Quality Assurance of HIV Prevention Counseling in a Multi-Center Randomized Controlled Trial

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SYNOPSIS

CURRENT HIV PREVENTION counseling strategies rely largely on interventions aimed at changing behaviors. Among these is HIV prevention counseling and testing, which has been a prominent component in the federally supported strategies for HIV/AIDS prevention in the United States. To assess the efficacy of HIV counseling in reducing risk behaviors and preventing HIV infection and other sexually transmitted diseases, a multicenter, randomized controlled trial is being conducted among sexually transmitted disease clinic patients (Project RESPECT). The trial compares three separate HIV prevention strategies on increasing condom use and decreasing new cases of sexually transmitted diseases. The strategies are (a) Enhanced HIV Prevention Counseling, a 4-session individual counseling intervention based on behavioral and social science theory; (b) HIV Prevention Counseling, a 2-session individual pre- and post test counseling strategy that attempts to increase perception of risk and reduce risk behaviors using small, achievable steps; and (c) HIV Education, a brief 2-session pre- and post-test strategy that is purely informational.

One difficulty in conducting randomized trials of behavioral interventions is assuring that the interventions are being conducted both as conceptualized and in a consistent manner by different counselors and, for multicenter studies, at different study sites. This article describes the quality assurance measures that have been used for Project RESPECT. These have included development of standard tools, standard training, frequent observation and feedback to study personnel, and process evaluation.

Along with HIV testing, HIV counseling has been a cornerstone of the federally supported strategies for preventing HIV infection and AIDS in the United States. Following the licensure of the human immunodeficiency virus (HIV) antibody test in 1985, HIV counseling was initially directed toward providing information about the test itself. By 1987, HIV counseling had shifted its focus to emphasize prevention, using a strategy that included voluntary notification and counseling and testing of partners, referral for medical treatment or psychosocial support, and informing clients about HIV transmission and how HIV infection could be avoided *(1)*. A list of high-risk behaviors was frequently used

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to help people recognize situations that might put them at risk for acquiring HIV. Using this strategy, HIV counseling sessions were observed to be more instructive; however, they also followed no standard format, tended to inundate clients with technical information about HIV and acquired immunodeficiency syndrome (AIDS), and used global HIV prevention messages not tailored to the client's unique circumstances *(2)*. Since 1987, a number of concerns about this information dissemination model have led to further changes in HIV counseling strategies. Many researchers and counselors challenged the belief that simply informing a client about high-risk behaviors is true counseling *(3)*. Furthermore, social scientists argued that providing people with information about a disease or informing them that they are at risk is not enough to change their behavior *(1, 4, 5)*.

Because of the ambiguity about what exactly constitutes "HIV counseling" and the varying ways in which HIV counseling is conducted, evaluating its impact on changing high-risk behavior has been controversial and challenging. The published literature suggests that HIV counseling, particularly for seronegative individuals, has not led to substantial behavioral change *(1, 6)*. However, this finding can be attributed in large part to methodologic limitations of the studies. Few studies have collected data with the explicit goal of evaluating the effect of HIV counseling on risk behavior. Few have randomly assigned participants to intervention groups or, in fact, employed any comparison group. Perhaps most surprising, few have described the counseling interventions that were used. The content of the counseling sessions, the duration of the sessions, the training for the counselors, and the quality assurance of the counseling sessions were rarely addressed *(6)*. Therefore, it is neither possible to know if clients were indeed "counseled," nor to reach any definitive conclusions about the effect of HIV counseling on risk behavior.

To evaluate the efficacy of individual HIV prevention counseling, investigators from the Centers for Disease Control and Prevention (CDC) and five U.S. cities are conducting a randomized controlled trial, Project RESPECT, in sexually transmitted disease (STD) clinics. In this study, we have defined "efficacy" as the effect of a prevention strategy in expert hands (trained, observed study personnel) under ideal study circumstances that may not be able to be replicated completely in the day-to-day STD clinic routine. "Counseling" for HIV prevention is defined as a process that engages the client in an interactive self-exploration of his or her behaviors in the context in which those behaviors take place *(3, 7)*, during which the counselor gives professional guidance, most often by helping the client arrive at a policy, plan of action, or behavior.

Description of Project RESPECT

The purpose of Project RESPECT is to determine the efficacy of different models of HIV prevention counseling in increasing condom use and preventing new cases of HIV and sexually transmitted diseases (STDs) among high-risk individuals *(8)*. The study subjects are HIV-negative, heterosexual STD clinic patients 15 years of age or older who give their informed consent to participate in the trial. Participants are randomly assigned to receive one of three individual HIV prevention interventions. This trial compares the efficacy of three interventions that accompany HIV testing:

1. HIV Education, an educational intervention
2. HIV Prevention Counseling, a client-centered counseling intervention that includes both an interactive exploration of behavior and the formulation of a behavioral risk-reduction strategy.
3. Enhanced HIV Prevention Counseling, an intervention that begins with the same client-centered HIV pretest session as HIV prevention counseling, but includes three 1-hour sessions based on behavioral and social science theory.

