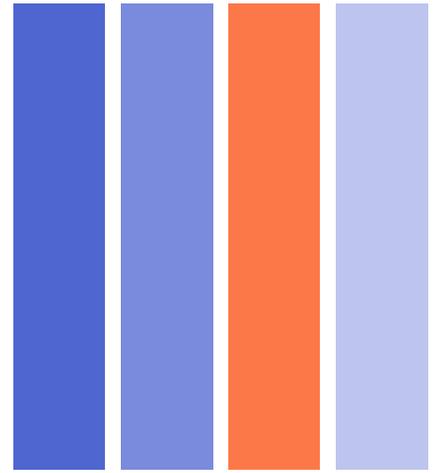


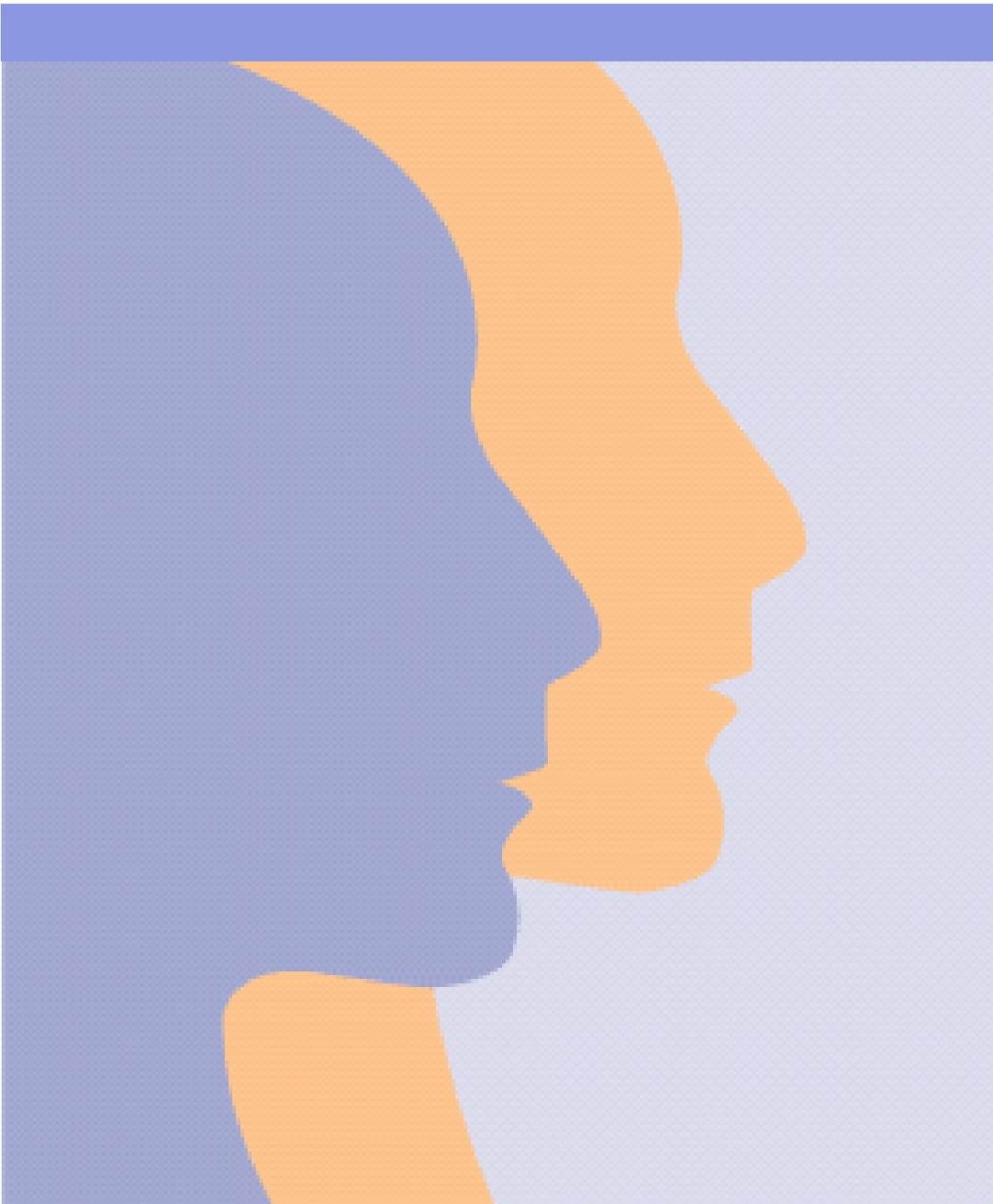
2-Session

RESPECT

HIV Prevention Counseling



Manual



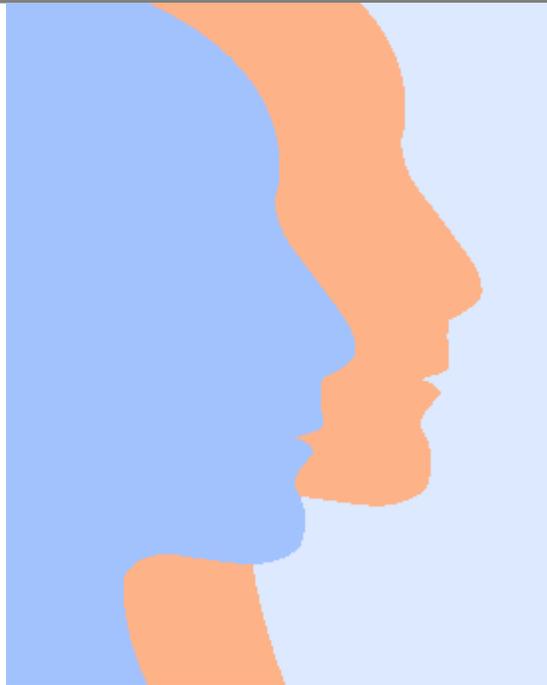
The 2-Session RESPECT model is an individual-level HIV prevention counseling model focusing on a client's unique, personal risk. It is designed to support individuals in reducing a client's HIV risk by increasing the client's sense of personal risk and developing incremental risk-reduction strategies.



2-Session

RESPECT

HIV Prevention Counseling



Manual

Version Dated:
March 25, 2004

This counseling protocol was developed by the Centers for Disease Control and Prevention (CDC) in collaboration with researchers and health departments in Baltimore, Denver, Long Beach, Newark, and San Francisco. This manual was developed by RTI International with funding from CDC (Contract numbers 200-97-0621, 025 and 200-2002-00776, 006)



Contents

RESPECT Models of HIV Prevention Counseling.....	1
Introduction	1
What Is the 2-Session RESPECT Model?	2
Why Use the Respect HIV Prevention Counseling Interventions?	2
Who Is the 2-Session RESPECT Model Intended For?	3
Core Elements of the 2-Session Respect HIV Prevention Counseling Model	5
What Are the Core Elements of the 2-Session RESPECT Model?	5
Getting Started.....	7
What Resources Are Needed to Conduct the 2-Session RESPECT Model?	7
How Can the RESPECT Model Be Adapted?	8
RESPECT Differs from Other Models	8
Merging this Model with Existing Service Systems and Programs	8
Using RESPECT with Rapid HIV Testing.....	8
What Is the Cost of Using the 2-Session RESPECT HIV Prevention Counseling Model?.....	9
The 2-Session RESPECT Materials	9
How Are the Sessions Organized?.....	9
Acknowledgements.....	13
Session 1: Risk Assessment and Risk-Reduction Step	17
Session 1	17
Component 1. Introduce and Orient Client to the Session	18
Objective	18
Guidance	18
Component 2. Enhance the Client’s Sense of Self-Risk	21
Objective	21
Guidance	21
Component 3. Explore the Specifics of the Most Recent Risk Incident	24
Objective	24
Guidance	24

Component 4. Review Previous Risk-Reduction	
Experiences	27
Objective	27
Guidance	27
Component 5. Summarize the Risk Incident and Risk	
Patterns	31
Objective	31
Guidance	31
Component 6. Negotiate a Risk-Reduction Step.....	34
Objective	34
Guidance	34
Component 7. Identify Sources of Support and Provide	
Referrals	39
Objective	39
Guidance	39
Component 8. Close the Session	42
Objective	42
Guidance	42
Session 2a: Negative HIV Test Result: Prevention Counseling.....	45
Session 2	45
Component 1. Provide Negative Test Result	46
Objective	46
Guidance	46
Component 2. Review the Risk-Reduction Step	49
Objective	49
Guidance	49
Component 3. Revise the Risk-Reduction Step	51
Objective	51
Guidance	51
Component 4. Identify Sources of Support	53
Objective	53
Guidance	53
Component 5. Provide Referral and End Session.....	55
Objective	55
Guidance	55
Session 2b: Positive HIV Test Result: Support and Prevention	
Counseling.....	59
Session 2	59
Component 1. Provide Positive HIV Test Result.....	60
Objective	60
Guidance	60
Component 2. Identify Sources of Support and Provide	
Referrals	62
Objective	62
Guidance	62
Component 3. Address Risk-Reduction Issues	65
Objective	65
Guidance	65
Component 4. Summarize and Close the Session.....	67
Objective	67
Guidance	67

Developing, Implementing, and Maintaining Quality Assurance	69
Introduction	69
Quality Assurance for RESPECT	69
Strategies for Implementing and Maintaining Quality Assurance	70
Training	70
Regular Observation of Counseling Sessions	71
Observation Procedures	71
Frequency of Observations	72
Completing Quality Assurance Forms	73
Post-Observation Activities	74
Review of Records	75
Providing Feedback About the Record Review	76
Frequency of Record Reviews	76
Regular Case Conferences and/or One-on-One Coaching	76
Frequency of Case Conferences	77
 Appendix A: Acknowledgements	 A-1
 Appendix B: Efficacy of Risk-Reduction Counseling to Prevent HIV and STDs (Research Paper)	 B-1
 Appendix C: Revised Guidelines for HIV Counseling, Testing, and Referral	 C-1
 Appendix D: Quality Assurance of HIV Prevention Counseling in a Multicenter, Randomized Controlled Trial (Research Paper)	 D-1
 Appendix E: Partner Counseling and Referral Services Guidelines	 E-1
 Appendix F: Cost to Implement RESPECT HIV Prevention Counseling	 F-1
 Appendix G: Quality Assurance Forms	 G-1

List of Figures

Figure 1	Example Section of RESPECT Counselor Cards.....	12
Figure 2	Risk-Reduction Step Form.....	35

List of Tables

Table 1	Session I	10
Table 2	Session 2: Negative Test Result	10
Table 3	Session 2: Positive Test Result	10
Table 4	Sample Observation Schedule for New Counselors in Training	73
Table 5	Sample Frequency of Observation for Trained/Experienced Counselors	73
Table 6	Sample Frequency of Record Reviews	76

RESPECT Models of HIV Prevention Counseling

INTRODUCTION

Despite advances in the treatment of human immunodeficiency virus (HIV) infection, there is still no cure. Programs that reduce unprotected sex, the sharing of used syringes and works, and other risky behaviors will remain the best way to control the spread of HIV. A great deal of progress has been made in the development and testing of programs to reduce risky behaviors.

These efforts have produced a number of effective, evidence-based interventions, including the 2-Session and 4-Session RESPECT HIV Prevention Counseling models (see *Appendix A*). The RESPECT counseling models were developed in a randomized control trial called Project RESPECT. The study was conducted in five public sexually transmitted disease (STD) clinics in Baltimore, Maryland; Denver, Colorado; Long Beach, California; Newark, New Jersey; and San Francisco, California. In this study, the effectiveness of 2-session and 4-session, client-focused counseling models was evaluated against an informational message model (see *Appendix B*).

Project RESPECT research produced two effective, evidence-based HIV prevention counseling models: the 2-session model, which consists of two brief (about 10 to 28 minutes) one-on-one counseling sessions; and the 4-session model, consisting of one brief (about 20 minutes) and three longer (about 60 minutes) one-on-one counseling sessions.

Materials for RESPECT counseling have been translated and packaged for use by HIV testing and counseling providers. In the sections that follow, you will learn more about the 2-Session

RESPECT HIV Prevention Counseling model (2-Session RESPECT) and how it works. You will be given information to help you determine the suitability of the 2-Session RESPECT model for your organization and the clients you serve. Also included in this intervention package is a manual for the 4-Session RESPECT HIV Prevention Counseling model (4-Session RESPECT).

WHAT IS THE 2-SESSION RESPECT MODEL?

The 2-Session RESPECT HIV Prevention Counseling model (2-Session RESPECT) focuses on the client's personal risk. It is designed to support individuals in reducing their risk of getting HIV and other STDs by increasing a client's perceptions of his or her personal risks, supporting incremental risk-reduction steps, increasing self-efficacy of safer sex behaviors, supporting positive beliefs and attitudes about using condoms, and examining norms about using condoms.

This counseling model consists of two, brief, one-on-one interactive counseling sessions. The sessions follow a structured protocol that guides the counselor to elicit and discuss the client's risk situations, conduct personalized risk assessment, and encourage and assist clients to develop a risk-reduction step. The 2-Session RESPECT model was designed for use with HIV testing that follows a "standard" protocol consisting of an enzyme immunoassay (EIA) followed by confirmatory testing, if indicated.

In Session 1, the client's understanding of his or her personal risk for becoming HIV infected is increased, and a realistic step toward risk reduction is developed and supported. A specimen is taken for HIV testing after the first session. In Session 2, the result of the HIV test is given to the client, and the client is guided by the counselor to review and revise his or her risk-reduction step.

WHY USE THE RESPECT HIV PREVENTION COUNSELING INTERVENTIONS?

Compared with information-giving, the two RESPECT HIV Prevention Counseling models were more effective at reducing sexually transmitted diseases—study participants reported using

condoms more and performing other risk-reduction behaviors. Because the focus of the counseling is on risk behaviors, it is assumed that the counseling is also effective at preventing other sexually transmitted and blood-borne diseases including HIV and hepatitis B and C.

Further, the 2-Session RESPECT model is recommended by the Centers for Disease Control and Prevention (CDC) guidelines for providing HIV counseling, testing, and referral (see *Appendix C*). The model is also consistent with the new CDC recommendations for advancing HIV prevention (AHP), which emphasize that people learn their HIV status and be provided with support for reducing HIV transmission and referral to care, treatment, and prevention services.

WHO IS THE 2-SESSION RESPECT MODEL INTENDED FOR?

The RESPECT HIV Prevention Counseling models were effective for HIV-negative heterosexuals who came to a clinic for STD testing and whose main risk for HIV was sexual transmission (see *Appendices B* and *D*). Although the effectiveness of the intervention for use with HIV-positive persons has not been studied, this intervention manual includes a counseling protocol for delivering positive test results to clients.

However, this counseling model has not been studied in other populations. Because it uses a client-focused counseling approach and includes a personalized risk assessment and development of a personalized risk-reduction step, it can be easily adapted and tailored to different HIV testing settings for a variety of populations. In other words, it can be offered to all persons at risk for HIV who seek testing in any setting, including traditional clinic settings and nontraditional settings, such as community-based or outreach venues. Similarly, because the model includes a protocol with specific prompts, it helps the counselor cover all important pieces of the protocol while ensuring that the counseling will be acceptable to target populations.

Core Elements of the 2-Session RESPECT HIV Prevention Counseling Model

WHAT ARE THE CORE ELEMENTS OF THE 2-SESSION RESPECT MODEL?

Core elements are critical features of an intervention's intent and design that must be maintained without change to ensure the intervention's effectiveness. To ensure the effectiveness of the 2-session model, it is essential that all six core elements are followed. The 2-Session RESPECT HIV Prevention Counseling model has six core elements:

1. Conduct one-on-one counseling.
2. Offer HIV testing with the counseling.
3. Follow the protocol components.
4. Focus on the client's specific behavior that puts him or her at risk for HIV, other STDs, and blood-borne infections.
5. Negotiate a realistic and achievable risk-reduction step.
6. Develop, implement, and maintain quality assurance procedures.

Project RESPECT research produced risk-reduction behaviors, such as increased condom use, and led to reduced rates of HIV and other STDs. To maximize the effectiveness of the RESPECT counseling, it is essential that the intervention be implemented faithfully by maintaining all six core elements. By following all of the core elements, you are more likely to see results similar to the

study and thus see a decrease in STD rates. Each of these core elements is described in more detail below.

1. **Conduct one-on-one counseling.** Conduct the sessions with only one client at a time. The RESPECT model is not applicable to group settings.
2. **Offer HIV testing with the counseling.** Have HIV testing available on site at the time of the counseling. The counseling is more relevant to a client when it is done alongside an HIV test.
3. **Follow the protocol components.** The protocols used with this counseling intervention were standardized during the research. As part of the standardization, counselor cards with prompts were developed to provide guidance and help the counselor focus the client on his or her specific risk behaviors related to HIV/STDs.
4. **Focus on the client's specific risk behavior that puts him or her at risk for HIV, other STDs, and blood-borne infections.** This model focuses on the client's specific and recent risk behavior and related circumstances. One of the main strengths of the counseling is its continuous focus on the client's risk for HIV. Similar to other crisis intervention models, this model avoids discussion of topics unrelated to the client's risk for HIV. Rather than using the session for HIV education, the focus is on the client's specific risk behavior. This counseling model requires that the counselor clarify only misconceptions related to the client's personal risk.
5. **Negotiate realistic and achievable risk-reduction steps.** This counseling model supports and encourages the client to develop an achievable, realistic step that would reduce his or her risk of infection in each session. These steps should support an overarching risk-reduction goal.
6. **Develop, implement, and maintain quality assurance procedures.** To ensure high-quality counseling, providers should develop, implement, and maintain a quality assurance protocol that supports consistent delivery of the intervention.

Getting Started

WHAT RESOURCES ARE NEEDED TO CONDUCT THE 2-SESSION RESPECT MODEL?

To conduct 2-Session RESPECT HIV Prevention Counseling model in a manner consistent with the research on the model, providers will need the following resources and training:

1. Counselors trained to deliver the 2-Session RESPECT HIV Prevention Counseling model. As a prerequisite to the 2-session training, all counselors should be trained or be competent in the fundamentals of HIV counseling, counseling principles, and their local organizational requirements for HIV testing, counseling, referral, and related interventions.
2. Supervisors who are trained and skilled in the counseling model and able to provide ongoing support, guidance, and quality assurance.
3. A private setting to comfortably speak with the client one-on-one.
4. Sufficient time to conduct a session with each client.
5. HIV testing capability. This counseling model was designed for use with standard HIV testing.
6. Contact information for referrals (e.g., health care, mental health, substance abuse, shelter).
7. The 2-Session RESPECT HIV Prevention Counseling intervention package.
8. Written quality assurance protocol and procedures and related forms.

HOW CAN THE RESPECT MODEL BE ADAPTED?

Agency and clinic environments may differ from the research conditions under which the RESPECT model was tested. Therefore, providers may need to adapt the counseling model to meet client and agency needs while keeping the core elements of the model intact.

RESPECT DIFFERS FROM OTHER MODELS

Many models of counseling are delivered to clients seeking HIV testing. Not all counseling models have the research foundation of the RESPECT model. Many models (for example, the CDC “Fundamentals of HIV Prevention Counseling”) are based on the RESPECT model, but do not replicate this intervention. The CDC’s “Fundamentals of HIV Prevention Counseling” course and similar counselor training courses are recommended as prerequisites to the training offered by this package.

MERGING THIS MODEL WITH EXISTING SERVICE SYSTEMS AND PROGRAMS

Because this counseling model is intended to be offered along with HIV testing, it is often imbedded within a service called “counseling and testing.” As recommended by CDC guidelines, these services often include additional components such as consenting processes, referral processes, partner notification services, and individual or group education programs (see *Appendices C and E*). In addition, local laws and organizational policies regulate provider programs. To effectively use this package, providers are encouraged to imbed the counseling protocol within their service or program in a way that minimizes disruption and any changes to the protocol.

USING RESPECT WITH RAPID HIV TESTING

As researched in Project RESPECT, the counseling was found effective when used with regular HIV counseling and testing. In another research study, it was modified for use with rapid HIV testing. At the time this package was developed, the effectiveness

of the model when used with rapid testing had not been determined.

WHAT IS THE COST OF USING THE 2-SESSION RESPECT HIV PREVENTION COUNSELING MODEL?

It is expected that any organization currently conducting HIV counseling and testing will be able to imbed RESPECT into its current services and programs easily. A cost sheet has been included to assist planning (see *Appendix F*).

THE 2-SESSION RESPECT MATERIALS

The counseling materials were packaged for HIV testing and counseling providers to use when implementing the RESPECT model of HIV prevention counseling.

The 2-Session RESPECT materials include

1. A manual of the 2-Session RESPECT model.
 2. Counselor Cards.
 3. Risk-Reduction Step forms.
 4. A 1-hour video that demonstrates correct 2-Session RESPECT counseling with a video guide.
 5. Quality assurance recommendations and forms.
-

HOW ARE THE SESSIONS ORGANIZED?

The 2-Session RESPECT model is designed to be a brief and focused intervention, with each session lasting 10 to 28 minutes. Each session protocol has several components that help the counselor carry out the counseling objectives. *Tables 1-3* show each component for each session.

Table 1. Session 1

Protocol Components	Time (in minutes)
1. Introduce and orient client to the session	1–2
2. Enhance the client’s sense of self-risk	2–3
3. Explore the specifics of the most recent risk incident	2–3
4. Review previous risk-reduction experiences	2–4
5. Summarize the risk incident and risk patterns	3–4
6. Negotiate a risk-reduction step	4–5
7. Identify sources of support and provide referrals	1–2
8. Close the session	3–5
Total Time	18–28

Table 2. Session 2: Negative Test Result

Protocol Components	Time (in minutes)
1. Provide negative HIV test result	2–10
2. Review the risk-reduction step	4–5
3. Revise the risk-reduction step	4–5
4. Identify sources of support for risk-reduction step	1–2
5. Provide referral and close the session	1–2
Total Time	12–24

Table 3. Session 2: Positive Test Result

Protocol Components	Time (in minutes)
1. Provide positive HIV test result	3–10
2. Identify sources of support and provide referrals	4–10
3. Address risk-reduction issues (as appropriate)	2–5
4. Summarize and close the session	1–2
Total Time	10–27

For each protocol component, this manual contains information to guide the counselor in carrying out the protocol effectively. Each protocol component is organized as follows:

Title of the protocol component—introduces the component.

Objective—describes what needs to be accomplished with the session component.

Guidance—describes, in detail, the purpose or rationale for each specific component of the session.

Table with protocol prompts and example dialogue—outlines the activities and the order to follow for each component and gives examples for delivering them.

As shown in *Figure 1*, the tables with the protocol components and prompts are essential pieces of the counseling model that must be maintained by the counselor. However, the example dialogues are just that—examples. They are provided to guide the counselor in delivering the essential components. The prompts also help keep the counselor focused, thus increasing the likelihood that the counselor counsels clients the same way it was done in the study. The counselor may choose to use these examples or may choose to deliver the intervention components using his or her own words, being careful to use words and language specifically tailored to the client. The protocol prompts and example dialogues are also found in the “counselor cards” in this counseling package.

Figure 1. Example Section of RESPECT Counselor Cards	
Protocol Prompts <i>(must be followed)</i>	Example Dialogue <i>(can be modified)</i>
<p>1. Assess communication about HIV with partners</p>	<ul style="list-style-type: none"> • How did you decide to have sex/shoot drugs? Did you or your partner(s) suggest using condoms/new or clean needles or equipment or not sharing needles and equipment? Tell me about that. • Did you talk about whether either you or any of your partners had been tested for HIV? • Would you have engaged in the same behavior had you known this person had HIV? Tell me more. • What did you and your partner(s) talk about in terms of HIV risk or about being safe?

The example dialogue is designed to encourage the client to do most of the speaking, with the counselor asking follow-up questions appropriate to the context. The counselor is encouraged to avoid asking questions that are not relevant to the client’s risk circumstances and to use language (words and terminology) that the client would understand. If the client does not use terms that are specific enough, decide on terms both of you are comfortable using.

The example dialogue includes questions that are specific to clients whose main HIV risk is from sex and to clients whose risk is from injecting drug use.

The example dialogue includes instructional text for the counselor in brackets that is similar to the protocol prompts in font and color.

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Session 1: Risk Assessment and Risk-Reduction Step

SESSION 1

Protocol Components	Time (in minutes)
1. Introduce and orient client to the session	1–2
2. Enhance the client's sense of self-risk	2–3
3. Explore the specifics of the most recent risk incident	2–3
4. Review previous risk-reduction experiences	2–4
5. Summarize the risk incident and risk patterns	3–4
6. Negotiate a risk-reduction step	4–5
7. Identify sources of support and provide referrals	1–2
8. Close the session	3–5
Total Time	18–28

COMPONENT 1. INTRODUCE AND ORIENT CLIENT TO THE SESSION

Objective

The purpose of this component is to describe the session and the amount of time it will take, explain the roles and responsibilities of client and counselor, and establish consensus with the client about the overall objectives of the session.

Time: 1–2 minutes

Guidance

Tip! Remember to follow the protocol prompts in the order they are numbered.

Show empathy. From the time the counselor sees the client, convey a positive regard, show genuine concern, and be empathetic toward the client. This will help build trust and will set the tone for the rest of the session.

Explain the process. Help the client feel comfortable with the process, your role, and the content and purpose of the session. If the client knows what to expect and understands the process, he or she will feel less anxious and will be able to focus better on the session. This will increase the chances that the client will come back for the HIV test result.

Be professional and respectful toward the client. It is important that you establish a cooperative atmosphere where you and the client are both committed to addressing risk-reduction issues. Recognize that sex behaviors and drug use behaviors may be sensitive and difficult issues for the client to discuss.

Repeat testers. If you see a client who has been tested before, especially a client who has been tested multiple times, he or she may feel that the counseling is unnecessary. The repeat tester may believe that he or she knows about all types of risk for HIV. The RESPECT HIV Prevention Counseling model is *not* about educating a client about risk, but increasing the client's understanding about *his or her own personal risks* and taking a step to reduce those risks. Thus, it is very important to let repeat testers know that this counseling is not about risks per se, but about the client, and his or her personal risks and behaviors. For this reason, you will want to focus educational discussions on the client's misconceptions.

Conduct the rest of the session as described on the following pages. If a change needs to be made, explain the reason to the client.

Component 1. Introduce and Orient Client to the Session		1–2 mins.
Protocol Prompts	Example Dialogue	
1. Introduce yourself to client	<ul style="list-style-type: none"> Hello, my name is _____. Since you've decided to have an HIV test, I'm going to be talking with you about your risk for HIV and some of the concerns that you might have about that. 	
2. Explain the role of the counselor	<ul style="list-style-type: none"> My role as a counselor is to help you explore those risks and look at ways that you might be able to do things differently to protect yourself. 	
3. Indicate the duration of the session	<ul style="list-style-type: none"> We'll have about 20 minutes to talk together. Everything we say here will be completely confidential. 	
4. Outline the content of the session a. Explore HIV (and STD) risks b. Identify challenges to risk reduction c. Discuss strategies to reduce risk	<ul style="list-style-type: none"> As I said, we'll be talking about your risks and concerns. Let me tell you what we'll be talking about. <ul style="list-style-type: none"> We'll talk about your risk(s) for HIV (and STDs). We'll look at how you have tried to reduce your risk. We'll talk about changes you could make to further reduce your risk and develop a plan for doing this. 	
5. Provide referrals	<ul style="list-style-type: none"> If we identify issues we can't address today, I'll make referrals that might help you. 	
6. Discuss activities with the client (including when the client will give laboratory specimens)	<ul style="list-style-type: none"> Before you leave, I will take you to the lab and someone will draw your blood for your test. 	

(continued)

Component 1. In Introduce and Orient Client to the Session (continued)

1–2 mins.

Protocol Prompts

Example Dialogue

7. Address immediate questions and concerns

- Before we go any further, what concerns or questions do you have?

COMPONENT 2. ENHANCE THE CLIENT'S SENSE OF SELF-RISK

Objective

Activities in this component will focus the client's attention on his or her risk behavior, increase his or her level of concern regarding these behaviors, and enhance his or her sense of personal risk.

Time: 2–3 minutes

Guidance

Focus on the client's main risk behavior and related circumstances. This discussion should help the counselor and client understand the client's behaviors. Focus the client on his or her main risk and the circumstances that affect that behavior. In some cases, clients may understand what behaviors are risky, but may not view their own behaviors as risky. Your discussion will shift based on the client's particular issues. Your first goal is to increase the client's sense of personal risk. Second, you should address any issues where the client's beliefs and behavior are at odds and any uncertainty about risk reduction.

Manage your feelings and discomfort. When you ask questions that increase the client's sense of personal risk or discuss when the client's behavior and beliefs are at odds, you may (or usually will) increase the client's realistic perception of risk. This may cause you to feel uncomfortable. You may want to avoid increasing the client's sense of self-risk. However, when you increase the client's understanding of his or her risk, you and the client are also setting the stage for developing a risk-reduction step that the client believes in and can successfully accomplish. Thus, this is a core element for conducting the RESPECT HIV Prevention Counseling model.

Use a client's request for STD/HIV services as the starting point. The client's presence in the clinic (or other setting) and request for STD/HIV services is the starting point for the counselor to address the client's risk. In this activity, the counselor is attempting to use the client's STD/HIV concerns to encourage him or her to examine HIV and his or her behavior. If this takes place in an STD clinic, the link between STD and HIV risk should be

emphasized. The process is intended to motivate the client to discuss HIV issues and concerns with the counselor.

For IDUs, confirm common terminology. For clients whose main risk is from injecting drugs, discuss and confirm common terminology for injecting. Unlike safer sex, clean or safe injecting is not necessarily common knowledge, and many people have different ideas about how to remain safe from HIV.

Component 2. Enhance the Client's Sense of Self-Risk		2–3mins.
Protocol Prompts	Example Dialogue	
1. Find out why the client has come for HIV (or STD) testing	<ul style="list-style-type: none"> • What brought you in today for your test? 	
2. Listen for and identify behaviors that are putting the client at risk for HIV (or STDs)	<ul style="list-style-type: none"> • What do you think may have put you at risk for HIV? • Do you practice safer sex? [If yes] Tell me what safer sex means to you. <p>If client reports injection drug use, you may ask</p> <ul style="list-style-type: none"> • Do you inject safely? • What does injecting safely mean to you? • Can you tell me step-by-step? [If necessary, ask the following:] <ul style="list-style-type: none"> ○ Do you share needles, syringes, cookers or spoons, cottons, and water for rinsing? ○ Do you reuse a needle or syringe after someone else has used it? ○ Do you ever add water or divide drugs with someone else's used syringe? 	
3. Assess the client's level of concern about having or acquiring HIV (or STDs)	<ul style="list-style-type: none"> • So, you know that the same things that put you at risk for [STD] can also put you at risk for HIV? • When you've had unprotected sex (or shared needles or other equipment), have you thought you might be putting yourself at risk for HIV or STD? • Which behaviors concern you the most? 	

(continued)

Protocol Prompts

Example Dialogue

<p>4. Discuss the client's HIV test history and behavior changes in response to previous test results</p>	<ul style="list-style-type: none"> • Have you been tested for HIV before? [If yes] What was that experience like for you? • How did the counseling or test results affect how you feel about HIV? • What did you and your counselor agree was placing you at risk for HIV?
<p>5. Assess whether the client is engaging in risky behavior because of previous HIV-negative test results</p>	<ul style="list-style-type: none"> • When you were tested for [HIV or an STD], did the counseling change your behavior in any way? • What have you done to stay negative since the test?
<p>6. Direct the client's attention toward risk behavior</p>	<ul style="list-style-type: none"> • From what you've said about your behavior, you could be at some real risk for HIV [if appropriate]. • It sounds like you have some HIV concerns that we should talk about today.
<p>7. Discuss examples of conflicts between the client's beliefs and behavior or examples of mixed feelings about risk reduction</p>	<ul style="list-style-type: none"> • Fortunately, we know that we can cure [STD], but there is no cure for HIV so far. I am wondering how having HIV would change your life? • You said earlier that you are concerned about HIV yet you had sex and didn't use condoms. Can you help me understand that? • You said you know your partner is shooting up yet you use condoms only some of the time. What makes you decide to not use them?

COMPONENT 3. EXPLORE THE SPECIFICS OF THE MOST RECENT RISK INCIDENT

Objective

The purpose of this component is to help the client understand the issues and circumstances that contribute to his or her most recent incident.

Time: 2–3 minutes

Guidance

Discuss the most recent incident in depth. Thoroughly discuss the most recent risk incident to help the client clarify, for the client and the counselor, how the risk incident occurred. To encourage the client to reflect on and examine his or her own behaviors, have an open and inquiring approach. In turn, this should stimulate the client’s curiosity, encourage him or her to reflect carefully on his or her behavior, and clarify how the incident(s) occurred.

Examine the frequency of risky behaviors. You will want to find out whether the risks are rare, ongoing, or episodic. If episodic, find out about the situations and circumstances that are associated with risk behavior. This discussion should help clarify for the client what led him or her to engage in risky behavior.

Work together to understand the context and patterns of risky behavior. Underlying circumstances may have contributed to the client’s decision to engage in risky behavior, especially if the behavior was unusual or “an accident.” Your questions should bring out a range of reasons for engaging in risky behavior. Emotions, recent life events (e.g., divorce, relationship break-up, death of a loved one), substance abuse, low self-esteem, and other issues may influence behavior. You and the client should work together to understand the context and patterns of the risk behavior.

Manage your feelings and discomfort. Discussing risk behavior may be difficult for both you and the client, and the tendency may be to discuss something other than the client’s risk incident. Sometimes discussions are redirected away from personal risk incidents to HIV risk in general (e.g., stating that unprotected

receptive anal sex is very risky). Remember to focus the conversation on exploring the client’s specific behaviors and circumstances.

Component 3. Explore the Specifics of the Most Recent Risk Incident		2–3mins.
Protocol Prompts	Example Dialogue	
<p>1. Explore the who, what, where, when, and how of recent risk incident</p>	<ul style="list-style-type: none"> • You said earlier that you came in for testing because you thought you had [STD]. Tell me a little bit about the last time you put yourself at risk for getting HIV or STDs. • Was that with someone you knew? • Where did you go to have sex (or inject)? • Was that something that happened before or was it out of the ordinary? • Is there a partner(s) that concerns you particularly? • Tell me a little about your partner (or the person you shared needles with). How did you meet this person? 	
<p>2. Assess the level of risk acceptable to the client</p>	<ul style="list-style-type: none"> • How comfortable were you with what happened? • Did you have any concerns about having sex (or sharing needles) with this person? • Could this person have had HIV?? 	

(continued)

Component 3. Explore the Specifics of the Most Recent Risk Incident (continued)

2–3mins.

Protocol Prompts

Example Dialogue

3. Assess communication about HIV with partner(s)

- Can you tell me what led up to having sex (or shooting drugs)?
- How did you decide to have sex (or shoot drugs)?
- Did you or your partner talk about using condoms (or new or clean needles or equipment or not sharing needles and equipment)?
- What did you and your partner talk about in terms of HIV risk or about being safe?
- Would you have engaged in the same behavior had you known this person had HIV? Tell me more.

4. Identify circumstances or situations that contributed to the risk incident

- What kept you from protecting yourself?
- When was the last time, before this situation, that you had a risky incident?
- Was anything similar about that situation?
- What was it about where you were or who you were with that allowed you to take this risk?

5. Identify vulnerabilities and triggers for the risk incident

- How does drinking alcohol or using other drugs influence your decision to have sex or to have sex without a condom (or share needles)?
- What do you think is the relationship between partying and having sex?
- What else is going on in your life that might be leading you to take risks?

6. Discuss examples of conflicts between the client's beliefs and behavior or examples of mixed feelings about risk reduction

- If you knew beforehand that [partner] had HIV, would you have had sex with him or her?
- Would knowing have made a difference?
- It sounds like HIV is really important to you and something you have a lot of concern about, and yet you are putting yourself in situations where you are at risk for HIV. Can you help me understand that a little more?

COMPONENT 4. REVIEW PREVIOUS RISK-REDUCTION EXPERIENCES

Objective

The purposes of this component are to discover and acknowledge a client's positive steps to reducing his or her risk of becoming infected with HIV, explore barriers to other ways the client could reduce his or her risks, and provide support for and reinforce the client's efforts in risk reduction.

Time: 2–4 minutes

Guidance

Discuss client's previous risk-reduction efforts and review risk behavior patterns. Ask about the client's patterns of risk behavior. Ask about any changes the client has begun to make to reduce his or her HIV risk. Support and reinforce any risk-reduction activities, no matter how small they are.

Tip! *Be sure to acknowledge and support any and all risk-reduction efforts.*

This discussion allows the client to talk about what he or she has done to reduce risk and the challenges he or she faced. It also provides you with insight about his or her strengths and difficulties in reducing risk for HIV, so you will be able to discuss the challenges of changing behaviors. Again, this may be a discussion that makes one or both of you feel uncomfortable. However, continue to focus the conversation on the client's personal and unique risk and behaviors.

Ask about friends' beliefs. If the client has difficulty discussing or articulating his or her experiences with HIV risk reduction, it may help to ask what the client's friends believe and do regarding HIV prevention.

Correct misconceptions as necessary. Provide information and correct critical misconceptions as needed to increase the client's sense of risk.

