INTERVENTION MANUAL

AIDSCAP/GPA/WHO Voluntary Counseling and Testing Efficacy Study

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Intervention

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1. Health Information and Condoms Intervention (HIC)

1.A. Rationale and Overview

1.A.1. Overview of HIC Intervention
The HIC intervention is a one session group intervention designed to provide accurate information regarding the definition of HIV/AIDS, how HIV is transmitted and how transmission can be prevented. The HIC intervention is led by the health information officer who oversees the showing of the videotape and leads a question and answer session. The HIC intervention is not to be facilitated by an interviewer or by a counselor.

The HIC intervention is intended to be presented on videotape; in the event of a power outage or equipment failure the health information officer may read the script and conduct a condom demonstration using a penis model. The information is standardized to ensure that all participants receive the same information and view the same condom demonstration. Following the presentation of the intervention material, the health information officer leads a brief question and answer session. All participants leave the session with a supply of condoms and a leaflet containing condom instructions. The health information officer may also provide referrals to participants as needed.

1.A.2. Expected outcomes of HIC intervention
The HIC intervention is intended to increase accurate knowledge of the definition of HIV and AIDS, to provide information regarding the prevention of HIV infection, to demonstrate correct condom use and to distribute condoms. Having accurate knowledge about HIV and access to condoms is expected to facilitate behavior change toward safer sexual behaviors.

1.B. HIC Video

1.B.1. Description of HIC video
The HIC intervention video is 15 minutes long and includes basic information regarding the transmission of HIV and how transmission can be prevented. The video also includes an explicit condom demonstration. The voice over for the video is in the local language.

The script of the HIC video is included in this manual.
1.B.2. Discussion after HIC video
Following the HIC intervention video, the presenter offers a brief question and answer period. This question and answer period should not last more than 15-20 minutes. It is important that the health information officer not provide individual counseling to participants; the health information officer is not trained to provide individualized risk assessment or to assist participants in developing an individualized risk reduction plan. Individuals requesting these services may be referred to community resources.

The presenter begins the question and answer period by asking if there are any questions about the videotape (or oral) presentation. If audience members do not ask questions, the presenter may facilitate discussion by asking if there are any questions about specific sections of the information (e.g. Are there any questions about how the virus can be passed from one person to another? Are there any questions about how to use condoms?).

1.C. Condom Distribution
Following the question and answer period, condoms are distributed to all participants. Each participant receives a supply of 25 condoms and a leaflet including written and pictorial instructions for correct condom use (as shown in the video). All participants are asked to take condoms, even those who state that they will not use them or do not need to use them. Participants are welcome to return to the center for additional condoms as needed.

2. Counseling and Testing Intervention (CT)

2.A. Rationale and Overview

2.A.1. The Client-Centered Counseling Approach
The client-centered HIV counseling approach decreases the emphasis on education, persuasion and test results in favor of personalized risk assessment and the development of a personalized risk reduction plan for each client. The emphasis in client-centered counseling is on developing a risk reduction plan for each client that takes into account his/her emotional reactions, interpersonal situation, specific risk behaviors and readiness to change. The content of the counseling sessions and the amount of counseling the participant receives is determined by his or her level of knowledge and specific, personal concerns about HIV/AIDS.

The client-centered approach to HIV counseling has been adapted for this research study. In usual practice, the client and counselor weigh whether taking the HIV antibody test at this time is
consistent with the client’s personal risk reduction goals. In this research study, however, all participants have indicated their willingness to be tested by consenting to join the study. While time is allotted to discuss the implications of receiving test results, and participants are free to leave the study at any time, the decision of whether or not the participant will be tested now is determined by random assignment to treatment condition (HIC or CT).

2.A.2. Overview of CT intervention
The counseling and testing intervention includes at least one, and as many as three, pre-test counseling sessions and at least one post-test counseling session (two post-test counseling sessions are preferred). It is anticipated that counseling sessions will last 30 minutes each. Pre- and post-test counseling is separated by the length of time required to generate test results (at least 2 weeks).