Following current practice, all three interventions contain at least two interactions, one before the HIV test and one when the participant returns for his or her test results.

Interventions. *HIV Education* consists of two 5-minute educational sessions about HIV and AIDS. The first educational message is given by the clinician (medical practitioner) who examines and treats the study participant for STDs during the initial clinic visit. The second message is given when the participant returns for the HIV test results, from 7 to 10 days later, either by a clinician or an HIV counselor (someone who has undergone standardized training to give HIV test results and to conduct counseling interventions). During the second session the participant is given the test results and is informed about the limitations of the test. HIV transmission risks are reiterated, and specific behaviors or circumstances that place the participant at risk for acquiring HIV or other STDs are identified.

HIV Prevention Counseling is based on a recently revised (1993) CDC model that has been recommended for HIV counseling in U.S. STD clinics *(10)*. The intervention consists of two 20-minute interactive counseling sessions with an HIV counselor. The first session takes place during the initial clinic visit, and the second session takes place 7-10 days later when the client returns for HIV test results. The intervention has three primary objectives: (a) assessment of the participant's risk and self-perception of risk; (b) identification of barriers to risk reduction; and (c) negotiation of a risk-reduction plan with the participant.

Table 1. Session structure of Project RESPECT HIV prevention counseling

Activity	Method	Time (Minutes)	Materials
Introduction/establish rapport	Discussion	1	Protocol
Risk assessment	Discussion/Questions	2	Protocol
Enhancement of self perception of risk	Discussion/Questions	3	Protocol
Identification of participant action	Discussion/Questions	2	Protocol
Identification of participant barriers	Discussion/Questions	2	Protocol
Negotiation or risk-reduction plan (condom)	Discussion/Questions	4	Documentation of plan
Appointment for post-test counseling	Discussion	1	Business/appointment cards
Total time required		15	

Enhanced HIV Prevention Counseling. Because it may be unrealistic to expect measurable behavior change following such a brief intervention, in the "enhanced" counseling, we added a more extended counseling intervention, grounded in behavioral prediction and change theories *(9)*. This intervention consists of four interactive counseling sessions with an HIV counselor. The first session takes place during the initial clinic visit and is identical to the first session of HIV Prevention Counseling. The remaining sessions take place over the next 3 weeks and last approximately 60 minutes each. The sessions in this intervention are designed to change key theoretical variables, such as skills in using latex condoms, attitudes toward condom use, self-efficacy for condom use, and perceived norms concerning condom use. Each succeeding session builds on previous sessions. More specifically, the three enhanced sessions may be described as follows:

1. Attitude Change. This session begins with a discussion on how well the participant was able to carry out his or her behavioral goal. If successful, the participant's actions are reinforced. If unsuccessful, the barriers to achieving the goal are discussed. However, the main focus of this session is on changing attitudes about condom use. The participant is encouraged to explore beliefs underlying condom use (for example, the perceived advantages and disadvantages of consistently using condoms). This discussion is followed by a condom skills-building training exercise. The session ends with the participant arriving at a strategy for taking a step toward behavior change before the next session.

2. Self-Efficacy. This session begins with a discussion of the HIV test results. The participant is then asked about the behavioral goal agreed upon in the previous session. However, the main focus of this session is on increasing self-efficacy (that is, one's belief that one can consistently use [or get one's partner to use] a condom under a variety of circumstances). The participant is encouraged to consider barriers to, and facilitators of, condom use under a variety of circumstances and to consider ways to overcome the barriers. This discussion is followed by a communications skills training exercise. Once again, the session ends with the participant arriving at a strategy for taking another step toward consistent condom use before the next session.

3. Perceived Norms. This session begins with a discussion about how well the participant was able to carry out the behavioral goal set in the previous session. However, the main focus of this session is on exploring community norms and social support for consistent condom use. The session ends with the participant arriving at a long-term strategy for reaching the goal of consistent condom use.

Study Phases. Project RESPECT was conducted in two phases. During an 18-month study preparation phase, personnel at the five participating clinics helped develop and pilot the counseling interventions that would be used in the evaluation phase, a randomized clinical trial that is currently underway. For the trial, study personnel at each STD clinic site approach eligible clinic patients systematically and enroll those who are interested in the trial. Individuals who agree to participate are randomly assigned to receive one of the three HIV prevention interventions. As of December 1995, more than 5,500 STD clinic patients have enrolled, with a target enrollment of 3,000 men and 3,000 women.