Protocol Prompts

Example Dialogue

1. Assess the client’s patterns of risk behavior (e.g., happening regularly, occasionally, due to an unusual incident) and establish the number of partners, type of partners, and number of new or different partners

- How often do you have sex with a new partner?
- Do you have sex (or share needles) more than once with any of those partners, like with a boyfriend or regular partner?
- How many different sex partners have you had in the past 3 months? [If yes] How about the past 6 months?
- How many different people have you shared needles or equipment with in the past 3 months? [If needed] How about the past 6 months?
- How often did you practice safer sex (or inject safely)?
- Where do you meet partners?
- How well do you know your partners before you have sex (or inject drugs)?

2. Identify successful attempts at practicing safer sex

- About how often do you use condoms (or clean needles)?
- How was [risk-reduction activity] for you?
- Do you remember a time when you chose to protect yourself by asking someone to use a condom or else not have sex (or clean needles or not inject)? Can you tell me about it?
- What made it work for you?
- It is great to hear you say that you have [describe risk-reduction effort].
- That reduces your chance of getting HIV.

(continued)

Protocol Prompts

Example Dialogue

3. Identify obstacles to risk reduction

- What do you think is the hardest thing about asking someone to use a condom?
- What is the difference between the times you have used condoms and the times you have not used condoms?
- What gets in the way of protecting yourself?
- What has been the most difficult part of reducing your HIV risk?
- With which partners do you find it most difficult to negotiate alternatives to sex or use of a condom (or using clean works or not sharing anything)?

4. Explore triggers and situations that increase the likelihood of high-risk behavior (if appropriate)

- Are there times or situations when you are more likely to take risks, e.g., not use a condom (or share needles and other equipment)? [If yes] What is the difference between the times you are safe and the times you are unsafe?
- Do alcohol and other drugs affect your decision to have high-risk sex? [If yes] Tell me about that.
- Are there particular people you find it difficult to negotiate with, to ask for safer sex (or to not share needles or other equipment)? Tell me about that.
- Are there times in your life (e.g., when you've felt depressed, been unemployed, or recently broken up with someone) when you felt it was more difficult to practice safer sex (or inject safely) to protect yourself?
- Tell me about what may be going on in your life that could be increasing your risk behavior.

5. Explore the client's communication about risk with friends and partners

- What do you and your friends talk about concerning HIV risks?
- When you talked about HIV risk reduction with a sex partner (or someone you inject with), how did the discussion go?
- Who brought up the topic?
- How did you feel about it?

(continued)

Protocol Prompts

Example Dialogue

6. Discuss the client's level of acceptable risk

- Are you comfortable with the risks you've taken?
- [If no] What would you be comfortable with?
- [If yes] This involves the risk of getting HIV, and you say you feel comfortable with that?
- What behaviors would you draw the line at?
- What do you consider too risky?

7. Discuss examples of conflicts between the client's beliefs and behavior or examples of mixed feelings about risk reduction

- The activities you say you feel comfortable with put you at some risk of becoming infected with HIV, yet you've said that you're concerned about HIV. It is important that we understand this.

COMPONENT 5. SUMMARIZE THE RISK INCIDENT AND RISK PATTERNS

Objective

The purpose of this component is to summarize and describe the client's risk behavior by identifying his or her patterns of risk behavior and noting specific things and situations that lead the client to high-risk behavior.

Time: 3–4 minutes

Guidance

Summarize risks and patterns. The purpose of this activity is to help the client understand the different situations that contribute to putting himself or herself at risk for HIV.

Be caring and nonjudgmental as you summarize his or her risks. Summarize with empathy and without judgment as this will help the client understand his or her behavior.

Convey a sense of urgency about the risk and the consequences of the behavior. The client needs to understand how his or her beliefs and actions affect his or her risk. Some counselors avoid communicating a sense of urgency because they fear being perceived as judgmental, but you can do it while showing that you care. For example, you can say, “It sounds like you are doing a lot of risky things. I’m really concerned about that.”

This discussion not only gives an objective view of the client's situation and also may increase the likelihood of the client working with you to develop a step-by-step plan for reducing his or her risk for HIV. This activity forms the basis for developing a risk-reduction step.

Component 5. Summarize the Risk Incident and Risk Patterns

3–4 mins.

Protocol Prompts

Example Dialogue

1. Provide feedback about the client's risk for HIV

- It's great that you are thinking about what is risky and what is not risky, and are taking some steps toward reducing your risk.
- From what you have told me, there have been _____ [quite a few, some, a couple of] risk situations that may have exposed you to HIV. It's really important that we work together to address this.

2. Summarize the information the client has provided

- Here's how I understand your risks for HIV and STDs. First of all, you came in because [name reason for coming in. Retell the client's story as clearly as possible, making connections between issues and situations, and summarizing the key issues identified by the client.]
- Does that sound right?

3. Note the pattern of risk behavior

- Let's talk about how often these risks happen. First, you've been able to protect yourself when [list circumstances that help the client reduce risk]. Is that right?
- However, when you [describe circumstance], you slip and find yourself engaging in risky behaviors. It is important that we understand this.

(continued)

Protocol Prompts

Example Dialogue

4. Identify triggers and things that make the client vulnerable

- Several things seem to have been going on in your life lately that affect your risk: [list issues you have learned from the client].
- In terms of relationships, there seem to be a few important issues: [list issues you have learned from the client]. In the future, you would like your relationships or life to be [describe].
- Several issues affect your risk behavior: [list specific behavior, communication, or substance-use issues].
- You seem more likely to engage in risky behavior when you _____ [drink, go to bars, travel, fall in love, meet someone new, other, lack needles, suffer withdrawal, other].
- Is this how you see your risk behavior?
- Does this make sense to you?
- Are there other issues we need to talk about?

5. Discuss examples of conflicts between the client’s beliefs and behavior or examples of mixed feelings about changing behavior

- You said that you would be less worried today if you had used condoms (or clean needles) more often in the past. How do you think you can work through that?
- How do you think you could make it happen?

6. Convey concern and urgency about the client’s risks (as appropriate)

- If you don’t make some changes, you could be putting yourself at risk continually, and that really concerns me.

7. Encourage and support the client in addressing risk issues

- Getting an HIV test and talking with me is a really great place to start because it shows you are taking care of yourself and doing something positive.

COMPONENT 6. NEGOTIATE A RISK-REDUCTION STEP

Objective

In this component, you and the client will negotiate a specific and incremental HIV risk-reduction step that the client can take.

Time: 4–5 minutes

Materials for the session:

1. Risk-Reduction Step form (see *Figure 2*)

Guidance

Support the client in developing a risk-reduction step. This risk-reduction step is an important aspect of the prevention counseling session. Help the client select a single behavior that he or she truly wants to change, is able to change, and is appropriate for his or her main risk. Provide support and encouragement to the client for developing a risk-reduction step.

Ask the client to be specific about the step. The step must be stated in small, detailed actions to ensure that the client can do it before the next session. The step should also be specific to one aspect of the client’s risk behavior. Avoid supporting a risk-reduction step that involves unreasonable or radical changes in the client’s life. As a result of an increased awareness of the HIV risk, the client may desire to curtail all risky behaviors, which may not be realistic. Global changes—such as “always use condoms”—are often *not* appropriate. Changes such as “always carry condoms,” “talk to partner about being faithful,” or “call the drug treatment program” are appropriate.

Ensure that the client agrees with the step and is committed to it. To increase the likelihood for success, you may discuss with the client potential problems or barriers and ways to overcome them. You may also role-play potential problems and develop a back-up or alternative step.

Write the step down. Write the client’s risk-reduction step on the Risk-Reduction Step form (see *Figure 2*). On the reverse side of the Risk-Reduction Step form, there is an appointment reminder

for the next session. It is helpful to document the step in your counselor's notes so you can review it before the next visit.

If the step puts the client's relationships or safety at risk (e.g., married and planning to use condoms with casual partners), consider cautioning the client about keeping the card in a safe place.

Figure 2. Risk-Reduction Step Form

Front	Back
	Space for counselor/agency to write down contact information
	Appointment
	Day _____ Day (mm/dd/yyyy)
	Time: _____
	Address: <input data-bbox="1040 1169 1395 1218" type="text"/>

Protocol Prompts

Example Dialogue

<p>1. Prioritize risk-reduction behavior</p>	<ul style="list-style-type: none"> • What do you think are the most important things to look at, the most important circumstances to address to reduce your risk? • Given what we've talked about, what do you think makes it most likely that you'll put yourself or others at risk?
<p>2. Explore behavior(s) that the client will be most motivated about or capable of changing</p>	<ul style="list-style-type: none"> • Realistically, what could you do to reduce your risk? • How would you most like to reduce your risk for HIV? • What do you believe you could reasonably do to reduce your risk? • [If the client selects a radical "always" or "never" approach] It's great that you really want to eliminate your risk. We know that change usually occurs in small steps. What would be the first step in reaching this goal? • [If the client is at a loss regarding how to reduce risk] You have some options for reducing your risk: [suggest some options].
<p>3. Identify a reasonable, yet challenging, step toward changing the identified behavior</p>	<ul style="list-style-type: none"> • Can you think of one small step you could complete in the next week that would move you closer to reducing your HIV risk?
<p>4. Break down the risk-reduction step into specific, concrete actions</p>	<ul style="list-style-type: none"> • You've identified something that you feel you can do. How are you going to make this happen? • What do you need to do first, second, third? • When do you think you could do this?

(continued)

Component 6. Negotiate a Risk-Reduction Step
(continued)

4–5 mins.

Protocol Prompts

Example Dialogue

<p>5. Problem-solve issues concerning the step</p>	<ul style="list-style-type: none"> • What might make this step more difficult? • What could help make it easier for you? • How will you handle it if something [specify] gets in the way of you trying this step? • What would be a good back-up step?
<p>6. Role-play the step (if applicable)</p>	<ul style="list-style-type: none"> • Let's practice how you'll handle this. Imagine that I am your partner. What would you say? • Let's switch roles.
<p>7. Identify supports for the risk-reduction step</p>	<ul style="list-style-type: none"> • What would help make this step easier for you? • Who would be supportive of you trying this? • How would you feel if you could complete this step?
<p>8. Confirm with the client that the step is reasonable and acceptable</p>	<ul style="list-style-type: none"> • How realistic does this sound? • How comfortable are you with this step? • How does it feel? If we need to, we can rework the step. • You will really have done something good for yourself by trying out this step. How committed are you to trying this?
<p>9. Acknowledge that the step is a challenge and that there will be an opportunity to review it in the follow-up session</p>	<ul style="list-style-type: none"> • It seems like you are committed to doing this. You really want to protect yourself and this is a great way. • Changing behavior takes time and practice. This is challenging—take it in small steps. A small change is the beginning of a larger one. • We'll review this step when you come back for your test result. You might encounter some problems, or something might come up that you didn't anticipate. Just pay attention to those things.

(continued)

Component 6. Negotiate a Risk-Reduction Step
(continued)

4–5 mins.

Protocol Prompts

Example Dialogue

10. Ask the client to try to be aware of strengths and weaknesses in the step while trying it out

- Try to notice what works and what doesn't work for you. Think about what might work for you more easily, and we will review it next time.

11. Document the risk-reduction step, keeping a copy for yourself

- Let's write it down on this piece of paper so you will have a reference for the coming week. Just a quick review, what is your step?

COMPONENT 7. IDENTIFY SOURCES OF SUPPORT AND PROVIDE REFERRALS

Objective

The purpose of this component is to identify resources that will help increase the client's ability to reduce risk.

Time: 1–2 minutes

Guidance

Discuss support and referrals. The purpose of this activity is to identify peer, community, and professional support for HIV risk reduction. Explore possible sources of support with the client.

Avoid overwhelming the client with multiple referrals. A single, appropriate referral is often more effective than several referrals to multiple support services. The referral may be part of the risk-reduction step. However, a referral should not be the client's entire risk-reduction step, unless no alternative is possible.

Referral Resource List

Your referral resource list should contain information on as many resources as possible. Examples of appropriate resources include, but are not limited to

- Alcohol and drug treatment programs
- Crisis intervention hotlines
- Emergency food sources
- Family planning clinics
- Financial assistance sources
- Free health care clinics (for persons without insurance)
- HIV treatment specialists
- Housing programs
- Legal aid sources
- Mental health professionals
- Services for sexually or physically abused persons

- Support groups and intensive HIV prevention intervention organizations
- Transportation programs

For each resource, your list should specify

1. Name of the provider or agency
2. Range of services provided
3. Target population(s)
4. Service area(s)
5. Contact names, telephone and fax numbers, street addresses, email addresses, Web site(s)
6. Directions, transportation information, and accessibility to public transportation
7. Hours of operation
8. Cost for services
9. Eligibility criteria
10. Application materials
11. Admission policies and procedures
12. Competence in providing services appropriate to the client's culture, language, gender, sexual orientation, age, and developmental level
13. Previous client's satisfaction with services

Component 7. Identify Sources of Support and Provide Referrals

1–2 mins.

Protocol Prompts

Example Dialogue

<p>1. Assess the client’s support system</p>	<ul style="list-style-type: none"> • Is there anybody in your life that you talk about those things with or get support from? • Is he or she a good person to talk to? • Is there someone who you feel you can talk with about your feelings and concerns? • Do you have people you spend time with? • Are these people you feel close to?
<p>2. Address the long-standing or tough-to-manage issues that contribute to risk</p>	<ul style="list-style-type: none"> • Your step sounds really good. We’ve identified some important issues that lead to your taking risks, specifically [name issue]. • Have you considered getting professional help with this to help reduce your HIV risk?
<p>3. Assess the client’s willingness to seek professional help or use a referral</p>	<ul style="list-style-type: none"> • Have you ever sought assistance, such as counseling, a support group, or substance abuse treatment? • How interested would you be in getting a referral for professional help to deal with this issue? • What would be hardest about seeking support for [name of issue]?
<p>4. Evaluate the types of referral the client would be most receptive to</p>	<ul style="list-style-type: none"> • Would you be more comfortable in one-on-one counseling or in a support group? • Is there a particular type of support or service you would consider using?
<p>5. Provide appropriate referrals</p>	<ul style="list-style-type: none"> • Here is the name and phone number of the service you should call to get assistance. • When do you think you could call or go there?

COMPONENT 8. CLOSE THE SESSION

Objective

The purpose of this component is to motivate the client to come back for the next appointment.

Time: 3–5 minutes

Guidance

This closing activity should help ensure that the client comes back for the HIV test result, so take the time to see how he or she best keeps appointments. Write the appointment day, date, time, and location on the back of the Risk-Reduction Step form. If your organization tracks clients for follow-up and the testing is confidential (not anonymous), ask for contact information.

This is a key opportunity to motivate the client to come back for the test result. If the client seems anxious about getting the result, encourage him or her to bring a friend or family member when he or she comes back for the next session, although the client may not be able to have anyone with him or her when he or she hears the results.

A note about post-Session 1 activities. After the session, complete necessary paperwork and direct the client to testing. Follow federal, state, and agency-specific guidelines for this process.

Component 8. Close the Session		3–5 mins.
Protocol Prompts	Example Dialogue	
1. Review the follow-up schedule with the client	<ul style="list-style-type: none">• It's important that you come back for your follow-up appointment.	
2. Identify ways for the client to remember follow-up appointment	<ul style="list-style-type: none">• What would help you remember to keep this appointment?• Do you keep a date book or calendar you can write the appointment in?	

(continued)

Protocol Prompts

Example Dialogue

3. Write down appointment and confirm contact information

- Is [day, date, time] okay?
- I am going to write your appointment down on the back of the piece of paper you wrote your step on so you will have it for easy reference.
- Let me make sure that you know how to contact me should you need to change the appointment.
- [If you trace clients and the testing is confidential] Let me be sure I know how to reach you [review phone number, address]
- [For anonymous testing] Remember, since there is no way we can contact you or know which result is yours, it is very important for you to come in for your next appointment for your test result. Also, please bring your ID number for the test result.

4. Proceed with your organization's guidelines to obtain specimen for HIV test

- Before we end this session, I need to take a moment to fill out a form and, if necessary, ask you a few additional questions. [Quickly fill out state-specific HIV surveillance form silently and ask any questions you don't have answers for.]
- Thank you for coming in to talk with me today. You have done a lot of hard work. And I think you have made a step that will really work for you. At our next meeting, I will give you your HIV test result, and we will go over how your risk-reduction behavior change went. It will take about 20 minutes.

Session 2a: Negative HIV Test Result: Prevention Counseling

SESSION 2

Protocol Components	Time (in minutes)
1. Provide negative HIV test result	2–10
2. Review the risk-reduction step	4–5
3. Revise the risk-reduction step	4–5
4. Identify sources of support	1–2
5. Provide referral and end the session	1–2
Total Time	12–24

Tip! *Most clients who receive their results will be HIV negative. However, this is still a key opportunity for you to help the client reduce his or her risks. **Don't cut this session short.***

Before the session:

- Review the notes from Session 1.
- Review the specific details of the risk-reduction step and the client's particular issues and vulnerabilities that may affect his or her attempt at changing HIV-related risk behaviors.
- Verify that the HIV test result is for this client. If the HIV test is positive, see page 53 for the protocol for clients with a positive test result.

COMPONENT 1. PROVIDE NEGATIVE TEST RESULT

Objective

The purpose of this component is to provide the negative HIV test result, emphasize risk reduction, and support the client's efforts to reduce his or her HIV risk.

Time: 2–10 minutes

Guidance

Provide the result in a calm and forthright manner at the very beginning of the session. The client may be very anxious to receive his or her test result. Greet the client warmly and then proceed with the session. Based on your sense of the client, ask if the client has concerns or questions before you provide the test result. The second session should then build on work started in the first session.

Provide the test result in simple terms, avoiding technical jargon. The client may be very relieved to receive the negative test result. Allow the client to experience his or her relief. At the same time, emphasize the need to continue behaviors that keep him or her safe and, if necessary, to take on other behaviors to remain safe. Talk about the client's feelings and beliefs about his or her negative test result, especially as they relate to the risk behavior described by the client in the previous session.

For some clients, a negative test result may make them feel more inclined to engage in high-risk behavior because they may believe that the test result is an indication that they made the “right choices.”

Discuss client's partner(s). Remind the client that the negative test result does not mean that the client's sex partner(s) is (are) not infected. Also, a negative test does *not* mean that the client is immune to HIV or that his or her behavior is less risky than the first session indicated.

Retest. With clients who have had a significant recent risk, a brief explanation of the possible need for retesting is important, but do not emphasize this too much and avoid any jargon such as the term “window period.” Counselors must be very careful with their

retest message. Too much attention on retesting detracts from the risk-reduction process and often distracts the client from the true meaning of the HIV-negative result.

If appropriate, remind the client that the current result does not cover any recent exposure. If a client has been exposed to HIV recently, recommend a retest and tests for STDs, at 3 months after the incident. If the client has not engaged in any high-risk behavior in the previous 3 months, then there is no need for an additional test.

Component 1. Provide the HIV Test Result		2–10 mins.
Protocol Prompts	Example Dialogue	
1. Welcome the client back	<ul style="list-style-type: none"> Welcome back. It's great to see you. How was your week? 	
2. State result clearly and simply	<ul style="list-style-type: none"> Now, let's look at your test result, and then we'll talk about how to best understand it. Are you ready to see it? The test result is negative, which means, as of 3 months ago, you had not been infected with HIV. 	
3. Review the meaning of the result	<ul style="list-style-type: none"> That means that you weren't infected as of 3 months ago. If you haven't had any risk exposures (i.e., unprotected sex, shared needles or other equipment) in the last 3 months, you don't have HIV. 	
4. Assess the client's reaction to the result	<ul style="list-style-type: none"> How does it feel to get a negative test result? What does this result mean to you? 	

(continued)

Protocol Prompts

Example Dialogue

5. Note the need to consider the test result in terms of the most recent risk exposure

- [If exposure occurred within 3 months] Given that you've had unprotected sex (or shared needles or other equipment) within the past 3 months that made you want to get tested for HIV, you may want to consider taking another HIV test on [3 months from exposure date].
- I know that waiting and going through this process again is tough. But, if you can stay protected for the next 3 months, you will have a definite answer. Otherwise, you might want to consider testing on a regular basis.
- Given your most recent risk, do you feel you need to get tested again?
- [If exposure occurred more than 3 months ago] Given your exposure was more than 3 months ago, there is no need to get tested again unless you have another potential exposure.

COMPONENT 2. REVIEW THE RISK-REDUCTION STEP

Objective

In this component, you and the client review the step the client agreed to take to reduce his or her risk, and his or her experience with carrying out the risk-reduction step. Another objective is to support and reinforce attempts by the client to put the step into action.

Time: 4–5 minutes

Guidance

Consider their risk circumstances as you review the risk-reduction step. The purpose of this component is to review the risk-reduction step. At the end of the session, you will come back to this idea by coming up with a new risk-reduction step. Not all clients will be able to perform their risk-reduction step for a variety of reasons. Be sensitive to the reasons the client was unable to carry out the step and remember them when you discuss a new risk-reduction step later. At the same time, convey a sense of urgency about any risky behavior.

Provide support and encouragement throughout the session.

You will probably provide encouragement or support when you assess the client's efforts to try out a risk-reduction step and when you identify supports for and barriers to a risk-reduction step. Further, depending on how successful and unsuccessful the client is with the risk-reduction step, you will need to adapt the questions accordingly.

Remember to reinforce any achievements—clients can build on achievements far more than they can build on failures.

However, sometimes clients have had problems and difficulties and were never able to achieve a risk-reduction effort. Support the client by noting that he or she came in for the session.

Protocol Prompts	Example Dialogue
<p>1. Assess the client's efforts to try out the risk-reduction step</p>	<ul style="list-style-type: none"> • What were your thoughts or reactions to last week's session? • How was/is it waiting for your result? • In the last session, we discussed some of your risks for HIV [list risks]. • We came up with a risk-reduction step for you to try before today's visit. How did that go for you? • Were you comfortable with how it went?
<p>2. Provide encouragement and support for client's risk-reduction efforts (as appropriate)</p>	<ul style="list-style-type: none"> • Sounds like you did a great job. • It's great you were able to do that. • I'm impressed with how you handled that. • You've really accomplished something for yourself. • [If not completed] Sounds like you had a hard time with it. I am glad that you came back today.
<p>3. Identify supports for and barriers to the risk-reduction step</p>	<ul style="list-style-type: none"> • How did you feel when you took the step to reduce your risk? • What parts of the step worked best? • Which parts of the step were challenging? • What stopped you? What made it difficult? • What were you feeling or thinking? • What would make it easier for you?
<p>4. Problem-solve issues concerning the step (if relevant)</p>	<ul style="list-style-type: none"> • How can we address the problems you had with reducing your risk? What would help you get this done?

COMPONENT 3. REVISE THE RISK-REDUCTION STEP

Objective

The purpose of this component is to renegotiate a new or revised risk-reduction step.

Materials for the session:

1. Risk-Reduction Step form

Time: 4–5 minutes

Guidance

Encourage the client to attempt an additional, more challenging step toward reducing risk. If the client encountered difficulty with the previous step, help him or her revise it. Together, refine the step as necessary, aiming toward a step that the client will be able to carry out.

Component 3. Revise the Risk-Reduction Step		4–5 mins.
Protocol Prompts	Example Dialogue	
1. Revise or develop a new step with the client	<ul style="list-style-type: none">• [If step was completed] You did an excellent job with the first risk-reduction step. What else could you try to further reduce your risk of getting HIV? What more do you think you could do?• [If step was not completed] What could you try that will reduce your risk of getting HIV?	
2. Discuss a more challenging step or revise the previous step	<ul style="list-style-type: none">• Remember that risk reduction and behavior change are best done in small, achievable steps. What do you need to do next to reduce your risk?	
3. Identify or clarify actions to achieve the step	<ul style="list-style-type: none">• Let's look at the issues that need to be addressed to reduce your risk and complete your new plan. [List issues]• What do you need to do first, second, third?	

(continued)

Protocol Prompts	Example Dialogue
<p>4. Confirm with the client that the step is reasonable and acceptable</p>	<ul style="list-style-type: none"> • Now, is this something you really feel you can do? • You need to feel that it will work for you.
<p>5. Document the revised risk-reduction step and give a copy to the client</p>	<ul style="list-style-type: none"> • Just as before, we'll write your step on this card, and we'll include all the actions needed to complete it. <i>[Write out actions.]</i> • Sometimes just looking at the card can help you remember the step and help you see yourself completing the step.
<p>6. Ask the client to be aware of strengths and weaknesses in the step while trying it out</p>	<ul style="list-style-type: none"> • When you try this step, think about what feels good and works for you, and which parts are hard or uncomfortable. • Try to think about how to improve or modify the step so it works better for you.
<p>7. Let the client know you have confidence in his or her ability to complete the step</p>	<ul style="list-style-type: none"> • Remember that doing something differently is sometimes awkward, but it gets easier with practice. • Changing behavior takes time and practice. Be patient with yourself. • This is a step you've come up with. It's a good step, and I believe it's something you can do. Revise the step if you need to in order to succeed. • You've really challenged yourself.

COMPONENT 4. IDENTIFY SOURCES OF SUPPORT

Objective

The objective of this component is to identify resources that will help increase the client’s ability to reduce risk.

Time: 1–2 minutes

Guidance

This activity is intended to identify peer and community support for the client’s HIV risk-reduction step.

Component 4. Identify Sources of Support for the Risk-Reduction Step		4–5 mins.
Protocol Prompts	Example Dialogue	
<p>1. Emphasize the importance of the client discussing with a trusted friend or relative the intention and content of the step</p>	<ul style="list-style-type: none"> • Since we will not be meeting again, it may be useful to share your step with someone who can support you in your efforts to reduce your risk. Who could you trust to tell about your visit here and talk with about this step? 	
<p>2. [If client didn’t talk to the trusted friend] Problem-solve</p>	<ul style="list-style-type: none"> • What do you think was the main reason you weren’t able to talk to this person? • What could you do next time to make sure you have a chance to talk to him or her about it? 	
<p>3. [If client didn’t identify someone last time] Identify a person to whom the client could comfortably disclose the step</p>	<ul style="list-style-type: none"> • Who in your life is supportive of you? • Could you talk with him or her about the step? • Who do you usually talk with about challenges you’re facing? • Do you and your friends ever talk about concerns about HIV? Could you talk with any of them about this step? 	

(continued)

Component 4. Identify Sources of Support for the Risk-Reduction Step (continued)

4–5 mins.

Protocol Prompts

Example Dialogue

4. Establish a concrete, specific approach for the client to use in sharing the step with a friend or relative

- So, you believe you could tell [name] about this step?
- It's important to tell [name] about your intentions concerning the step and then to report on how it went.
- When and how will you tell [name]?

COMPONENT 5. PROVIDE REFERRAL AND END SESSION

Objective

The objective of this component is to ensure that the client knows where or to whom to go for help and intends to follow up.

Materials for the session:

1. Referral note (not provided with RESPECT package)

Time: 1–2 minutes

Guidance

Support the client in seeking a referral. This component was covered in the first session, and you may cover it again here if you think the client is open to seeking professional services. If either you or the client identified a need for professional services (drug treatment, support group, mental health counseling, etc.), give specific provider names and phone numbers to the client. Provide referrals that are appropriate and comfortable for the client, and confirm that the referral is something the client is willing to consider. (For more information, see page 35).

Avoid giving too many referrals, as this may discourage the client. A single, appropriate referral is often better than referrals to several support services. The referral may help the client carry out the risk-reduction step, but should not be the risk-reduction step itself.

Protocol Prompts	Example Dialogue
<p>1. If a referral was provided in the previous session, follow up on the client's completion of the referral</p>	<ul style="list-style-type: none"> • [If a referral was provided in the previous session] When we talked last week, I gave you a referral to [name]. Were you able to call and make an appointment? <ul style="list-style-type: none"> ○ How did it go? • [If client did not complete the referral] What made it difficult to follow through? <ul style="list-style-type: none"> ○ What got in the way? ○ What can we do that will help you get the assistance you need?
<p>2. Address the long-standing or hard-to-manage issues that contribute to risk (optional)</p>	<ul style="list-style-type: none"> • Your step seems really good, yet some important issues contribute to your risk that may best be handled with the help or assistance of professionals. • Since we've talked about how [drug use and/or alcohol] affects your risk, since last time, have you considered getting help in dealing with this?
<p>3. Assess the client's willingness to seek professional help and use a referral (optional; repeat from Session 1)</p>	<ul style="list-style-type: none"> • What about seeking assistance (e.g., counseling or a support group, methadone treatment, Narcotics Anonymous)? Have you (re)considered this? • How interested would you be in getting a referral for services to deal with the issue? • What would be the hardest thing about seeking support for [name the issue]?
<p>4. Evaluate the types of referral the client would be most receptive to (optional)</p>	<ul style="list-style-type: none"> • Would you be more comfortable talking to an individual counselor or going to a support group? • Is there a particular type of support or service you would be willing to consider using?
<p>5. Provide appropriate referral (optional)</p>	<ul style="list-style-type: none"> • Here is the name and phone number of the agency you should call to get assistance with the issue we discussed. <ul style="list-style-type: none"> ○ Do you feel comfortable doing this? ○ Do you have any questions?

(continued)

Component 5. Provide Referral and End Session

1–2 mins.

Protocol Prompts

Example Dialogue

6. Provide closure

- Thank you for coming in for both sessions. If you have any concerns in the future, please don't hesitate to come by or call.

Session 2b: Positive HIV Test Result: Support and Prevention Counseling

SESSION 2

Protocol Components	Time (in minutes)
1. Provide positive HIV test result	3–5
2. Identify sources of support and provide referrals	4–10
3. Address risk-reduction issues (as appropriate)	2–5
4. Summarize and close the session	1–2
Total Time	10–22

Before the session:

- Review the client record and the notes from Session 1.
- Prepare appropriate referral options.
- Prepare yourself emotionally so you are able to manage discomfort while providing the positive test result.
- Verify that the HIV test result is for this client.

COMPONENT 1. PROVIDE POSITIVE HIV TEST RESULT

Objective

The objectives of this component are to ensure that the client is ready to receive the result, provide the positive test result, allow time for the client to absorb the meaning of the result, ensure that the client understands the result, and validate the client's feelings.

Time: 3–5 minutes

Guidance

Avoid “projecting” the result. The client may be very anxious to receive his or her result upon returning. Greet the client warmly and be careful not to “telegraph” the result by facial expression or body language.

Ensure that the client is ready to receive the result. After introducing yourself to the client and re-explaining confidentiality protections, ensure that the client is ready to receive the result. If not verified prior to the session, verify that the result is for this client.

Provide the test result in simple terms, avoiding technical jargon. Be sure the client clearly understands the test result.

Support the client in coping with the result. Some clients receiving a positive test result may enter a state of shock that allows them to respond but not retain information. Validate the client's feelings. Allow time for the client to get past this initial shock. Provide ample opportunity for the client to absorb, respond to, and ask questions about the test result.

Component 1. Provide Positive HIV Test Results 3–5 mins.

Protocol Prompts	Example Dialogue
<p>1. Welcome the client back</p>	<ul style="list-style-type: none"> Hello, my name is _____ and I will be your counselor today.
<p>2. Re-explain confidentiality</p>	<ul style="list-style-type: none"> As in your first session, everything we discuss here will remain confidential. That is, it will only be shared with those who have an absolute need to know. Everything here is protected and secured as any medical record.
<p>3. Verify that the result belongs to the client</p>	<ul style="list-style-type: none"> Let me check the numbers on your card with the numbers on the result to make sure this is your result.
<p>4. Assess client's readiness to receive result</p>	<ul style="list-style-type: none"> Are you ready to receive your result?
<p>5. Provide result clearly and simply</p>	<ul style="list-style-type: none"> This test shows that you do have HIV.
<p>6. Allow the client time to absorb the meaning of the result</p>	<ul style="list-style-type: none"> [Allow for silence.] Take your time. We have plenty of time to talk about the result.
<p>7. Explore client's understanding of the result</p>	<ul style="list-style-type: none"> What does this result mean to you?
<p>8. Assess how client is coping with result</p>	<ul style="list-style-type: none"> How are you doing? How are you feeling about this test result? What are you thinking right now?
<p>9. Address immediate concerns and fears</p>	<ul style="list-style-type: none"> I am wondering what I can do to help you deal with this result?
<p>10. Acknowledge the challenges of dealing with a positive result</p>	<ul style="list-style-type: none"> You may need time to adjust to this. What do you think you might do in the next few hours or day?

COMPONENT 2. IDENTIFY SOURCES OF SUPPORT AND PROVIDE REFERRALS

Objective

The purpose of this component is to identify existing support for the client and provide referrals to medical care and psychosocial, partner counseling, and risk-reduction support as appropriate.

Time: 4–10 minutes

Guidance

Identify support for reducing risks. Identify peer and community support for risk reduction. In addition to a medical referral, it is often helpful to identify any need for referrals to professional services (e.g. prevention case management, drug treatment, support group, mental health services) that will support risk reduction and coping with being HIV positive.

Assess client's receptiveness to referral. Provide a referral appropriate to client situation, gender, culture, and risk-reduction issue (for information on referrals, see page 35). Provide referrals consistent with the client's readiness to receive help and interest in using the services. Assess the type of service the client would be most comfortable with (individual or group setting, etc.). Help clients access referral services (e.g., give specific provider names and phone numbers, make the phone call to set up initial contact, explore barriers, provide links to childcare or transportation). Ensure that the client is not overwhelmed with numerous referrals. A single appropriate referral is often better than several referrals to various support services.

Component 2. Identify Sources of Support and Provide Referrals

4–10 mins.

Protocol Prompts

Example Dialogue

1. Assess whom the client would like to tell about his or her positive test result

- Who are the people you can go to for support?
- You'll want to tell someone you trust, someone who will keep your confidence.
- Who would you like to share your test result with?
- How can you inform your sex (or needle sharing) partner(s)?
- How do you think your partner(s) will react?
- What do you think he or she will say?
- How has he or she responded in the past when you needed his or her help?

2. Identify person, family member, or friend to help the client through the process of dealing with HIV

- a. Coping and support**
- b. Planning for the future**
- c. Medical follow-up**

- It is sometimes helpful to have someone to help you as you weigh options and make decisions.
- Who in your life could help you adjust to living with HIV?
- Paying attention to your emotional and physical health and your medical care are important parts of living positively. Who will support you in this?

3. Discuss wellness strategies

- What have you heard about how people live with HIV?
- People who take care of their health and have good medical care have a much better chance of staying well longer.
- Good care can help people live healthier longer. What have you heard about this (e.g., getting HIV medical treatment, eating well)?

(continued)

Component 2. Identify Sources of Support and Provide Referrals (continued)

4–10 mins.

Protocol Prompts	Example Dialogue
<p>4. Identify current health care resources</p>	<ul style="list-style-type: none"> • Where do you go now when you need medical attention? • When was the last time you received medical care? • How difficult is it for you to access care (transportation, resources, etc.)?
<p>5. Address the need for health care providers to know client’s test result</p>	<ul style="list-style-type: none"> • It is important that you discuss this test result with your doctor so he or she can give you the best care possible.
<p>6. Explore client’s access to medical services</p> <p>a. STD exam</p> <p>b. Routine medical care</p> <p>c. TB screening</p>	<ul style="list-style-type: none"> • Now that you have HIV, it is important for you to receive specific medical follow-up. • Other infections can make HIV more problematic. It will be important to get checked for STDs, TB, and other conditions. • Could I help you get a medical appointment?
<p>7. Identify needed medical referrals</p>	<ul style="list-style-type: none"> • We’ve talked about a lot. Now let’s prioritize the steps that you might take first. What medical care is going to be most difficult for you to access? • How can I help you with this?
<p>8. Assess client’s receptiveness to referral</p>	<ul style="list-style-type: none"> • How do you feel about me linking you up to some services that will help you?
<p>9. Help client access referral services</p>	<ul style="list-style-type: none"> • Here are some options for care. I can call now to set up an appointment. When would you like to go? • What might interfere with you keeping the appointment? • How will you get there? What time of day will be good? • What about childcare? • Call appropriate agencies, organizations, persons, if possible.

COMPONENT 3. ADDRESS RISK-REDUCTION ISSUES

Objective

In this component, you and the client address risk-reduction issues.

Time: 2–5 minutes (as appropriate)

Guidance

Refocus client to risk-reduction step. Depending on the state of the client and whether he or she will be able to discuss the risk-reduction step, bring up the topic and address the issue of risk reduction. If the client is not able to discuss this issue, skip to the next protocol component.

Encourage and support client strategies for risk reduction and disclosure to current and future partners. If the client is able to discuss risk-reduction issues, it may be helpful to discuss risk reduction and disclosure to current and future partners. It is often difficult to think about telling current and future partners that one is HIV positive. This section helps the client develop strategies to do so. Address obstacles to protecting others from HIV and protecting self from additional infections.

Component 3. Address Risk-Reduction Issues		2–5 mins.
Protocol Prompts	Example Dialogue	
1. Refer to client's risk-reduction step	<ul style="list-style-type: none">• What does this test result mean for your risk-reduction step?	
2. Assess client's plan to reduce risk of transmission to current partners	<ul style="list-style-type: none">• Tell me how you plan to protect yourself from STDs?• How will you protect partner(s) from HIV?• How will you be intimate and close without spreading HIV? What will you do about sex?	
3. Explore client's plan for reducing the risk of transmission to future partners	<ul style="list-style-type: none">• When you have a new partner, how are you going to protect that partner from HIV?	

(continued)

**Component 3. Address Risk-Reduction Issues
(continued)**

2–5 mins.

Protocol Prompts

Example Dialogue

4. Address disclosure of HIV status to current and future partners

- How are you going to tell your current partner, and any future partners, that you have HIV?

