and opinion leaders were selected to be involved with Project Accept. Each time the form is filled out, it should include new information gathered since the last meeting (i.e., newly identified social networks and opinion leaders; or new information on previously identified social networks and opinion leaders). If there is no new information gathered since the last meeting for a particular question, write, “No change since report dated _______,” and fill in with the date from the last form containing new information. This form is turned in to the Project Director for inclusion in QC reports.

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 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 showing an overall rating of 3 (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. 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 site staff. 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
- Identifying Social Networks and Opinion Leaders
- CBOV Outreach Support Sessions
- 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 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, 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 CM time is roughly standardized across sites.

CM staff dose will be measured by the amount of time that CM staff conduct formal outreach – as documented on the Community Outreach Log utilization form. Additionally, the weekly hours of CM support to CBOV will be documented on CM Hours Log.

As previously noted, accurately measuring the amount of outreach that CBOVs conduct is challenging. After completing the monthly support sessions with CBOVs, CM staff will estimate as best they can the average number of weekly CM hours that each CBOV conducted.

The intervention core will distribute dose calculations and expectations for each site.

_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.
### CM: Quality Control Procedures Flowchart

<table>
<thead>
<tr>
<th>Staff Member</th>
<th>Responsibility</th>
<th>Form</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Staff outreach worker</strong></td>
<td>Deliver CM</td>
<td>CM CBOV Outreach-Support Meeting</td>
<td>Following monthly Support Sessions with CBOV</td>
</tr>
<tr>
<td></td>
<td>Perform formal outreach</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Support CBOVs</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>CM Identifying Social Networks &amp; Opinion Leaders</td>
<td>Monthly CM Staff Meetings</td>
</tr>
</tbody>
</table>
| **Coordinator**       | Asses staff performance and complete QC evaluation | CM Evaluation CBOV Evaluation | Month 1: 15 %
|                       |                |                                           | Months 2-6: 10%
|                       |                |                                           | Month 7+: 5%                                  |
|                       |                | CM Support Hours Log                      | Weekly                                        |
|                       |                | CM CBOV Outreach-Support Meeting          | Following monthly Support Sessions with CBOV |
|                       |                | CM Identifying Social Networks & Opinion Leaders | Following monthly CM Staff Meetings           |