Quality Assurance of Counseling Interventions

Multi-center randomized trials require quality assurance in a number of areas. This paper focuses only on the quality assurance methods that have been employed in Project RESPECT to ensure that the three behavioral interventions are properly and consistently conducted.

Elements of quality assurance. In drug treatment trials, the protocol specifies the treatments to be evaluated, the nature of the treatment structure (for example, dosage, frequency of dosage, and duration of therapy), and the way the treatments are to be administered (for example, route of administration) *(11, 13)*. Likewise, multicenter studies evaluating the efficacy of behavioral interventions require assurances that the interventions be (a) conducted as conceptualized, and (b) comparably conducted by different counselors across different sites.

Box 1. Project RESPECT HIV Prevention Counseling Purpose, Goals, Objectives Guidelines

Purpose

The purpose of this session is to help participants assess their personal risks for HIV and establish a risk-reduction plan that incorporates a self-identified behavior goal.

Goals

Session 1 will enable participants to:

1. Initiate a behavioral change process that will be effective in preventing HIV infection.
2. Increase self-perception of HIV risk(s).
3. Recognize and obtain reinforcement for HIV risk-reduction efforts.
4. Increase understanding of personal barriers to HIV risk reduction.
5. Articulate an action plan for reducing HIV risk.
6. Utilize the counseling relationship in risk-reduction planning.
7. Understand resources available for support of behavior change.

Objectives

By end of Session 1, participants will:

1. Establish rapport with the counselor.
2. Assess personal risk for HIV infection or transmission.
3. Develop a realistic perception of personal HIV risk behaviors.
4. Identify and plan specific actions related to increasing personal use of condoms.
5. Obtain reinforcement and support from counselor for previous and planned risk-reduction efforts.
6. Obtain appropriate referrals to resources for support of desired behavior change.

Guidelines

- Strict protection of confidentiality is maintained for all persons offered HIV counseling.
- At the beginning of each session, explain to the participant the purpose of the session, its expected duration, and what is hoped to happen in the session.
- The session is interactive and client-focused: that means you should enhance the person's participation in the session (participant should be speaking more than counselor in the session), and the session should be responsive and relevant to the participant's particular needs. Listen effectively to what the participant says, use open-ended questions, do not interrupt needlessly, and respond to questions appropriately.
- Avoid making a preconceived set of points during the session, and focus on (1) exploring client-specific issues to HIV risk behaviors and 2) developing goals for the participant rather than simply providing information.
- During the session, communicate at the participant's level of understanding, avoiding technical terms, jargon, or words beyond the participant's comprehension (e.g., "window period," or "nonreactive").
- Take what the participant says at face value, while exploring relevant circumstances and details of the participant's life and risks to establish a context for what the participant reports or believes.
- Optimize opportunities to reinforce the participant's intentions and reported actions relative to addressing HIV or STD issues in his or her life.
- Respond appropriately to what the participant states and to the participant's feelings.
- Help the participant to understand dissonant statements when they come up (for example, dissonance between reported behavior and risk perception, between behavior and intentions, between reported behavioral and conflicting information).

We used the following processes to ensure adherence to these two principles. First, in order to maximize the likelihood that the interventions were implemented as conceived, written protocols described each intervention session separately and in detail, using the order that counselors were expected to follow. All investigators carefully reviewed the components of the intervention protocols and agreed to each of the elements outlined. We asked counselors and clinicians conducting the interventions to follow the protocols strictly.

Second, to promote standard procedures and minimize error, an experienced trainer conducted training sessions for counselors and supervisors. When more than one training session was needed, the original trainer was asked to conduct the additional sessions in order to ensure that the courses were consistent. The trainer used a standard format to conduct the training sessions and allotted time for the counselor-trainees to discuss any problems.

Third, to help ensure that the interventions were being performed consistently and according to protocol, supervisors regularly observed the counselors conducting the interventions. This process allowed problems to be identified early and corrected through immediate feedback to counselors. Supervisors completed structured quality assurance forms for each intervention session observed, so that the data from these sessions could be used to assess whether or not specific study objectives were met. In addition to the observations conducted by supervisors, an independent observer (a CDC staff member who underwent the same training sessions as study supervisors and counselors) regularly observed interventions at each study site. This process of observing intervention sessions both internally (by site supervisors) and externally (by the independent observer) was done at each site throughout the duration of the study.

Fourth, to measure the participant's perception of the nature and quality of the counseling provided, semi-structured post-intervention questionnaires focusing on the participants' reports of what occurred during each of the intervention sessions were used.