5. Encourage the client to protect others

- It is important for you to care for yourself and to protect others from HIV. You can prevent a lot of infection by being honest with your partners and ensuring you engage only in safer behaviors. What do you think your biggest challenge will be in talking to partners?
- How can we help prepare you for this?
- What will you say?
- What do you think the response will be?

COMPONENT 4. SUMMARIZE AND CLOSE THE SESSION

Objective

The counselor should provide support and close the session.

Time: 1–2 minutes

Guidance

Provide support and encouragement. Validate feelings. Offer continued support and encouragement. Ensure that the client is ready to terminate the session. Be sure that he or she knows how to contact you again.

Summarize issues discussed and follow-up needs. Discuss any referrals and the need for the client’s partner to be tested. Review how to contact client for follow-up. Ensure that the client knows what to do next. Elicit client plans for the next step after leaving this appointment.

Component 4. Summarize and Close the Session (continued)		1–2 mins.
Protocol Prompts	Example Dialogue	
1. Validate client feelings	<ul style="list-style-type: none">This can be overwhelming. At the same time, there are very few decisions you have to make right this minute.	
2. Summarize key issues addressed	<ul style="list-style-type: none">We linked you up with some additional resources and we talked about partners. I wonder if there is anything else we need to address before you leave?	
3. Review contact information and arrange for follow-up	<ul style="list-style-type: none">Let me just make sure that you know how to contact me if you need to.Let me be sure I know how to reach you [review address, phone number] so I can call and see how you are doing later.What is the best way to contact you?	

(continued)

Component 4. Summarize and Close the Session
(continued)

1–2 mins.

Protocol Prompts

Example Dialogue

4. Get the client's plans for the next step

- Where do you plan to go when you leave here? What about the **next** couple of days?
- Who will you talk to?

5. Close the session

- We have talked about a lot today. This can be a very difficult time. Take some time. Be kind to yourself as you adjust to this news. You may forget some of what we talked about, so be sure to call if you have questions later. And, remember, it is possible to lead a long and satisfying life.

Developing, Implementing, and Maintaining Quality Assurance

INTRODUCTION

Quality assurance is one of the core elements of the RESPECT HIV Prevention Counseling model and, as such, is critical to the integrity of this intervention. Quality assurance is an ongoing process that is intended to ensure that counselors deliver the RESPECT HIV Prevention Counseling model as it was delivered in the research project and described in this intervention package.

The Project RESPECT study found that this intervention resulted in significant reductions in sexually transmitted disease (STD) rates and increases in use of condoms among study participants (see *Appendix B*). Although this research was conducted across multiple sites, comparable results were obtained across all of the sites because all sites followed quality assurance procedures.

This section provides **recommendations** on implementing and maintaining quality assurance in organizations that conduct HIV prevention counseling, testing, and referral services. It is included to assist these organizations with implementing this evidence-based intervention in a consistent manner.

QUALITY ASSURANCE FOR RESPECT

For the purposes of this RESPECT HIV Prevention Counseling package, the focus of quality assurance is on the delivery of the counseling intervention itself and does not include quality assurance protocol recommendations for other aspects of services such as testing, informed consent, or test decision counseling. For more information on quality assurance recommendations, see

CDC's Revised Guidelines for Counseling, Testing, and Referral (*Appendix B*).

Quality assurance involves assessment, feedback, and strategizing. These tasks can be carried out through a variety of activities, including

- Training and continuing education (for both counselors and supervisors).
- Regular observation, with follow-up feedback, of counselors delivering prevention counseling sessions.
- Review of records to ensure appropriate, accurate, and consistent documentation.
- Holding regular case conferences to discuss specific counseling sessions. Case conferences also serve as a means of developing staff skills and consistent delivery of the intervention.

STRATEGIES FOR IMPLEMENTING AND MAINTAINING QUALITY ASSURANCE

Training

The training includes workshops on the RESPECT HIV Prevention Counseling. The training reviews basic HIV counseling concepts and skills, reviews each session in depth, provides an opportunity for participants to practice RESPECT counseling, and reviews quality assurance activities. Training for RESPECT HIV Prevention Counseling also provides a setting in which counselors and supervisors can practice their skills.

Prior to taking the training on RESPECT HIV Prevention Counseling, counselors and supervisors should be trained in counseling skills and concepts, HIV basics such as information on transmission routes, and information on state and local policies. This training ensures that all counselors and supervisors have similar counseling background information and understand the basics of HIV counseling.

Regular Observation of Counseling Sessions

Observation of counseling sessions is the process in which a supervisor or senior counselor directly observes a session or reviews one by listening to an audiotape of a session. To ensure quality counseling, adherence to protocol, and consistency in delivery of the intervention by all counseling staff, it is recommended that sessions be observed or taped on a regular basis. Observation and feedback by supervisors or other senior counselors have proven effective in ensuring that counselors understand how to conduct the counseling and maintain the integrity of the protocol.

By observing counselors, a supervisor or lead counselor can assess whether they are following the protocol. Observation may also help in assessing the counselor's style of counseling and whether he or she is using key counseling concepts (e.g., open body language, nonjudgmental language). See *Appendix G* for the quality assurance forms.

Observation Procedures

Counselors can be observed by their supervisor in person or the session can be taped for later review. Either way, it is important that the client is aware of and agrees to the observation or recording of the session. Also, the client should understand that he or she can refuse to have the observer in the room and can ask the observer to leave at any time. If the counselor will be observed directly, the counselor should explain to the client that the observer will focus on the counselor's work during the session and not on the issues presented by the client.

To decrease any anxiety and help prepare the counselor, it is recommended that the observer schedule the observation ahead of time and discuss any anxiety the counselor may have concerning the observation process. It is also recommended that the observer attempt to sit in so that he or she is able to observe the counselor without interfering with the counselor-client interaction. The observer should avoid sitting in the client's or counselor's line of sight. It is critical that the counselor maintain control of the session; thus, it is recommended that the observer avoid any discussion during the session.

Taping of sessions can be advantageous because it is less intrusive. No other person has to be in the room. Also, it allows the counselor and the observer to review the tape together. This allows both the counselor and the observer to understand any issues about the session.

If the session is to be taped for later review, the counselor should explain to the client that

- The recording will be used for later review of the counselor, not the client.
- The tape will be listened to by a supervisor or other lead counselor.
- The tape will be erased or destroyed once the staff member has listened to it.
- The client has a right to refuse to be audio-taped.

Frequency of Observations

Guidelines for the frequency of observations appropriate to staff are provided below for both new and experienced counselors. It may be helpful for new counselors to observe a given type of counseling session five times prior to being observed conducting that type of session (see *Table 4*). When a new counselor begins conducting sessions, he or she should be observed by an experienced counselor or supervisor five times for each type of counseling session. If the entire agency is new to RESPECT HIV Prevention Counseling, supervisors and counselors might take turns observing each other, or they may seek technical assistance.

After training, periodic observation of counseling sessions is usually helpful to ensure high-quality work. Based on the number of clients your agency sees, or your agency's requirements, your organization may choose to vary the frequency at which counselors are observed. *Table 5* provides a potential schedule of observations for trained and/or experienced counselors. For example, a counselor who has implemented the RESPECT counseling model for six months or less should be observed once a week.

Table 4. Sample Observation Schedule for New Counselors in Training

	Number of Sessions to Observe Experienced Counselor	Number of Sessions to BE Observed
Session 1	5	5
Session 2 Negative	5	5
Session 2 Positive	1	1

Table 5. Sample Frequency of Observation for Trained/Experienced Counselors

	Experience Using the RESPECT Counseling Model		
	< 6 Mo.	6–12 Mos.	1+ Yrs.
Frequency of Observations	Once a week	Once a month	Quarterly

COMPLETING QUALITY ASSURANCE FORMS

Three quality assurance forms are enclosed for session assessments. The purpose of the observation is to evaluate adherence to intervention protocols. These forms will help provide feedback to counselors. The three forms—Session 1, Session 2 negative, and Session 2 positive—are tailored to the specific protocol and content of each session.

The shaded rows of the form represent the protocol components. The non-shaded rows are the specific tasks to be accomplished within each component. The forms are designed for the observer to note whether the counselor has or has not met the expectations for the component. The forms follow the structure and flow of the protocol in the counselor cards. Due to the nature of the counseling interaction, the client may present issues in a manner that does not follow the protocol order. Such a diversion from the flow of the protocol is not because the counselor failed to follow the protocol. However, a skilled counselor should be able to steer the session according to the protocol and get the discussion to follow the proper order.

The quality assurance forms include three ratings: “Achieved,” “Not Achieved,” and “Not Applicable.” In general, each protocol component is usually addressed in each session. A rating of “Achieved” reflects completion of a task and adherence to the protocol. If the task is missed or skipped entirely, the rating would be “Not Achieved.” The “Not Applicable” column is used when a component of the session is not relevant to a particular client.

POST-OBSERVATION ACTIVITIES

At the end of the observed session, it is recommended that the observer carefully review the form content to ensure completion. Because immediate feedback will be most useful, it is recommended that observers provide feedback to the counselor as soon as possible following the observed session. The assessment of the counselor’s work is a joint activity by the supervisor or senior counselor and the counselor and should be conducted in a supportive manner. If kept as record, it is recommended that the observation forms are filed in a manner that ensures confidentiality and security.

The following tips are provided to help the observing supervisor or senior counselor provide feedback:

- **Ask the counselor to provide feedback on what he or she thought went well and what could have been better.** This brings the counselor into the process, clarifies what the counselor perceives were the difficulties as well as the strengths of his or her observed session, facilitates agreement to the process, and expedites strategizing for staff development.
- **Be specific.** Specifically identify content and intervention delivery issues by component and, if possible, by the protocol prompt. The more specific feedback is, the more helpful it should be for the counselor’s development.
- **Identify aspects that need modification after discussing quality work.** In a supportive manner, discuss the “Not Achieved” aspects with minimal judgment or inference. This will help the counselor explore the observation and discuss alternative approaches to the situation. Focus on

things that the counselor can do something about and not about things over which the counselor has no control.

- **Focus on main areas that need strengthening.** This is especially important if the issue has come up before with the counselor. Focus on strengthening areas rather than on problems since it is easier to understand and use information on areas to strengthen. If a counselor has difficulty following the protocol, he or she may benefit from additional one-on-one coaching or more frequent observation. A counselor overwhelmed with corrective feedback may be unable to make any changes. If a counselor can improve in a number of areas, prioritize key issues rather than addressing all of them. This discussion should be done thoughtfully to ensure that it is collaborative and useful. Like the RESPECT counseling model, let the counselor come up with a step or steps to assist him or her in developing the knowledge and skill to provide this counseling intervention as intended.
- **Use information from the observations for potential discussion topics during the case conferences.** If the session was an especially interesting one, it might be useful to discuss it with a group.

REVIEW OF RECORDS

Your agency may already include reviewing records as part of its ongoing quality assurance procedures. The purpose of reviewing records for RESPECT is to ensure consistent documentation of counseling sessions and to have some indication of the session content. In addition to key testing data requirements such as demographics, date, consent, return of test result, etc. when delivering the RESPECT counseling session, data collected might include indicators such as:

- Main risks and circumstances related to client's most recent risk incident (to determine if the session focused on most recent risk and circumstance).
- Date of most recent risk incident.
- The risk-reduction step (to determine if it's realistic, incremental, and achievable).

- Referrals and rationale for the referral (appropriateness of the referral).

As part of your agency’s overall quality assurance and services evaluation activities, record reviews may also be part of your regular ongoing reviews of signed consent forms, documentation of completed surveillance and client demographic information, and timely submission of required forms to local or state health departments.

Providing Feedback About the Record Review

Because immediate feedback is most useful, it is recommended that supervisors provide feedback to the counselor as soon as possible following the record review.

Frequency of Record Reviews

For regular record reviews, follow your agency policies and procedures, or, if there are none, consider using the guidelines provided in *Table 6*. For example, counselors with less than six months of experience using RESPECT counseling could have their records reviewed twice each month.

Table 6. Sample Frequency of Record Reviews

	Experience Using the RESPECT Counseling Model			
	< 6 Mo.	6–12 Mos.	1–2 Yrs.	2+ Yrs.
Frequency of Record Reviews	Twice a month	Once a month	Quarterly	Twice a year

REGULAR CASE CONFERENCES AND/OR ONE-ON-ONE COACHING

Case conferences are meetings among counselors and staff either in a group or one-on-one for coaching purposes. They provide a place for supervisors and counselors to exchange constructive feedback. Case conferences also provide an opportunity to discuss important issues and create a collaborative and competent counseling team.

Case conference activities can vary. The following is a list of possible activities for a group case review. All of these activities provide an opportunity for counselors to learn from one another.

1. Present challenging, interesting, and especially effective sessions. When presenting a session, counselors should provide a brief description of the client and his or her situation, any unique client issues or concerns, an account of the session's content and adherence to the protocol, and the counselor's questions or concerns. Sessions should be conducted with respect to client confidentiality, minimizing specifics to protect client identification.
2. Role-play cases, particularly difficult cases, to strategize and practice new techniques.
3. Practice using package materials such as counselor cards and observation forms.
4. Discuss and review components of RESPECT counseling. For example, if counselors find that they are having problems discussing risk reduction, the supervisor might lead a discussion to identify specific issues and come up with ways to overcome the discomfort of discussing a client's risks.
5. Problem-solve alternative approaches to dealing with challenging clients and issues.
6. Develop or enhance counseling skills. Discuss difficult and emotionally laden sessions in a supportive environment.

If you are a supervisor or one of the counselors who is not presenting, provide feedback that is reinforcing and supportive. Discuss and review components of the protocol and strategize alternative approaches to dealing with challenging clients and issues. It may help to role-play to practice alternative approaches.

Frequency of Case Conferences

Case conferencing can be a very powerful tool for staff development and support. Scheduling conferences monthly to meet staff needs will enhance agency ability to develop and sustain consistent delivery of this intervention.

Appendix A: Acknowledgements

The Centers for Disease Control and Prevention (CDC) acknowledge the support provided by RTI International through a task order contract numbers 200-97-0621, 025 and 200-2002-00776, 006 for the development of this product. The *2-Session RESPECT HIV Prevention Counseling* model is one in a series of products sponsored by CDC's Prevention Research Branch—*Replicating Effective Programs*, which also includes:

Community Peers Reaching Out and Modeling Intervention Strategies (Community PROMISE)

Center for Behavioral Research and Services
California State University, Long Beach
1250 Bellflower Blvd (PSY 440)
Long Beach, CA 90840

Healthy Relationships

Community Prevention and Intervention Unit
University of Texas Southwestern Medical Center at Dallas
400 South Zang Blvd., Suite 520
Dallas, TX 75208

Mpowerment

Center for AIDS Prevention Studies (CAPS)
University of California, San Francisco
74 New Montgomery, Suite 600
San Francisco, CA 94105

Partnership for Health

Keck School of Medicine
University of Southern California
Norris CC
1441 Eastlake Ave., Suite 3409
Los Angeles, CA 90089-9175

Popular Opinion Leader (POL) and Project LIGHT

Center for AIDS Intervention Research (CAIR)
Medical College of Wisconsin
2071 North Summit Avenue
Milwaukee, WI 53202

Real AIDS Prevention Project (RAPP)

Family Health Council, Inc.
960 Penn Avenue, Suite 600
Pittsburgh, PA 15222

Street Smart

Center for Community Health
University of California, Los Angeles
10920 Wilshire Blvd., Suite 350
Los Angeles, CA 90024-6521

TLC

UCLA Neuropsychiatric Institute
Center for Community Health
10920 Wilshire Blvd., Ste. #350
Los Angeles, CA 90024

**Video Opportunities for Innovative Condom
Education and Safer Sex (VOICES/VOCES)**

Education Development Center, Inc.
55 Chapel Street
Newton, MA 02158-1060

**Appendix B:
Efficacy of Risk-
Reduction Counseling
to Prevent HIV and
STDs (Research Paper)**

Efficacy of Risk-Reduction Counseling to Prevent Human Immunodeficiency Virus and Sexually Transmitted Diseases

A Randomized Controlled Trial

Mary L. Kamb, MD, MPH; Martin Fishbein, PhD; John M. Douglas, Jr, MD; Fen Rhodes, PhD; Judy Rogers, MS; Gail Bolan, MD; Jonathan Zenilman, MD; Tamara Hoxworth, PhD; C. Kevin Malotte, DrPH; Michael Iatesta, MA; Charlotte Kent, MPH; Andrew Lentz, MPA; Sandra Graziano, PhD; Robert H. Byers, PhD; Thomas A. Peterman, MD, MSc; for the Project RESPECT Study Group

Context.—The efficacy of counseling to prevent infection with the human immunodeficiency virus (HIV) and other sexually transmitted diseases (STDs) has not been definitively shown.

Objective.—To compare the effects of 2 interactive HIV/STD counseling interventions with didactic prevention messages typical of current practice.

Design.—Multicenter randomized controlled trial (Project RESPECT), with participants assigned to 1 of 3 individual face-to-face interventions.

Setting.—Five public STD clinics (Baltimore, Md; Denver, Colo; Long Beach, Calif; Newark, NJ; and San Francisco, Calif) between July 1993 and September 1996.

Participants.—A total of 5758 heterosexual, HIV-negative patients aged 14 years or older who came for STD examinations.

Interventions.—Arm 1 received enhanced counseling, 4 interactive theory-based sessions. Arm 2 received brief counseling, 2 interactive risk-reduction sessions. Arms 3 and 4 each received 2 brief didactic messages typical of current care. Arms 1, 2, and 3 were actively followed up after enrollment with questionnaires at 3, 6, 9, and 12 months and STD tests at 6 and 12 months. An intent-to-treat analysis was used to compare interventions.

Main Outcome Measures.—Self-reported condom use and new diagnoses of STDs (gonorrhea, chlamydia, syphilis, HIV) defined by laboratory tests.

Results.—At the 3- and 6-month follow-up visits, self-reported 100% condom use was higher ($P < .05$) in both the enhanced counseling and brief counseling arms compared with participants in the didactic messages arm. Through the 6-month interval, 30% fewer participants had new STDs in both the enhanced counseling (7.2%; $P = .002$) and brief counseling (7.3%; $P = .005$) arms compared with those in the didactic messages arm (10.4%). Through the 12-month study, 20% fewer participants in each counseling intervention had new STDs compared with those in the didactic messages arm ($P = .008$). Consistently at each of the 5 study sites, STD incidence was lower in the counseling intervention arms than in the didactic messages intervention arm. Reduction of STD was similar for men and women and greater for adolescents and persons with an STD diagnosed at enrollment.

Conclusions.—Short counseling interventions using personalized risk reduction plans can increase condom use and prevent new STDs. Effective counseling can be conducted even in busy public clinics.

IN THE UNITED STATES, an estimated 580 000 people are infected with human immunodeficiency virus (HIV). New acquired immunodeficiency syndrome (AIDS) cases are declining among gay men and injection drug users but continue to rise among heterosexuals and women.¹ AIDS is now the leading cause of death for black women aged 25 through 44 years.² Among heterosexual patients attending publicly funded sexually transmitted disease (STD) clinics, HIV prevalence is 50% to 100% higher than in the general population.³

Recent therapeutic breakthroughs have led to marked improvement in morbidity and mortality for HIV-infected persons; however, treatment costs are high and there is still no cure.⁴ Sound policy recommendations for disease pre-

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A complete list of the members of the Project RESPECT Study Group appears at the end of this article.

Reprints: Reprint Services, Office of Communications, NCHSTP, Mailstop E-06, Centers for Disease Control and Prevention, 1600 Clifton Rd NE, Atlanta, GA 30333. Additional information is available at http://www.cdc.gov/nchstp/hiv_aids/projects/RESPECT.

JAMA. 1998;280:1161-1167



Figure 1.—Study visits were calculated from the enrollment date to occur at 3-month intervals. The first visit occurring during each calculated 3-month interval was considered as the follow-up visit. For the first follow-up visit (3-month visit), the interval began 7 days before the calculated date 3 months after enrollment and may have occurred up to 7 days before the calculated date 6 months after enrollment. HIV indicates human immunodeficiency virus.

vention depend on reliable efficacy data, preferably based on the results of well-conducted randomized controlled trials measuring disease outcomes.⁵⁻⁷ However, there are limited data supporting the impression that current HIV prevention strategies, including HIV/STD counseling, are effective in reducing new infections. In the case of HIV counseling, studies that have attempted to evaluate counseling efficacy have been limited by inadequate experimental designs, interventions, and outcomes.^{5,8,9}

Considerable debate has occurred on the content and duration of counseling necessary to achieve meaningful change in risk behaviors. Many HIV counseling programs focus on collecting risk data and providing general information about HIV/AIDS. However, a number of health professionals have argued that, for greatest benefit, counseling should be an interactive process aimed at personal risk reduction.¹⁰ Brief intervention strategies have been successfully applied in behavioral interventions for other health risks such as alcohol use,¹¹ but other experts maintain that changing sex behaviors requires multiple (ie, ≥ 10) intervention sessions.¹²

Project RESPECT was a randomized controlled trial specifically designed to as-

sess the efficacy of HIV prevention counseling in reducing high-risk sexual behaviors and preventing new sexually transmitted infections. We studied counseling approaches believed by experts to have the highest likelihood for success and, thus, evaluated risk reduction counseling models that used an interactive process between counselor and client. We were also concerned about feasibility and coverage of the interventions, and thus, we studied interventions that were acceptable to participants and able to be replicated in busy public clinic settings. This project evaluated one-on-one HIV/STD prevention counseling models—one with 4 sessions (200 minutes total) and the other with 2 sessions (40 minutes total). We compared the counseling models with each other and with brief, didactic messages that approximate the one-on-one prevention approach typically used in STD clinics and other HIV test sites.

METHODS

Study Design

The trial was conducted from July 1993 through September 1996 among patients from public, inner-city STD clinics in Baltimore, Md; Denver, Colo; Long Beach, Calif; Newark, NJ; and San Fran-

cisco, Calif, in collaboration with the Centers for Disease Control and Prevention (CDC), Atlanta, Ga. Eligible participants were HIV-negative men and women aged 14 years or older who came to one of the clinics for a full diagnostic STD examination and agreed to have an HIV test. Men who reported having a male sex partner in the past 12 months or who identified themselves as bisexual or homosexual were excluded from the study. All potential participants whose command of English would limit full participation in the interventions and those who had declined to participate in the study at earlier clinic visits were excluded also. All participants gave written, informed consent, and the institutional review boards at each site reviewed and approved the protocol.

Participants were assigned randomly to 1 of 4 intervention arms (Figure 1). Those assigned to arms 1, 2, or 3 were asked to return for follow-up appointments 3, 6, 9, and 12 months after enrollment. We included arm 4 to assess the possible intervention effects of repeated follow-up contacts, because it was speculated that these might be of sufficient magnitude to obscure differences between the interventions. Arm 4 participants had no follow-up visits scheduled after the intervention but results for syphilis and gonorrhea tests (routinely done at all 5 clinics) were obtained each time they voluntarily returned to the clinic during the 12-month study interval. To assess the effects of repeated contact, we excluded from the analysis STDs diagnosed for arm 3 participants at study-prompted follow-up visits, and we compared participants in arm 3 with arm 4 on the proportion for whom syphilis or gonorrhea was diagnosed at voluntary (unscheduled) visits. In addition, 12 months after enrollment, arm 4 participants were sought and, if located, interviewed. Their recent condom use was compared with arm 3 participants.

Randomization

Random assignment took place after enrollment and before the baseline interviews and examinations. Allocation concealment procedures were defined by protocol and complied with published recommendations.¹³ A data management company provided each site with opaque, sealed envelopes containing computer-generated random assignments. To ensure the numbers in arms were roughly equal, random assignments were made within blocks that varied in size from 4 to 20 and were done separately for men and women at each site. Once a number was assigned, it was not reassigned even if participants dropped out of the study.

Interventions

Participants were assigned to 1 of 3 individual face-to-face HIV prevention strategies that each involved an HIV test. All interventions encouraged consistent condom use for vaginal and anal sex with all partners; however, interventions were tailored to each individual's personal risks.¹⁰ For arm 1, the 4 sessions were completed within 4 weeks of enrollment. For arms 2, 3, and 4, both sessions were completed within 10 days. Whenever possible, the same counselor conducted all of a participant's sessions. The counselor conducting an intervention never collected outcome data for that participant. No interactive counseling was provided at follow-up visits; however, regardless of assigned intervention, whenever HIV tests were obtained counselors provided brief information about the test and answered any questions.

Patients assigned to arm 1 received enhanced counseling.¹⁰ This 4-session intervention, based on the theory of reasoned action and social cognitive theory,¹⁴⁻¹⁶ sought to change key theoretical elements (eg, self-efficacy, attitudes, and perceived norms) underlying condom use. Session 1 lasted 20 minutes and was conducted during the initial clinic visit; the remaining sessions were 60 minutes each. Test results for HIV were given during session 3. Each session built on lessons from the preceding session. The first 3 sessions concluded with a behavioral goal-setting exercise in which the participant arrived at a small behavioral risk-reduction step that could be achieved before the next session. At the final session, a longer-term, risk-reduction plan for each participant was agreed on.

Participants assigned to arm 2 received brief counseling, a 2-session intervention modeled after CDC's recommended HIV counseling for patients attending public clinics and HIV test sites.^{17,18} Session 1 (20 minutes) was conducted during the initial clinic visit and was identical to the first session of enhanced counseling. Session 2 (20 minutes) included a discussion of the HIV test result as well as additional counseling. The objectives of brief counseling were to assess actual and self-perceived HIV/STD risk, to help the participant recognize barriers to risk reduction, to negotiate an acceptable and achievable risk-reduction plan, and to support patient-initiated behavior change. The first session concluded with a behavioral goal-setting exercise in which the participant arrived at a small risk-reduction step that could be achieved before the second session. At the second session, progress in completing the behavioral step was reviewed, barriers and facilitators to completing the behavioral step were dis-

cussed, and a longer-term risk-reduction plan was developed.

Participants assigned to arms 3 and 4 received didactic messages. This 2-session informational intervention was designed to approximate what was being done in most STD clinics.¹⁰ Two brief messages about HIV and STD prevention were delivered, explicitly not engaging the participant in interactive counseling. Session 1 (5 minutes) was conducted by the clinician who had examined and treated the participant during the STD clinic visit. In session 2 (5 minutes), participants were informed about their HIV test results and limitations of the test and were given didactic prevention messages about HIV and STD pertinent to their reported risks. Participants were asked whether they had questions.

To ensure the quality and consistency of interventions, counselors and clinicians received a standard training course from a single trainer, used structured intervention protocols, and had routine observation and feedback by on-site supervisors and an outside observer who traveled to all sites (6% of the sessions were observed). In addition, process evaluations assessing intervention content and client satisfaction with the interventions were performed periodically by surveying participants, counselors, and clinicians.¹⁰

Study Outcomes

Principal outcomes were defined before the trial. Incident STDs were defined by laboratory tests, with gonorrhea defined as a positive culture for *Neisseria gonorrhoeae* or, for men, gram-negative intracellular diplococci on a Gram stain of a urethral swab; chlamydia as a positive *Chlamydia trachomatis* polymerase chain reaction from an endocervical (women) or a urine (men) specimen; syphilis as a suggestive history and physical examination with supportive treponemal and nontreponemal antibody test results; and HIV infection as a repeatedly reactive enzyme immune assay for HIV antibody with a positive confirmatory test result. Study clinicians collected specimens necessary for each of these tests from participants assigned to arms 1, 2, or 3, at the baseline, at 6- and 12-month visits, and at all voluntary (unscheduled) clinic visits. Specimens were also obtained at 3- and 9-month visits if participants or their sex partners had symptoms of an STD or if participants requested tests. Study clinicians used standard procedures to collect the study specimens and used an order specified by protocol. Specimen collection procedures were periodically monitored. Arm 4 participants returning to the clinic during a self-initiated visit underwent only tests routinely performed at the clin-

ics (ie, gonorrhea culture and syphilis serology). Participants found to have STDs at the baseline or subsequent visits were treated according to standard treatment guidelines and were advised (when applicable) about the importance of partner treatment.¹⁹ Participants found to have HIV were referred for early intervention services, available at all 5 clinics.

We planned to use self-reported 100% condom use during vaginal and anal sex as principal behavioral end points. However, anal sex was rarely reported. At enrollment, 10% of the participants reported having anal sex during the past 3 months and half of these reported only 1 episode. Thus, we used self-reported 100% condom use during vaginal sex with all sex partners as the principal behavioral outcome, measured as "no unprotected vaginal sex" (ie, either no sexual contact or condom use during every sex episode). Interviewers asked about behaviors during the preceding 3 months, including frequency of vaginal sex and condom use with primary and any other sex partners. We calculated condom use from the total number of times condoms were used and from the total number of sex episodes. Interviewers also asked participants about number of sex partners they had; about the risks of their sex partners; and about the participants' and partners' condom use beliefs, attitudes, self-efficacy, intentions, and perceived norms regarding consistent use of condoms. Participants in arms 1, 2, and 3 were interviewed at enrollment, immediately after the final intervention session, and at the 3-, 6-, 9-, and 12-month visits.

Incentives

For intervention sessions, participants were offered free condoms at every visit and \$15 for each session attended after the first session (ie, for enhanced counseling, a maximum of \$45, and for brief counseling and didactic messages, a maximum of \$15). For collection of outcome data, participants who returned for scheduled follow-up visits were offered \$15 for each questionnaire and \$25 for each STD examination. No incentives were given for voluntary (unscheduled) STD examinations, including those completed at the 3- and 9-month visits.

Data Analysis

Assuming 15% per year cumulative incidence of STD among didactic messages participants,²⁰ we calculated a recruitment goal of 6000 (1500 per arm) for 80% power to detect a 25% reduction in STDs between counseling and control arms. For preliminary analyses of principal outcomes, analysts were blinded to intervention arm. For all analyses, any patient as-

Table 1.—Baseline Characteristics of Participants According to Intervention Arm (N = 5758)*

Characteristics	Arm 1 Enhanced Counseling (n = 1438)	Arm 2 Brief Counseling (n = 1447)	Arm 3 Didactic Messages (n = 1443)	Arm 4 Didactic Messages (n = 1430)†
Sex, %				
Female	43	43	43	43
Male	57	57	57	57
Site, %				
Baltimore, Md	19	19	19	19
Denver, Colo	24	24	24	24
Long Beach, Calif	18	19	18	18
Newark, NJ	21	21	20	20
San Francisco, Calif	18	18	18	18
Report of previous HIV test, %	72	71	69	72
Report of previous STD, %	61	64	64	63
STD at enrollment, %	33	31	30	33
Injected drugs, %	2	2	1	2
Ever had a sex partner who had injected drugs, %	16	14	14	18
Ever had a known HIV-positive sex partner, %	2	1	1	2
Ever gave (men) or took (women) money for sex, %				
Men	8	7	6	8
Women	12	13	16	17
Sex partners last 3 mo, mean/median No.	2.1/1	2.3/1	2.5/1	2.4/1
At least 1 new sex partner in last 3 mo, %	49	46	48	48
Have a primary partner, %				
Men	76	75	77	76
Women	88	89	89	87
Have a nonprimary partner, %				
Men	61	60	59	61
Women	38	36	38	40
Vaginal sex episodes with a condom in last 3 mo, %				
None	38	38	38	38
1-49	24	23	25	26
50-99	23	25	24	24
100	16	13	13	12

*HIV indicates human immunodeficiency virus; STD, sexually transmitted disease.

†For arm 4, screening demographic data were collected on all participants, but full behavioral questionnaires were collected only on a sample (484 [34%]) of the 1430 participants.

signed a random number was included except for 75 persons whose baseline HIV test result was positive (Figure 1). Outcome analyses were performed using data on all participants, whether or not they completed their assigned intervention (intent to treat).^{20,21} For STD outcomes, we compared the cumulative percentage of participants with any STD from enrollment until the end of a specified visit interval. For behavioral outcomes, we compared the proportion of subjects reporting the behavior during the 3 months before each scheduled visit, first considering all participants who came to any follow-up visit and then only those who came to all 4 follow-up visits (51% of all enrolled). For comparisons between interventions, we used χ^2 tests, relative risks with 95% confidence intervals (CIs), and generalized estimating equations²² to account for correlations due to repeated observations on the same subject. In addition to the principal outcomes, we performed 5 subset analyses, stratifying on sex, site, age (≤ 20 vs ≥ 21 years), STD diagnosis at enrollment vs no STD, and report at enrollment of a prior HIV test vs no prior test.

RESULTS

Participants

From July 1993 through June 1995, 13 471 eligible patients were invited, and 5833 (43%) agreed to participate. After excluding 75 patients with positive baseline HIV test results, there were 3269 men and 2489 women (Figure 1). Study participants resembled the clinics' total populations in that they were young (median age, 25 years), minority (59% black, 19% Hispanic, 16% white, 6% other races), and low income (54% unemployed, 42% with annual income $<$ \$5000). Study participants and those who had refused were similar in age, racial and ethnic background, and education (median, 12 years). But compared with those who had refused, participants were more likely to be women (relative risk [RR], 1.49; 95% CI, 1.44-1.55), to have had an STD at enrollment (RR, 1.19; 95% CI, 1.14-1.24), and to have been previously tested for HIV (RR, 1.13; 95% CI, 1.08-1.18). The intervention arms were similar at baseline with respect to demographic characteristics, risk behaviors, condom use, and STD diagnoses at enrollment (Table 1).

Intervention Adherence

Of 5758 patients enrolled, 82% completed all assigned intervention sessions. Completion was lower ($P < .001$) for those in the 4-session enhanced counseling arm (72%) than for those in either of the 2-session interventions (brief counseling, 85%; didactic messages, 85%). For the enhanced counseling arm, 99% of participants completed the first session, 80% completed the second session, 72% completed the third session, and 72% completed all 4 sessions. Regardless of assignment, most participants ($>85%$) surveyed about the interventions reported that the sessions were "informative," "good," and "helpful."

Coverage at Follow-up Visits

Of the 4328 participants assigned to follow-up visits every 3 months, 71% returned for the 3-month, 70% for the 6-month, 64% for the 9-month, and 66% for the 12-month visits. Of all 4328 participants, 81% returned for at least 1 of the 4 follow-up visits; 73% for at least 2 visits; 63% for 3 visits; and 51% for all 4 scheduled visits. Return for follow-up visits did not differ significantly between intervention arms.

Intervention Efficacy Behaviors

At the follow-up visits, reported condom use and "no unprotected vaginal sex" increased substantially over baseline for all 3 interventions (Figure 2). At the 3- and 6-month visits the greatest increases were among those in the 2 counseling intervention arms, with enhanced counseling participants most frequently reporting any condom use (86%) and "no unprotected vaginal sex" (46%). At the 3-month visit, enhanced counseling participants reported "no unprotected vaginal sex" significantly more often than participants in the didactic messages control intervention arm (46% vs 38%; RR, 1.21; 95% CI, 1.09-1.35). This was also true for brief counseling participants vs didactic messages participants (44% vs 38%; RR, 1.15; 95% CI, 1.03-1.27). Differences in "no unprotected vaginal sex" between enhanced counseling and brief counseling were small (46% vs 44%; RR, 1.06; 95% CI, 0.96-1.17). Frequency of sex was similar among the interventions. At the 6-month visit, differences in "no unprotected vaginal sex" between interventions were less pronounced, although trends were similar (39% enhanced counseling vs 34% didactic messages; RR, 1.14; 95% CI, 1.01-1.28; and 39% brief counseling vs 34% didactic messages; RR, 1.12; 95% CI, 1.00-1.25). At the 9- and 12-month visits, any condom use and "no unprotected vaginal sex" were reported more

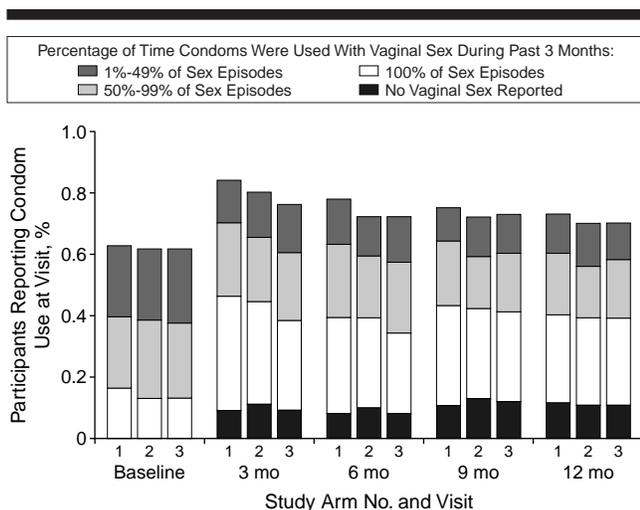


Figure 2.—Percentage of participants reporting condom use with vaginal sex during the preceding 3 months, baseline, and 3-, 6-, 9-, and 12-month visits.

frequently than at enrollment, but there were no significant differences among interventions. Considering only the 2732 participants who came to all 4 follow-up visits, we observed similar results. Using generalized estimating equations, we found enhanced counseling participants were more likely to report “no unprotected sex” than participants in the other interventions at 12 months ($P = .02$).