The first meeting will begin by confirming that informed consent has been obtained and assuring the participant that his/her confidentiality will be protected. The counselor will review any HIV knowledge the participant is unsure of and correct any misperceptions about the transmission of HIV. The counselor will then engage the participant in an assessment of his or her own HIV-related risk behavior and negotiating a personalized risk reduction plan. This is followed by preparation for testing (pre-test counseling), notification of test results (post-test counseling) and follow-up counseling sessions and referrals as needed.

2.A.3. Expected outcomes of CT intervention
The goal of the counseling intervention is to increase accurate HIV knowledge and accurate assessment of risk in order to promote behavior change that reduces the likelihood of becoming infected with HIV. The expected outcomes of the counseling intervention are: increased knowledge about HIV transmission, increased readiness to change, increased behavioral skill to prevent HIV infection and increased self-efficacy to perform the behaviors that will prevent HIV transmission. There may also be negative effects of HIV counseling and testing as a result the stigma of receiving HIV services and/or, for those who test positive, the trauma of receiving a positive test result. Consequently counselors are trained in emotional coping interventions and referral as well as in risk-reduction counseling.
2.B. Content of Counseling and Testing intervention

2.B.1. Personalized risk assessment
Client-centered HIV counseling is distinguished by the development of a personalized risk reduction plan for each client. In order to create this plan, the participant’s individual risk situation must be assessed. This risk assessment includes gathering information about the participant’s sexual and other risk behavior as well as their interpersonal, social and resource situation. The counselor may initiate the assessment by reviewing the ways in which HIV can be transmitted and asking the participant to discuss possible exposures. Readiness to change risk behavior and perceived self-efficacy to change risk behavior are also assessed. The counselor summarizes the clients risk assessment findings by stating (and listing, if appropriate), for each risk behavior identified, the participant's resources and barriers to change. [For example, 'You identified having unprotected sex with women other than your wife as an HIV risk for you; you wonder if some of these women are infected with HIV. You have used condoms before, but you aren't sure you can remember to use one or have one handy if you have been drinking'].

2.B.2. Personalized risk reduction plan
After the participant’s risk behaviors have been identified, the counselor asks the participant if she/he would like to propose any strategies to reduce their risk. At this point the counselor may initiate the discussion of risk reduction by listing several alternative risk reduction behaviors for the participant to consider. [For example, 'To reduce the risk that you will contract HIV from having sex with women other than your wife, you could avoid having intercourse with them or you could use a condom when you do. You could also protect your wife by using condoms when you have sex with her'].

For each risk reduction behavior the counselor assesses internal and external barriers to change, perceived efficacy to enact the new behavior, readiness to change and the availability of resources to change. In supporting the participant’s enactment of the personalized risk reduction plan, the counselor will acknowledge and support the participant's strengths (e.g. social support, efficacy, previous success in changing behavior) and offer problem solving in areas of concern or expected difficulty in enacting the plan.

Finally, the counselor elicits a commitment from the participant to make specific behavior changes before the next counseling session. When appropriate, the risk reduction plan can be written and given to the participant to cue and reinforce behavior change. [For example, 'You said that you would be willing to use condoms every time you have sex with women other than
your wife. You have used condoms sometimes before, and that’s great-but, now you want to use them every time. You mentioned that your friends have started using condoms with other women, too. Would you be willing to carry condoms with you for the next two weeks? Let’s see if that helps you to remember to use them, even when you’ve been drinking].

2.B.3. Preparation for testing
The counselor engages the participant in pre-test counseling by soliciting her/his knowledge about the antibody test and any previous testing experiences, providing information about the test as needed and correcting any misconceptions about testing and/or test results. The meaning of a negative test result and a positive test result is explicitly stated, and participants are asked to discuss a plan of action in the case of a negative test result or in the case of a positive test result. When scheduling the post-test counseling appointment, the counselor will negotiate a specific plan for the participant to return for test results and solicit a personal commitment to return. Pre-test counseling is intended to be completed in the first counseling session. One or two additional pre-test counseling sessions may be provided if the participant is unsure or has additional questions about antibody testing.