To illustrate specific aspects of quality assurance, we have included here some of the tools that are currently being used for one of the counseling interventions (HIV prevention counseling) studied in Project RESPECT.

Development of Quality Assurance Tools

Intervention protocols. Scripted study protocols were written for each separate session in the three interventions. Each session protocol included an overall statement of purpose and several precise goals; specific objectives that participants were expected to meet by the end of the session; a structured plan that outlined each activity or element in the session in the order in which they should be conducted; and an approximate time needed for each element (Table 1, Box 1). The protocol also detailed specific guidelines that counselors were expected to apply consistently in the interven-

Box 2. Project RESPECT HIV Prevention Counseling Intervention

SESSION I INTERVENTION SCRIPT

***Introduction/Establish Rapport*–1 minute**

Introduce yourself as health counselor. **Describe** the purpose of the session, the expected duration, and what is hoped to be achieved in the session. **Seek consensus** from the participant as to the objectives of the session and agreement to maintain this focus throughout the intervention.
During the session, **be polite**, professional, and **display** respect, empathy, and sincerity to the participant. **Become** involved and invested in the process and **convey** an appropriate sense of concern and urgency relative to the participant's HIV risk behaviors and STD clinic visit. **Use** plausible and factual motivations, and **seek** to deal with the participant's concerns.

Suggested open-ended introductory questions:

→ What have you heard about AIDS?
→ How do you think the virus is passed from one person to another?
→ How did you decide to take the HIV test today?
→ Why did you come to the clinic today?
→ What would you like to know before you leave here today?

***Risk Assessment*–2 minutes**

Focus on the participant's specific sexual behavior(s) and the circumstance that affect that behavior. **Attempt** to build from the presenting problem (symptoms, referral, etc.) that brought the participant to the clinic. (**Refer** to the screening form and the participant's responses to the above questions.) **Establish** an atmosphere that conveys a collaborative and creative exploration of the relevant issues. With the participant, **identify** the categories and range of behaviors that place him or her at risk for HIV while attempting to **focus** the participant on specific behaviors, situations, and partner encounters that contribute to his or her HIV risks.

- The exploration of behaviors during the risk assessment is an integral component of the HIV prevention counseling intended to facilitate the participant's self-understanding of his or her risks. It is not intended as a screening tool or a data collection process.

Suggested open-ended risk assessment questions:

→ What do you think will be the outcome of the test? Why?*
→ If you were infected, how do you think you may have been infected?
→ Have you been tested before? If so, when and why? What were the results?*
→ How many different people do you have sex with? How often?
  • Do they shoot up drugs? How often?
  • How many people are they having sex with?
→ When was the last time that you put yourself at risk for HIV?* What was happening then?
→ When do you have sex without a condom?
→ What are the riskiest things that you are doing?*
→ What are the situations in which you are most likely to be putting yourself at risk for HIV?
→ How often do you use drugs or alcohol? How does this influence your HIV risk behaviors?

***Enhanced Self-Perception of Risk*–3 minutes**

Help the participant relate his or her sexual behavior to the STD clinic staff and **help** the participant recognize specific sexual behaviors that place him or her at risk for HIV.

- The enhancement of participant risk perception begins within the context of the risk assessment.

Suggested open-ended risk awareness questions:

→ What kinds of conversations have you had with your sex partner(s) about AIDS?
→ Why are you interested in having HIV test?
→ What role did a friend or sex partner play in your coming in for the test?
→ What other STDs have you been diagnosed with?
→ What do you do to put yourself at risk for this infection?
→ How often do you do drugs, specifically drugs that you shoot?
→ How would you describe your own risk of being infected?
→ How do you think you got [STD]?
→ How often do you use condoms with your steady partner?
→ How often do you use condoms with partners whom you do not know very well?
→ How have your behaviors that we have discussed put you at risk for HIV?

***Identification of Participant Actions*–2 minutes**

Help the participant identify any self-initiated changes already made in response to HIV/AIDS and **inquire** into the participant's social (peer) and community perception of HIV/AIDS. **Reinforce/support** the participant's actions, intentions, and communications about safer sex behavior. **Clarify** misinformation and educate only as needed in the participant's specific situation.*

Suggested open-ended questions to explore participant HIV-related intentions, concerns, and risk-reduction attempts:

→ What are you presently doing to protect yourself?*
→ What would you like to do to reduce your risk of HIV?*
→ Whom have you talked to about your HIV concerns or risks?
→ What have your friends or partner(s) said about HIV/AIDS?
→ Explain to me when you use condoms. How has that worked?
→ Whom do you use condoms with?
→ How often do you use condoms with your steady partner?
→ What thoughts have you had about reducing your risk for HIV infection?
→ Do you know anyone with HIV infection? How does that situation impact your own sense of risk?
→ What have you seen or heard about HIV in your [this] community?
→ When have you reduced your risk? What was going on that made that possible?
→ How is that working for you?