The interventions focused on consistent condom use, but we observed modest differences among them for some other “safe” behaviors (Table 2). At the 3- and 6-month visits, more participants in each counseling intervention reported safe behaviors compared with those in the didactic messages arm. For measures of condom use (eg, “any use” and “condoms with last sex”), enhanced counseling participants tended to report safe behaviors most often, followed by those who were assigned to the brief counseling arm and then those who were assigned to the didactic messages arm. But for safe behaviors unrelated to condoms (eg, “no casual partners” and “no new partners”), brief counseling participants tended to report safe behaviors most often, followed by those assigned to the enhanced counseling arm, and then by those assigned to the didactic messages arm. At the 9- and 12-month visits, there were no significant differences between the interventions.

Sexually Transmitted Diseases

Through the 12-month visit, a total of 549 participants (12.7%) were diagnosed as having a new STD, including 314 men (12.8%) and 235 women (12.6%). There were 271 participants (6.3%) diagnosed as having gonorrhea; 315 (7.3%) as having chlamydia; 25 (0.6%) as having syphilis; and 8 (0.2%) as having HIV. Some

participants had multiple diagnoses.

Fewer participants assigned to either of the interactive counseling intervention arms developed new STDs compared with participants assigned to the didactic messages control arm (Figure 3). Through the 6-month visit, 149 participants (10.4%) in the didactic messages arm had new STDs compared with 103 (7.2%) in the enhanced counseling arm (RR, 0.69; 95% CI, 0.54-0.88) and 107 (7.3%) in the brief counseling arm (RR, 0.71; 95% CI, 0.58-0.89). Through the 12-month visit, 211 participants (14.6%) in the didactic messages arm had developed new STDs, compared with 165 (11.5%) in the enhanced counseling arm (RR, 0.78; 95% CI, 0.64-0.94) and 173 (12.0%) in the brief counseling arm (RR, 0.81; 95% CI, 0.67-0.98). The 2 interactive counseling interventions had very similar cumulative incidence of STD through the 6- and 12-month visits. The number of participants counseled per STD averted during the 12-month study interval was 31 for the enhanced counseling arm and 38 for the brief counseling arm.

The STD reduction associated with the interactive counseling interventions was similar among men and women, that is, about 30% fewer participants had new STDs at the 6-month visit and 20% fewer participants had new STDs at the 12-month visit, respectively. Consistently at all 5 study sites fewer participants in the counseling intervention arms had new STDs compared with those in the didactic messages arm. Considering specific STDs as outcomes, counseling was equally effective for gonorrhea and chlamydia. For HIV, there were 4 new infections among those in the didactic messages arm, 4 in those assigned to the enhanced counseling arm, and none in those assigned to the brief counseling arm

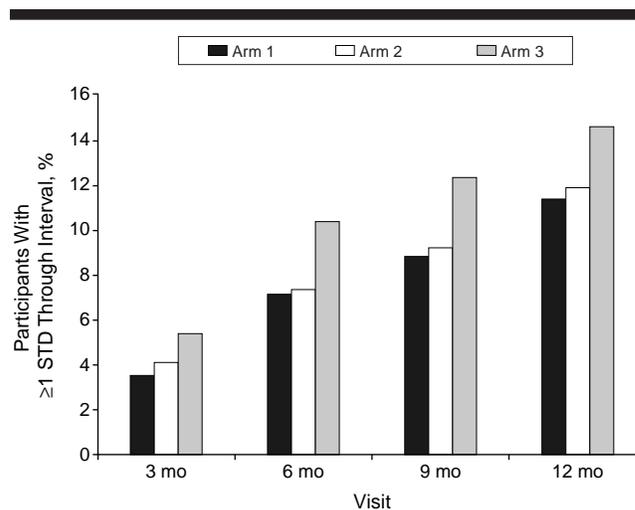


Figure 3.—Percentage of participants with a new sexually transmitted disease through the 3-, 6-, 9-, and 12-month visits.

($P = .06$) through the 12-month visit. In the subgroup analyses, efficacy was highest in the subgroups with highest risk (ie, highest STD incidence), although differences were not significant at $P < .05$. The relative effectiveness of counseling was greatest for patients aged 20 years or younger (vs those older), patients reporting no prior HIV test (vs those reporting a test), and patients who had an STD diagnosed at the enrollment visit (vs those with no STD).

Effect of Repeated Contact

Gonorrhea and syphilis were diagnosed at voluntary clinic visits less often among arm 3 participants (3.3%) than arm 4 participants (4.1%), although observed differences may have been due to chance (RR, 0.80; 95% CI, 0.55-1.17). At 12 months, only 462 arm 4 participants (32%) were found and interviewed. However, compared with these, arm 3 participants were more likely to report “no episodes of unprotected vaginal sex” during the previous 3 months (39% vs 34%; RR, 1.15; 95% CI, 0.99-1.33). Although some biases are possible, these analyses were consistent in suggesting that repeated contact with study personnel, instruments, or both may have themselves had a modest intervention effect.

COMMENT

Project RESPECT demonstrated that interactive, client-centered HIV/STD counseling resulted in an overall reduction in STD incidence of about 30% after 6 months and 20% after 12 months of follow-up. The STD reduction occurred among both men and women and was observed consistently at all 5 study sites. Since 1994, CDC has recommended client-centered HIV prevention counseling for persons determined to be at risk for HIV infec-

Table 2.—Proportion of Participants With Selected Safe Behaviors by Intervention Arm at the 3-Month and 6-Month Visits*

Safe Sex Behavior Last 3 Mo	Arm 1 Enhanced Counseling		Arm 2 Brief Counseling		Arm 3 Didactic Messages	
	3 mo, %	6 mo, %	3 mo, %	6 mo, %	3 mo, %	6 mo, %
	Any condom used	83†‡	78†‡	79	73	76
≤1 Sex partner	71†	70	72†	70	66	66
No casual partners	70	69	73†	70	66	66
Condoms last sex, primary partner§	63†	59	61	59	58	54
Condoms last sex, other partner	79†	78	80†	77	73	74
No new partners	72	71	75†	73	71	70
If new partner, asked if partner:						
Tested for HIV	58	56	61†	50	50	52
Tested for STDs	44	46	50†	41	41	38
Ever injected drugs	40	39	41	38	35	35

*HIV indicates human immunodeficiency virus; STD, sexually transmitted disease.

† $P < .05$ compared with arm 3 (didactic messages) at same study visit.

‡ $P < .05$ compared with arm 2 (brief counseling) at same study visit.

§For those reporting a primary sex partner.

||For those reporting a nonprimary ("other") sex partner.

tion.^{17,18} Several observational studies and a few randomized trials using behavioral outcomes support that direct, personalized ("client-centered") counseling is likely to initiate the behavior changes that might lead to reduction in new HIV infections.^{8,9,23,24} However, the efficacy of such counseling in reducing HIV or other STDs had not been shown. This large randomized controlled trial evaluating interactive risk reduction counseling among STD clinic patients is the first to report that counseling leads to reduction in sexually transmitted infections. In addition to concerns about efficacy, concerns that interactive counseling is not feasible for busy, publicly funded clinics, or cannot be conducted by the personnel currently employed by health departments, should now be put to rest.

The follow-up results indicate that interactive counseling had greatest disease reduction benefit during the first 6 months after intervention completion but suggest that some counseling benefits continued over time. Even if the counseling benefits wane, a 20% STD reduction over 12 months is important for several reasons. A 20% STD reduction in these clinic patients will diminish disease prevalence in the community. In addition, reducing or eliminating STDs such as syphilis, gonorrhea, chlamydia, and herpes may directly reduce new HIV infections, as the presence of these STDs has been found to enhance HIV acquisition and transmission.^{7,25} Furthermore, even transient reduction in risk for an individual may have large effects on lifetime risk if the behavior changes occur when the likelihood of infection is high (eg, during adolescence). As for whether the STD reduction found with counseling would hold true for HIV as well, we cannot say this with certainty. To the extent that sexual trans-

mission of the condom-preventable STDs we studied here and HIV are similar, client-centered counseling is likely to have the same disease prevention benefits. Human immunodeficiency virus seroconversion is relatively rare in the United States, even among this high-risk population. To find a 20% reduction in HIV transmission in this population with incidence of 0.3% per year would require a study size of 241 000 in order to have an 80% likelihood of detecting a difference. The cost of such a study would be prohibitive. But the cost of counseling programs for 241 000 people (which we estimate at \$8 per patient over current costs) would be easily recovered in savings from preventing an expected 145 new AIDS cases, which cost an estimated \$100 000 to \$200 000 per case.⁴

The finding that the 4-session enhanced counseling and the much shorter 2-session brief counseling had equivalent STD reduction was surprising and is good news for public health programs. Conventional wisdom has suggested that multiple-session interventions are needed for effective change of sexual behavior,¹² but our results challenge this viewpoint. Timing may be an important element for intervention success; it is possible that individuals who seek STD testing and treatment are particularly amenable to behavior change. However, this is not the first study indicating that brief interventions may be as effective as longer therapies. Recently published results of a large alcohol treatment study indicate that a brief motivational intervention was as effective in achieving alcohol cessation as a longer, more intensive counseling intervention.¹¹ A brief intervention in active drug users has also been reported as being effective as a longer intervention in changing risk behaviors.²⁶ We studied 4-session coun-

seling because we were not convinced that CDC's recommended 2-session counseling would have such a powerful disease reduction impact. Although long recommended and supported by counselors, client-centered HIV prevention counseling is seldom done in STD clinics, probably because program managers also have not believed that a 2-session intervention could have a significant impact. However, this brief counseling model was designed for implementation, at low cost and with existing personnel, in the context of routine health care services. The intervention adherence we found suggests that 2-session counseling would have at least the same retention as the didactic approach that is currently used and would have greater retention than longer therapies.

This study has several strengths. The randomized controlled design, if well conducted, permits the most unbiased comparison of effects. In conducting this trial, we sought to comply with recommended procedures that have since been published as guidelines for conducting and reporting randomized controlled trials.²⁷ The use of disease as an outcome measure can help validate self-reported data. More important, measuring disease outcomes allowed us to measure directly the interventions' disease reduction effects, and thus permit counseling to be directly compared with other HIV/STD prevention strategies. Losses to follow-up could be an important source of bias if those not returning differed in risk from those who returned for follow-up. Our 66% follow-up after 12 months (81% with at least 1 follow-up visit) is within an acceptable range for prospective studies. Follow-up was similar for all intervention arms, and our study population rarely sought STD care at other locations,²⁸ so the differences between interventions are unlikely to be caused by loss to follow-up. We also attempted to minimize biases in the analysis by identifying principal outcomes before the trial and by masking investigators to intervention strategies during preliminary analyses. An additional strength of this study was the use of several quality-control procedures, helping ensure that the counseling interventions were conducted by counselors at all sites consistently and as conceived.¹⁰ Also, the long follow-up period allowed us to measure the interventions' effects over time.

We were unable to avoid some potential biases. One limitation mentioned earlier was the use of STDs as a surrogate for HIV infection. Although STDs inform about unprotected sex and partner risk, they may not be an accurate measure of heterosexual HIV risk.²⁹ Generalizability of results is also of concern. We studied 5 widely located STD clinics that we believe

to be fairly representative of the range of public clinics in the United States. However, the 43% enrollment rate was low (although not unexpected, given the length and intensity of the follow-up that participants were asked to complete). Intervention enrollment may be higher in practice because participants would not need to return for the study-related follow-up. However, participation may be lower without the \$15 incentive used in this study. Perhaps more important, results may not pertain to other populations or settings. Since we studied only heterosexual STD clinic patients, we cannot know whether similar counseling sessions would be effective in other settings where HIV tests are performed, such as alternative test sites (where many gay men go for testing), among injection drug users, or at managed care plans (where many adolescents and young women receiving Medicare obtain health care). However, the individually tailored approach used in the counseling models studied here could be easily adapted to different settings.

We conclude that brief, interactive HIV/STD prevention counseling prevents new STDs and, by inference, HIV infections. This quality of counseling can be successfully conducted in busy public clinic settings. These results have several implications for existing programs, particularly those serving populations with a high HIV/STD prevalence. First, most clinics already employ HIV counselors who collect risk data, discuss the HIV test, and provide didactic prevention messages.³⁰ These counselors could prevent new infections if they adopted interactive HIV/STD prevention counseling aimed at risk reduction. The Project RESPECT counselors were health department staff members who were motivated and enthusiastic but typically did not have advanced degrees or long experience in interactive counseling. Second, quality-control measures are critical to intervention success and are feasible for most programs.¹⁰ Quality assurance should be approached as an integral part of the process and as a means of providing a better product. Third, some programs might consider targeting counseling to higher-risk clients, such as adolescents and individuals with previous STDs, to reduce costs while retaining large effects on disease reduction. Finally, given our finding that counseling benefits may wane over time, we wonder if an additional interactive counseling session done some months after brief 2-session counseling might be beneficial and might sustain or even enhance the risk-reduction benefits observed in this trial.

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References

- Centers for Disease Control and Prevention. *HIV/AIDS Surveillance Report*. Atlanta, Ga: Centers for Disease Control and Prevention; 1997:861-867. Report 46.
- Centers for Disease Control and Prevention. Update: mortality attributable to HIV infection among persons aged 25-44 years—United States, 1996. *MMWR Morb Mortal Wkly Rep*. 1996;45:121-125.
- Weinstock HS, Sidhu J, Gwinn M, Karon J, Petersen LR. Trends in HIV seroprevalence among persons attending sexually transmitted disease clinics in the United States, 1988-1992. *J Acquir Immune Defic Syndr Hum Retrovirol*. 1995;9:514-522.
- Holtgrave DR, Pinkerton SD. Updates of cost of illness and quality of life estimates for use in economic evaluations of HIV prevention programs. *J Acquir Immune Defic Syndr Hum Retrovirol*. 1998;16:54-62. (In press-anticipated date is April 1998).
- Oakley A, Fullerton D, Holland J. Behavioural interventions for HIV/AIDS prevention. *AIDS*. 1995;9:479-486.
- Peterman TA, Aral SO. Evaluating behavioral interventions. *JAMA*. 1993;269:2845.
- Grosskurth H, Mosha F, Todd J, et al. Impact of improved treatment of sexually transmitted diseases on HIV infection in rural Tanzania: randomized controlled trial. *Lancet*. 1995;346:530-536.
- Higgins DL, Galavotti C, O'Reilly KR, et al. Evidence for the effects of HIV antibody counseling and testing on risk behaviors. *JAMA*. 1991;226:2419-2429.
- Wolitsky RJ, MacGowan JR, Higgins DL, Jorgensen CM. The effects of HIV counseling and test-

- ing on risk-related practices and help-seeking behavior. *AIDS Educ Prev*. 1997;9(suppl 3):52-67.
- Kamb ML, Dillon B, Fishbein M, Willis KL, Project RESPECT Study Group. Quality assurance of HIV prevention counseling in a multi-center randomized controlled trial. *Public Health Rep*. 1996; 111(suppl 1):99-107.
- Project MATCH Research Group. Matching alcoholism treatments to client heterogeneity. *J Stud Alcohol*. 1997;58:7-29.
- Rotheram-Borus MJ, Koopman C, Haignere C, et al. Reducing HIV risk behaviors among runaway adolescents. *JAMA*. 1991;266:1237-1241.
- Schulz KF. Subverting randomization in controlled trials. *JAMA*. 1995;274:1456-1458.
- Ajzen I, Fishbein M. *Understanding Attitudes and Predicting Behavior*. Englewood Cliffs, NJ: Prentice Hall; 1980.
- Fishbein M, Bandura A, Triandis HC, et al. *Factors Influencing Behavior and Behavior Change: Final Report—Theorist's Workshop*. Rockville, MD: National Institute of Mental Health; 1992.
- Fishbein M, Middlestadt SE, Hitchcock PJ. Using information to change sexually transmitted disease-related behaviors. In: Wasserheit JN, Aral SO, Holmes KK, eds. *Research Issues in Human Behavior and Sexually Transmitted Diseases in the AIDS Era*. Washington, DC: American Society for Microbiology; 1991:243-257.
- Centers for Disease Control and Prevention. *HIV Counseling, Testing, and Referral Standards and Guidelines*. Atlanta, Ga: US Dept of Health and Human Services, Centers for Disease Control and Prevention; 1994.
- Centers for Disease Control and Prevention. Technical guidance on HIV counseling. *MMWR Morb Mortal Wkly Rep*. 1993;42:11-17.
- Centers for Disease Control and Prevention. 1993 Sexually transmitted diseases treatment guidelines. *MMWR Morb Mortal Wkly Rep*. 1993;42(RR-14):1-102.
- Richeart CA, Peterman TA, Zaidi AA, Ransom RL, Wroten JE, Witte JJ. A method for identifying persons at high risk for sexually transmitted infections. *Am J Public Health*. 1993;83:520-524.
- Schulz KF, Chalmers I, Hayes RJ, Altman DG. Empirical evidence of bias: dimensions of methodological quality associated with estimates of treatment effects in controlled trials. *JAMA*. 1995;273: 408-412.
- Zeiger SL, Liang KY. Longitudinal data analysis for discrete and continuous outcomes. *Biometrics*. 1986;42:121-130.
- Kelly JA, St Lawrence JS, Hood HV, Brasfield TL. Behavioral intervention to reduce AIDS risk activities. *J Consult Clin Psychol*. 1989;57:60-67.
- DiClemente RJ, Wingood GM. A randomized controlled trial of an HIV sexual risk-reduction intervention for young African-American women. *JAMA*. 1995;274:1271-1276.
- Wasserheit JN. Epidemiologic synergy: interrelationships between human immunodeficiency virus infection and other sexually transmitted diseases. *Sex Transm Dis*. 1992;19:61-77.
- Rhodes F, Malotte CK. HIV risk interventions for active drug users. In: Oskamp S, Thompson SC, eds. *Understanding and Preventing HIV Risk Behavior: Safer Sex and Drug Use*. Thousand Oaks, Calif: Sage Publications Inc; 1996:211-214.
- Standards of Reporting Trial Groups. A proposal for structured reporting of randomized controlled trials. *JAMA*. 1994; 272:1926-1931.
- Lawrence J, Kamb ML, Iatesta M, et al, and the Project RESPECT Study Group. Additional sources of care for STD clinic patients. In: Program and abstracts of the 11th International Conference on AIDS; July 7-12, 1996; Vancouver, British Columbia.
- Flemming TR, DeMets DL. Surrogate endpoints in clinical trials: are we being misled? *Ann Intern Med*. 1996;125:605-613.
- Centers for Disease Control and Prevention. *HIV Counseling and Testing in Publicly Funded Sites: 1995 Summary Report*. Atlanta, Ga: US Dept of Health and Human Services, Centers for Disease Control and Prevention; September 1997.

Appendix C: Revised Guidelines for HIV Counseling, Testing, and Referral



November 9, 2001 / Vol. 50 / No. RR-19



***Recommendations
and
Reports***

Inside: Two Continuing Education Examinations

Revised Guidelines for HIV Counseling, Testing, and Referral

and

Revised Recommendations for HIV Screening of Pregnant Women

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention (CDC)
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Contents

Revised Guidelines for HIV Counseling, Testing, and Referral	1
Introduction	1
Targeted Versus Routinely Recommended HIV CTR	7
HIV Counseling	13
HIV Testing	27
HIV Referral	36
HIV CTR Services in Nontraditional Settings	39
Quality Assurance and Evaluation of HIV CTR Services	43
Conclusion	45
Additional Resources	45
References	46
Glossary	54
Continuing Education Examination	CE-1-19a1
Revised Recommendations for HIV Screening of Pregnant Women	59
Introduction	63
Background	65
Recommendations	75
Conclusions	81
References	81
Continuing Education Examination	CE-1-19a2

Notice to Readers

This *MMWR* contains two articles, each with a continuing education examination. Each examination is printed on blue paper and placed directly after its accompanying article. The first examination is labeled RR-19a1, and the second is labeled RR-19a2. Please make sure you complete and submit the correct response form for the article for which you want to receive continuing education credit. You may take both examinations and receive credit for both articles.

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HIV Counseling, Testing, and Referral Guidelines
February 18–19, 1999
Atlanta, Georgia**

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Revised Guidelines for HIV Counseling, Testing, and Referral

Summary

These guidelines replace CDC's 1994 guidelines, HIV Counseling, Testing, and Referral Standards and Guidelines, and contain recommendations for public- and private-sector policy makers and service providers of human immunodeficiency virus (HIV) counseling, testing, and referral (CTR). To develop these guidelines, CDC used an evidence-based approach advocated by the U.S. Preventive Services Task Force and public health practice guidelines. The recommendations are based on evidence from all available scientific sources; where evidence is lacking, opinion of "best practices" by specialists in the field has been used.

This revision was prompted by scientific and programmatic advances in HIV CTR, as well as advances in prevention and the treatment and care of HIV-infected persons. These advances include a) demonstrated efficacy of HIV prevention counseling models aimed at behavioral risk reduction; b) effective treatments for HIV infection and opportunistic infections; c) effective treatment regimens for preventing perinatal transmission; and d) new test technologies.

Although the new guidelines include many aspects of the previous ones (e.g., encouragement of confidential and anonymous voluntary HIV testing, need for informed consent, and provision of HIV prevention counseling that focuses on the client's own risk), the new guidelines differ in several respects, including

- giving guidance to all providers of voluntary HIV CTR in the public and private sectors;*
- using an evidence-based approach to provide specific recommendations for CTR;*
- underscoring the importance of early knowledge of HIV status and making testing more accessible and available;*
- acknowledging providers' need for flexibility in implementing the guidelines, given their particular client base, setting HIV prevalence level, and available resources;*
- recommending that CTR be targeted efficiently through risk screening and other strategies; and*
- addressing ways to improve the quality and provision of HIV CTR.*

INTRODUCTION

Purpose of the Guidelines

These guidelines were developed for policy makers and service providers in the many settings that offer voluntary human immunodeficiency virus (HIV) counseling, testing, and referral (CTR) — public and private, urban and rural, and those with high and low HIV prevalence (Box 1). The guidelines are intended to be used to develop CTR services and policies in traditional clinical settings (e.g., sexually transmitted disease

BOX 1. HIV counseling, testing, and referral (CTR) settings

Settings that provide HIV CTR include but are not limited to the following traditional clinical and nontraditional settings:

- Adolescent health clinics, school-based health centers, university health centers
- AIDS services organizations
- Clinics serving men who have sex with men
- Community-based organizations
- Community health centers
- Correctional facilities
- Drug or alcohol prevention and treatment programs
- Family planning clinics
- Freestanding HIV test sites
- Hospital emergency departments
- Hospitals/other urgent care centers
- Managed care organizations
- Men's health clinics
- Migrant health centers
- Occupational/employee health clinics
- Outreach programs (e.g., syringe exchange programs)
- Prenatal clinics
- Private-sector service providers
- Publicly funded counseling and testing sites
- Sexually transmitted disease clinics
- Tuberculosis clinics
- Women's health clinics

[STD] clinics, private physicians' offices) and nontraditional settings (e.g., community-based or outreach settings [homeless shelters, bars]), which can be important places to provide access to CTR to persons at increased HIV risk. The Public Health Service is responsible for ensuring the quality of services in publicly funded programs, and many aspects of these guidelines focus on such programs. The guidelines could also be useful for CTR in other settings (e.g., for insurance, military, and blood donation purposes). Recommendations should be tailored to fit the needs of clients, communities, and programs within local, state, and federal rules and regulations.

Evolution of the Guidelines

These guidelines revise and update several sets of CDC guidelines for HIV CTR. The first CDC guidelines, published in 1986, highlighted the importance of offering voluntary testing and counseling and maintaining confidential records (1). In 1987, new guidelines emphasized the need to decrease barriers to counseling and testing, especially disclosure of personal information (2). In 1993, an additional report described the model of HIV prevention counseling currently recommended — an interactive rather than didactic model focusing on a personalized HIV risk-reduction plan (3). In 1994, *HIV Counseling, Testing and Referral Standards and Guidelines* focused on standard counseling and testing procedures and reiterated the importance of the HIV prevention counseling model and the need for confidentiality of counseling (4).

Because of recent advances in HIV treatment and prevention (5–32, *Revised Recommendations for HIV Screening of Pregnant Women*), CDC consulted with multiple partners to revise the 1994 guidelines using an evidence-based approach (33,34) and to expand the target audience to all providers of HIV CTR in the United States (33). Where scientific findings were lacking, recommendations were guided by “best practices” from specialists in the field. These guidelines were developed through the following five-step approach:

- **Address user needs.** A survey was conducted of publicly funded sites that offer HIV CTR to assess user satisfaction with the 1994 CDC guidelines for HIV CTR. Internal and external content specialists were consulted on key areas to address.
- **Review scientific literature.** Approximately 5,000 abstracts were screened and approximately 600 relevant publications were reviewed and synthesized where appropriate. Approximately 20 previously published CDC guidelines related to HIV CTR also were summarized.
- **Obtain technical opinion.** A panel of technical specialists from public and private sectors; governmental and nongovernmental agencies; and legal, ethics, and policy fields was convened to review the recommendations.
- **Obtain user input.** Internal CDC comments, public and private provider assessments, key consultant interviews, broad external reviews, and public comments through the Federal Register were obtained.
- **Publish electronically and in hard copy.** Single copies of this report are available from CDC’s National Prevention Information Network (NPIN) website at <<http://www.cdcnpin.org>> or by calling (800) 458-5231. The guidelines are also available at the HIV Counseling, Testing, and Referral website at <<http://www.cdc.gov/hiv/ctr>>. They will be updated and posted periodically.

Similarities and Differences Between Current and Previous Guidelines

Aspects of previous CDC HIV guidelines that are unchanged include

- encouraging availability of anonymous as well as confidential HIV testing;
- ensuring that HIV testing is informed, voluntary, and consented;
- emphasizing access to testing and effective provision of test results;
- advocating routine recommendation of HIV CTR in settings (e.g., publicly funded clinics) serving clients at increased behavioral or clinical risk for HIV infection;
- recommending use of a prevention counseling approach aimed at personal risk reduction for HIV-infected persons and persons at increased risk for HIV; and
- stressing the need to provide information regarding the HIV test to all who take the test.

Differences in the new guidelines include

- giving guidance to all providers of voluntary HIV CTR in the public and private sectors;
- using an evidence-based approach to provide specific recommendations for CTR;
- underscoring the importance of early knowledge of HIV status and making HIV testing more accessible and available;
- acknowledging providers' need for flexibility in implementing the guidelines, given their particular client base, setting HIV prevalence level, and available resources;
- recommending that CTR be targeted efficiently through risk screening and other strategies; and
- addressing ways to improve the quality and provision of HIV CTR.

Advances in HIV/AIDS Prevention and Treatment Interventions

During the past 2 decades, HIV infection and severe HIV-related diseases (e.g., acquired immunodeficiency syndrome [AIDS]) have become a leading cause of illness and death in the United States. As of December 31, 2000, a total of 774,467 persons were reported with AIDS, and 448,060 of these persons had died; the number of persons living with AIDS (322,865) was the highest ever reported (35). Approximately 800,000–900,000 persons in the United States are infected with HIV, and approximately 275,000 of these persons might not know they are infected (36).

Since the last CTR guidelines were published, many advances have been made in HIV/AIDS prevention and treatment, including development of effective antiretroviral therapies that have reduced HIV-related illness and death. However, although medical treatment has improved the quality and length of life for HIV-infected persons, it cannot cure HIV disease. Furthermore, the successes of new medical therapies might have led to relaxed attitudes toward safer sex (e.g., increased incidence of unprotected anal sex by young men who have sex with men) by HIV-infected persons and uninfected persons at increased risk (36,37). Additional advances include improved understanding of HIV transmission; a wider array of HIV test technologies; effective prevention counseling approaches; and practical, beneficial referral strategies — all of which could reduce the impact of the HIV epidemic in the United States.

Early knowledge of HIV infection is now recognized as a critical component in controlling the spread of HIV infection (38). Cohort studies have demonstrated that many infected persons decrease behaviors that transmit infection to sex or needle-sharing partners once they are aware of their positive HIV status (39–46). HIV-infected persons who are unaware of their infection do not reduce risk behaviors (42,47–49). Persons tested for HIV who do not return for test results might even increase their risk for transmitting HIV to partners (50). Because medical treatment that lowers HIV viral load might also reduce risk for transmission to others (51), early referral to medical care could prevent HIV transmission in communities while reducing a person's risk for HIV-related illness and death.

The array of HIV test technologies available has expanded, possibly enhancing a person's willingness to be tested and learn his or her HIV status. HIV tests can use specimens collected by less-invasive methods (e.g., oral fluid, urine, and finger-stick

blood), in addition to serum specimens collected by venipuncture. Rapid HIV testing allows clients to receive results the same day, which is useful in urgent medical circumstances and settings where clients tend not to return for HIV test results (e.g., some STD clinics). HIV testing can also be conducted using commercially available home sample collection devices (52).

Also during the 1990s, randomized controlled trials demonstrated that, for persons at increased HIV risk, certain prevention counseling approaches can be effective in reducing high-risk behaviors and new sexually transmitted infections (5,18–21). The counseling approach used is critical to effectiveness; interactive counseling approaches directed at a client's personal risk and the situations in which risk occurs are more effective than didactic, informational approaches (5). Because personalized prevention counseling can require more provider time and training than traditional counseling approaches, providing it to everyone receiving HIV testing might not be feasible. This recognition has led to a new area of health services research — developing strategies that effectively target CTR services to persons most likely to benefit from them.

The improved health of HIV-infected persons on antiretroviral therapy, along with new test technologies and effective counseling approaches, has contributed to an improved understanding of the importance of referral to needed services. In addition, new guidelines for partner counseling and referral services (PCRS) (27) and prevention case management (28) were developed specifically for publicly funded clinics and could also be useful to providers in other settings. Specialists in the field have also identified situations in which additional counseling or psychosocial support services might benefit HIV prevention efforts. Finally, advances in several areas have led to new guidelines for preventing mother-to-child transmission (see *Revised Recommendations for HIV Screening of Pregnant Women*), treating opportunistic infections (23,53) and other sexually transmitted (29) and bloodborne diseases (30–32), and managing occupational and nonoccupational exposure and prophylaxis (54,55). These developments were considered in the formulation of the new CTR guidelines.

Despite these advances in HIV prevention and care, a substantial number of opportunities for HIV prevention through CTR are missed. At publicly funded sites, approximately 70% of persons tested received their results and information regarding the test, but fewer persons likely received HIV prevention counseling and referrals. In private settings, a lower proportion of all clients are tested, and few receive prevention counseling and referrals (56–59). In many potential testing settings (e.g., emergency departments), HIV prevention counseling and testing are not uniformly offered, and data regarding types, completion, and effectiveness of referrals are not routinely collected.

Goals of HIV CTR

- Ensure that HIV-infected persons and persons at increased risk for HIV
 - have access to HIV testing to promote early knowledge of their HIV status;
 - receive high-quality* HIV prevention counseling to reduce their risk for transmitting or acquiring HIV; and

* Delivered according to recommended protocols (for counseling, referral, and evaluation) or regulatory standards (for testing).

- have access to appropriate medical, preventive, and psychosocial support services.
- Promote early knowledge of HIV status through HIV testing and ensure that all persons either recommended or receiving HIV testing are provided information regarding transmission, prevention, and the meaning of HIV test results.

Principles of HIV CTR

Effective HIV CTR is based on the following principles:

- **Protect confidentiality of clients who are recommended or receive HIV CTR services.** Information regarding a client's use of HIV CTR services should remain private (i.e., confidential). Personal information should not be divulged to others in ways inconsistent with the client's original consent.
- **Obtain informed consent before HIV testing.** HIV testing should be voluntary and free of coercion. Informed consent before HIV testing is essential. Information regarding consent may be presented orally or in writing and should use language the client can understand. Accepting or refusing testing must not have detrimental consequences to the quality of care offered. Documentation of informed consent should be in writing, preferably with the client's signature. State or local laws and regulations governing HIV testing should be followed.

Information regarding consent may be presented separately from or combined with other consent procedures for health services (e.g., as part of a package of tests or care for certain conditions). However, if consent for HIV testing is combined with consent for other tests or procedures, the inclusion of HIV testing should be specifically discussed with the client. For a discussion of HIV testing in pregnant women, consult the guidelines for HIV screening of pregnant women (see *Revised Recommendations for HIV Screening of Pregnant Women*).

- **Provide clients the option of anonymous HIV testing.** Anonymous testing (i.e., consented voluntary testing conducted without a client's identifying information being linked to testing or medical records, including the request for testing or test results) has been used widely and effectively. Anonymous testing can benefit the health of individual persons and the public by prompting earlier entry into medical care (60). Persons who would otherwise not be tested might seek anonymous HIV testing and learn their HIV status. Consistent with public health best practices, states in which anonymous testing is not available should reconsider their policy. When the client has no clear preference regarding testing type, confidential testing (i.e., information documented in client's record) should be recommended to promote receipt of test results and linkage to follow-up counseling and referral for needed services. Clients opting for anonymous testing should be informed that the provider cannot link the client's test result to the client by name. Therefore, if the client does not return for test results, the provider will not be able to contact the client with those results.
- **Provide information regarding the HIV test to all who are recommended the test and to all who receive the test, regardless of whether prevention counseling is provided.** The information should include a description of ways in which HIV is transmitted, the importance of obtaining test results, and the meaning of HIV test results.

- **Adhere to local, state, and federal regulations and policies that govern provision of HIV services.** Laws at the local, state, and federal levels might address aspects of HIV services or regulate how services are provided to particular persons (e.g., minors). In addition, policies, local ordinances, funding source requirements, and planning processes could also affect a provider's decisions regarding which services to provide and how to provide them.
- **Provide services that are responsive to client and community needs and priorities.** Providers should work to remove barriers to accessing services and tailor services to individual and community needs. To ensure that clients find services accessible and acceptable, services can be offered in nontraditional settings (i.e., community-based or outreach settings); hours of operation can be expanded or altered; unnecessary delays can be eliminated (e.g., integrating counseling and testing for STDs/HIV with counseling and testing for hepatitis); test results can be obtained more easily (e.g., with rapid testing or by telephone in certain situations); and less-invasive specimen collection can be used (e.g., oral fluid, urine, or finger-stick blood).
- **Provide services that are appropriate to the client's culture, language, sex, sexual orientation, age, and developmental level.** These factors could affect how the client seeks, accepts, and understands HIV services. Providers should consider these factors when designing and providing HIV services to increase the likelihood of return for test results and acceptance of counseling and referral services.
- **Ensure high-quality services.** To ensure ongoing, high-quality services that serve client and community needs, providers should develop and implement written protocols for CTR and written quality assurance and evaluation procedures. Many state and local health departments have substantial expertise in providing and monitoring the quality of HIV CTR services and can be a resource to private providers or community-based or outreach settings initiating these services.

TARGETED VERSUS ROUTINELY RECOMMENDED HIV CTR

Providers in all settings (traditional and nontraditional) should ideally recommend CTR to all clients on a routine basis to ensure that all clients who could benefit from CTR receive these services. However, resources might be insufficient to permit this practice. Therefore, these guidelines contain recommendations aimed at ensuring that as many persons as possible who are HIV-infected or at risk for HIV who do not know their HIV status have access to testing, prevention counseling, and referrals.

Routinely Recommending CTR to All Clients Versus Targeting CTR to Selected Clients

Studies have documented that, in settings serving clients at increased behavioral and clinical risk for HIV infection, targeting HIV testing based on reported risk factors will miss many HIV-infected clients (61–69). However, in low prevalence settings, where most clients have minimal risk, targeting clients for HIV testing based on risk screening might be more feasible for identifying small numbers of HIV-infected persons (70). Providers should consider three factors in determining whether to recommend HIV CTR to all clients or to target only selected clients.

- Type of setting.
- HIV prevalence of the setting.
- Behavioral and clinical HIV risk of the individual clients in the setting.

Although certain types of settings serve populations at increased risk (e.g., STD clinics), others might serve individual clients at increased risk (e.g., private physicians' offices in areas of low prevalence). Individual risk can be ascertained through risk screening. Under certain circumstances — perinatal transmission, acute occupational exposure, and acute nonoccupational (i.e., high-risk sexual or needle-sharing) exposure — providers should recommend HIV CTR regardless of setting prevalence or behavioral or clinical risk, based on the respective guidelines (*Revised Recommendations for HIV Screening of Pregnant Women*,54,55).

Using Prevalence Data to Establish Service Priorities

Few data exist to define “high” and “low” HIV prevalence and describe how these definitions could help develop and prioritize HIV CTR services. A study conducted in the early 1990s for acute care hospitals with $\geq 1\%$ HIV prevalence reported that routine voluntary HIV testing of all patients within a specific age range could be a feasible way to identify a large proportion of HIV-infected patients (71). This 1% prevalence can be used as general guidance for whether to routinely recommend or target HIV counseling and testing in other settings.

The threshold of HIV prevalence that should lead to routine recommendations for HIV testing of all clients within a setting can vary within and across settings and should be set in consideration of available resources. Services could be routinely recommended in settings with HIV prevalence rates $< 1\%$ but higher than other settings in the community, according to U.S. prevalence data (72). If HIV prevalence data are outdated or unknown, providers should consult their local or state health department for assistance in determining appropriate HIV CTR strategies. Alternatively, providers could employ routine voluntary testing to obtain information on prevalence in their particular settings.

Because of the availability of antiretroviral therapy to reduce the risk for perinatal HIV transmission, all pregnant women should be recommended HIV testing regardless of setting prevalence or behavioral or clinical risk (see *Revised Recommendations for HIV Screening of Pregnant Women*).