2.B.4. Giving test results
At least two post-test counseling sessions are preferred (although those who attend a single post-test session will be included in the study). The first post-test counseling session begins with the disclosure of test results. Counselors disclose test results in a direct, neutral tone of voice and wait for the participant’s reaction before proceeding. While the progression of this counseling session depends on the participant’s emotional reaction to the test result, the counselor will assist the participant to understand the meaning of the test results, cope with the emotional impact of the test result and modify the risk reduction plan as needed.

In the post-test counseling sessions, for participants who are HIV positive, the counselor will assist in making a plan to inform partners and will provide appropriate referrals for medical and social services. Implications of the positive result for that participant will be discussed; the individualized risk reduction plan will be reviewed with the goal of preventing re-infection and protecting partners. For participants who are HIV negative, the implications of the negative test result will be discussed and the individualized risk reduction plan will be reviewed with the goal of preventing HIV infection.
All participants are offered a second post-test counseling session. Additional sessions with the counselor may be offered for additional emotional support, further support of the risk reduction plan or to assist in overcoming practical, emotional and interpersonal barriers to changing behavior. All participants will be informed of additional counseling services available at that Counseling Center and/or referred to community resources if they are in need of services that are not available at the Counseling Center.

2.B.5. Number of sessions
Participants assigned to the Counseling and Testing Intervention are expected to attend at least one pre-test counseling session, receive their test result, and have at least one (preferably two) post-test counseling sessions. Some individuals will require additional counseling sessions. Although participants assigned to Counseling and Testing are eligible to return for as many sessions as needed, counselors should be aware that it is not the intention of the study to provide ongoing counseling or psychotherapy.

2.B.6. Counseling couples
Some percentage of subjects will be recruited into the study as couples; those who enter the study as a couple may be counseled together. First, the counselor assures that each individual has given their consent for counseling and testing, and that each individual is aware that they are expected to disclose their test results to their partner. Pre-test counseling may be conducted either together or individually, although some individual time with the counselor is usually necessary for accurate risk assessment. Test results are given individually first, then the members of the couples are facilitated by the counselor to share their test results with each other at the counseling center. After the disclosure of test results, post-test counseling may proceed with both partners present. Individuals who are reluctant to disclose their test result to their partner will be counseled and encouraged to disclose with the assistance of the counselor. Counselors must be aware, however, that they may not disclose an individual’s test result without his/her permission.

2.B.7. Tracking the counseling intervention
Each participant’s utilization of counseling services at the Counseling Center is recorded on the Counseling Contact Form. After each of the participant’s visits to the Counseling Center, the counselor completes the Counseling Contact Form and gives the form to the administrator for filing. A Counseling Contact Form is completed for each individual and for each counseling session.
2.A.8. Protecting participants’ confidentiality

It is extremely important that participants’ privacy (confidentiality) be protected. Participants’ serostatus is to be considered the most confidential of information and must be protected at all times. Counseling must be conducted in private where the conversation between the participant and counselor cannot be overheard. All record forms, even those identified only with a participant number, must be kept in locked file drawers at all times when they are not in use. Discussions between counselors and counselor supervisors, including case discussions in supervision, will protect the privacy of participants by not referring to the participant by name. Participant confidentiality will also be protected in conversations between counselors and other project staff. Breeches in participant confidentiality may be grounds for dismissal of counselors and other staff.

2.C. Counselor Selection and Training

2.C.1. Selection of Counselors
Individuals who have proven their ability to establish rapport, demonstrate good listening skills and to be supportive, respectful and non-judgmental will be chosen as counselors for this study. These individuals should also have demonstrated proficiency in basic counseling skills (active listening, reflection and information gathering), and the basic facts of HIV transmission, antibody testing and human sexuality. Peer or lay counselors are not appropriate for this study because of the extreme importance of confidentiality and because of the level of counseling skill required to conduct the intervention.