(Continued)

Box 2. Project RESPECT HIV Prevention Counseling Intervention (continued)

Suggested statements reinforcing positive change already made:

- → It's great that you are here!
- → You've taken the first step; you're doing a great job; keep it up!
- → The fact that you are concerned about HIV is important.
- → It is important that you recognize how you have clearly been thinking about reducing your HIV risk.

***Identification of Participant Barriers*–2 minutes**

Help the participant identify barriers to safer sex behavior, particularly condom use. **Explore** risk-reduction attempts in detail, and **identify** and **define** impasses and difficulties. Focus on the participant's sense of self-efficacy for specific risk-reduction activities, community and peer norms, and relevant attitudes and beliefs.

Suggested open-ended questions to identify participant barriers:

- → What has been the most difficult part of changing your behavior?
- → When, and in what situations, do you not use condoms?
- → How often do they break?
- → When are you least likely to use condoms?
- → When do you have the most difficulty in discussing condoms?
- → What have you discussed with your partner(s)?
- → With which partners has it been hardest to talk about or suggest the use of condoms?
- → What was the role of drugs and alcohol in your decision to engage in high-risk sex?
- → In what situations are you most likely to be putting yourself at risk for HIV?

Negotiation of Risk Reduction Plan– 4 minutes*

Help the participant establish a reasonable yet challenging risk-reduction step toward condom use that will reduce his or her risk for acquiring HIV. This plan should address the particpant's baseline risk behavior identified in the risk assessment phase of the session and should incorporate the participant's previous attempts and perceived barriers to reducing HIV risk. **Discuss** how the participant will operationalize the plan, using specific and concrete steps, and **establish** a back-up plan. **Encourage** the participant to develop a plan that involves condom use to reduce HIV/STD risk; however, plans not involving condom use are also acceptable.
Confirm that this plan is personalized and is acceptable to the participant. **Document** the plan, give a copy to the participant, and retain a copy for the file. **Acknowledge** that the plan is a challenge and **assure** the participant that you will work with him or her to discuss and review the out come at the next visit. **Explain** that together you can renegotiate the plan, if necessary, in the post-test session. Ask the participant to repeat his or her plan back to you to make sure that you are clear and can help look at the plan again at the next session. **Solicit** questions and **validate** the participant's initiative in agreeing to try to negotiate a risk-reduction plan.

Suggested open-ended questions to use when negotiating a risk-reduction plan:

- → What one thing can you do to reduce your risk right now?
- → What can you do that would work for you?
- → What could you do differently?
- → How and when will you use condoms?
- → How are you going to bring up condoms with your sex partner(s)?
- → How do you think your partner(s) will respond to using condoms?
- → What will you say?
- → When do you think you will have the opportunity to first try this (behavior, discussion, etc.)?
- → How realistic is this plan for you?
- → What will be the most difficult part of this for you?
- → Who can help you?
- → What might be good about changing this?
- → What will you need to do differently?
- → How will things be better for you if you...?
- → How will your life be easier or safer if you change...?
- → How would your drug practices have to change to stay safe?

***Closure and Appointment To Receive Test Results (Post-Test Counseling)*–1 minute**

Make an appointment with the participant to return for his or her test results and post-test counseling. **Note** the day, time, and place of the appointment on your business card and **give** this to the participant. **Emphasize** to the participant the need to call and reschedule if he or she is unable to keep the appointment. If the participant is assigned to the enhanced intervention, **schedule** the next enhanced appointment.

***RETEST:** All asterisks represent points in the session when it may be appropriate to discuss retesting based on participant risk behaviors. If this has not been broached by the beginning of the negotiated risk-reduction plan, discuss the specific risk behavior(s) and the period during which the participant should return for retesting. The negotiated risk-reduction plan should be conceptualized as the short-range plan, and an explanation and recommendation of retesting addressed in the context of the longer-range plans. A brief explanation of this need for retesting is critical, but should not be over-emphasized, for example, **"Because you had unprotected sex during the last 3 months, the test today may not tell you all you need and want to know about your exposure to HIV. In order for these exposures to show up on the test, you will need to return in [specific month] for another test."**

tion (for example, "the intervention is interactive and client-focused," or "communicate at the participant's level of understanding, avoiding technical terms or other jargon"). A list of all materials required in a session (appointment cards, fact sheets, condoms, lubricant) was placed for easy reference by the counselor. Suggested scripts were included, such as statements to help build rapport in different situations, with open-ended questions to facilitate discussion for risk assessment or other elements of the intervention (box 2).