Determining Individual HIV Risk Through Risk Screening*

A client's individual HIV risk can be determined through risk screening based on self-reported behavioral risk (Box 2) and clinical signs or symptoms. Behavioral risks include injection-drug use or unprotected intercourse with a person at increased risk for HIV. Clinical signs and symptoms include STDs, which indicate increased risk for HIV infection, or other signs or symptoms (e.g., of acute retroviral or opportunistic infections), which might suggest the presence of HIV infection. Insufficient data exist to support the efficacy of any one risk-screening approach over others (e.g., face-to-face discussion or interviews, self-administered questionnaires, computer-assisted interviews, or simple open-ended questions asked by providers) (Box 2) (61,70).

* Risk screening differs from risk assessment, which is a part of HIV prevention counseling (see HIV Prevention Counseling).

BOX 2. Examples of two risk-screening strategies to elicit client-reported HIV risks

- Open-ended question by provider, “What are you doing now or what have you done in the past that you think may put you at risk for HIV infection?”
- Screening questions* (i.e., a checklist) for use with a self-administered questionnaire, face-to-face or computer-assisted interview, or other instrument: “Since your last HIV test (if ever), have you
 - injected drugs and shared equipment (e.g., needles, syringes, cotton, water) with others?”
 - had unprotected intercourse with someone that you think might be infected (e.g., a partner who injected drugs, has been diagnosed or treated for a sexually transmitted disease [STD] or hepatitis, has had multiple or anonymous sex partners, or has exchanged sex for drugs or money)?”
 - had unprotected vaginal or anal intercourse with more than one sex partner?”
 - been diagnosed or treated for an STD, hepatitis, or tuberculosis?”
 - had a fever or illness of unknown cause?”
 - been told you have an infection related to a ‘weak immune system’?”

* Clients who respond affirmatively to ≥ 1 of these questions should be considered at increased risk for HIV.

Recommendations for Routinely Recommended and Targeted CTR by Setting and Circumstance

Decisions regarding whether to recommend routine or targeted services are based on the behavioral and clinical HIV risk of the client population in the setting, the level of HIV prevalence of the setting, and the behavioral and clinical HIV risk of individual clients (Box 3). These factors should not be used to determine recommendations for CTR in circumstances in which treatment potential exists (i.e., perinatal transmission and acute occupational or nonoccupational exposure).

Settings Serving Populations at Increased Behavioral or Clinical Risk

HIV CTR should be routinely recommended for all clients in settings where the client population is at increased behavioral or clinical risk for acquiring or transmitting HIV infection, regardless of setting prevalence (Box 4 and Figure 1). These services should be provided on-site. In these settings, clients with ongoing risk behaviors should be linked to additional HIV prevention and support services (e.g., PCRS, drug or alcohol prevention and treatment), as appropriate. HIV-infected clients should receive ongoing HIV prevention counseling applicable to their personal situation.

BOX 3. Clients who should be recommended HIV prevention counseling, testing, and referral

- All clients in settings serving client populations at increased behavioral or clinical HIV risk (regardless of setting HIV prevalence).
- Individual clients in settings with <1%* HIV prevalence who[†]
 - have clinical signs or symptoms suggesting HIV infection (e.g., fever or illness of unknown origin, opportunistic infection [including active tuberculosis disease] without known reason for immune suppression),
 - have diagnoses suggesting increased risk for HIV infection (e.g., another sexually transmitted disease [STD] or bloodborne infection),
 - self-report HIV risks (see Box 2), or
 - specifically request an HIV test.
- All clients in settings with a $\geq 1\%$ [§] HIV prevalence.[¶]
- Regardless of setting prevalence or behavioral or clinical risk,
 - all pregnant women,[¶]
 - all clients with possible acute occupational exposure, and
 - all clients with known sexual or needle-sharing exposure to an HIV-infected person.

* Or lower than other settings in the community.

[†] Constitutes risk screening; see Determining Individual HIV Risk Through Risk Screening.

[§] Or higher than other settings in the community.

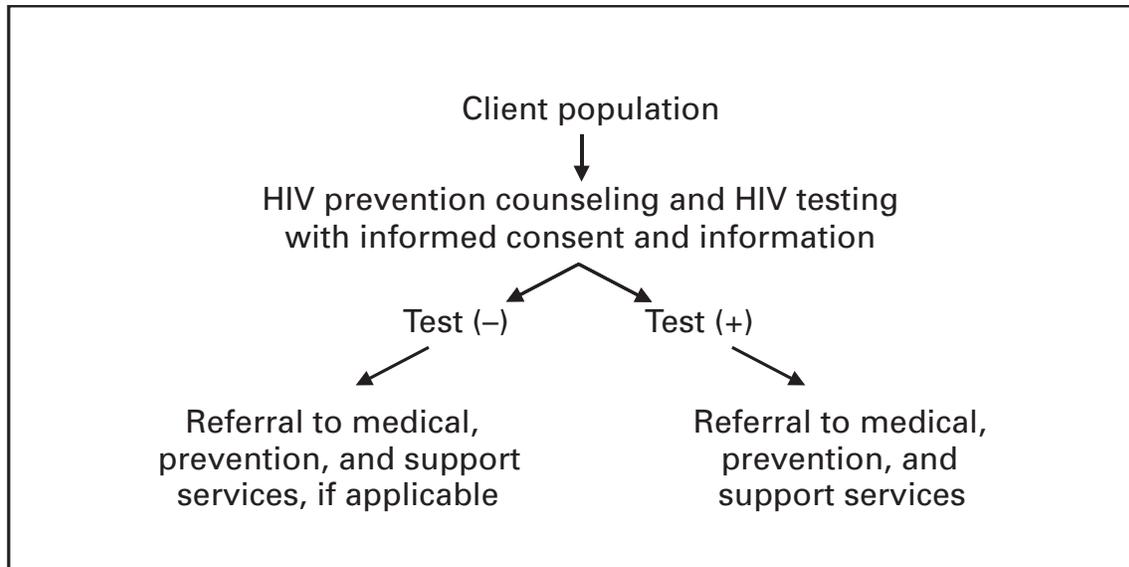
[¶] Clients should be routinely recommended testing, and if risk is identified during risk screening, they should also be recommended HIV prevention counseling and referral.

BOX 4. Examples of settings that serve populations at increased behavioral or clinical risk for HIV infection

- | | |
|--|---|
| • Adolescent or school-based health clinics with high rates of sexually transmitted diseases (STD) | • Freestanding HIV test sites |
| • Clinics serving men who have sex with men | • Homeless shelters |
| • Correctional facilities, prisons, juvenile detention centers | • Outreach programs (e.g., syringe exchange programs) |
| • Drug or alcohol prevention and treatment programs | • STD clinics |
| | • Tuberculosis (TB) clinics* |

* Only persons with confirmed or suspected TB and their contacts should routinely be recommended HIV CTR.

FIGURE 1. An example of counseling, testing, and referral in settings serving populations at increased behavioral or clinical HIV risk



Low Prevalence Settings

In low prevalence settings (e.g., <1%, see Using Prevalence Data to Establish Service Priorities) where the client population is generally not at increased behavioral or clinical HIV risk, CTR should be targeted to clients based on risk screening (Figure 2). Prevention counseling and referral are recommended for persons at increased risk even if HIV testing is declined. Any client who requests HIV testing should receive it, regardless of risk. These settings likely represent most health-care settings.

High Prevalence Settings

In high prevalence settings (e.g., $\geq 1\%$), all clients should be routinely recommended HIV testing (Figure 3). Risk screening should be used to determine if HIV prevention counseling and referral should also be recommended. CTR should be provided on-site. In these settings, clients with ongoing risk behaviors identified during risk screening should be linked to additional HIV prevention and support services (e.g., PCRS and drug or alcohol prevention and treatment), as appropriate.

Circumstances For Which HIV Preventive Treatment Exists

Prophylaxis exists for a limited number of situations: perinatal transmission, acute occupational exposure, and acute nonoccupational (i.e., high-risk sexual or needle-sharing) exposure. Regardless of population risk, setting prevalence, or individual behavioral or clinical risk, voluntary HIV testing should be routinely recommended to a) all pregnant women, b) clients with acute occupational exposure, and c) clients with acute nonoccupational (e.g., high-risk sexual or needle-sharing) exposure. Regardless of whether a client receives an HIV test, HIV prevention counseling and referral should

FIGURE 2. An example of HIV counseling, testing, and referral in low prevalence settings

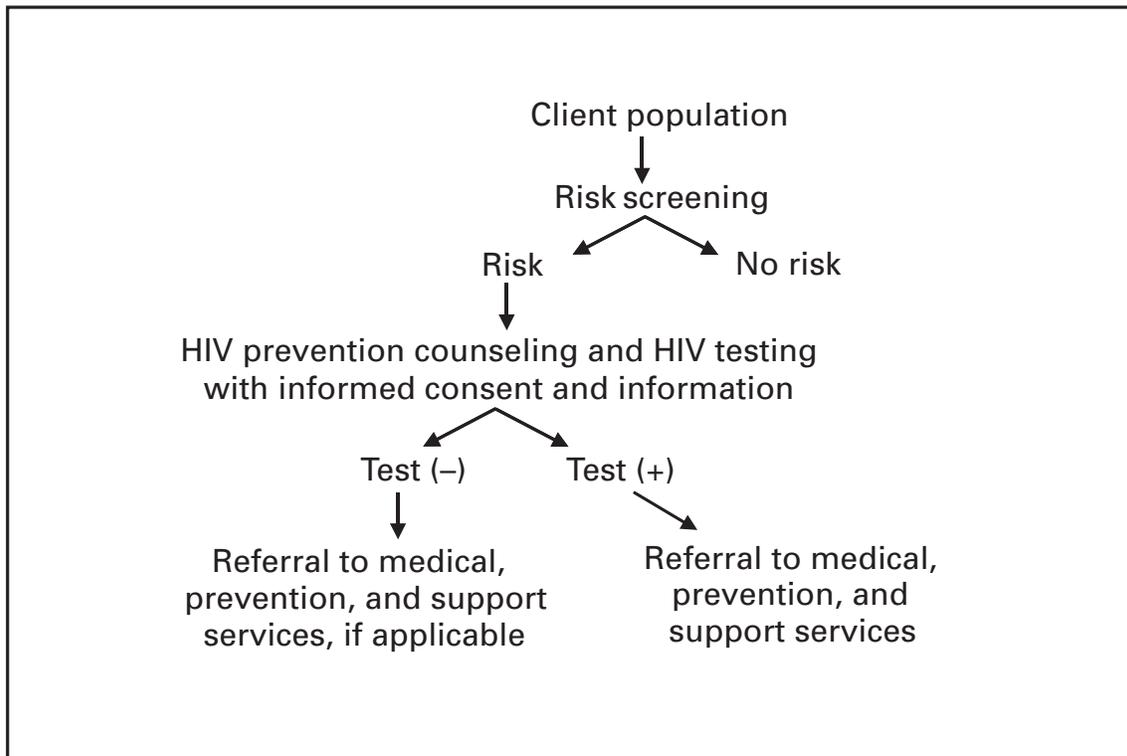
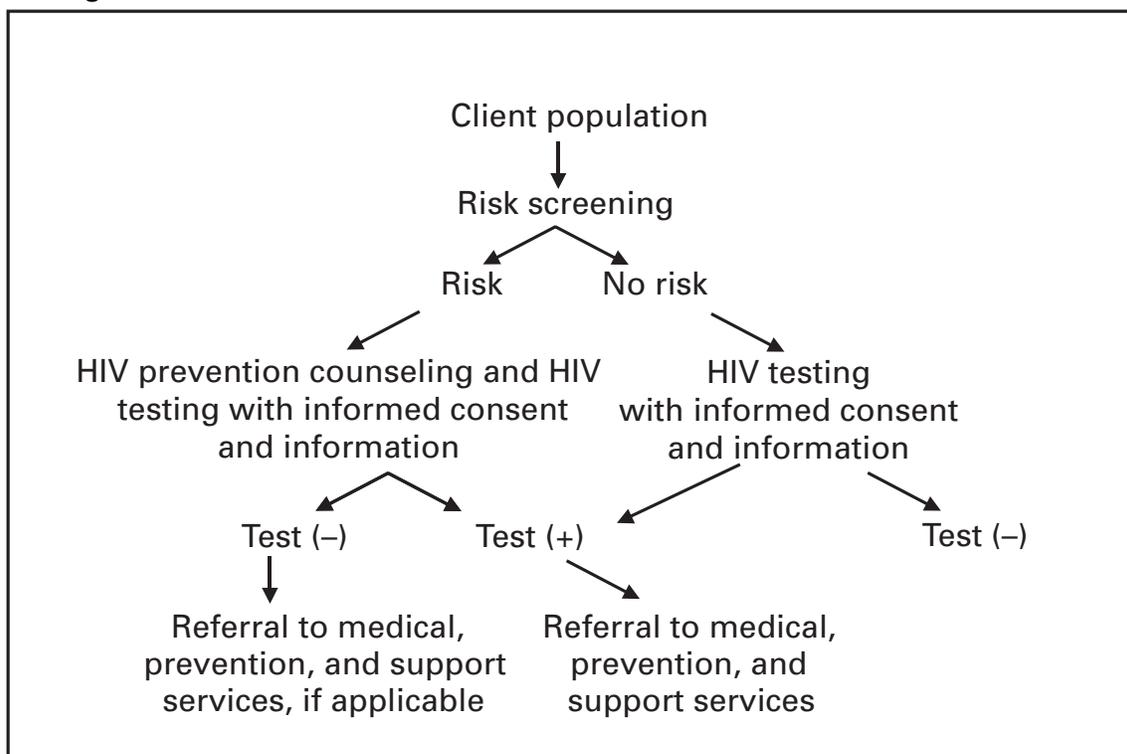


FIGURE 3. An example of HIV counseling, testing, and referral in high prevalence settings



target pregnant women based on risk screening and be routinely recommended to clients with either acute occupational or nonoccupational exposures. For further information, consult the respective guidelines on perinatal transmission, acute occupational exposure, and acute nonoccupational exposure (*Revised Recommendations for HIV Screening of Pregnant Women, 54,55*).

A Framework for Implementing HIV CTR

CTR are interrelated interventions that ideally should be integrated and offered in all settings. However, these guidelines acknowledge public and private providers' needs for flexibility. Certain providers might be able to offer prevention counseling but not an HIV test, whereas others might be able to offer an HIV test but not prevention counseling. Although all providers in settings serving populations at increased behavioral or clinical risk for HIV (e.g., STD clinics) should provide HIV CTR on-site, not all can. These providers should maintain clear and appropriate methods of referral to providers of prevention counseling or testing elsewhere. To ensure client referral, providers who offer HIV counseling and testing should collaborate with providers serving populations at increased risk for HIV who might not provide these services.

HIV COUNSELING

HIV counseling seeks to reduce HIV acquisition and transmission through the following:

- **Information.** Clients should receive information regarding HIV transmission and prevention and the meaning of HIV test results. Provision of information is different from informed consent.
- **HIV prevention counseling.** Clients should receive help to identify the specific behaviors putting them at risk for acquiring or transmitting HIV and commit to steps to reduce this risk. Prevention counseling can involve ≥ 1 sessions.

Information

All clients who are recommended or who request HIV testing should receive the following information, even if the test is declined:

- Information regarding the HIV test and its benefits and consequences.
- Risks for transmission and how HIV can be prevented.
- The importance of obtaining test results and explicit procedures for doing so.
- The meaning of the test results in explicit, understandable language.*
- Where to obtain further information or, if applicable, HIV prevention counseling.
- Where to obtain other services (see Typical Referral Needs).

* For example, "A negative test means no HIV was found. But if you were exposed to HIV recently — in the last 1–2 months — this test may not be able to pick that up." See Negative HIV Test Results.

In certain settings where HIV testing is offered, other useful information includes a) descriptions or demonstrations of how to use condoms correctly; b) information regarding risk-free and safer sex options (73); c) information regarding other sexually transmitted and bloodborne diseases; d) descriptions regarding the effectiveness of using clean needles, syringes, cotton, water, and other drug paraphernalia; e) information regarding drug treatment; and f) information regarding the possible effect of HIV vaccines on test results for persons participating in HIV vaccine trials (see Additional Counseling Considerations for Special Situations and Positive HIV Test Results).

For efficiency, information can be provided in a pamphlet, brochure, or video rather than a face-to-face encounter with a counselor. This approach allows the provider to focus face-to-face interactions on prevention counseling approaches proven effective with persons at increased risk for HIV infection. Information should be provided in a manner appropriate to the client's culture, language, sex, sexual orientation, age, and developmental level. Certain informational videos and large-group presentations that provide explicit information regarding correct use of condoms have proven effective in reducing new STDs (19–21,74) and could be effective in reducing HIV.

HIV Prevention Counseling

HIV prevention counseling should focus on the client's own unique circumstances and risk and should help the client set and reach an explicit behavior-change goal to reduce the chance of acquiring or transmitting HIV. HIV prevention counseling is usually, but not always, conducted in the context of HIV testing. The client-centered* HIV prevention counseling model involves two brief sessions (4,5,75), whereas other effective models are longer or involve more sessions (5–8,10,11,13–18,76–79). Regardless of the model used, in HIV prevention counseling, the counselor or provider focuses on assessing the client's personal risk or circumstances and helping the client set and reach a specific, realistic, risk-reduction goal. These guidelines avoid using the terms "pretest" and "posttest" counseling to underscore that prevention counseling is a risk-reduction process that might involve only one or >1 session.

Several models for HIV prevention counseling in conjunction with HIV testing have been developed, evaluated in controlled studies, and documented to be efficacious in changing behavior or reducing sexually transmitted infections, including individual face-to-face counseling (5,12), large- and small-group counseling with a facilitator (6,16,18,79), and video-based counseling (19). For more information regarding interventions, see *The Compendium of HIV Prevention Interventions with Evidence of Effectiveness* at <<http://www.cdc.gov/hiv/pubs/hivcompendium.pdf>>.

Client-Centered HIV Prevention Counseling

Since 1993, CDC has recommended one interactive counseling model, called client-centered HIV prevention counseling (3,4), which involves two face-to-face sessions with a provider or counselor (3–5,75,80). This model has traditionally used a two-step HIV

* Client-centered is used here to mean that the counseling sessions focus on the client's own risk circumstances, risk behaviors, and prevention needs. This term should not be confused with the more intensive, client-centered approach advocated by psychologist Carl R. Rogers, although some skills and strategies that involve the client in the prevention counseling process might be similar (Rogers CR. *Client-centered therapy: its current practice, implications, and theory*. Boston, MA: Houghton Mifflin, 1951).

testing approach in which clients are physically present at a setting for the HIV test (initial session) and then return for HIV test results (follow-up session). Each session might require 15–20 minutes (including testing and referral) for clients at increased risk for HIV, but could take only a few minutes for those at lower risk. In the first session, a personalized risk assessment* encourages clients to identify, understand, and acknowledge the behaviors and circumstances that put them at increased risk for acquiring HIV. The session explores previous attempts to reduce risk and identifies successes and challenges in these efforts. This in-depth exploration of risk allows the counselor to help the client consider ways to reduce personal risk and commit to a single, explicit step to do so. In the second session, when HIV test results are provided, the counselor discusses the test results, asks the client to describe the risk-reduction step attempted (and acknowledges positive steps made), helps the client identify and commit to additional behavioral steps, and provides appropriate referrals (e.g., to PCRS).

In one large, randomized, controlled trial, this model was reported to be

- effective at reducing high-risk sexual behaviors and new STDs (5);
- feasible to use even in busy publicly funded clinics;
- acceptable to clients, counselors, and health-care providers (80); and
- cost-effective at preventing STDs in persons at increased risk for HIV (81–83).

The model was reported to be especially effective among adolescents and persons with ongoing sexual risk behaviors (e.g., newly diagnosed STDs) (5). Although the benefits of client-centered HIV prevention counseling in reducing high-risk drug behaviors are unknown, studies have indicated that similar counseling approaches that help clients explore risks and set specific risk-reduction goals reduce risky drug use behaviors (39–41,84).

Observational studies and reviews of programs in various settings have indicated that many counselors are still unfamiliar with the specific goals of the client-centered HIV prevention counseling model (75,85) (Amy S. DeGross, M.P.H., written communication, 2000). Because “client-centered” is sometimes misinterpreted as “face-to-face,” providers in many HIV test sites deliver face-to-face informational messages in response to a generic checklist risk assessment. This type of counseling provides advice rather than encouraging client participation or discussion of personal risk; it seldom focuses on personal goal setting. “Client-centered” can also be misinterpreted to mean that the counselor should avoid directing the session. Although attentive listening and respect for clients’ concerns are important elements of effective counseling, the primary goal of client-centered HIV prevention counseling is risk reduction. HIV prevention counseling usually requires provider training and support and ongoing quality assurance to achieve optimal benefit. Providers can contact their state health department’s HIV/AIDS program office for information on local training opportunities. For information on client-centered counseling with rapid testing, see Addressing Barriers to HIV Prevention Counseling.

* Personal risk assessment is an essential element of HIV prevention counseling in which the client and counselor work to understand and acknowledge the client’s personal risk for HIV. Risk assessment is not synonymous with risk screening (see Determining Individual Client Risk Through Risk Screening and Box 2), which helps determine which clients should be recommended HIV CTR.

Elements of HIV Prevention Counseling

Regardless of the HIV prevention counseling model used, some counseling elements have been used repeatedly in effective interventions and are recognized by many specialists as critical in counseling success (Technical Expert Panel Review of CDC HIV Counseling, Testing, and Referral Guidelines; February 18–19, 1999; Atlanta, Georgia).

The following elements should be part of all HIV prevention counseling sessions:

- **Keep the session focused on HIV risk reduction.** Each counseling session should be tailored to address the personal HIV risk of the client rather than providing a predetermined set of information. Although counselors must be willing to address problems that pose barriers to HIV risk reduction (e.g., alcohol use in certain situations), counselors should not allow the session to be distracted by the client's additional problems unrelated to HIV. Certain counseling techniques (e.g., open-ended questions [Box 5], role-play scenarios, attentive listening, and a nonjudgmental and supportive approach) can encourage the client to remain focused on personal HIV risk reduction.
- **Include an in-depth, personalized risk assessment.** Sometimes called "enhancing self-perception of risk," risk assessment allows the counselor and client to identify, acknowledge, and understand the details and context of the client's HIV risk (17,86,87). Keeping the assessment personal, instead of global, will help the client identify concrete, acceptable protective measures to reduce personal HIV risk (Box 6). The risk assessment should explore previous risk-reduction efforts and identify successes and challenges in those efforts. Factors associated with continued risk behavior that might be important to explore include using drugs or alcohol before sexual activity, underestimating personal risk, perceiving that precautionary changes are not an accepted peer norm, perceiving limited self-efficacy for successful change efforts, receiving reinforcement for frequent unsafe practices (e.g., a negative HIV test result after risk behaviors), and perceiving that vulnerability is associated with "luck" or "fate" (86–89).
- **Acknowledge and provide support for positive steps already made.** Exploring previous risk-reduction efforts is essential for understanding the strengths and challenges faced by the client in reducing risk. Support for positive steps already taken increases the clients' beliefs that they can successfully take further HIV risk-reduction steps. For some clients, simply agreeing to an HIV test is an important step in reducing risk (5,75).
- **Clarify critical rather than general misconceptions.** In most situations, counselors should focus on reducing the client's current risk and avoid discussions regarding HIV transmission modes and the meaning of HIV test results. However, when clients believe they have minimal HIV risk but describe more substantial risk, the counselor should discuss the HIV transmission risk associated with specific behaviors or activities the clients describe and then discuss lower-risk alternatives (73). For example, if clients indicate that they believe oral sex with a risky sex partner poses little or no HIV risk, the counselor can clarify that, although oral sex with an infected partner might result in lower HIV transmission risk than anal sex, oral sex is not a risk-free behavior, particularly when commonly practiced. If clients indicate that they do not need to be concerned about HIV transmission among needle-sharing partners if they use clean needles, the counselor can clarify that

BOX 5. Examples of closed-ended versus open-ended questions

Closed-ended questions, which might interfere with client-centered human immunodeficiency virus (HIV) prevention counseling	Open-ended questions, which promote client-centered HIV prevention counseling
Have you ever injected drugs? OR	What are you doing that you think may be putting you at risk for HIV infection?
Have you (for a male client) ever had sex with a man? OR	What are the riskiest things that you are doing?
Have you (for a female client) ever had sex with a bisexual man?	If your test comes back positive, how do you think you may have become infected?
Have you ever had sex when you were under the influence of alcohol or drugs?	When was the last time you put yourself at risk for HIV? What was happening then?
Do you (always) use condoms when you have sex? OR	How often do you use drugs or alcohol?
Can you always use condoms when you have sex?	How do you think drugs or alcohol influence your HIV risk?
	How often do you use condoms when you have sex?
	When/with whom do you have sex without a condom? When with a condom?
Can you always use clean works (i.e., needles, syringes, cottons, or cookers*) when you inject?	What are you currently doing to protect yourself from HIV? How is that working?
	What kinds of things do you do to protect your partner from getting infected with HIV? (for HIV-infected clients) Tell me about specific situations when you have reduced your HIV risk. What was going on that made that possible?
	How risky are your sex/needle-sharing partners? For example, have they been recently tested for HIV?

* Cottons are filters used to draw up the drug solution. Cookers include bottle caps, spoons, or other containers used to dissolve drugs.

BOX 6. Examples of global versus specific risk-reduction steps for HIV prevention counseling

Global risk-reduction steps, which are unlikely to be effective in changing behavior	Specific risk-reduction steps, which are more likely to be effective in changing behavior
Always use condoms.	Buy a condom tomorrow and try it on.
	Carry a condom next time I go out (e.g., to the bar/nightclub).
	Starting today, put condoms on the night stand beside the bed.
	Starting tonight, require my partner to use a condom next time, or I will not have vaginal (anal) sex.
Have fewer or less risky partners.	Stop seeing (specific partner) who is seeing other people.
	Break up with (specific partner) before getting together with someone new.
Have safer sex.	Talk honestly with (specific partner) about my HIV status and ask about his/her HIV status.
	Next time I'm out with friends and may have sex, avoid getting "high" on drugs or alcohol.
	Only kissing, etc., with (specific partner) until we both have an HIV test.
	Tomorrow, ask (specific partner) if he or she has had a recent HIV test and has been tested for other sexually transmitted diseases.
Stop injecting drugs.	Obtain clean works (i.e., needles, syringes, cottons, or cookers*) tomorrow so I have them before I use next time.
	Contact drug treatment center and make appointment.

* Cottons are filters used to draw up the drug solution. Cookers include bottle caps, spoons, or other containers used to dissolve drugs.

HIV can be transmitted through the cooker, cotton, or water used by several persons sharing drugs. With newly identified or uninformed HIV-infected clients, the counselor should discuss HIV transmission risks associated with specific sexual or drug-use activities, including those in which the client might not be currently engaged.

- **Negotiate a concrete, achievable behavior-change step that will reduce HIV risk.** Although the optimal goal might be to eliminate HIV risk behaviors, small behavior changes can reduce the probability of acquiring or transmitting HIV. Behavioral risk-reduction steps should be acceptable to the client and appropriate to the client's situation. For clients with several high-risk behaviors, the counselor should help clients focus on reducing the most critical risk they are willing to commit to changing. The step does not need to be a personal behavior change. For many clients, knowledge of a partner's recent HIV status (and talking with the partner about getting an HIV test) might be more critical than personal behavior changes. The step should be relevant to reducing the client's own HIV risk and should be a small, explicit, and achievable goal, not a global goal (Box 6). Identifying the barriers and supports to achieving a step, through interactive discussion, role-play modeling, recognizing positive social supports, or other methods will enhance the likelihood of success (90). Writing down the goal might be useful. For clients with ongoing risk behaviors, referral to additional prevention and support services is encouraged.
- **Seek flexibility in the prevention approach and counseling process.** Counselors should avoid a "one-size-fits-all" prevention message (e.g., "always use condoms"). Behaviors that are safe for one person might be risky for another (91). For example, unprotected vaginal intercourse might be unsafe with anonymous partners whose HIV status is unknown, but safe for uninfected persons in a mutually monogamous relationship. The length of counseling sessions will vary depending on client risk and comfort (e.g., adolescents might require more time than adults).
- **Provide skill-building opportunities.** Depending on client needs, the counselor can demonstrate or ask the client to demonstrate problem-solving strategies such as a) communicating safer sex commitments to new or continuing sex partners; b) using male latex condoms properly; c) trying alternative preventive methods (e.g., female condoms); d) cleaning drug-injection equipment if clean syringes are unavailable; or e) communicating safer drug-injection commitments to persons with whom the client shares drug paraphernalia (86,92–94).
- **Use explicit language when providing test results.** Test results should be provided at the beginning of the follow-up session. Counselors should never ask the client to guess the test results. Technical information regarding the test can be provided through a brochure or other means so the session can focus on personal HIV risk reduction for clients with negative tests and other considerations for clients with positive or indeterminate test results (see Additional Counseling Considerations for Special Situations). In-depth, technical discussions of the "window period (i.e., the time from when a person is infected until they develop detectable HIV antibody) should be avoided because they could confuse the client and diffuse the

importance of the HIV prevention message. Counselors should clarify that negative test results do not mean the client has no HIV risk and work with the client to reconsider ongoing HIV risk behaviors and the benefits of taking steps to reduce those risks. A client with ongoing risk behaviors should not be given a false sense of the safety of those behaviors (i.e., avoid statements like “whatever you were doing seems to be safe” or “continue to do whatever you are doing now”).

These counseling elements are considered necessary for high-quality counseling. Specialists in the field (Technical Expert Panel Review of CDC HIV Counseling, Testing, and Referral Guidelines; February 18–19, 1999; Atlanta, Georgia) also suggested adoption of the following:

- **Ensure that the client returns to the same counselor.** Consistency of the client and counselor relationship helps the client feel secure, reduces misunderstanding, and promotes the likelihood of effective risk reduction. Effective counseling models tended to use the same counselor for all sessions. When follow-up prevention counseling sessions must be provided by a different counselor, careful record-keeping is recommended to ensure high-quality counseling. See *The Compendium of HIV Prevention Interventions with Evidence of Effectiveness* at <<http://www.cdc.gov/hiv/pubs/hivcompendium.pdf>>.
- **Use a written protocol to help counselors conduct effective sessions.** A structured protocol outlining session goals can help keep the counselor focused on risk reduction. The protocol can include examples of open-ended questions (to help a new counselor avoid closed-ended questions) and a list of explicit risk-reduction steps (to help a new counselor avoid accepting a client’s suggestion of global risk-reduction steps) (95).
- **Ensure ongoing support by supervisors and administrators.** Supervisory support is essential for effective counseling. Training in HIV counseling approaches that focus on personal risk reduction is recommended for persons supervising counselors. Staff appraisals should acknowledge that completion of critical counseling elements has higher priority than completion of paperwork.
- **Avoid using counseling sessions for data collection.** If required, paperwork should be completed at the end of the counseling session or by staff members who are not counseling. Checklist risk assessments driven by data collection forms are detrimental to effective counseling because they can encourage even skilled counselors to use closed-ended questions, limit eye contact, and miss critical verbal and nonverbal cues. The relevance of any routinely collected data should be periodically assessed.
- **Avoid providing unnecessary information.** An emphasis on providing information might prompt counselors to miss critical HIV prevention opportunities and cause clients to lose interest. Discussion of theoretical HIV risks (e.g., sex with a person with hemophilia or needle exposures through tattoos) tends to shift the focus away from the client’s actual HIV risk situations to topics that are more “comfortable” or easy to discuss but irrelevant to the client’s risk.

Who Should Deliver Prevention Counseling

In any setting where HIV testing is provided, existing personnel can be effective counselors if they have the desire and appropriate training and employ the essential counseling elements (5,80). Advanced degrees or extensive experience are not necessary for effective HIV prevention counseling, though training is (80). Training in counseling is available (see Ensuring High-Quality HIV Prevention Counseling). In situations where primary health-care providers (e.g., physicians) might not be able to provide prevention counseling, auxiliary health professionals trained in HIV prevention counseling models can provide this service. Although peer counseling has been successful in certain situations (18), research does not support an explicit risk-reduction need or benefit to matching clients with counselors based on same or similar backgrounds, sex, ethnicity, age, or peer group for intervention efficacy (96–98). The following skills and counselor characteristics were identified by specialists in the field as important for effective HIV prevention counseling (Technical Expert Panel Review of CDC HIV Counseling, Testing, and Referral Guidelines; February 18–19, 1999; Atlanta, Georgia):

- Completion of standard training courses in client-centered HIV prevention counseling or other risk-reduction counseling models.
- Belief that counseling can make a difference.
- Genuine interest in the counseling process.
- Active listening skills.
- Ability to use open-ended rather than closed-ended questions (Box 5).
- Ability and comfort with an interactive negotiating style rather than a persuasive approach.
- Ability to engender a supportive atmosphere and build trust with the client.
- Interest in learning new counseling and skills-building techniques.
- Being informed regarding specific HIV transmission risks (73).
- Comfort in discussing specific HIV risk behaviors (i.e., explicit sex or drug behaviors).
- Ability to remain focused on risk-reduction goals.
- Support for routine, periodic, quality assurance measures.

Additional Counseling Considerations for Special Situations

- **Persons with newly identified HIV infection.** Clients with newly identified HIV infection have immediate and long-term needs. Some clients might be better prepared to receive positive test results than others. The emotional impact of hearing an HIV-positive test result might prevent clients from clearly understanding information during the session in which they receive their results. Providers should provide appropriate referrals (see Typical Referral Needs) and, when necessary, additional sessions.

When a client receives the test result, the provider should ensure that the client understands it. As part of HIV prevention counseling, providers should explicitly discuss and clarify any misconceptions regarding HIV transmission risk to partners associated with specific sexual or needle-sharing activities. Clients should be advised to refrain from donating blood, plasma, or organs. For sexually active clients who are not in mutually monogamous partnerships, providers should also address strategies to prevent other sexually transmitted or bloodborne infections (e.g., gonorrhea, syphilis, chlamydia, herpes simplex virus, human herpes virus type 8 [the virus linked to Kaposi sarcoma], hepatitis B virus, hepatitis C virus, and cytomegalovirus).

The first few months after persons learn they are HIV infected are important for accessing medical and other support services to help them obtain treatment and establish and maintain behavior changes that reduce the likelihood of transmitting the virus to others. For example, persons with ongoing risks might be referred for prevention counseling to prevent transmission to others or for prevention case management. For all newly identified clients, a follow-up appointment 3–6 months after diagnosis is recommended by some specialists (99) to assess whether clients were able to initiate medical care, minimize transmission risk to uninfected partners, and access other needed services (e.g., partner counseling and referral services). See guidance on partner counseling and referral services (27) and prevention case management (28).

- **Persons with a single, recent nonoccupational HIV exposure.** After a reported sexual, injection-drug use, or other nonoccupational exposure to HIV (55), providers should refer clients for prompt initiation of evaluation, counseling, and follow-up services. Early postexposure prophylaxis could reduce the likelihood of becoming infected with HIV, although the degree to which early treatment can prevent new infection after acute nonoccupational HIV exposure is unclear. Further guidance on nonoccupational HIV exposure is available (55).
- **Persons with indeterminate HIV test results.** Until follow-up test results are available, persons with an indeterminate result should receive information regarding the meaning of test results. HIV prevention counseling should be the same as for a person with newly identified HIV infection. Behaviors that minimize the risk for HIV transmission to sex and needle-sharing partners should be emphasized, even if the client reports no risk behaviors. Clients with repeated indeterminate test results ≥ 1 month apart are unlikely to be HIV-infected and can be provided test results in the same way as clients with negative test results, unless recent HIV exposure is suspected (see Indeterminate Test Results).
- **Persons seeking repeat HIV testing.** In addition to brief prevention counseling sessions, ongoing HIV prevention counseling aimed at personal risk reduction might be useful for persons seeking repeated HIV testing who have continued HIV risk. Counselors should encourage clients to explore alternative prevention strategies and to identify and commit to additional risk-reduction steps. Clients with ongoing risk behaviors might benefit from referral to other HIV prevention and support services because their current risk behavior might be reinforced by repeated negative HIV test results or they might view HIV testing as protective (100). More information on prevention case management is available (28) (see Ongoing Exposure).

- **Persons who use drugs.** Persons who inject drugs might also be at increased risk for acquiring HIV through unprotected sex with an HIV-infected partner (101–103). For injection-drug users (IDUs), intervention studies indicate that personalized, interactive prevention counseling models using goal-setting strategies might be effective in reducing injection-drug and sexual-risk behaviors (39–41,84). Evidence also supports the efficacy of community strategies (e.g., methadone maintenance programs or other drug treatment programs, outreach programs, and syringe exchange) to reduce new HIV infections among IDUs (104–108). Specialists in the field advocate recommending such strategies, along with individual HIV prevention counseling, to persons who inject drugs.
- **Sex or needle-sharing partners of HIV-infected persons.** Sex or needle-sharing partners of HIV-infected persons should be encouraged to have HIV prevention counseling and testing. Partners who are HIV discordant (i.e., one person is HIV-infected and the other is uninfected) should receive counseling aimed at preventing HIV transmission from the infected to the uninfected partner, including explicit discussion and clarification of any misconceptions regarding HIV transmission risk associated with specific sexual or needle-sharing activities. In addition, many HIV-discordant couples benefit from ongoing HIV prevention counseling aimed at personal risk reduction or from couples counseling that teaches safe sexual practices and proper condom use (27,109–111). Little evidence exists to conclusively support or refute whether simultaneous infection with ≥ 2 subtypes of HIV is likely to occur or, if it does, whether it is associated with more aggressive or resistant disease (112). Researchers are divided on the value of recommending consistent condom use to prevent HIV sequelae for mutually monogamous, HIV-infected partners.
- **Health-care workers after an occupational exposure.** After an occupational exposure, health-care workers should use measures to prevent transmission during the follow-up period (54). HIV-exposed health-care workers should be advised that, although HIV is infrequently transmitted through an occupational exposure, they should abstain from sex or use condoms and avoid pregnancy until they receive a negative follow-up test result. In addition, they should not donate blood, plasma, organs, tissue, or semen; if a woman is breast-feeding, she should consider discontinuing (54). Health-care workers should also be advised of the rationale for postexposure prophylaxis, the risk for occupationally acquired HIV infection from the exposure, the limitations of current knowledge of the efficacy of antiretroviral therapy when used as postexposure prophylaxis, the toxicity of the drugs involved, and the need for postexposure follow-up (including HIV testing), regardless of whether antiretroviral therapy is taken. Further guidance on occupational HIV exposure is available (54).
- **Participants in HIV vaccine trials.** HIV-vaccine-induced antibodies may be detected by current HIV tests and may cause a false-positive result. Trial participants should be advised that HIV CTR is best provided at the vaccine trial sites, the vaccine is of unknown efficacy, and HIV risk behavior can result in their becoming HIV-infected (see Positive Test Results).