2.C.2. Training Procedures for Counselors
After counselors are selected, they will receive a 5-day training program outlined in the Counselor Training Manual. Counselors must complete the entire training program. After completion of the counselor training, the counselor supervisor will observe the counselor completing each step of the intervention with a volunteer ‘participant’ before certifying the counselor to conduct the intervention for the study.
3. Quality Assurance/Supervision

3.A. Quality Assurance for HIC intervention

3.A.1. Periodic evaluation by Coordinating Center (objective evaluation)
The quality and consistency of the HIC intervention will be assessed periodically by a visiting evaluator from the Coordinating Center. The evaluator will observe a selection of HIC intervention sessions and rate the health information officer’s performance using the HIC Session Evaluation Form. Periodically HIC intervention sessions will also be videotaped for evaluation; participants will not appear on these videotapes.

3.A.2. Exit interviews (subjective evaluation)
Participants’ perceptions of the quality and effectiveness of the HIC intervention will also be assessed by surveying participants leaving selected sessions. Participants leaving selected HIC intervention sessions will be interviewed briefly using the HIC Exit Interview Form.

3.A.3. Supervision of Health Information Officer
The health information officer who presents the HIC intervention must not also serve as a counselor or interviewer for this study. The HIC presenter will be supervised by the counselor supervisor in individual weekly meetings and will receive training updates as needed.

3.B. Quality Assurance for the CT intervention

3.B.1. Periodic evaluation by Coordinating Center (objective evaluation)
Each counselor will be periodically reviewed by a visiting evaluator from the Coordinating Center to ensure that the counseling intervention is consistent and complete. Counseling Contact Forms will also be reviewed. The evaluator will observe counseling sessions (with the permission of all participants) and evaluate counselor skills with the Counseling Session Evaluation Form. Periodically counseling sessions will be audiotaped (with the permission of all participants), and these tapes will be reviewed to evaluate the counselor's performance in delivering the intervention. Any tapes recorded for this purpose will be promptly erased or destroyed to protect participants' confidentiality.
3.B.2. Evaluation of counseling experience (subjective evaluation)

Qualitative evaluations of the experience of participants in the CT intervention will be conducted periodically to ensure satisfaction with the counseling services.

3.B.3. Supervision of Counselors

After they are certified as having passed the counselor training program, counselors will continue to receive supervision and periodic training workshops to maintain their knowledge and skills. Counselors will attend weekly individual supervision and weekly group supervision. Counselors will be paid for their time attending supervision if that time falls outside the counselor’s regular shift. Participants’ confidentiality will be respected in all discussions among counseling staff and supervisors by not referring to participants by name, and not discussing details of participants’ lives unless it is directly relevant to the supervision of the counselor’s work performance.

3.B.4. Periodic training updates for counselors

In addition to their weekly individual and group supervision, counselors will attend a monthly inservice presentation on an aspect of HIV counseling selected by the counselor supervisor. These topics may include counseling techniques or updated information on HIV transmission and prevention. These sessions may include training presented by the counselor supervisor or by speakers/facilitators from outside the Counseling Center. Attendance to monthly inservice presentations is required, and counselors will be paid for their time attending these meetings if the inservice is scheduled at a time when the counselor is not on duty.
4. Script of HIC Video

[Counselor enters the interview room with a man and a woman. They sit down to talk]

Counselor (CO): Welcome, I’m glad you’ve come here to learn more about HIV, the virus that causes AIDS.

Male client (MCL): Thank you. I hear a lot about AIDS, and I am not sure what is true and what is not true. I wonder if we are at risk for AIDS, and wonder if there is anything that we can do to prevent infection and getting the disease.

CO: Let’s start with the facts. AIDS is caused by a virus called HIV. HIV stands for the Human Immunodeficiency Virus. The virus is passed from an infected person by the exchange of blood, semen or vaginal secretions. The virus cannot be passed from an infected person by casual contact.