Principal investigators, study team supervisors, and counselors participated in developing and pilot-testing the protocols for the interventions. The final protocols were developed by a consensus of these groups, and all agreed to implement them exactly as written. Study counselors and clinicians were asked to memorize the protocols, including the order of activities and the scripted suggestions for each session, and were encouraged to keep the protocols in front of them and refer to them whenever necessary during intervention sessions.

Standard Training. An experienced trainer (Nancy Rosenshine, NOVA, Inc.), who had helped develop the intervention protocols, also developed and conducted a training course for the counseling interventions. At the start of the randomized trial, the trainer conducted courses (one east coast, one west coast) for study supervisors and counselors. Several months later, she conducted two additional courses to allow newly recruited counselors to undergo a similar type of training.

One full day was used for each intervention training course. Before the course, counselors were asked to become familiar with the scripts and to memorize the order of each intervention. Using the study protocols, the trainer reviewed each session of the Enhanced and HIV Prevention counseling interventions with the counselor-trainees, discussing how activities should be used, pointing out important pitfalls to avoid, and encouraging feedback from the counselors. Counselors practiced interventions in groups of three, playing the role of the counselor, the client, or the observer for each session. After each role-playing session, the trainer and observers pointed out important positive and negative features of each session to the large group.

For the educational intervention, a CDC clinician who participated in developing the intervention and clinical protocols conducted 90-minute standard training courses for study clinicians at each of the study sites. Before the training session, clinicians were asked to memorize the HIV Education intervention protocol. During the sessions the protocol was discussed, and the clinicians were given specific patient examples and asked to act out a 5-minute educational message applicable to that patient. After each role-playing session, the trainer and other clinicians pointed out important positive and negative features of the session in the large group.

At the end of the intervention training courses, the trainers asked the counselors and clinicians to give feedback about the course. Trainers also asked for feedback about the protocols as problems arose. These comments were used to clarify areas of ambiguity in the protocols and to improve future training courses.

Observation and Feedback Guides. An observation and feedback guide for each intervention session was developed and used for two purposes: (a) as a mechanism to assess whether different counselors (both within and across study sites) were conducting the interventions similarly and according to the intervention protocols, and (b) to provide immediate feedback to counselors on study protocol issues (table 2). The structured instruments for each session listed each important communications skill or activity stipulated in that session's protocol in order of its appearance. Observers were asked to use a scale of 1 to 5 to rate counselors or clinicians on whether they achieved, did not achieve, or excelled at meeting each specified objective in the protocol. Before initiating the observation process, we asked counselors and supervisors at the participating study sites to read and pilot-test the form and to suggest revisions.

For the randomized trial, we asked the supervisors in charge of the interventions to conduct observations of each counselor and clinician at their sites, requiring that each counselor be observed conducting at least one session per month of each of the two counseling interventions, and each clinician be observed conducting at least one session per month of the education intervention. In addition, an external observer from CDC visited sites every 3 to 4 months, observing as many counseling sessions as possible at that visit. The goal for each study team was that 10 per-

Table 2. Project RESPECT observation and feedback guide, HIV prevention counseling

Site: _____ Observation date: __/__/__
Observer: _____ Session Duration: ___ minutes
Counselor: _____ Participant Study ID: __ __ __ __ __ __

Session 1:

	Not Achieved		Achieved	Excelled	
1. Demonstrated professionalism throughout session	1	2	3	4	5
2. Established rapport (introduction, defined scope and duration of session)	1	2	3	4	5
3. Listened effectively; let participant speak without needless interruption	1	2	3	4	5
4. Used open-ended questions.	1	2	3	4	5
5. Communicated at the participant's level of understanding	1	2	3	4	5
6. Clarified important misconceptions	1	2	3	4	5
7. Solicited the participant's feedback	1	2	3	4	5
8. Consistently provided the participant reinforcement	1	2	3	4	5
9. Used appropriate nonverbal communications	1	2	3	4	5
10. Assisted the participant in recognizing risks (linked STD symptoms, history, concerns to HIV risks)	1	2	3	4	5
11. Identified, reinforced and supported participant concerns intentions, actions and/or communications about HIV/AIDS	1	2	3	4	5
12. Addressed community, peer perception of HIV/AIDS	1	2	3	4	5
13. Counselor asked participant to help him or her understand dissonance (behavior risk perception; behavior intentions; and conflicting information	1	2	3	4	5
14. Maintained focus on the participant's sexual behavior and circumstances that affect that behavior	1	2	3	4	5
15. Assessed barriers to HIV risk reduction; identified and defined impasses and difficulties	1	2	3	4	5
16. Negotiated a realistic plan to help the participant reduce HIV risks	1	2	3	4	5
17 Established a reasonable yet challenging incremental step	1	2	3	4	5
18. Operationalized risk reduction into concrete and specific steps	1	2	3	4	5
19. Confirmed with the participant that the plan was reasonable and acceptable.	1	2	3	4	5
20. Documented risk-reduction plan, copy to both counselor and participant	1	2	3	4	5
21. Established a plan for receiving results	1	2	3	4	5