Addressing Barriers to HIV Prevention Counseling

Several factors can prevent provision of high-quality HIV prevention counseling, including unavailability of trained prevention counselors at the setting in which the HIV test was conducted, client reluctance, and low rates of client return for test results. Recommended strategies for addressing these common barriers include a) providing counseling on-site, b) enhancing client acceptance of counseling by examining and improving the counseling provided, and c) considering alternate counseling methods.

Provide On-Site Counseling

Cost, lack, or turnover of trained staff members and space constraints are barriers to providing HIV prevention counseling (113). However, given the proven efficacy of prevention counseling models, in settings where HIV prevalence is high or the population served is at increased risk, the ability to provide such counseling on-site is a high priority, and efforts should be made to address and remove barriers to providing HIV prevention counseling on-site. Health educators or other auxiliary staff members trained to discuss preventive activities such as healthy eating, prenatal education, or smoking cessation could, if adequately trained, be effective HIV prevention counselors. In the interim, alternative resources should be identified, and clearly defined referrals should be made to settings that can provide high-quality prevention counseling for clients at increased HIV risk. Systems to ensure that referrals are completed should be established (see HIV Referral).

Enhance Client Acceptance of HIV Prevention Counseling

Clients who agree to HIV testing but decline HIV prevention counseling often report they lack time or already are aware of HIV transmission modes. However, experienced counselors report that clients mainly refuse counseling because they do not perceive the service to be personally beneficial (Technical Expert Panel Review of CDC HIV Counseling, Testing, and Referral Guidelines; February 18–19, 1999; Atlanta, Georgia). These counselors believe that most of these clients are concerned about a specific risk, which they would be willing to explore if the counseling seemed useful. Three of the most commonly reported barriers to the perceived usefulness of counseling are the type of counseling provided, how it is recommended, and the setting of the counseling. In settings where many clients are declining counseling, these barriers and others should be examined. The counseling might be providing information only rather than addressing personal risks. Counselors might not be offering counseling in ways appropriate to the client's culture, language, sex, sexual orientation, age, or developmental level. The setting might inhibit open discussion of risk (e.g., some outreach settings are not private). Counseling skills (e.g., attentive listening, use of open-ended questions) that allow clients to participate might have been overlooked. Even when clients at increased risk refuse counseling, use of 1–2 open-ended questions that urge clients to examine their personal situations could prompt personal exploration of risk (e.g., "What were your concerns that led you to decide to get tested today?").

Consider Alternative Methods for HIV Prevention Counseling

HIV prevention counseling models proven effective have all used face-to-face (individual or group) encounters between counselor and client and involved ≥ 2 brief sessions.

Thus, face-to-face prevention counseling is preferred for clients at increased HIV risk. Most HIV test sites use an enzyme immunoassay (EIA) and confirmatory test algorithm that requires several days for final results. The return visit for test result offers an opportunity to continue prevention counseling in a second, face-to-face meeting. However, in some settings (e.g., STD clinics, managed care organizations, and other private settings), many clients do not return for their results (50,114–116). In such settings, providers can adopt strategies that increase clients' receipt of test results, and counseling strategies might need to be adapted (117).

Telephone Counseling. Limited studies among STD clinic clients at lower risk indicated that substantially more clients learned their HIV infection status when negative test results were provided by telephone rather than in person (12,117,118). Although home sample collection provides a precedent for providing counseling by telephone to persons with either negative or positive HIV test results, the efficacy of telephone counseling in reducing HIV risk behaviors or the number of new HIV infections has not been studied. One study indicated that telephone notification of positive results was associated with delay in linkage to care (119). However, not learning positive test results at all guarantees a delay in linkage to care. Many specialists recommend that provision of HIV test results and prevention counseling by telephone be limited to clients whose results are negative (Technical Expert Panel Review of CDC HIV Counseling, Testing, and Referral Guidelines; February 18–19, 1999; Atlanta, Georgia). Also, given the known risk-reduction benefits of face-to-face counseling, lack of efficacy data on telephone counseling, and concerns regarding disinhibition (e.g., "since my test result is negative, whatever risks I am taking now may be okay"), telephone counseling should be limited to clients without known ongoing HIV risk behaviors (e.g., unprotected sex or needle-sharing with an HIV-infected [or status unknown] partner).

Single-Session Prevention Counseling with Rapid Testing. Rapid tests allow clients to receive their HIV test results the same day. This process could reduce the number of clients receiving two prevention counseling sessions. Studies of the efficacy of single HIV prevention counseling sessions for use with a rapid test are under way. Although some single-session counseling protocols have been successfully implemented in busy clinics and are well-accepted by most clients, how well a single counseling session reduces risk behaviors or the number of new HIV infections is unknown. A counseling protocol for use with a rapid test is being studied; information is available at <<http://www.cdc.gov/hiv/projects/respect-2>>. For clients with identified risk behaviors, referral or rescheduling for ongoing counseling should be considered.

Ensuring High-Quality HIV Prevention Counseling

All CTR providers should conduct routine, periodic assessments for quality assurance to ensure that the counseling being provided includes the recommended, essential counseling elements.

Supervisors must be aware of HIV prevention counseling goals and necessary counselor skills. Supervisor and administrator support of HIV counseling models that focus on personal risk reduction (distinct from provision of information) is critical to effective counseling. Quality assurance for counseling should contain the following elements:

- **Training and continuing education.** Basic training in the use of ≥ 1 of the interactive HIV prevention counseling models aimed at personal risk reduction is recommended for counselors and supervisors. Counselors should know the communities they serve and the available referral opportunities. They also might benefit from formal training on a) transmission and prevention of HIV and other sexually transmitted and bloodborne diseases, b) the natural history of HIV, c) recognition and treatment of opportunistic infections, d) new therapeutic agents used to treat HIV and AIDS, e) PCRS, f) prevention case management, and g) other HIV prevention and support services available in the community (e.g., services related to substance abuse assessment, cultural competence, adolescent concerns, domestic abuse, and health concerns for gay or lesbian clients). Additional training in specific counseling skills is also warranted (e.g., training on how to facilitate groups for counselors conducting group sessions). For training opportunities, providers or supervisors can contact their state health department's HIV/AIDS program office.
- **Supervisor observation and immediate feedback to counselors.** Direct observation of counseling sessions can help ensure that objectives are being met (80). Supervisors can perform this task periodically (with client consent). Sessions might also be audiotaped (with client consent), or counseling can be demonstrated through role-play scenarios between the counselor and supervisor. Observation and feedback should be structured, and the outcome should be constructive, not punitive. Supervisors should support positive elements of the prevention counseling session and provide specific, constructive comments regarding content areas needing improvement. Observation and feedback should be conducted regularly for routine counseling. Staff discomfort with observation typically wanes over time; many counselors report that the sessions are useful in enhancing skills. When observation is offered routinely, clients seldom refuse to participate. A suggested time frame for routine, direct observation of an HIV prevention counselor by the supervisor is twice monthly for the first 6 months, monthly for the second 6 months, and quarterly for counselors with >1 year of experience. After observation, supervisors should provide feedback to counselors quickly, preferably the same week. Observation and feedback forms used in research studies of client-centered HIV prevention counseling are available at <http://www.cdc.gov/hiv/projects/RESPECT/default.htm>.
- **Periodic evaluation of physical space, client flow, and time concerns.** Counseling sessions should be conducted in a private space where discussion cannot be overheard. Clients should not wait for long periods between testing and counseling, and information could be provided during waiting times (e.g., through videos). Periodic time-flow analyses or client surveys can be used to evaluate adequacy of space, client flow, and length of waiting period.
- **Periodic counselor or client satisfaction evaluations.** Evaluations of client satisfaction can ensure that counseling meets client needs. These evaluations also can provide important feedback to counselors who otherwise might not see the benefits of what they do. Evaluations can be brief. Surveys should address whether specific counseling goals were met, the type of interaction (e.g., "who talked more, the counselor or the client?"), and, when applicable, specifics of

development of the risk-reduction plan (e.g., “what was the behavior change step that you agreed to work on?”). Linking client and counselor descriptions of a particular session might be useful. Conducting such evaluations only occasionally (e.g., for 1–2 weeks once or twice a year) decreases the programmatic burden and is probably sufficient to identify problems. For more information, see Quality Assurance and Evaluation of HIV CTR Services.

- **Case conferences.** Regularly scheduled meetings of counselors allow supervisors to understand counselors’ skills and areas that need improvement and can help counselors learn techniques from their colleagues. Case conferences are an opportunity for counselors to discuss specific or problematic questions asked by clients, allowing providers to better understand the concerns facing clients who are HIV-infected or at increased risk for HIV. Case conferences can help offset counselor fatigue and “burn out” by providing a positive outlet for dealing with difficult situations. Discussion might focus on a hard-to-address client or specific elements (e.g., developing acceptable and practical risk-reduction plans with clients who deny the magnitude of their HIV risk). Frequency of case conferences should be balanced with client volume, with efforts made to meet at least monthly.

HIV TESTING

Characteristics and Applications of HIV Test Technologies

Only FDA-approved HIV tests should be used for diagnostic purposes. Routine screening in the United States for HIV-2 and HIV-1 group O infections is not generally recommended unless geographic, behavioral, or clinical information indicates that infection with these strains might be present. Several HIV test technologies have been approved by FDA for diagnostic use in the United States. These tests enable testing of different fluids (i.e., whole blood, serum, plasma, oral fluid, and urine) (Table). The available technologies

- enable specimen collection procedures that are less invasive and more acceptable than venipuncture, thus helping expand HIV testing into nontraditional settings (with home sample collection tests, oral fluid tests, and urine-based tests) (25);
- enable provision of HIV test results during a single visit at the time of testing (with rapid tests) (120); and
- increase the convenience of HIV testing (with home sample collection tests) (52).

The decision to adopt a particular test technology in a clinical or nontraditional setting should be based on several factors, including

- accuracy of the test,
- client preferences and acceptability,
- likelihood of client returning for results,
- cost and mechanism for provider reimbursement,
- ease of sample collection,

TABLE. Performance attributes and potential applications of HIV test technologies approved by the U.S. Food and Drug Administration (FDA) for diagnostic use

Test type	Specimen (mode of collection)	Test complexity*	Screening; confirmatory	Strains detected [†]	Provision of results	Advantages	Potential settings
Standard HIV test	Serum or plasma (phlebotomy)	High	Enzyme immunoassay (EIA); Western blot or immunofluorescence assay (IFA)	HIV-1 and HIV-2	HIV negative: Test result at return visit (typically a few days to 1–2 weeks) HIV positive: Confirmed result at return visit	<ul style="list-style-type: none"> • High sensitivity • Rare false-positives • High-volume processing • Utility for testing for other conditions (e.g., sexually transmitted diseases [STDs]) 	<ul style="list-style-type: none"> • Blood screening • Various settings and populations
Rapid test	Serum, plasma, whole blood (phlebotomy, finger stick)	Moderate [§]	Rapid EIA; Western blot/IFA [¶]	HIV-1	HIV negative: Test result at time of testing (typically 10–60 minutes) HIV positive: Preliminary positive test result at time of testing; ** confirmed result at return visit	<ul style="list-style-type: none"> • Convenience • Increased receipt of test results • Use in urgent medical circumstances (e.g., postexposure prophylaxis) 	<ul style="list-style-type: none"> • Settings with low return rates • Perinatal/labor and delivery for prophylaxis • Health-care settings for decisions regarding postexposure prophylaxis
Home sample collection test ^{††}	Dried blood spot (finger stick)	High	EIA; Western blot/IFA	HIV-1	HIV negative: Test result when client telephones (typically 3–7 days) HIV positive: Confirmed result when client telephones	<ul style="list-style-type: none"> • Convenience • Anonymity • Privacy • Conservation of public resources 	<ul style="list-style-type: none"> • Outreach settings • Community-based settings • Syringe exchange programs • Rural areas • Settings serving clients not at increased risk • Home

TABLE. (Continued) Performance attributes and potential applications of HIV test technologies approved by the U.S. Food and Drug Administration (FDA) for diagnostic use

Test type	Specimen (mode of collection)	Test complexity*	Screening; confirmatory	Strains detected†	Provision of results	Advantages	Potential settings
Oral fluid test	Oral mucosal transudate (oral fluid collection device)	High	EIA; Oral mucosal transudate Western blot	HIV-1	HIV negative: Test result at return visit (typically 1–2 weeks) HIV positive: Confirmed result at return visit	<ul style="list-style-type: none"> • Noninvasive • Nontechnical collection • No venipuncture • Decreased infectious hazard • Utility in nonclinical settings 	<ul style="list-style-type: none"> • Outreach settings • Community-based settings • Syringe exchange programs • Drug treatment centers • Adolescent and school-based clinics and university health centers
Urine-based test	Urine (Urine cup)	High	EIA; Urine Western blot	HIV-1	HIV negative: Test result at return visit (typically 1–2 weeks) HIV positive: Test result at return visit; further confirmation by blood sample recommended because of lower specificity of urine Western blot compared with serum-based Western blot/IFA	<ul style="list-style-type: none"> • Noninvasive • Nontechnical collection • No venipuncture • Decreased infectious hazard • Utility in nonclinical settings • Utility for testing for other conditions (e.g., STDs) 	<ul style="list-style-type: none"> • Outreach settings • Community-based settings • Syringe exchange programs • Drug treatment centers • Adolescent and school-based clinics and university health centers

* Complexity of specimen collection and testing as categorized by the Clinical Laboratory Improvement Amendments (CLIA). (Schochetman G, George JR, eds. AIDS testing: a comprehensive guide to technical, medical, social, legal, and management issues. 2 ed. New York, NY: Springer-Verlag, 1994.)

† All licensed enzyme immunoassays (EIAs) detect HIV-1, but not all detect HIV-2. EIAs that can detect HIV-1 and HIV-2 are required for blood donor screening and are recommended for diagnostic screening only where HIV-2 infection is likely. No licensed confirmatory test exists for HIV-2. Although current tests detect most HIV-1 group O infections, few detect all such infections.

§ The one rapid test licensed by FDA, Abbott Murex Single Use Diagnostic System (SUDS) HIV-1 test (Abbott Laboratories, Inc., Abbott Park, Illinois) is classified as a moderate-complexity test and requires on-site laboratory testing capability. Future rapid tests could be classified by CLIA as “waived” and not require on-site laboratory testing capability, depending on the expertise required to perform the test correctly.

¶ Future rapid tests might be able to be confirmed with a second rapid test to provide an immediate test result with high sensitivity, specificity, and predictive value comparable with EIA/Western blot (Stetler HC, Granade TC, Nunez CA, et al. Field evaluation of rapid HIV serologic tests for screening and confirming HIV-1 infection in Honduras. AIDS 1997;11:369–75).

** Information on providing “preliminary” positive test results from a single rapid test is available elsewhere (CDC. Update: HIV counseling and testing using rapid tests—United States, 1995. MMWR 1998;47:211–5).

†† Home sample collection is different from home-use testing. FDA has approved home sample collection, but not home-use HIV test kits (Kassler WJ. Advances in HIV testing technology and their potential impact on prevention. AIDS Educ Prev 1997;9[suppl B]:27–40).

- complexity of laboratory services required for the test,
- availability of trained personnel, and
- FDA approval of the test.

Home Testing Versus Home Sample Collection

FDA has not approved home-use HIV test kits, which allow consumers to purchase a test kit, collect a sample in private, and interpret their own HIV test results in a few minutes. The Federal Trade Commission has warned that some home-use HIV test kits, many of which are available on the Internet and in the "gray" market (i.e., unauthorized imports), supply inaccurate results (121). These tests are different from FDA-approved home sample collection kits (52), which allow consumers to purchase test kits, collect a sample in private, send the sample to a laboratory for testing, and telephone for their HIV test result, counseling, and referral.

HIV-2 and HIV-1 Group O Infections

Although most HIV infections in the United States are of HIV-1 group B subtype, current EIAs can accurately identify infections with nearly all non-B subtypes and many infections with group O HIV subtypes (122). Infections with HIV-2 and HIV-1 group O are rare in the United States (123,124), and routine screening for these subtypes is not generally recommended as part of diagnostic testing except in areas where several such infections have been identified. Routine screening for HIV-2 might be appropriate in certain populations where potential risk for HIV-2 infection is higher (e.g., in areas where West African immigrants have settled) (125). Since June 1992, FDA has recommended routine screening for antibody to HIV-2 (in addition to HIV-1) for all blood and plasma donations (125). Clients with clinical, epidemiologic, or laboratory history that suggests HIV infection and negative or indeterminate HIV-1 screening tests should receive further diagnostic testing to rule out HIV infection, potentially including testing for HIV-1 non-B subtypes (122) and HIV-2 (125).

Other Test Uses

Viral load and HIV-1 p24 antigen assays are not intended for routine diagnosis but could be used in clinical management of HIV-infected persons in conjunction with clinical signs and symptoms and other laboratory markers of disease progression. Although HIV-1 p24 antigen assays are used for routine screening in blood and plasma centers, routine use for diagnosing HIV infection has been discouraged because the estimated average time from detection of p24 antigen to detection of HIV antibody by standard EIA is 6 days, and not all recently infected persons have detectable levels of p24 antigen (126).

Interpreting HIV Test Results

Standard Testing Algorithm

HIV-1 testing consists of initial screening with an EIA to detect antibodies to HIV-1. Specimens with a nonreactive result from the initial EIA are considered HIV-negative unless new exposure to an infected partner or partner of unknown HIV status has

occurred. Specimens with a reactive EIA result are retested in duplicate. If the result of either duplicate test is reactive, the specimen is reported as repeatedly reactive and undergoes confirmatory testing with a more specific supplemental test (e.g., Western blot or, less commonly, an immunofluorescence assay [IFA]). Only specimens that are repeatedly reactive by EIA and positive by IFA or reactive by Western blot are considered HIV-positive and indicative of HIV infection. Specimens that are repeatedly EIA-reactive occasionally provide an indeterminate Western blot result, which might represent either an incomplete antibody response to HIV in specimens from infected persons or nonspecific reactions in specimens from uninfected persons (127). Although IFA can be used to resolve an indeterminate Western blot sample, this assay is not widely used. Generally, a second specimen should be collected ≥ 1 month later and retested for persons with indeterminate Western blot results. Although much less commonly available, nucleic acid testing (e.g., viral RNA or proviral DNA amplification method) could also help resolve an initial indeterminate Western blot in certain situations. A small number of tested specimens might provide inconclusive results because of insufficient quantity of specimen for the screening or confirmatory tests. In these situations, a second specimen should be collected and tested for HIV infection.

Modified Testing Algorithms

FDA has licensed only one rapid test, but modified testing algorithms are anticipated when additional rapid HIV tests are approved. If ≥ 2 sensitive and specific rapid HIV tests became available, one positive rapid test could be confirmed with a different rapid test. This combination has provided positive predictive value compared with the EIA/Western blot or IFA algorithm (128). However, no such algorithms have been adequately assessed or approved for diagnostic use in the United States.

Positive HIV Test Results

An HIV test should be considered positive only after screening and confirmatory tests are reactive. A confirmed positive test result indicates that a person has been infected with HIV. False-positive results when both screening and confirmatory tests are reactive are rare. However, the possibility of a mislabeled sample or laboratory error must be considered, especially for a client with no identifiable risk for HIV infection. HIV-vaccine-induced antibodies may be detected by current tests and may cause a false-positive result. Persons whose test results are HIV-positive and who are identified as vaccine trial participants should be encouraged to contact or return to their trial site or an associated trial site for HIV CTR services.

Negative HIV Test Results

Because a negative test result likely indicates absence of HIV infection (i.e., high negative predictive value), a negative test need not be repeated in clients with no new exposure in settings with low HIV prevalence. For clients with a recent history of known or possible exposure to HIV who are tested before they could develop detectable antibodies (129,130), the possibility of HIV infection cannot be excluded without follow-up testing (29). A false negative result also should be considered in persons with a negative HIV-1 test who have clinical symptoms suggesting HIV-1 infection or AIDS. Additional testing for HIV-2 and HIV-1 group O infection might be appropriate for these persons.

Indeterminate HIV Test Results

Most persons with an initial indeterminate Western blot result who are infected with HIV-1 will develop detectable HIV antibody within 1 month (127, 131, 132). Thus, clients with an initial indeterminate Western blot result should be retested for HIV-1 infection ≥ 1 month later.* Persons with continued indeterminate Western blot results after 1 month are unlikely to be HIV-infected and should be counseled as though they are not infected unless recent HIV exposure is suspected.

Nucleic acid tests for HIV DNA or RNA exist, but are not approved by FDA for diagnostic purposes and are not generally recommended for resolving indeterminate Western blot results. However, in consultation with clinical and laboratory specialists, nucleic acid testing (if available) might also be useful for determining infection status among persons with an initial indeterminate Western blot result.

Informing Clients of Test Results

Because low rates of return for test results occur in many settings offering HIV CTR (133), providers should work to ensure that clients tested for HIV infection receive their test results, particularly HIV-infected clients who might benefit from earlier entry into care and initiation of antiretroviral therapy. Reducing barriers to testing can maximize the number and proportion of persons tested for HIV who receive their test results in a timely manner (see Addressing Barriers to HIV Testing). Adoption of new HIV test technologies and alternative methods of providing HIV-negative test results should be considered when face-to-face rates of return for test results are low. Strict confidentiality of the receipt of the HIV test and the HIV test result must be maintained, regardless of the method used. Providers unable to locate clients who do not return for test results should seek support from their local or state health department.

Because knowledge of HIV status is a critical HIV prevention strategy and essential for entry into care, providers should stress to clients the importance of returning to receive their test results and establish a plan for doing so with the client. Reminder systems might be useful. Using alternate HIV test technologies might increase the percentage of tested persons who learn their HIV status.

Providing Test Results by Telephone

Many clinicians routinely notify clients of negative test results for various diseases and conditions by means other than face-to-face (e.g., by telephone). They also ask clients to return to discuss positive test results that might indicate potential life-threatening illnesses. This strategy can also be applied, under limited circumstances, to notifying clients of their HIV test results. Face-to-face provision of HIV test results is strongly encouraged for HIV-infected clients and HIV-uninfected clients at increased risk who might benefit from HIV prevention counseling and referral to medical, preventive, and support services. Providing uninfected clients who are not at increased risk the option of receiving HIV test results and counseling by telephone — with the understanding that provider assurance of client confidentiality is of paramount importance — might be appropriate. Limited research indicates that offering clients the option of contacting

* Studies on repeat testing for persons with indeterminate Western blot results have not included pregnant women (see *Revised Recommendations for HIV Screening of Pregnant Women*).

the provider by telephone to receive negative HIV results might increase rates of receipt of results, satisfy client preferences for options, and preserve setting resources without apparent adverse consequences (52,117,118). Although no published research exists regarding use of telephones for providing positive HIV test results with most HIV test technologies, limited experience exists on using this method to provide HIV-positive test results for home sample collection testing (52).

Providing Test Results During the Initial Visit Through Rapid Tests

More clients receive their HIV test results with rapid tests because results can be provided at the testing visit (120). Rapid test technology could be useful in urgent medical circumstances (e.g., when decisions must be made regarding postexposure prophylaxis) and in nontraditional settings with low return rates (e.g., community-based or outreach settings).

During the initial visit, the provider can definitively tell clients who have had a single rapid HIV test with negative results that they are not infected (120), except when retesting might be indicated because of recent known or possible exposure to HIV. A reactive rapid HIV test result should be considered preliminary until the completion of confirmatory testing, and results should be carefully communicated to the client because of the possibility of a false-positive result.

The likelihood that a positive screening test truly indicates the presence of HIV infection decreases as HIV prevalence in the tested population becomes lower. Therefore, false-positive HIV test results are more likely in settings where the tested population prevalence is lower than in settings where the tested population prevalence is higher. When a preliminary, positive rapid test is explained to clients, phrases like “a good chance of being infected” or “very likely infected” can be used to indicate the likelihood of HIV infection and qualified based on the HIV prevalence in the setting and the client’s individual risk (120). Further testing is always required to confirm a reactive screening test result.

Follow-up Testing in Clients with Negative HIV Test Results

A negative HIV test usually indicates the absence of HIV infection (29). Because recent infection cannot be excluded without follow-up testing (see Negative HIV Test Results), the appropriate timing and frequency for follow-up testing among clients with negative HIV test results has not been firmly established. Providers should consider the following factors related to individual client needs when recommending the timing and frequency for follow-up HIV testing:

- Timing of the last potential exposure.
- Probability of HIV infection given type of exposure.
- Presence or likelihood of ongoing risk behavior.
- Likelihood of returning for follow-up HIV testing, prevention counseling, and referral.
- Client anxiety.
- Provider and client relationship.
- Resource constraints.

Recent Exposure

Follow-up testing might be appropriate for clients who have negative test results but who have not had time to develop detectable antibody after a recent documented occupational (54) or nonoccupational (sexual or needle-sharing) (55) exposure to HIV-infected persons or persons at increased risk for HIV with unknown HIV status. The timing of follow-up testing should provide assurance that the exposure did not lead to infection. Follow-up testing should be conducted in a timely manner so clients identified as HIV-infected can receive appropriate antiretroviral treatment and prevention and support services as soon as possible.

Single Possible or Known Exposure

Most infected persons will develop detectable HIV antibody within 3 months of exposure (126). If the initial negative HIV test was conducted within the first 3 months after exposure, repeat testing should be considered ≥ 3 months after the exposure occurred to account for the possibility of a false-negative result. If the follow-up test is nonreactive, the client is likely not HIV-infected. However, if the client was exposed to a known HIV-infected person or if provider or client concern remains, a second repeat test might be considered ≥ 6 months from the exposure. Rare cases of seroconversion 6–12 months after known exposure have been reported (134). Extended follow-up testing beyond 6 months after exposure to account for possible delayed seroconversion is not generally recommended and should be based on clinical judgment and individual clients needs (54).

Ongoing Exposure

Persons with continued HIV risk behavior pose a special challenge for follow-up testing. In some settings, clients with ongoing risk represent a substantial proportion of those receiving HIV CTR. In most circumstances, follow-up HIV testing should be recommended periodically for clients with ongoing risk behavior. Follow-up testing would monitor the client's HIV status, but also promote continued client contact, opportunities for HIV prevention counseling (see Additional Counseling Considerations for Special Situations), and referral to additional preventive and support services.

No Identifiable Risk

In general, persons with no recent identifiable risk for HIV infection should receive additional HIV prevention counseling and follow-up testing when requested. Efforts should be made to understand why these clients repeatedly seek follow-up testing. These clients should be considered for in-depth prevention counseling and referral to support services, where appropriate.

Special Considerations

General recommendations for follow-up testing might not be applicable in all circumstances. In certain circumstances (e.g., when persons are simultaneously exposed to hepatitis C virus and HIV [54] and when persons have received HIV vaccines), guidance should be provided only after consultation with specialists.

Addressing Barriers to HIV Testing

Knowledge of HIV infection status can benefit the health of individual persons and the community. Thus, HIV testing should be as convenient as possible to promote client knowledge of HIV infection status. Efforts should be made to remove or lower barriers to HIV testing by ensuring that

- testing is accessible, available, and responsive to client and community needs and priorities;
- anonymous and confidential HIV testing are available;
- the testing process considers the client's culture, language, sex, sexual orientation, age, and developmental level; and
- confidentiality is maintained (see Principles of HIV Counseling, Testing, and Referral).

Acceptance of HIV testing is reportedly lower when clients have been tested previously and are fearful of their ability to cope with their test results (112,113). Testing is more likely to be accepted when

- clients perceive their own HIV risk and acknowledge behaviors placing them at increased risk (135);
- testing is voluntary and routinely offered to clients rather than clients having to request it (113,136);
- protections for client confidentiality are in place (113,137);
- anonymous testing is available (113,138);
- alternate HIV test technologies are offered to clients (26);
- providers recommend testing as part of appropriate medical care (139,140); and
- providers (141) and clients (113) perceive HIV counseling and testing to be beneficial for early diagnosis and prevention purposes.

Ensuring High-Quality Testing

Testing activities should be coordinated with state and local laboratories to ensure high-quality HIV testing through proper specimen collection, storage, and transport. Laboratory errors most often occur in the preanalytic (i.e., specimen collection, labeling, transporting, processing, and storing) and postanalytic steps of testing (i.e., results validation and reporting) (142–144) rather than during the test itself. Laboratories performing HIV testing must be enrolled in proficiency testing programs and conduct activities in accordance with regulatory standards outlined by the Clinical Laboratory Improvement Amendments (CLIA) of 1988 (145). Many states have additional licensing requirements for laboratories conducting diagnostic HIV testing.

HIV REFERRAL

Definition of Referral

In the context of HIV prevention counseling and testing, referral is the process by which immediate client needs for care and supportive services are assessed and prioritized and clients are provided with assistance (e.g., setting up appointments, providing transportation) in accessing services. Referral should also include follow-up efforts necessary to facilitate initial contact with care and support service providers.

In this context, referral does not include ongoing support or management of the referral or case management. Case management is generally characterized by an ongoing relationship with a client that includes comprehensive assessment of medical and psychosocial support needs, development of a formal plan to address needs, substantial assistance in accessing referral services, and monitoring of service delivery.

Typical Referral Needs

Clients should be referred to services that are responsive to their priority needs and appropriate to their culture, language, sex, sexual orientation, age, and developmental level. Examples of these services include

- **Prevention case management.** Clients with multiple and complex needs that affect their ability to adopt and sustain behaviors to reduce their risk for transmitting or acquiring HIV should receive or be referred for prevention case management services, including ongoing prevention counseling (28). Prevention case management can help coordinate diverse referral and follow-up concerns.
- **Medical evaluation, care, and treatment.** HIV-infected clients should receive or be referred to medical services that address their HIV infection (including evaluation of immune system function and screening, treatment, and prevention of opportunistic infections) (23,29–32,53). Screening and prophylaxis for opportunistic infections and related HIV-conditions (e.g., cervical cancer) are important for HIV-infected persons. In addition, coinfection with HIV and communicable diseases (e.g., TB, STDs, and hepatitis) can, if untreated, pose a risk to susceptible community members. Thus, providers of HIV testing should be familiar with appropriate screening tests (e.g., TB), vaccines (e.g., hepatitis A and B), STD and prophylactic TB treatment, and clinical evaluation for active TB disease to ensure that these communicable diseases are identified early and appropriate clinical referrals are made, even if clients forego outpatient HIV treatment.
- **Partner counseling and referral services.** Persons with HIV-positive test results should receive or be referred to services to help them notify their sex or injection-drug-equipment-sharing partners or spouses regarding their exposure to HIV and how to access CTR. Guidelines for PCRS are available (27).
- **Reproductive health services.** Female clients who are pregnant or of childbearing age should receive or be referred to reproductive health services. HIV-infected pregnant women should be referred to providers who can provide prevention counseling and education, initiate medical therapy to prevent perinatal transmission, and provide appropriate care based on established treatment

guidelines (see *Revised Recommendations for HIV Screening of Pregnant Women*).

- **Drug or alcohol prevention and treatment.** Clients who abuse drugs or alcohol should receive or be referred to substance or alcohol abuse prevention and treatment services.
- **Mental health services.** Clients who have mental illness, developmental disability, or difficulty coping with HIV diagnosis or HIV-related conditions should receive or be referred to appropriate mental health services.
- **Legal services.** Clients who test positive should be referred to legal services as soon as possible after learning their test result for counseling on how to prevent discrimination in employment, housing, and public accommodation by only disclosing their status to those who have a legal need to know.
- **STD screening and care.** Clients who are HIV-infected or at increased risk for HIV are at risk for other STDs and should receive or be referred for STD screening and treatment (146).
- **Screening and treatment for viral hepatitis.** Many clients who are HIV-infected or at increased risk for HIV are at increased risk for acquiring viral hepatitis (A, B, and C). Men who have sex with men and IDUs should be vaccinated for hepatitis A. All clients without a history of hepatitis B infection or vaccination should be tested for hepatitis B, and if not infected, should receive or be referred for hepatitis B vaccination. In addition, clients who inject drugs should be routinely recommended testing for hepatitis C. All clients who are infected with hepatitis viruses should be referred for appropriate treatment. Further guidance is available (30,32).
- **Other services.** Clients might have multiple needs that can be addressed through other HIV prevention and support services (e.g., assistance with housing, food, employment, transportation, child care, domestic violence, and legal services). Addressing these needs can help clients access and accept medical services and adopt and maintain behaviors to reduce risk for HIV transmission and acquisition. Clients should receive referrals as appropriate for identified needs.

Implement and Manage Referral Services

Clients should receive help accessing and completing referrals, and completion of referrals should be verified. In the context of HIV prevention counseling and testing, the following elements should be considered essential to the development and delivery of referral services (99).

Assess Client Referral Needs

Providers should consult with the client to identify essential factors that a) are likely to influence the client's ability to adopt or sustain behaviors to reduce risk for HIV transmission or acquisition or b) promote health and prevent disease progression. Assessment should include examination of the client's willingness and ability to accept and complete a referral. Service referrals that match the client's self-identified priority needs are more likely to be successfully completed than those that do not (147). Priority should be placed

on ensuring that HIV-infected clients are assessed for referral needs related to medical care, PCRS, and prevention and support services aimed at reducing the risk for further transmission of HIV. When a provider cannot make appropriate referrals or when client needs are complex, clients should be referred to a case management system.

Plan the Referral

Referral services should be responsive to clients' needs and priorities and appropriate to their culture, language, sex, sexual orientation, age, and developmental level. In consultation with clients, providers should assess and address any factors that make completing the referral difficult (e.g., lack of transportation or child care, work schedule, cost). Research has indicated that referrals are more likely to be completed if services are easily accessible to clients (147).

Help Clients Access Referral Services

Clients should receive information necessary to successfully access the referral service (e.g., contact name, eligibility requirements, location, hours of operation, telephone number). Research has indicated that providing assistance (e.g., setting an appointment, addressing transportation needs) for some clients promotes completion of referrals (148). Clients must give consent before identifying information to help complete the referral can be shared. Outreach workers and peer counselors/educators can be an important and effective resource to help clients identify needs and plan successful referrals (149). Referrals are more likely to be completed after multiple contacts with outreach workers (147).

Document Referral and Follow-Up

Providers should assess and document whether the client accessed the referral services. If the client did not, the provider should determine why; if the client did, the provider should determine the client's degree of satisfaction. If the services were unsatisfactory, the provider should offer additional or different referrals. Documentation of referrals made, the status of those referrals, and client satisfaction with referrals should help providers better meet the needs of clients. Information obtained through follow-up of referrals can identify barriers to completing the referral, responsiveness of referral services in addressing client needs, and gaps in the referral system.

Ensure High-Quality Referral Services

Providers of referral services should know and understand the service needs of their clients, be aware of available community resources, and be able to provide services in a manner appropriate to the clients' culture, language, sex, sexual orientation, age, and developmental level, given local service system limitations.

Education and Support of Staff Members

Staff members providing referral services must understand client needs, have skills and resources to address these needs, have authority to help the client procure services, and be able to advocate for clients.

Training and Education. Providers should ensure that staff members receive adequate training and continuing education to implement and manage referrals. Training

and education should address resources available and methods for managing referrals, as well as promote understanding of factors likely to influence the client's ability and willingness to use a referral service (e.g., readiness to accept the service, competing priorities, financial resources). Referrals are more likely to be completed when a provider is able to correctly evaluate a client's readiness to adopt risk-reducing behaviors (147). Research has indicated that cross-training increases knowledge and understanding of community resources among providers and can indicate gaps in services (148).

Authority. Staff members providing referrals must have the authority necessary to accomplish a referral. Supervisors must ensure that staff members understand referral policy and protocol and have the necessary support to provide referrals. This requires the authority of one provider to refer to another (e.g., through memoranda of agreement) or to obtain client consent for release of medical or other personal information.

Advocacy. Staff members who negotiate referrals must possess knowledge and skills to advocate for clients. Such advocacy can help clients obtain services by mediating barriers to access to services and promoting an environment in which providers are better informed regarding the needs and priorities of their clients.

Provider Coordination and Collaboration

Providers should develop and maintain strong working relationships with other providers and agencies that might be able to provide needed services. Providers who offer HIV prevention counseling and testing but not a full range of medical and psychosocial support services should develop direct, clearly delineated arrangements with other providers who can offer needed services. Coordination and collaboration promotes a shared understanding of the specific medical and psychosocial needs of clients requiring services, current resources available to address these needs, and gaps in resources.