Female client (FCL): What do you mean, casual contact?

CO: The virus cannot be passed from person to person by kissing, hugging, eating together, sharing eating utensils or sharing bed linens. The virus is also not passed from person to person by insects. It is entirely safe to work and live with someone who has the virus.

FCL: That is a relief to know. So how is the virus passed from person to person?

CO: As I said, the virus can only be passed by sharing blood, semen or vaginal secretions. So, the virus can be spread by sharing instruments used to cut (razors, needles and knives) or receiving a blood transfusion from a person who is infected. It can be passed from an infected mother to her unborn baby in the womb, during birth or through breast feeding. HIV can also be spread by sexual intercourse; this is the most common way to spread the virus.

MCL: So the biggest risk is having sexual intercourse with an infected person?

CO: That’s right. But there are ways to protect yourself from infection. And by protecting yourself, you protect your partners and your children. Some people choose to protect themselves by using condoms when they have sexual intercourse. Others chose to avoid having sexual intercourse, finding other ways to have sexual pleasure together (add appropriate examples here). Another way to protect yourself is by having sexual intercourse only with partners who are not infected. The problem with this strategy is that it is difficult to know who is infected. HIV is an unusual virus; it is possible to have the virus and not feel or look sick but be able to pass the virus to other people.
MCL: People who do not look sick can have the virus and pass it to other people?

CO: That’s right. You can’t tell by looking at someone if they have the AIDS virus. Over time, people who are infected with HIV slowly lose their ability to fight off infections. A person who is infected with the virus is said to have AIDS when their body can no longer fight off infections and they become ill. But a person does not have to be ill to pass the virus to others; it is possible to contract the virus by having unprotected sexual intercourse with a person who has the virus and is not yet ill.

FCL: I have heard about using condoms to protect against the virus that causes AIDS. How are condoms used?

[Condom demonstration shown during following voice-over may be drawings or person putting condom on model depending on what is most appropriate to cultural context]

Keep condoms handy so you can find them easily when you want to have sex. Get in the habit of carrying a condom with you when you go out so that you will have one to use if you have sex away from home.

Store them in a cool, dry place away from heat or sunlight. Exposure to heat and sunlight weakens condoms and may cause them to break.

Do not use oil based lubricants with condoms. Exposure to oil (like cooking oil or petroleum jelly) weakens condoms and causes them to break. Use lubricated latex condoms or use only water-based lubricants with condoms.

Use condoms before the expiration date on the package (show condom package with expiration date circled). Do not use condoms if the package is open, dry or cracked.

When you are ready to use a condom, open the package carefully. Use a new condom each time you have sexual intercourse. The condom must be worn for the entire time of sexual intercourse.

To put the condom on, unroll the condom so it covers the entire erect penis. If the man is not circumcised, the foreskin should be pulled back before covering the penis with the condom.

With thumb and forefinger, gently press any air out of the tip of the condom.

After ejaculation, hold onto the base of the condom to avoid spilling as the penis is pulled out (withdrawn).

Throw the used condom away; do not reuse condoms. Used condoms may be tied to avoid spilling, then burned or buried with other household garbage.
CO: I encourage you to talk together about using condoms to protect yourselves from HIV. It can be uncomfortable to start talking about condoms; I hope the information you received today will help you to talk together about ways to reduce your risk for HIV.

MCL: Thank you, I feel reassured knowing how the virus can be passed from one person to another, and knowing that there are things we can do to prevent being infected with HIV. We will talk about condoms as a way of protecting ourselves against HIV.

FCL: Yes, this information is very useful and will help us to talk about using condoms.

CO: Please take these condoms with you [hands condoms to male client and to female client. They put the condoms in their pockets/purse]. If you have any more questions, I hope that I can help you.

CO: [Turns to viewer] I hope that this information will be useful to you also. At the end of this tape, you will have the opportunity to ask questions about what you have seen and you will receive a supply of condoms to take with you.