cent of their interventions be observed either by site supervisors or by the external observer. As of December 1995, four of the five sites had achieved that goal. Counselors and clinicians received feedback immediately after each session, and specific aspects of the session that did not meet the study protocol were discussed. The external observer entered and tabulated the observational data centrally and returned to the study supervisors the results for each counselor on each intervention. Observed problem areas as well as particularly useful techniques were highlighted during routine staff meetings with study supervisors, during group meetings conducted at the end of site visits from the external observer, on bimonthly conference calls, and at biannual meetings of principal investigators and study supervisors.

Two examples illustrate the usefulness of the observation and feedback guides. First, when observers noted that several counselors at one site had difficulty achieving the protocol objectives for an intervention, we asked the trainer to conduct a second training course at that site. After that, observers found that the interventions were being conducted according to protocol. Second, immediately after starting the randomized trial, the external observer reported that two related and sequential activities were consistently problematic for counselors at most sites. Counselors were observed using inconsistent, free-form approaches that tended to blur the two activities. When asked about this during site visits and conference calls, supervisors reported that the directions and scripts for the two activities were less clearly documented than other parts of the protocol. They noted that many counselors found this exercise to be their least favorite part of the Enhanced HIV Counseling intervention because participants were less engaged than in other parts of the intervention. As a response to this, we combined the two activities, wrote more detailed instructions and scripts, and added a visual tool and interactive dialogue cards to help participants follow the activity more closely. After the modifications, the external observer found that counselors across sites delivered this intervention consistently and according to the revised protocol.

Participant perception of the intervention. A process evaluation instrument was developed and given to study participants in each of the three interventions. The purpose of this instrument was to evaluate whether or not participants experienced the activities described in the intervention protocols. Using a semistructured instrument, an interviewer who was not the original counselor asked participants at the end of their final intervention session to describe and rate the different activities of their intervention. The process evaluation interviews were conducted for 6 weeks shortly after the randomized trial was initiated, for 6 weeks at a mid-point in enrollment, and, finally, during the last 6 weeks of enrollment. Results of the first two sets of interviews with participants indicated that the counselors did introduce key intervention elements and that counselors used an interactive approach and clinicians a didactic approach, which is consistent with the protocols. In general, participants reported being very pleased with the intervention they received.

Discussion

Given the need for HIV prevention interventions that can be genuinely evaluated and, if effective, replicated and transferred to appropriate settings, it is critical that studies have strong quality assurance components that are systematically applied. Each component requires detailed written protocols and evaluation tools. This is particularly true in a multi-center study such as the one described here, where the consistent application of several complex behavioral interventions is fundamentally important to the evaluation. The development of written protocols, training of staff, rigorous observation of the interventions, and process evaluations all contribute to the reliability of the overall data.

A study such as Project RESPECT, enrolling thousands of participants over an extended period, and requiring repetition of 5-minute to 1-hour sessions with individual clients, clearly has the potential to become redundant for counselors. This situation may lead to short-cuts, omissions, decreased emphasis on critical points in the interventions, and indifference among counselors that may be conveyed to the participants. The quality assurance procedures used in this study maintain high performance expectations on study personnel and have resulted in consistent and comprehensive delivery of the interventions. However, the intensity and duration of this study have contributed to some staff turnover.

The quality assurance strategies used in this project have been particularly useful in helping supervisors decide when new counselors have developed the skills needed to begin performing the interventions. For example, new counselors occasionally perform intervention activities in the wrong order. Since the enhanced intervention was designed to have a cumulative effect on each participant, it is critical that the study counselors maintain the strict intervention protocol, including the sequence of the sessions and the activities within each session. Early quality assurance monitoring of new personnel prevented the habituation of incorrect approaches to the interventions and assisted the experienced counselors in fine-tuning the complex counseling interventions and maintaining good skills.

Supervisory observation and corresponding feedback became a routine expectation of the project study personnel. External observation and feedback became progressively less threatening, and the quality assurance process also helped maintain a useful, somewhat competitive, cross-site tension or anticipation of high quality evaluations. Study counselors were sufficiently comfortable with observation of their sessions that their requests for participant consent for the observation were routine and profes-

sional. As a result, study participants seldom declined the counselors' requests that an observer be present.