Memoranda of agreement or other forms of formal agreement are useful in outlining provider/agency relationships and delineating roles and responsibilities of collaborating providers in managing referrals. When confidential client information is shared between coordinating providers, such formal agreements are essential. These agreements should be reviewed periodically and modified as appropriate.

Referral Resources

Knowledge of available support services is essential for successful referrals. When referral resources are not available locally, providers should identify appropriate resources and link clients with them. A resource guide should be developed and maintained to help staff members make appropriate referrals (Box 7). Information regarding community resources can be obtained from local health planning councils, consortia, and community planning groups. Local, state, and national HIV/AIDS information hotlines or websites (e.g., NPIN), community-based health and human service providers, and state and local public health departments can also provide information.

HIV CTR SERVICES IN NONTRADITIONAL SETTINGS

CTR should be provided in community-based and outreach settings as well as clinical settings. Data from publicly supported CTR programs have indicated that doing so could promote use of these services by persons at increased risk for HIV. When HIV CTR are not readily available, accessible, or acceptable, persons at increased risk might not take

BOX 7. Contents of a referral resource guide

For each resource, the referral resource guide should specify the following:

- Name of the provider or agency
- Range of services provided
- Target population
- Service area(s)
- Contact names and telephone and fax numbers, street addresses, e-mail addresses
- Hours of operation
- Location
- Competence in providing services appropriate to the client's culture, language, sex, sexual orientation, age, and developmental level
- Cost for services and acceptable methods of payment
- Eligibility
- Application materials
- Admission policies and procedures
- Directions, transportation information, and accessibility to public transportation
- Client satisfaction with services

advantage of them. Expanding CTR into nontraditional settings can be accomplished through partnership with community-based service providers and use of new, FDA-approved HIV test technologies that offer portability, less-invasive sample collection, less-complex sample collection and processing, and reduced biohazard. To ensure effective CTR that is responsive to client needs, providers should develop and implement written quality assurance protocols and procedures specifically for services provided in nontraditional settings.

Privacy and Confidentiality

Ensuring clients' privacy and confidentiality during CTR is essential, but could present unique challenges in some nontraditional settings. Confidentiality can more easily be breached in settings where clients and providers can be seen or heard by others. Suggested strategies for maintaining privacy and confidentiality in nontraditional settings include the following:

- Use a separated area in a mobile van.
- Use rooms with locking doors.

- Mark a specific room with a “do not disturb” or “occupied” sign.
- Designate an area in the setting that provides physical privacy.
- In parks and similar locations, seek areas with as much privacy as possible.
- Provide counseling and testing services in the client’s home or other secure setting.
- Have clients return to the setting to receive test results and counseling and referral.

Informed Consent

Staff members providing CTR services should be sensitive to barriers that can interfere with obtaining true informed consent, including alcohol and drug use, mental illness, and peer pressure in venues where persons congregate or socialize. Suggested strategies for obtaining informed consent in nontraditional settings include the following:

- Schedule an appointment to test at a later date/time.
- Follow up at a later time with the client if contact information is available.
- Read the informed consent form to the client.
- Use verbal prompts to ensure that the client understands information in the informed consent form.

Counseling

Staff members working in community-based and other nontraditional settings should know and use risk-screening strategies to determine whether HIV prevention counseling should be recommended. Staff members should be trained in HIV prevention counseling or other approaches aimed at personal HIV risk reduction. When appropriate (e.g., among IDUs), information regarding other STDs and bloodborne diseases should be incorporated into the counseling sessions (29,30).

Testing

The decision to offer HIV testing in nontraditional settings should be based on several factors, including availability of resources and feasibility of providing test results and follow-up. In some cases, referral to other providers is appropriate. The selection of a specific HIV test technology should be based on logistical issues (e.g., field conditions related to collection, transport, and storage of specimens; worker safety; and the likelihood that clients will receive HIV test results). Providers must understand the extent to which field conditions can affect specimens (e.g., extreme temperatures or time lapse from collection to processing). Test specimens should be collected, stored, and transported according to manufacturer instructions.

Provision of Test Results

Clear protocols for provision of test results and prevention counseling should be developed. The following strategies might be useful in ensuring the provision of results in nontraditional settings:

- Provide a telephone number that clients can call to receive test results.
- Make an appointment with the client at the time of testing to receive results.
- Provide incentives (e.g., food certificates, hygiene kits, food).
- Return to a site on a regularly scheduled basis.
- Provide reminders when contact information is available.

Referral

Staff members working in community-based and outreach settings should be trained to implement and manage referrals. Providers should establish appropriate collaborative relationships for referrals. Arranging for PCRS staff members or case managers to be available to clients at the time test results are provided might help promote referral.

Record Keeping

Maintaining the confidentiality of client records is critical. Providers should develop written protocols for record keeping that address transport of client records to and from outreach venues. Strategies to maintain confidentiality of client records in nontraditional settings include the following:

- Return all client records to the office immediately after the CTR session.
- Use codes or unique identifiers rather than client names.
- Store all records in a secured area (e.g., locked file drawers).
- Provide option of anonymous counseling and testing as well as confidential counseling and testing.
- Verify identity of client (e.g., match client signature with that provided for informed consent or check identification card) when providing test results.
- Store paperwork in a lockbox while in outreach settings.
- Password protect and encrypt electronically stored client records.

Where allowed by state/local statute, clients can choose anonymous HIV testing. Procedures to ensure client anonymity (i.e., no indication of testing in the client's record and no recording of personal identifying information on laboratory requests) should be developed. Even when staff members providing CTR services know the client (including name and locating information) from other activities, the client's right to be tested anonymously should be protected.

Staff Safety

Providing services in outreach settings (e.g., bars, parks) might compromise staff safety, which must be considered in development of outreach protocols. Appropriate training and precautions (e.g., working in teams) should be developed in planning services in nontraditional settings.

QUALITY ASSURANCE AND EVALUATION OF HIV CTR SERVICES

Quality Assurance

Written quality assurance protocols should be developed, made available to all staff members providing CTR services, and routinely implemented. All staff members should receive training and orientation regarding quality assurance. For information specific to ensuring high-quality CTR services, see Ensuring High-Quality HIV Prevention Counseling, Ensuring High-Quality Testing, and Ensuring High-Quality Referral Services. Quality assurance activities should address the following:

- Accessibility of services (e.g., hours of operation, location, availability of supplies and materials such as brochures, posters, test kits, safe injection materials, condoms, or lubricant).
- Compliance with written protocols for provision of service to an individual client (e.g., appropriate counseling protocols, timely return of HIV test results, referral for services responsive to client's priority needs).
- Services and materials appropriate to the client's culture, language, sex, sexual orientation, age, and developmental level.
- Staff performance/proficiency (e.g., competence, skills, credentials, and training).
- Supervision of staff members, including routine, timely feedback.
- Compliance with program guidelines and performance standards.
- Appropriateness of services to client needs, measured with client satisfaction tools (e.g., surveys or suggestion boxes).
- Record-keeping procedures, including confidentiality and security.
- Community resources (availability and collaborative arrangements).
- Collection, handling, and storage of specimens.
- Assurance of adequate funding and institutional support for CTR services.

Evaluation

CTR services should be continually evaluated to improve services to clients and provide accountability to stakeholders (150, 151). Evaluation should be interactive, involving individual persons and organizations affected by the services (150). In public health settings, the community goals outlined in community health planning processes and other relevant local planning processes could be incorporated.

Providers should identify the key, relevant program goals and objectives that reflect services to the program, community, and client, and then determine what data are needed to evaluate those goals and objectives. Information obtained from the evaluation should be used to plan and prioritize provision of CTR services within a setting. For example, information from the HIV Counseling and Testing System (133) or locally available

sources could be used during local community planning (e.g., HIV prevention community planning) to help develop or revise an HIV/AIDS prevention plan or describe who needs services. If resources for evaluation are limited, comprehensive evaluations (e.g., examining outcome or impact) might not be possible. However, even with limited resources, providers can conduct meaningful evaluations by focusing on relevant local outcomes (82).

Data

Data collected should have a clear, anticipated use and should not be the focus of or interfere with provision of CTR services. Data should be used to evaluate the extent to which the goals of CTR and locally defined service outcomes (e.g., targeted return rates, knowledge of HIV infection status, proportion of successful referrals) are met. Although sound data are essential for evaluation of services, the primary purpose of each visit should be to provide the best possible service to the client. Data should be recorded outside the time reserved for CTR discussions between the provider and the client. Clients could complete a questionnaire or intake information form on admission, providers could complete the forms immediately after meeting with a client, or a combination of the two approaches could be used.

Data collection methods should be compatible with the evaluation needs and priorities of the CTR setting and locally defined service outcomes. Data should be collected with a standard collection instrument throughout the program. Simple data collection instruments (e.g., intake forms, medical record reviews) should be developed so data can be collected unobtrusively as part of the provision of services.

Publicly funded CTR sites collect data on client demographic characteristics, risk behavior/exposure category, test acceptance, and type of site where service is provided (133). Most sites record the date of visit, anonymous or confidential test status, previous test result, current test result, and return for current test result for each client encounter. Additional data can be useful for evaluation of services, including date of previous test, type of current test (e.g., standard, rapid, oral fluid), risk-reduction plan summary, information relevant to any referrals made (e.g., provider and service description, information and materials provided, whether an appointment was made), whether the referral was received, type of service provided, dates when services were provided, and other relevant information (e.g., follow-up required, additional service needs).

Confidentiality

Any data collected or recorded must be collected or recorded in a manner that ensures the confidentiality of the client. Clear procedures and protocol manuals must be developed and used.

Ensuring High-Quality Evaluation

- The system used to collect the information must be monitored periodically to ensure data quality, which depends on the cooperative efforts of all persons providing CTR services. Periodically, data collection systems should check records at each level of the data-collection process to ensure that information is recorded consistently and completely.

- Adequate training in the use of data collection instruments should be provided to all staff members to ensure that the evaluation process is not interfering with the provision of high-quality CTR services.
- The information assembled during the evaluation process should be analyzed and reported in a timely manner to individual persons and organizations affected by the service.
- Information and feedback gained during the evaluation process should be used to improve the services offered by the site to the client.

CONCLUSION

Advances in HIV prevention and medical treatment increase the importance of HIV CTR services. Prevention counseling and knowledge of HIV status can help persons who are HIV-infected or at increased risk for HIV infection reduce their risk for transmitting or acquiring HIV infection. Referral can help persons access relevant medical, preventive, and psychosocial support services to reduce their risk for transmitting or acquiring HIV infection. These guidelines recommend how CTR can be provided to clients who could most benefit from these services across various settings and client populations.

ADDITIONAL RESOURCES

Additional information on HIV CTR can be obtained from the following sources:

- CDC's National Center for HIV, STD, and TB Prevention website at <<http://www.cdc.gov/nchstp/od/nchstp.html>>.
- CDC National AIDS Hotline in English, (800) 342-2437.
- CDC National AIDS Hotline in Spanish, (800) 344-7432.
- CDC National AIDS Hotline TTY, (800) 243-7889.
- CDC National STD Hotline, (800) 227-8922.
- CDC's National Prevention Information Network at <<http://www.cdcnpin.org>> or (800) 458-5231 (information available in English and Spanish).
- HIV/AIDS Treatment Information Service at <<http://www.hivatis.org>> or (800) 448-0440 (information available in English and Spanish).
- AIDS Clinical Trials Information Service at <<http://www.actis.org>> or (800) 874-2572 (information available in English and Spanish).
- National Clinicians' Post-Exposure Prophylaxis Hotline at <<http://pepline.ucsf.edu/PEPLine>> or (888) 448-4911.

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References

1. CDC. Current trends: additional recommendations to reduce sexual and drug abuse-related transmission of human T-lymphotropic virus type III/lymphadenopathy-associated virus. *MMWR* 1986;35:152-5.
2. CDC. Perspectives in disease prevention and health promotion: Public Health Service guidelines for counseling and antibody testing to prevent HIV infection and AIDS. *MMWR* 1987;36:509-15.
3. CDC. Technical guidance on HIV counseling. *MMWR* 1993;42(No. RR-2):5-9.
4. CDC. HIV counseling, testing and referral standards and guidelines. Atlanta, GA: US Department of Health and Human Services, Public Health Service, CDC, 1994.
5. Kamb ML, Fishbein M, Douglas JM Jr, et al. Efficacy of risk-reduction counseling to prevent human immunodeficiency virus and sexually transmitted diseases: a randomized controlled trial. *JAMA* 1998;280:1161-7.
6. The National Institutes of Mental Health (NIMH) Multisite HIV Prevention Trial Group. The NIMH multisite HIV prevention trial: reducing HIV sexual risk behavior. *Science* 1998;280:1889-94.
7. Boyer CB, Barrett DC, Peterman TA, Bolan G. Sexually transmitted disease (STD) and HIV risk in heterosexual adults attending a public STD clinic: evaluation of a randomized controlled behavioral risk-reduction intervention trial. *AIDS* 1997;11:359-67.
8. St. Lawrence JS, Brasfield TL, Jefferson KW, Alleyne E, O'Bannon RE, III, Shirley A. Cognitive-behavioral intervention to reduce African American adolescents' risk for HIV infection. *J Consult Clin Psychol* 1995;63:221-37.
9. McCusker J, Willis G, McDonald M, Sereti SM, Lewis BF, Sullivan JL. Community-wide HIV counselling and testing in central Massachusetts: who is retested and does their behavior change? *J Community Health* 1996;21:11-22.
10. Kelly JA, Murphy DA, Washington CD, et al. The effects of HIV/AIDS intervention groups for high-risk women in urban clinics. *Am J Pub Health* 1994;84:1918-22.
11. Tudiver F, Myers T, Kurtz RG, et al. The talking sex project: results of a randomized controlled trial of small-group AIDS education for 612 gay and bisexual men. *Evaluation and the Health Professions* 1992;15:26-42.
12. Wenger NS, Linn LS, Epstein M, Shapiro MF. Reduction of high-risk sexual behavior among heterosexuals undergoing HIV antibody testing: a randomized clinical trial. *Am J Pub Health* 1991;81:1580-5.
13. Orr DP, Langefeld CD, Katz BP, Caine VA. Behavioral intervention to increase condom use among high-risk female adolescents. *J Pediatr* 1996;128:288-95.
14. Hobfoll SE, Jackson AP, Lavin J, Britton PJ, Shepherd JB. Reducing inner-city women's AIDS risk activities: a study of single, pregnant women. *Health Psychol* 1994;13:397-403.
15. Kelly JA, St. Lawrence JS, Hood HV, Brasfield TL. Behavioral intervention to reduce AIDS risk activities. *J Consult Clin Psychol* 1989;57:60-7.
16. Valdiserri RO, Lyter DW, Leviton LC, Callahan CM, Kingsley LA, Rinaldo CR. AIDS prevention in homosexual and bisexual men: results of a randomized trial evaluating two risk reduction interventions. *AIDS* 1989;3:21-6.
17. Jemmott JB, III, Jemmott LS, Fong GT. Reductions in HIV risk-associated sexual behaviors among black male adolescents: effects of an AIDS prevention intervention. *Am J Pub Health* 1992;82:372-7.
18. Shain RN, Piper JM, Newton ER, et al. A randomized, controlled trial of a behavioral intervention to prevent sexually transmitted disease among minority women. *N Eng J Med* 1999;340:93-100.
19. O'Donnell C, O'Donnell L, San Doval A, Duran R, Labes K. Reductions in STD infections subsequent to an STD clinic visit: using video-based patient education to supplement provider interactions. *Sex Transm Dis* 1998;25:161-7.

20. Cohen DA, MacKinnon DP, Dent C, Mason HRC, Sullivan E. Group counseling at STD clinics to promote use of condoms. *Public Health Rep* 1992;107:727–31.
21. Cohen D, Dent C, MacKinnon D. Condom skills education and sexually transmitted disease reinfection. *J Sex Research* 1991;28:139–44.
22. Palella FJ Jr, Delaney KM, Moorman AC, et al. Declining morbidity and mortality among patients with advanced human immunodeficiency virus infection. *N Eng J Med* 1998;338:853–60.
23. CDC. 1999 USPHS/IDSA guidelines for the prevention of opportunistic infections in persons infected with human immunodeficiency virus. *MMWR* 1999;48(No. RR-10):1–59.
24. Connor EM, Sperling RS, Gelber R, et al. Reduction of maternal-infant transmission of human immunodeficiency virus type 1 with zidovudine treatment. *N Eng J Med* 1994;331:1173–80.
25. Kassler WJ. Advances in HIV testing technology and their potential impact on prevention. *AIDS Educ Prev* 1997;9(suppl B):27–40.
26. Spielberg B, Goldbaum G, Branson B, Wood B. Acceptance of alternate HIV counseling and testing strategies [Abstract]. Presented in the 1999 National HIV Prevention Conference, Atlanta, GA, 1999.
27. CDC. HIV partner counseling and referral services: guidance. Atlanta, GA: US Department of Health and Human Services, Public Health Service, CDC, 1998.
28. CDC. HIV prevention case management: guidance. Atlanta, GA: US Department of Health and Human Services, CDC, 1997.
29. CDC. 1998 guidelines for treatment of sexually transmitted diseases. *MMWR* 1998;47(No. RR-1):1–30. (These guidelines will be updated in 2002 and available at <<http://www.cdc.gov/nchstp/od/nchstp.html>>.)
30. CDC. Recommendations for prevention and control of hepatitis C virus (HCV) infection and HCV-related chronic disease. *MMWR* 1998;47(No. RR-19):1–39.
31. CDC. Prevention of hepatitis A through active or passive immunization: recommendations of the Immunization Practices Advisory Committee (ACIP). *MMWR* 1999;48(No. RR-12):1–37.
32. CDC. Hepatitis B virus: a comprehensive strategy for eliminating transmission in the United States through universal childhood vaccination: recommendations of the Immunization Practices Advisory Committee (ACIP). *MMWR* 1991;40(No. RR-13):1–25.
33. US Preventive Services Task Force. DiGuseppi C, Atkins D, Woolf SH, eds. *Guide to clinical preventive services*. 2nd ed. Baltimore, MD: Williams & Wilkins, 1996.
34. CDC. *CDC guidelines: improving the quality*. Atlanta, GA: US Department of Health and Human Services, Public Health Service, CDC, 1996.
35. CDC. HIV and AIDS—United States, 1981–2000. *MMWR* 2001;50:430–4.
36. CDC. Guidelines for national human immunodeficiency virus case surveillance, including monitoring for human immunodeficiency virus infection and acquired immunodeficiency syndrome. *MMWR* 1999;48(No. RR-13):1–28.
37. Collis TK, Celum CL. The clinical manifestations and treatment of sexually transmitted diseases in human immunodeficiency virus-positive men. *Clin Infect Dis* 2001;32:611–22.
38. Valdiserri RO, Holtgrave DR, West GR. Promoting early HIV diagnosis and entry into care. *AIDS* 1999;13:2317–30.
39. Rietmeijer CA, Kane MS, Simons PZ, et al. Increasing the use of bleach and condoms among injecting drug users in Denver: outcomes of a targeted, community-level HIV prevention program. *AIDS* 1996;10:291–8.
40. Rhodes F, Malotte CK. HIV risk interventions for active drug users. In: S.Oskamp, S.Thompson, eds. *Understanding HIV risk behavior: safer sex and drug use*. Thousand Oaks, CA: Sage Publications, 1996:297–36.
41. Gibson DR, Lovelle-Drache J, Young M, Hudes ES, Sorensen JL. Effectiveness of brief counseling in reducing HIV risk behavior in injecting drug users: final results of randomized trials of counseling with and without HIV testing. *AIDS and Behavior* 1999;3:3–12.

42. Doll LS, O'Malley PM, Pershing AL, Darrow WW, Hessel NA, Lifson AR. High-risk sexual behavior and knowledge of HIV antibody status in the San Francisco City Clinic Cohort. *Health Psychol* 1990;9:253-65.
43. Cleary PD, Van Devanter N, Rogers TF, et al. Behavior changes after notification of HIV infection. *Am J Pub Health* 1991;81:1586-90.
44. Fox R, Odaka NJ, Brookmeyer R, Polk BF. Effect of HIV antibody disclosure on subsequent sexual activity in homosexual men. *AIDS* 1987;1:241-6.
45. van Griensven GJP, de Vroome EMM, Tielman RAP, et al. Effect of human immunodeficiency virus (HIV) antibody knowledge on high-risk sexual behavior with steady and nonsteady sexual partners among homosexual men. *Am J Epidemiol* 1989;129:596-603.
46. Coates TJ, Morin SF, McKusick L. Behavioral consequences of AIDS antibody testing among gay men [Letter]. *JAMA* 1987;258:1889.
47. Wenger NS, Kusseling FS, Beck K, Shapiro MF. Sexual behavior of individuals infected with the human immunodeficiency virus: the need for intervention. *Arch Intern Med* 1994;154:1849-54.
48. Desenclos J-C, Papaevangelou G, Ancelle-Park R, for the European Community Study Group on HIV in Injecting Drug Users. Knowledge of HIV serostatus and preventive behaviour among European injecting drug users. *AIDS* 1993;7:1371-7.
49. Dawson J, Fitzpatrick R, McLean J, Hart G, Boulton M. The HIV test and sexual behavior in a sample of homosexually active men. *Soc Sci Med* 1991;32:683-8.
50. Otten MW Jr, Zaidi AA, Wroten JE, Witte J, Peterman TA. Changes in sexually transmitted disease rates after HIV testing and posttest counseling, Miami, 1988 to 1989. *Am J Pub Health* 1993;83:529-33.
51. Quinn TC, Wawer MJ, Sewankambo N, et al. Viral load and heterosexual transmission of human immunodeficiency virus type 1. *N Eng J Med* 2000;342:921-9.
52. Branson BM. Home sample collection tests for HIV infection. *JAMA* 1998;280:1699-701.
53. CDC. Prevention and treatment of tuberculosis among patients infected with human immunodeficiency virus: principles of therapy and revised recommendations. *MMWR* 1998;47(No. RR-20):1-25.
54. CDC. Updated U.S. Public Health Service guidelines for the management of occupational exposures to HBV, HCV, and HIV and recommendations for postexposure prophylaxis. *MMWR* 2001;50(No. RR-11):1-54.
55. CDC. Management of possible sexual, injecting-drug-use, or other nonoccupational exposure to HIV, including considerations related to antiretroviral therapy. *MMWR* 1998;47(No. RR-17):1-14.
56. Tao G, Irwin KL, Kassler WJ. Missed opportunities to assess STDs in US adults during routine medical checkups. *Am J Prev Med* 2000;18:109-14.
57. CDC. HIV prevention practices of primary care physicians—United States, 1992. *MMWR* 1994;42:988-92.
58. Tiara DA, Safran DG, Seto TB, Rogers WH, Tarlov AR. The relationship between patient income and physician discussion of health risk behaviors. *JAMA* 1997;278:1412-7.
59. Schwartz JS, Lewis CE, Clancy C, Kinosian MS, Radany MH, Koplan JP. Internists' practices in health promotion and disease prevention. *Ann Intern Med* 1991;114:46-53.
60. Bindman AB, Osmond D, Hecht FM, et al. Multistate Evaluation of anonymous HIV testing and access to medical care. *JAMA* 1998;280:1416-20.
61. Chen Z, Branson B, Ballenger A, Peterman TA. Risk assessment to improve targeting of HIV counseling and testing services of STD clinic patients. *Sex Transm Dis* 1998;25:539-43.
62. Quinn TC, Glasser D, Cannon RO, et al. Human immunodeficiency virus infection among patients attending clinics for sexually transmitted diseases. *N Eng J Med* 1988;318:197-203.

63. Erickson B, Wasserheit JN, Rompalo AM, Brathwaite W, Glasser D, Hook EW III. Routine voluntary HIV screening in STD clinic clients: characterization of infected clients. *Sex Transm Dis* 1990;17:194-9.
64. Groseclose S, Erickson B, Quinn T, Glasser D, Campbell C, Hook E. Characteristics of patients accepting and refusing routine, voluntary HIV antibody testing in public sexually transmitted disease clinics. *Sex Transm Dis* 1994;21:31-5.
65. Kassler WJ, Zenilman JM, Erickson B, Fox R, Peterman TA, Hook EW III. Seroconversion in patients attending sexually transmitted disease clinics. *AIDS* 1994;8:351-5.
66. Asch SM, London AS, Barnes PF, Gelberg L. Testing for human immunodeficiency virus infection among tuberculosis patients in Los Angeles. *Am J Respir Crit Care Med* 1997;155:378-81.
67. Pitchenik AE, Burr J, Suarez M, Fertel D, Gonzalez G, Moas C. Human T-cell lymphotropic virus-III (HTLV-III) seropositivity and related disease among 71 consecutive patients in whom tuberculosis was diagnosed. *Am Rev Respir Dis* 1987;135:875-9.
68. Shafer RW, Chirgwin KD, Glatt AE, Dahdouh MA, Landesman SH, Suster B. HIV prevalence, immunosuppression, and drug resistance in patients with tuberculosis in an area endemic for AIDS. *AIDS* 1991;5:399-405.
69. Theuer CP, Hopewell PC, Elias D, Schechter GF, Rutherford GW, Chaisson RE. Human immunodeficiency virus infection in tuberculosis patients. *J Infect Dis* 1990;162:8-12.
70. Peterman TA, Todd KA, Mupanduki I. Opportunities for targeting publicly funded human immunodeficiency virus counseling and testing. *J Acquir Immune Defic Syndr* 1996;12:69-74.
71. Janssen RS, St. Louis ME, Satten GA, et al. HIV infection among patients in U.S. acute care hospitals: strategies for the counseling and testing of hospital patients. *New Eng J Med* 1992;327:445-52.
72. CDC. HIV prevalence trends in selected populations in the United States: results from national serosurveillance, 1993-1997. Atlanta, GA: US Department of Health and Human Services, CDC, 2001.
73. Kelly JA, St. Lawrence JS. The prevention of AIDS: roles for behavioral intervention. *Scand J Behav Therapy* 1987;16:5-19.
74. Cohen DA, Dent C, MacKinnon D, Hahn G. Condoms for men, not women: results of brief promotion programs. *Sex Transm Dis* 1992;19:245-51.
75. Sikkema KJ, Bissett RT. Concepts, goals, and techniques of counseling: review and implications for HIV counseling and testing. *AIDS Educ Prev* 1997;9(suppl B):14-26.
76. Roffman RA, Kalichman SC, Kelly JA, et al. HIV antibody testing of gay men in smaller US cities. *AIDS Care* 1995;7:405-13.
77. DiClemente RJ, Wingood GM. A randomized controlled trial of an HIV sexual risk-reduction intervention for young African-American women. *JAMA* 1995;274:1271-6.
78. Kelly JA, St. Lawrence JS, Diaz YE, et al. HIV risk behavior reduction following intervention with key opinion leaders of population: an experimental analysis. *Am J Pub Health* 1991;81:168-71.
79. Kelly JA, St. Lawrence JS. Behavioral intervention and AIDS. *The Behavioral Therapist* 1986;6:121-5.
80. Kamb ML, Dillon BA, Fishbein M, Willis KL, and the Project RESPECT Study Group. Quality assurance of HIV prevention counseling in a multi-center randomized controlled trial. *Public Health Rep* 1996;111(suppl 1):99-107.
81. Holtgrave DR, Valdiserri RO, Gerber AR, Hinman AR. Human immunodeficiency virus counseling, testing, referral, and partner notification services: a cost-benefit analysis. *Arch Intern Med* 1993;153:1225-30.
82. Holtgrave DR, Reiser WJ, DiFranceisco W. The evaluation of HIV counseling-and-testing services: making the most of limited resources. *AIDS Educ Prev* 1997;9(3 suppl):105-18.

83. Kamb ML, Kassler W, Peterman TA, and the Project RESPECT Study Group. Cost of preventing HIV via counseling: results from a randomized trial (Project RESPECT) [Abstract 33263]. Presented at the XII International Conference on AIDS, Geneva, Switzerland, 1998:644.
84. Booth RE, Kwiatkowski CF, Stephens RC. Effectiveness of HIV/AIDS interventions on drug use and needle risk behaviors for out-of-treatment injection drug users. *J Psychoactive Drugs* 1998;30:269–78.
85. Castrucci BC, Kamb ML, Hunt K. Assessing use of the 1994 HIV counseling, testing, and referral standards and guidelines—how closely does practice conform to existing recommendations? [Abstract P125]. Presented at the 2000 National STD Prevention Conference, December 4–7, Milwaukee, WI, 2000.
86. Kelly JA, Murphy DA, Sikkema KJ, Kalichman SC. Psychological interventions to prevent HIV infection are urgently needed: new priorities for behavioral research in the second decade of AIDS. *Am Psychol* 1993;48:1023–34.
87. McCusker J, Stoddard AM, Zapka JG, Zorn M, Mayer KH. Predictors of AIDS-preventive behavior among homosexually active men: a longitudinal study. *AIDS* 1989;3:443–8.
88. Kelly JA, Murphy DA. Some lessons learned about risk reduction after ten years of the HIV/AIDS epidemic. *AIDS Care* 1991;3:251–7.
89. Kelly JA, Murphy DA. Psychological interventions with AIDS and HIV: prevention and treatment. *J Consult Clin Psychol* 1992;60:576–85.
90. American Public Health Association. *AIDS prevention in the community: lessons from the first decade*. Washington, DC: American Public Health Association, 1995.
91. Wiktor SZ, Biggar RJ, Melbye M, et al. Effect of knowledge of human immunodeficiency virus infection status on sexual activity among homosexual men. *J Acquir Immune Defic Syndr* 1990;3:62–8.
92. Kelly JA, St. Lawrence JS, Betts R, Brasfield TL, Hood HV. A skills-training group intervention model to assist persons in reducing risk behaviors for HIV infection. *AIDS Educ Prev* 1990;2:24–35.
93. Sikkema KJ, Winett RA, Lombard DN. Development and evaluation of an HIV-risk reduction program for female college students. *AIDS Educ Prev* 1995;7:145–59.
94. Kelly JA, Kalichman SC. Increased attention to human sexuality can improve HIV-AIDS prevention efforts: key research issues and directions. *J Consult Clin Psychol* 1995;63:907–18.
95. CDC. *Compendium of HIV prevention interventions with evidence of effectiveness*. Atlanta, GA: US Department of Health and Human Services, CDC, 1999.
96. Higgins DL, Galavotti C, O'Reilly KR, et al. Evidence for the effects of HIV antibody counseling and testing on risk behaviors. *JAMA* 1991;266:2419–29.
97. Wolitski RJ, MacGowan RJ, Higgins DL, Jorgenson CM. The effects of HIV counseling and testing on risk-related practices and help-seeking behavior. *AIDS Educ Prev* 1997;9(suppl B):52–67.
98. Flaskerud JH. Matching client and therapist ethnicity, language, and gender: a review of research. *Issues in Mental Health Nursing* 1990;11:321–36.
99. Kilmarx PH, Hamers FF, Peterman TA. Living with HIV: experiences and perspectives of HIV-infected sexually transmitted disease clinic patients after posttest counseling. *Sex Transm Dis* 1998;25:28–37.
100. Cates W, Handsfield HH. HIV counseling and testing: does it work? *Am J Public Health* 1988;78:1533–4.
101. Calsyn DA, Saxon AJ, Freeman G, Whittaker S. Ineffectiveness of AIDS education and HIV antibody testing in reducing high risk behaviors among injection drug users. *Am J Public Health* 1992;82:573–5.
102. Edlin BR, Irwin KL, Faruque S, et al. Intersecting epidemics—crack cocaine use and HIV infection among inner-city young adults. *N Eng J Med* 1994;331:1422–7.

103. Cottler LB, Leukefeld C, Hoffman J, et al. Effectiveness of HIV risk reduction initiatives among out-of-treatment non-injection drug users. *J Psychoactive Drugs* 1998;30:279-90.
104. Nicolosi A, Molinari S, Musicco M, Saracco A, Ziliani N, Lazzarin A. Positive modification of injecting behavior among intravenous heroin users from Milan and Northern Italy 1987-1989. *Brit J Addiction* 1991;86:91-102.
105. Neaigus A, Sufian M, Friedman S, et al. Effects of outreach intervention on risk reduction among intravenous drug users. *AIDS Educ Prev* 1990;2:253-71.
106. Obermeyer TE, Streeter A. Street outreach HIV education to intravenous drug users and other substance abusers. *AIDS Patient Care* 1991;5:312-4.
107. Hagan H, Jarlais DC, Friedman SR, Purchase D, Alter MJ. Reduced risk of hepatitis B and hepatitis C among injection drug users in the Tacoma Syringe Exchange Program. *Am J Public Health* 1995;85:1531-7.
108. Jones TS, Vlahov D. Use of sterile syringes and aseptic drug preparation are important components of HIV prevention among injection drug users. *J Acquir Immune Defic Syndr* 1998;18(suppl 1):S1-S5.
109. Padian NS, O'Brien TR, Chang Y, Glass S, Francis DP. Prevention of heterosexual transmission of human immunodeficiency virus through couple counseling. *J Acquir Immune Defic Syndr* 1993;6:1043-8.
110. Kamenga M, Ryder RW, Jingu M, et al. Evidence of marked sexual behavior change associated with low HIV-1 seroconversion in 149 married couples with discordant HIV-1 serostatus: experience at an HIV counselling center in Zaire. *AIDS* 1991;5:61-7.
111. De Vincenzi I. A longitudinal study of human immunodeficiency virus transmission by heterosexual partners. *N Eng J Med* 1994;331:341-6.
112. Levy J, Fox S, Valle M. What you don't know can hurt you: the influence of prior HIV testing on serostatus results at repeat testing [Abstract 43113]. Presented at the 12th World AIDS Conference, Geneva, Switzerland, 1998:869.
113. Irwin KL, Valdiserri RO, Holmberg SD. The acceptability of voluntary HIV antibody testing in the United States: a decade of lessons learned. *AIDS* 1996;10:1707-17.
114. Valdiserri RO, Moore M, Gerber AR, Campbell CH Jr, Dillon BA, West GR. A study of clients returning for counseling after HIV testing: implications for improving rates of return. *Public Health Rep* 1993;108:12-8.
115. Catania JA, Gibson DR, Marin B, Coates TJ, Greenblatt RM. Response bias in assessing sexual behaviors relevant to HIV transmission. *Evaluation and Program Planning* 1990;13:19-29.
116. Weber JT, Frey R Jr, Horsley R, Gwinn ML. Publicly funded HIV counseling and testing in the United States, 1992-1995. *AIDS Educ Prev* 1997;9(suppl B):79-91.
117. Branson B, Ballenger A, Olthoff G. HIV test results and post-test counseling by telephone [Abstract PC0535]. Presented at the Tenth International Conference on AIDS, 1994.
118. Schluter WW, Judson FN, Baron AE, McGill WL, Marine WM, Douglas JM Jr. Usefulness of human immunodeficiency virus post-test counseling by telephone for low-risk clients of an urban sexually transmitted diseases clinic. *Sex Transm Dis* 1996;23:190-7.
119. Samet JH, Freedberg KA, Stein MD, et al. Trillion virion delay: time from testing positive for HIV to prevention for primary care. *Arch Intern Med* 1998;158:734-40.
120. CDC. Update: HIV counseling and testing using rapid tests—United States, 1995. *MMWR* 1998;47:211-5.
121. Federal Trade Commission. Home-use tests for HIV can be inaccurate, FTC warns [Consumer Alert]. 1999. Available at <<http://www.ftc.gov/bcp/conline/pubs/alerts/hivalrt.htm>>. Accessed July 13, 2001.
122. CDC. Identification of HIV-1 group O infection—Los Angeles County, California, 1996. *MMWR* 1996;45:561-5.
123. Sullivan PS, Do AN, Robbins K, et al. Surveillance for variant strains of HIV: subtype G and group O HIV-1 [Letter]. *JAMA* 1997;278:292.