In retrospect, some aspects of the quality assurance could have been enhanced. For example, about 6 months after beginning enrollment, supervisors at some sites suggested that peer observations of the interventions could be a supplementary quality assurance tool. Although peer observation was encouraged at all study sites, it was not uniformly adopted, and was a matter of routine at only a few sites. For this study, the process was used to enhance counselors' techniques rather than as a quality assurance process. Therefore, peers did not use the observation and guides to "rate" each other on adherence to study protocols. Training is another area that could have been enhanced, had funding allowed. Repeating the standardized training courses for all counselors midway through study enrollment would have helped ensure that new counselors approached interventions consistently and according to protocol, and would have allowed counselors to observe first-hand useful techniques used by counselors at other sites. An additional quality assurance strategy that has not been used is audiotaping the intervention sessions. Some investigators have found this approach to be well accepted by clients and helpful in allowing sessions to be evaluated at the supervisor's convenience and by more than one rater. This would also allow the potential to assess inter-rater reliability *(14)*.

The introduction of strict quality assurance procedures has had a synergistic effect on the researchers as well as the counselors and supervisors at each site. For example, study team personnel at the sites requested that researchers develop tools to ensure that other aspects of the study, such as recruitment, were performed consistently. Also, in spite of the fact that study sites were between 500 and 2,500 miles apart, study supervisors requested, and were encouraged, to visit the other study sites, and were able to observe and critique the application of study protocols and quality assurance activities by their counterparts. As a result of these site visits, supervisors were able to incorporate particularly innovative or useful management approaches developed at other sites into their own clinic settings. Thus, there has been a transfer of technology between study sites both through the site visits by supervisory counterparts and through the quality assurance site visits by an external observer.

The emphasis on consistent and rigorous quality assurance of the behavioral interventions in Project RESPECT has enhanced the integrity and quality of the study and the researchers' ability to interpret study results. If the client-based counseling interventions are found to be effective, quality assurance should continue to play an important role in replicating the interventions for HIV prevention programs.

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References

1. Doll, L. S., and Kennedy, M. B.: HIV counseling and testing: what is it and how well does it work? *In* AIDS testing. A comprehensive guide to technical, medical, social, legal, and management issues, edited by G. Schochetman and J. R. George. Ed. 2. Springer-Verlag, New York, NY, 1994, pp. 301-319.
2. Macro International Inc.: Executive summary. Assessment of CDC-funded counseling, testing, referral, and partner notification (CTRPN) services for prevention of HIV transmission, 1992, pp. ii-ix.
3. CDC Advisory Committee on the Prevention of HIV Infection: External review of CDC's HIV prevention strategies. Public Health Service, Washington, DC, June 1994.
4. Turner, C. F., Miller, H. G., and Moses, L. E., editors: AIDS sexual behavior and intravenous drug use. National Academy Press, Washington, DC, 1989.
5. Fishbein, M., Middlestadt, S. E., and Hitchcock, P. J.: Using information to change sexually transmitted disease-related behaviors: an analysis based on the theory of reasoned action. *In* Research issues in human behavior and sexually transmitted diseases in the AIDS era, edited by J. N. Wasserheit, S. O. Aral, and K. K. Holmes. American Society for Microbiology, Washington, DC, 1991, pp. 243-257.
6. Higgins, D. L., et al.: Evidence for the effects of HIV antibody counseling and testing on risk behaviors. JAMA 226: 2419-2429 (1991).
7. Centers for Disease Control and Prevention: HIV counseling, testing, and referral standards and guidelines. May 1994.
8. Centers for Disease Control and Prevention: Distribution of STD clinic patients along a stage-of-behavioral-change continuum—selected sites, 1993. MMWR Morb Mortal Wkly Rep 42: 880-883, Nov. 19, 1993.
9. Fishbein, M., et al.: Factors influencing behavior and behavior change: final report—theorist's workshop. National Institute of Mental Health, Rockville, MD, 1992.
10. Centers for Disease Control and Prevention: Technical guidance on HIV counseling. MMWR Morb Mortal Wkly Rep 42: 11-17, Jan. 15, 1993.
11. Pocock, S.: Clinical trials—a practical approach. John Wiley & Sons Ltd., New York, NY, 1983, pp. 1.
12. Meinert, C. L.: Clinical trials—design, conduct and analysis. Oxford University Press, New York, NY, 1986, pp. 306.
13. Friedman, L. M., Furberg, C. D., and DeMets, D. L.: Fundamentals of clinical trials. John Wright PSG, Inc., Boston, MA, 1942, pp. 115.
14. Foster S. L., and Cone, J. D.: Design and use of direct observation procedures. *In* Handbook of behavioral assessment, edited by A. R. Ciminero, K. S. Calhoun, and H. E. Adams. Ed. 2. John Wiley and Sons, New York, NY, 1986, pp. 253-324.