124. CDC. Human immunodeficiency virus type 2. Atlanta, GA: US Department of Health and Human Services, CDC, 1998. Available at <<http://www.cdc.gov/hiv/pubs/facts/hiv2.htm>>. Accessed July 4, 2001.
125. CDC. Testing for antibodies to human immunodeficiency virus type 2 in the United States. *MMWR* 1992;41(No. RR-12):1-9.
126. CDC. U.S. Public Health Service guidelines for testing and counseling of blood and plasma donors for human immunodeficiency virus type 1 antigen. *MMWR* 1996;45(No. RR-2):1-9.
127. Celum CL, Coombs RW, Lafferty W, et al. Indeterminate human immunodeficiency virus type 1 Western blots: seroconversion risk, specificity of supplemental tests, and an algorithm for evaluation. *J Infect Dis* 1991;164:656-64.
128. Stetler HC, Granada TC, Nunez CA, et al. Field evaluation of rapid HIV serologic tests for screening and confirming HIV-1 infection in Honduras. *AIDS* 1997;11:369-75.
129. Horsburgh CR Jr, Jason J, Longini I, et al. Duration of human immunodeficiency virus infection before detection of antibody. *Lancet* 1989;2:637-40.
130. Busch MP, Lee LLJ, Satten GA, et al. Time course of detection viral and serologic markers preceding human immunodeficiency virus type 1 seroconversion: implications for screening of blood and tissue donors. *Transfusion* 1995;35:91-7.
131. Jackson JB, MacDonald KL, Cadwell J, et al. Absence of HIV infection in blood donors with indeterminate Western blot tests for antibody to HIV-1. *N Eng J Med* 1990;322:217-22.
132. Dock NL, Kleinman SH, Rayfield MA, Schable CA, Williams AE, Dodd RY. Human immunodeficiency virus infection and indeterminate Western blot patterns: prospective studies in a low prevalence population. *Arch Intern Med* 1991;151:525-30.
133. CDC. HIV counseling and testing in publicly funded sites: annual report, 1997 and 1998. Atlanta, GA: US Department of Health and Human Services, CDC, 2001.
134. Ciesielski CA, Metler RP. Duration of time between exposure and seroconversion in healthcare workers with occupationally acquired infection with human immunodeficiency virus. *Am J Med* 1997;102:115-6.
135. CDC. HIV testing among populations at risk for HIV infection—nine states, November 1995–December 1996. *MMWR* 1998;47:1086-91.
136. Wykoff RF, Jones JL, Longshore ST, et al. Notification of the sex and needle-sharing partners of individuals with human immunodeficiency virus in rural South Carolina: 30 month experience. *Sex Transm Dis* 1991;18:217-22.
137. Exner TM, Ehrhardt A, Loeb I, Zawadzki R. HIV counseling and testing: women's experiences and the role of testing as a prevention strategy [Abstract We.C.3529]. In: *Proceedings of the XI International Conference on AIDS, 1996;11(2):150*.
138. Kassler WJ, Meriwether RA, Klimko TB, Peterman TA, Zaidi A. Eliminating access to anonymous HIV antibody testing in North Carolina: effects on HIV testing and partner notification. *J Acquir Immune Defic Syndr* 1997;14:281-9.
139. Simpson WM, Johnstone FD, Goldberg DJ, Gormley SM, Hart GJ. Antenatal HIV testing: assessment of a routine voluntary approach. *BMJ* 1999;318:1660-1.
140. Lee JH, Mitchell B, Nolt B, Robbins B, Thomas MC, Branson BM. Targeted opt-in vs. routine opt-out HIV testing in an STD clinic [Abstract 153]. Presented at the 1999 National HIV Prevention Conference, August 29–September 1, Atlanta, GA, 1999.
141. Rahimian A, Driscoll M, Taylor D, Cohen M. Barriers to building a comprehensive system of HIV counseling and testing by consent to women of reproductive age in Chicago, Illinois [Abstract Tu.D. 2772]. In: *Proceedings of the XI International Conference on AIDS, 1996;1:396*.
142. Nutting PA, Main DS, Fischer PM, et al. Problems in laboratory testing in primary care. *JAMA* 1996;275:635-9.

143. Boone DJ, Steindel SD, Herron R, et al. Transfusion medicine monitoring practices: a study of the College of American Pathologists/CDC Outcomes Working Group. *Arch Path Lab Med* 1995;119:999-1006.
144. Witte DL, VanNess SA, Angstandt DS, Pennell BJ. Errors, mistakes, blunders, outliers, or unacceptable results: how many. *Clin Chem* 1997;43:1352-6.
145. Schochetman G, George JR, eds. *AIDS testing: a comprehensive guide to technical, medical, social, legal, and management issues*. 2 ed. New York, NY: Springer-Verlag, 1994.
146. Institute of Medicine. Eng TR, Butler WT, eds. *The hidden epidemic: confronting sexually transmitted diseases*. Washington, DC: National Academy Press, 1997.
147. Greenberg JB, MacGowan R, Neumann M, et al. Linking injection drug users to medical services: role of street outreach referrals. *Health Soc Work* 1998;23:298-309.
148. Marx R, Hirozawa AM, Chu PL, Bolan GA, Katz M. Linking clients for HIV antibody counseling and testing to prevention services. *J Community Health* 1999;24:201-14.
149. Hymel MS, Greenberg BL. The Walden House Young Adult HIV Project: meeting the needs of multidagnosed youth. *J Adolesc Health* 1998;23S:122-31.
150. CDC. Framework for program evaluation in public health. *MMWR* 1999;48(No. RR-11):1-40.
151. CDC. *Evaluating CDC-funded health department HIV prevention programs. Volume 1: guidance*. Atlanta, GA: US Department of Health and Human Services, CDC, 1999.

Glossary

AIDS: Acquired immunodeficiency syndrome. AIDS can affect the immune and central nervous systems and can result in neurological problems, infections, or cancers. It is caused by human immunodeficiency virus (HIV).

Anal sex: A type of sexual intercourse in which a man inserts his penis in his partner's anus. Anal sex can be insertive or receptive.

Anonymous: In anonymous testing, client identifying information is not linked to testing information, including the request for tests or test results.

Antiretroviral therapy: Treatment with drugs designed to prevent HIV from replicating in HIV-infected persons. Highly active antiretroviral therapy (HAART) is an antiretroviral regimen that includes multiple classifications of antiretroviral drugs.

Client-centered HIV prevention counseling: An interactive risk-reduction counseling model usually conducted with HIV testing, in which the counselor helps the client identify and acknowledge personal HIV risk behaviors and commit to a single, achievable behavior change step that could reduce the client's HIV risk.

Confidentiality: Pertains to the disclosure of personal information in a relationship of trust and with the expectation that it will not be divulged to others in ways that are inconsistent with the original disclosure. Confidentiality must be maintained for persons who are recommended and/or who receive HIV counseling, testing, and referral (CTR) services.

Confidential HIV test: An HIV test for which a record of the test and the test results are recorded in the client's chart.

Confirmatory test: A highly specific test designed to confirm the results of an earlier (screening) test. For HIV testing, a Western blot or, less commonly, an immunofluorescence assay (IFA) is used as a confirmatory test.

EIA: Enzyme immunoassay. Sometimes referred to as ELISA (see next definition). A commonly used screening test to detect antibodies to HIV.

ELISA: Enzyme-linked immunosorbent assay. A type of EIA (see previous definition). A commonly used screening test to detect antibodies to HIV.

Evaluation: A process for determining how well health systems, either public or private, deliver or improve services and for demonstrating the results of resource investments.

False negative: A negative test result for a person who is actually infected.

False positive: A positive test result for a person who is actually not infected.

Freestanding HIV test site: A site that provides only HIV services. Sometimes referred to as alternate test site or anonymous test site.

HIV: Human immunodeficiency virus, which causes AIDS. Several types of HIV exist, with HIV-1 being the most common in the United States.

HIV test: More correctly referred to as an HIV antibody test, the HIV test is a laboratory procedure that detects antibodies to HIV, rather than the virus itself.

HIV prevention counseling: An interactive process between client and counselor aimed at reducing risky sex and needle-sharing behaviors related to HIV acquisition (for HIV-uninfected clients) or transmission (for HIV-infected clients). See also client-centered HIV prevention counseling.

Home sample collection test: A test that a consumer purchases and uses to collect blood (or other bodily fluid) and then send it out for testing. Counseling and test results are typically provided by telephone using user-generated codes to ensure confidentiality and anonymity.

Incidence: In epidemiology, the number of new cases of infection or disease that occur in a defined population within a specified time.

Indeterminate test result: A possible result of a Western blot, which might represent a recent HIV infection or a false-positive.

Information: In the context of HIV counseling, information encompasses the topics HIV transmission and prevention and the meaning of HIV test results.

Informed consent: The legally effective permission of a client or legally authorized representative (e.g., parent or legal guardian of a minor child) to undergo a medical test or procedure.

Negative predictive value: A negative predictive value estimates the probability that a person with a negative diagnostic test result will actually not be infected.

Nonoccupational HIV exposure: A reported sexual, injection-drug-use, or other non-occupational HIV exposure that might put a patient at high risk for acquiring HIV infection.

Nucleic acid amplification testing: A type of testing that identifies viral genes (e.g., specific sequences of nucleic acids) using gene amplification technologies such as polymerase chain reaction (PCR).

Occupational HIV exposure: An occupational exposure to HIV that occurs during the performance of job duties. Defined as a percutaneous injury (e.g., a needlestick or cut with a sharp object), contact of mucous membranes, or contact of skin (especially when the exposed skin is chapped, abraded, or afflicted with dermatitis or the contact is prolonged or involving an extensive area) with blood, tissues, or other body fluids to which universal precautions apply.

Oral fluid test: A test using oral mucosal transudate, a serous fluid. To differentiate this fluid from saliva, an absorbent material is left in the mouth for several minutes. In an HIV-infected person, oral mucosal transudate is likely to contain HIV antibodies.

Oral sex: A type of sexual intercourse in which the partner's genitals are stimulated by mouth and tongue.

Partner counseling and referral services (PCRS): A prevention activity that aims to a) provide services to HIV-infected persons and their sex and needle-sharing partners so they can reduce their risk for infection or, if already infected, can prevent transmission to others and b) help partners gain earlier access to individualized counseling, HIV testing, medical evaluation, treatment, and other prevention and support services.

Perinatal HIV transmission: Transmission of HIV from the mother to the fetus or infant during pregnancy, delivery, or breast-feeding.

Positive predictive value: A positive predictive value estimates the probability that a person with a positive diagnostic test result will actually be infected.

Positive test: For HIV, a specimen sample that is reactive on an initial ELISA test, repeatedly reactive on a second ELISA run on the same specimen, and confirmed positive on Western blot or other supplemental test indicates that the client is infected.

Prevalence: The number or percentage of persons in a given population with a disease or condition at a given point in time.

Prevention case management (PCM): A client-centered HIV prevention activity that promotes adoption of HIV risk-reduction behaviors by clients with multiple, complex problems and risk-reduction needs. PCM is a hybrid of HIV prevention counseling and traditional case management that provides intensive, on-going, individualized prevention counseling, support, and referral to other needed services.

Prevention counseling: An interactive process between client and counselor aimed at reducing risky sex and needle-sharing behaviors related to HIV acquisition (for HIV-uninfected clients) or transmission (for HIV-infected clients). See also client-centered HIV prevention counseling and HIV prevention counseling.

Quality assurance: An ongoing process for ensuring that the CTR program effectively delivers a consistently high level of service to the clients.

Rapid HIV test: A test to detect antibodies to HIV that can be collected and processed within a short interval of time (e.g., approximately 10–60 minutes).

Referral: The process through which a client is connected with services to address prevention needs (medical, prevention, and psychosocial support).

Risk assessment: Risk assessment is a fundamental part of a client-centered HIV prevention counseling session in which the client is encouraged to identify, acknowledge, and discuss in detail his or her personal risk for acquiring or transmitting HIV.

Risk screening: A brief evaluation of HIV risk factors, both behavioral and clinical, used for decisions about who should be recommended HIV counseling and testing. Risk screening is different from risk assessment.

Screening test: An initial test, usually designed to be sensitive, to identify all persons with a given condition or infection (e.g., enzyme immunoassay [EIA] or enzyme-linked immunosorbent assay [ELISA]).

Sensitivity: The probability that a test will be positive when infection or condition is present.

Seroconversion: Initial development of detectable antibodies specific to a particular antigen; the change of a serologic test result from negative to positive as a result of antibodies induced by the introduction of antigens or microorganisms into the host.

Specificity: The probability that a test will be negative when the infection or condition is not present.

Tuberculosis (TB) disease: Active disease caused by *Mycobacterium tuberculosis*, as evidenced by a confirmatory culture, or, in the absence of culture, suggestive clinical symptoms, including productive cough lasting ≥ 3 weeks, chest pain, hemoptysis, fever, night sweats, weight loss, and easy fatigability. Active TB is a communicable disease that is treatable, curable, and preventable, and persons with active TB disease should be under the care of a health-care provider. Active TB disease could indicate immune deficiency. For HIV-infected persons, active TB disease is considered an opportunistic infection and a qualifying condition for AIDS.

Tuberculosis (TB) infection: Infection with the bacteria *M. tuberculosis*, as evidenced by a positive tuberculin skin test (TST) that screens for infection with this organism. Sometimes, TST is called a purified protein derivative (PPD) or Mantoux test. A positive skin test might or might not indicate active TB disease (see tuberculosis disease). Thus, any person with a positive TST should be screened for active TB and, once active TB is excluded, evaluated for treatment to prevent the development of TB disease. TB infection alone is not considered an opportunistic infection indicating possible immune deficiency.

Vaginal sex: A type of sexual intercourse in which the man's penis enters the woman's vagina.

Voluntary HIV testing: HIV testing that is offered free of coercion. With voluntary HIV testing, participants have the opportunity to accept or refuse HIV testing.

Western blot: A laboratory test that detects specific antibodies to components of a virus. Chiefly used to confirm HIV antibodies in specimens found repeatedly reactive using ELISA.

**Continuing Education Activity
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Revised Guidelines for HIV Counseling, Testing, and Referral

EXPIRATION — November 9, 2004

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INSTRUCTIONS

By Internet

1. Read this *MMWR* (Vol. 50, RR-19, *Revised Guidelines for HIV Counseling, Testing, and Referral*), which contains the correct answers to the questions beginning on the next page.
2. Go to the *MMWR* Continuing Education Internet site at <<http://www.cdc.gov/mmwr/cme/conted.html>>.
3. Select which exam you want to take and select whether you want to register for CME, CEU, or CNE credit.
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5. Select exam questions. To receive continuing education credit, you must answer all of the questions. Questions with more than one correct answer will instruct you to "Indicate all that apply."
6. Submit your answers no later than **November 9, 2004**.
7. Immediately print your Certificate of Completion for your records.

By Mail or Fax

1. Read this *MMWR* (Vol. 50, RR-19, *Revised Guidelines for HIV Counseling, Testing, and Referral*), which contains the correct answers to the questions beginning on the next page.
2. Complete all registration information on the response form, including your name, mailing address, phone number, and e-mail address, if available.
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4. Select your answers to the questions, and mark the corresponding letters on the response form. To receive continuing education credit, you must answer all of the questions. Questions with more than one correct answer will instruct you to "Indicate all that apply."
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GOAL AND OBJECTIVES

This *MMWR* provides recommendations regarding human immunodeficiency virus (HIV) counseling, testing, and referral (CTR). These recommendations were prepared by CDC using an evidence-based approach advocated by the U.S. Preventive Services Task Force and public health practice guidelines. The goal of this report is to provide guidance to public- and private-sector policy makers and service providers on HIV CTR. Upon completion of this continuing education activity, the reader should be able to a) identify the goals of HIV counseling, testing, and referral, b) describe the primary focus and essential elements of HIV prevention counseling, c) describe the factors that determine who should be offered an HIV test, and d) identify the factors that should be considered when determining the timing of follow-up HIV testing.

To receive continuing education credit, please answer all of the following questions.

- 1. Which of the following are goals of HIV CTR?**
 - A. Ensure that HIV-infected persons and persons at increased risk for HIV have access to HIV testing to promote early knowledge of their HIV status.
 - B. Ensure that HIV-infected persons and persons at increased risk for HIV receive high-quality HIV prevention counseling to reduce their risk for transmitting or acquiring HIV.
 - C. Ensure that HIV-infected persons and persons at increased risk for HIV have access to appropriate medical, preventive, and psychosocial support services.
 - D. All of the above.

- 2. HIV counseling conducted along with HIV testing serves the following purposes:**
 - A. Provides information regarding how HIV infection is transmitted and prevented, the importance of obtaining test results, and the meaning of HIV test results.
 - B. Helps clients identify HIV risks and commit to steps to reduce their risks for acquiring or transmitting HIV infection.
 - C. Both A and B.
 - D. None of the above.

- 3. The primary focus of HIV prevention counseling is to . . .**
 - A. ensure that the counseling is sensitive to the client's culture, language, sex, sexual orientation, age, and developmental level.
 - B. remain respectful of the client and maintain a nonjudgmental approach.
 - C. ensure that the client fully interacts with the counselor in the counseling session.
 - D. reduce the client's personal risk for HIV acquisition or transmission.

- 4. Essential elements of HIV prevention counseling include all of the following except:**
 - A. Keep the session focused on HIV risk reduction.
 - B. Include an in-depth, personalized risk assessment.
 - C. Acknowledge and provide support for HIV prevention steps already taken.
 - D. Ensure that all of the client's misconceptions regarding HIV infection, including those not related to the client's personal risk, are clarified.

5. **Procedures that help ensure high-quality HIV prevention counseling include all of the following except:**
- A. Training and continued education for counseling staff members.
 - B. Routine, periodic observation and feedback of counseling sessions.
 - C. Routine collection of key data elements for evaluation during the counseling session.
 - D. Support from supervisors and policy makers.
6. **Anonymous testing for HIV infection is beneficial in the following ways:**
- A. Increasing the number of persons who know their HIV status.
 - B. Promoting follow-up.
 - C. Promoting earlier treatment.
 - D. All of the above.
7. **Which of the following factors help determine who should be recommended an HIV test?**
- A. Behavioral HIV risk of client population.
 - B. HIV prevalence of population at facility.
 - C. Availability of effective treatment for HIV prevention (e.g., perinatal transmission).
 - D. All of the above.
8. **Which of the following is the best definition of referral?**
- A. An ongoing relationship with a client that includes assessing a client's medical and psychosocial support needs and providing care for those needs.
 - B. A process in which a client's need for medical, preventive, and supportive services is assessed, and the client is assisted in accessing appropriate services.
 - C. An interactive process aimed at reducing risky behaviors related to HIV acquisition or transmission.
 - D. An evaluation of risk factors for HIV infection used to make decisions regarding who should be offered HIV testing.
9. **Which statement is true regarding counseling, testing, and referral services in nontraditional settings (e.g., community-based and outreach settings)?**
- A. These services could benefit from the use of new HIV test technologies.
 - B. These services require quality assurance protocols and procedures tailored specifically for these settings.
 - C. These services help reach persons at increased risk for HIV infection.
 - D. All of the above.

10. Indicate your work setting.

- A. State/local health department.
- B. Other public health setting.
- C. Hospital clinic/private practice.
- D. Managed care organization.
- E. Academic institution.
- F. Other.

11. Which best describes your professional activities?

- A. Laboratory/pharmacy.
- B. Counseling.
- C. Administration.
- D. Patient care — private medical setting.
- E. Client care — publicly funded site.
- F. Public health.

12. I plan to use these guidelines as the basis for . . . (Indicate all that apply.)

- A. health education materials.
- B. insurance reimbursement policies.
- C. local practice guidelines.
- D. public policy.
- E. other.

13. Each month, approximately how many HIV-infected patients/clients do you see?

- A. None.
- B. 1–5.
- C. 6–20.
- D. 21–50.
- E. 51–100.
- F. >100.

14. How much time did you spend reading this report and completing the exam?

- A. Fewer than 1.5 hours.
- B. More than 1.5 hours but fewer than 2 hours.
- C. 2–2.5 hours.
- D. More than 2.5 hours but fewer than 3 hours.
- E. 3 hours or more.

- 15. After reading this report, I am confident I can identify the goals of HIV counseling, testing, and referral.**
- A. Strongly agree.
 - B. Agree.
 - C. Neither agree nor disagree.
 - D. Disagree.
 - E. Strongly disagree.
- 16. After reading this report, I am confident I can describe the primary focus and essential elements of HIV prevention counseling.**
- A. Strongly agree.
 - B. Agree.
 - C. Neither agree nor disagree.
 - D. Disagree.
 - E. Strongly disagree.
- 17. After reading this report, I am confident I can describe the factors that determine who should be offered an HIV test.**
- A. Strongly agree.
 - B. Agree.
 - C. Neither agree nor disagree.
 - D. Disagree.
 - E. Strongly disagree.
- 18. After reading this report, I am confident I can identify the factors that should be considered when determining the timing of follow-up HIV testing.**
- A. Strongly agree.
 - B. Agree.
 - C. Neither agree nor disagree.
 - D. Disagree.
 - E. Strongly disagree.
- 19. The objectives are relevant to the goal of this report.**
- A. Strongly agree.
 - B. Agree.
 - C. Neither agree nor disagree.
 - D. Disagree.
 - E. Strongly disagree.

20. The tables and figures are useful.

- A. Strongly agree.
- B. Agree.
- C. Neither agree nor disagree.
- D. Disagree.
- E. Strongly disagree.

21. Overall, the presentation of the report enhanced my ability to understand the material.

- A. Strongly agree.
- B. Agree.
- C. Neither agree nor disagree.
- D. Disagree.
- E. Strongly disagree.

22. These recommendations will affect my practice.

- A. Strongly agree.
- B. Agree.
- C. Neither agree nor disagree.
- D. Disagree.
- E. Strongly disagree.

23. How did you learn about this continuing education activity?

- A. Internet.
- B. Advertisement (e.g., fact sheet, *MMWR* cover, newsletter, or journal).
- C. Coworker/supervisor.
- D. Conference presentation.
- E. *MMWR* subscription.
- F. Other.

Correct answers for questions 1-9
1. D; 2. C; 3. D; 4. D; 5. C; 6. D; 7. D; 8. B; 9. D.

**MMWR Response Form for Continuing Education Credit
November 9, 2001/Vol. 50/No. RR-19a1**

Revised Guidelines for HIV Counseling, Testing, and Referral

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Fill in the appropriate blocks to indicate your answers. Remember, you must answer all of the questions to receive continuing education credit!

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Signature Date I Completed Exam

**Revised Recommendations
for HIV Screening
of Pregnant Women**

Perinatal Counseling and Guidelines Consultation April 26–27, 1999 Atlanta, Georgia

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Revised Recommendations for HIV Screening of Pregnant Women

Summary

These guidelines replace CDC's 1995 guidelines, U.S. Public Health Service Recommendations for Human Immunodeficiency Virus Counseling and Voluntary Testing for Pregnant Women, and are for public- and private-sector service providers who provide health care for pregnant women. In 1998, the Institute of Medicine (IOM) published a report that recommended simple, routine, and voluntary human immunodeficiency virus (HIV) testing for all pregnant women in antenatal settings, given the effective interventions available to treat HIV-infected women and reduce risk for perinatal HIV transmission. In 1999, CDC convened consultation groups to discuss and comment on the IOM report. These guidelines are based on input from these meetings, the IOM report, and public comment on draft guidelines published in Fall 2000 in the Federal Register. These guidelines were also prompted by scientific and programmatic advances in the prevention of perinatally acquired HIV and care of HIV-infected women. These recommendations are consistent with the Revised Guidelines for HIV Counseling, Testing, and Referral.

Major revisions from the 1995 guidelines include

- emphasizing HIV testing as a routine part of prenatal care and strengthening the recommendation that all pregnant women be tested for HIV;*
- recommending simplification of the testing process so that pretest counseling is not a barrier to testing;*
- making the consent process more flexible to allow for various types of informed consent;*
- recommending that providers explore and address reasons for refusal of testing; and*
- emphasizing HIV testing and treatment at the time of labor and delivery for women who have not received prenatal testing and antiretroviral drugs.*

These guidelines recommend voluntary HIV testing to preserve a woman's right to participate in decisions regarding testing to ensure a provider-patient relationship conducive to optimal care for mothers and infants and to support a woman's right to refuse testing if she does not think it is in her best interest.

INTRODUCTION

In 1994, after the announcement of the results of Pediatric AIDS Clinical Trials Group (PACTG) protocol 076 (1), the Public Health Service (PHS) published guidelines for zidovudine (ZDV) use to reduce perinatal human immunodeficiency virus (HIV) transmission (2). In 1995, PHS issued guidelines recommending universal counseling and voluntary HIV testing of all pregnant women and treatment for those infected (3). Publication of these recommendations was followed by rapid implementation by health-care providers, widespread acceptance of chemoprophylaxis by HIV-infected women, and a steep

and sustained decline in perinatal HIV transmission (4,5). Observational studies have confirmed the effectiveness of ZDV in reducing the risk for perinatal transmission (6–8). This reduction in transmission risk resulted in an 83% decline in perinatal acquired immunodeficiency syndrome (AIDS) cases diagnosed in 1999, compared with the peak incidence of 907 cases in 1992 (7).

Despite this progress, children are still being infected perinatally. CDC estimates that 280–370 infants are born with HIV infection each year in the United States (CDC, unpublished data, 2000). These continued infections underscore the need for improved strategies to ensure that all pregnant women are offered HIV testing and, if positive, treatment to reduce their transmission risk and to safeguard their health and the health of their infants.

Several lessons have been learned from evaluation of the 1995 PHS guidelines. Many women, especially those who used illicit drugs, were not tested for HIV during pregnancy because of lack of prenatal care (8). In addition, many women refused testing because their health-care providers did not strongly recommend it. Some women declined testing because of perceived low risk, and some providers failed to offer testing because of perceived low risk, perceived difficulties and complexity of required counseling, and misunderstanding of counseling requirements. The logistics of testing, if too complex, also were considered a potential barrier to testing.

In December 1998, the Institute of Medicine (IOM) completed a study commissioned by Congress to assess the impact of current approaches for reducing perinatal HIV transmission, identify barriers to further reductions, and determine ways to overcome these barriers (9). IOM concluded that continued perinatal transmission was mainly caused by a lack of awareness of HIV status among some pregnant women. This problem was attributed to some health-care providers not offering HIV testing to all pregnant women because the providers believed they could predict which women were most at risk and that standard HIV testing protocols, particularly the requirement for extensive pretest counseling, were too burdensome to conduct for all women. IOM concluded that HIV testing should be simplified and made routine. They recommended that the United States adopt a national policy of universal HIV testing, with patient notification, as a routine component of prenatal care. That is, testing should be offered to all pregnant women as part of the standard battery of prenatal tests, regardless of risk factors and the prevalence rates in the community. IOM also recommended that women be informed when an HIV test is conducted and of their right to refuse testing.

Since 1994–1995, major scientific advances in the prevention of perinatal transmission and the care of HIV-infected persons have occurred. These advances increased the benefit of knowing one's HIV status, especially during pregnancy. More effective treatment has prolonged survival of HIV-infected persons and improved their quality of life (10). Clinical trials proved the effectiveness of prophylactic therapy for preventing perinatal transmission in women who are not treated until the time of delivery (11). Studies have indicated that women with nondetectable viral load rarely transmit HIV infection (12–14). Finally, new testing technologies (e.g., rapid testing, urine sampling) offer new options for HIV screening.

To address the lessons learned, IOM findings, and scientific advances, as well as the causes of continued HIV infection in children, PHS convened specialists in the field in April 1999 and sought widespread public comment in revising the 1995 guidelines for HIV counseling and testing for pregnant women. Consultation groups included researchers,

professional health-care provider organizations (e.g., American Academy of Pediatrics, American College of Obstetricians and Gynecologists), clinicians, women living with HIV, and representatives from community organizations and PHS agencies overseeing care of HIV-infected pregnant women.

The resulting guidelines are presented in this document. They differ from the 1995 guidelines in that they

- emphasize HIV testing as a routine part of prenatal care and strengthen the recommendation that all pregnant women be tested for HIV,
- recommend simplifying the testing process so that pretest counseling is not a barrier to testing,
- increase the flexibility of the consent process to allow for various types of informed consent,
- recommend that providers explore and address reasons for refusal of testing, and
- emphasize HIV testing and treatment at the time of labor and delivery for women who have not received prenatal testing and chemoprophylaxis.

These guidelines maintain a voluntary approach to HIV testing. This voluntary approach preserves a woman's right to make decisions regarding testing and supports a woman's right to refuse testing if she does not think it is in her best interest.

This document replaces the 1995 PHS guidelines (3). These recommendations are primarily intended for providers of health care for women, with a focus on HIV screening of pregnant women to reduce mother-to-child transmission of HIV. This report does not address other concerns related to continued perinatal transmission (e.g., lack of prenatal care). CDC programs targeted to states with the highest incidence of perinatal HIV infection address these ongoing public health problems (information on these programs is available on the Internet at <<http://www.cdc.gov/hiv/projects/perinatal/default.htm>>). Other PHS guidelines address the importance of prevention interventions, including testing in the general population (see *Revised Guidelines for HIV Counseling, Testing, and Referral*). This report applies only to the United States; different recommendations, especially on breast-feeding, will apply in other countries.

BACKGROUND

HIV Infection and AIDS in Women and Children

Of the approximately 750,000 AIDS cases reported to CDC through the end of 1999, approximately 129,000 were in women. Approximately 64,000 women were living with AIDS in 1999, a 31% increase from 1996, reflecting improved survival with new combination treatment regimens (15). However, women with AIDS represent only a fraction of the number of HIV-infected women who need medical and social services. An estimated 120,000–160,000 HIV-infected women reside in the United States, 80% of whom are of childbearing age (16).

Most women with HIV/AIDS in the United States reside in the Northeast and the South. The highest numbers of cases were first observed in the Northeast, but the South has reported the greatest increases in recent years. African-American and Hispanic

women are disproportionately affected by the epidemic and account for 80% of AIDS cases reported in U.S. women in 1999. Over time, the proportion of cases in women attributable to injection-drug use has declined, whereas the proportion of cases from heterosexual contact has increased, particularly among young women.

During 1985–1995, approximately 6,000–7,000 HIV-infected women gave birth in the United States each year (7). During the early 1990s, before perinatal chemoprophylaxis was available, an estimated 1,000–2,000 infants were born with HIV infection annually. By June 2000, a total of 8,027 perinatally acquired AIDS cases were recorded nationwide, most (85%) in African-American and Hispanic children (7,15). Before the results of the PACTG 076 trial using prenatal, intrapartum, and postpartum ZDV for perinatal prophylaxis, the risk for mother-to-child transmission ranged from 16% to 25% in studies from North America and Europe (17–19), up to 24% in Thailand (20), and 25–40% in Africa (21,22). Worldwide, approximately 600,000 infants each year become infected through mother-to-child transmission of the HIV virus.

In the United States, widespread implementation of the PHS guidelines for universal counseling and testing and perinatal use of ZDV has sharply reduced transmission risk and the number of perinatally acquired HIV infections (7). By 1995, several cohort studies had documented transmission rates of $\leq 11\%$ (19,23). During 1996–2000, U.S. studies indicated that transmission rates had declined to 5%–6% (12,24) and $< 1\%$ in women with nondetectable plasma viral loads (12,14,25). During 2000–2001, perinatal transmission rates of $\leq 2\%$ have been achieved with combination antenatal antiretroviral drugs (26) or with ZDV combined with cesarean section (27–29). Analysis of U.S. perinatal AIDS surveillance data (15) reported through June 2000 indicated a sharp decline in the number of perinatal AIDS cases; this decline was temporally associated with increasing ZDV use among pregnant women aware of their HIV status (7). To more accurately monitor trends in perinatal HIV transmission and the implementation and impact of perinatal prevention programs (including HIV counseling and testing recommendations), CDC, the Council of State and Territorial Epidemiologists (CSTE), and the American Academy of Pediatrics (AAP) recommended national reporting of perinatal HIV exposure and HIV infection to help identify and target populations where prevention opportunities are missed (30,31).

Despite the declines, cases of perinatal HIV transmission continue to occur, largely because of missed opportunities for prevention, particularly among women who lack prenatal care or who are not being offered voluntary HIV counseling and testing during pregnancy. The estimated 280–370 infants born with HIV infection each year represent populations in which prevention efforts are impeded by lack of timely HIV testing and treatment of pregnant women (7). Of 329 children with perinatally acquired AIDS born during 1995–1996, a total of 112 (34%) were born to mothers not tested for HIV before the child's birth and 67 (20%) to mothers for whom the time of testing was not known.

Dynamics of Perinatal HIV Transmission

Perinatal transmission can occur during pregnancy (intrauterine), during labor and delivery (intrapartum), or after delivery through breast-feeding (postpartum). In the absence of breast-feeding, intrauterine transmission accounts for 25%–40% of infection, and 60%–75% of transmission occurs during labor and delivery (32). Among women who breast-feed, approximately 20%–25% of perinatal infections are believed to be

associated with intrauterine transmission, 60%–70% with intrapartum transmission or very early breast-feeding, and 10%–15% with later postpartum transmission through breast-feeding (33). In a randomized trial of formula feeding versus breast-feeding, approximately 44% of HIV infection was attributed to breast-feeding (34). In breast-feeding populations, a shift toward an increasing proportion of transmission related to breast-feeding is likely to occur as a consequence of successful preventive interventions directed at late prenatal and intrapartum transmission.

Intrapartum transmission can occur during labor through maternal-fetal exchange of blood or during delivery by contact of the infant's skin or mucous membranes with infected blood or other maternal secretions (32). Several studies have indicated that most infections transmitted through breast-feeding probably occurred during the first few weeks to months of life (34–36). Risk factors during breast-feeding include viral load in breast milk (37,38), subclinical or clinical mastitis (37,39,40), breast abscesses (39,40), and maternal seroconversion during the lactation period (39,41).

Several risk factors are associated with perinatal HIV transmission. Clinical factors that increase the likelihood of transmission include immunologically or clinically advanced HIV disease in the mother, high plasma viral load (12,25,42), maternal injection-drug use during pregnancy, preterm delivery, nonreceipt of the PACTG 076 regimen, and breast-feeding (32). No link has been established between perinatal HIV transmission and maternal age, race/ethnicity, or history of having a previously infected child.

Obstetric factors also influence HIV transmission risk. The risk for perinatal transmission increases per hour duration of membrane rupture after controlling for other risk factors (43). Delivery >4 hours after the rupture of the fetal membranes can double the risk for HIV transmission (19,44). Maternal infection with another sexually transmitted disease (STD) during pregnancy and certain obstetrical procedures can also increase risk (45). Chorioamnionitis (i.e., uterine infection) has been associated with an increased risk for HIV transmission (23,46).

Most of these risk factors were identified before the recommended use of ZDV to prevent perinatal HIV transmission. Their effects are unknown now that most pregnant women infected with HIV are receiving ZDV chemoprophylaxis to prevent mother-to-child transmission, as well as combination therapy for their own health. Because of the sharp reductions in perinatal HIV transmission associated with effective antiretroviral interventions, factors that interfere with women or their infants receiving ZDV treatment (e.g., barriers to prenatal care, lack of HIV testing for some pregnant women) are increasingly important (9).

Prevention of Perinatal Transmission

The birth of every perinatally HIV-infected infant is a sentinel health event signaling either a missed prevention opportunity or, more rarely, a failure of prophylaxis. An opportunity is missed whenever a woman of childbearing age is unaware of her HIV status or her risk for HIV or when an HIV-infected pregnant woman a) does not receive prenatal care, b) is not offered HIV testing, c) is unable to obtain HIV testing, d) is not offered chemoprophylaxis, e) is unable to obtain chemoprophylaxis, or f) does not complete the chemoprophylaxis regimen. Prophylaxis failures occur when an infant becomes infected despite chemoprophylaxis and other preventive interventions (9). Each of these missed opportunities or failures deserves attention from service providers and prevention programs.

Early Prenatal Care

Maximum reduction of perinatal transmission depends on preventing HIV infection in women or identifying HIV infection before pregnancy or as early as possible during pregnancy. Diagnosis allows a woman to receive effective antiretroviral therapies for her own health and preventive drugs (e.g., ZDV) to improve the chances that her infant will be born free of infection. Early knowledge of maternal HIV status is also important for decisions regarding obstetrical management. Achieving these goals requires increased access to and use of prenatal care.

Four states that conducted enhanced HIV surveillance reported that during 1993–1996, approximately 15% of HIV-infected pregnant women in the United States received no prenatal care, compared with only 2% of women in the general population (5). HIV-infected women who used illicit drugs during pregnancy were at the highest risk for not receiving prenatal care — 35% compared with 6% for HIV-infected women who were not drug users. During 1997–1998, the HIV transmission rate among women in New York State was 17.5% (30/171) among those with no prenatal care, 16.2% (23/142) among those with 1–2 prenatal visits, and 8.0% (90/1,124) among those with ≥ 3 prenatal visits, indicating the importance of prenatal care in providing services that prevent perinatal transmission (47).

Offer and Acceptance of HIV Testing

Most women who have given birth since the 1995 PHS guidelines have received information or counseling regarding HIV infection and have been offered testing. This has occurred independently of state-to-state variations in application of recommended practices, type of prenatal health-care provider, type of patient insurance, or maternal demographic characteristics (9). A 14-state study of HIV counseling and testing data for 1996–1997 reported that the proportion of pregnant women voluntarily tested for HIV was 58%–81% (30). Women most likely to receive HIV counseling and testing during pregnancy were those who were African-American, had less than a high school education, were aged <25 years, received care in public rather than private health-care settings, and were Medicaid beneficiaries.

When offered, most women (approximately 70% in most settings) will accept HIV testing. In a multicity study of prenatal clinic patients, 74%–95% of participants accepted HIV testing (48). Reasons most commonly cited for acceptance were a) belief that knowledge of positive HIV serostatus during pregnancy (and subsequent chemoprophylaxis) can be beneficial to both mother and infant and b) strong provider endorsement for prenatal HIV testing. The most common reasons for declining the test were no perceived risk, administrative scheduling difficulties, history of previous testing, and lack of provider endorsement.

Although most providers agreed that all women should be tested for HIV, some offered testing only to women whom they considered at risk for infection (49,50). Risk-based testing approaches identified fewer HIV-infected women than routine voluntary testing of all pregnant women (3) and also decreases in effectiveness as more women are infected through heterosexual contact without knowing their partner's HIV risk status.

Receipt of ZDV Chemoprophylaxis

The primary strategy to prevent perinatal transmission (in addition to avoidance of breast-feeding) is antiretroviral chemoprophylaxis using ZDV, now often part of a combined antiretroviral therapy regimen that reduces viral load as low as possible near the

time of delivery. In the PACTG 076 protocol, chemoprophylaxis consisted of three components: ZDV administered orally to the mother during the second and third trimesters of pregnancy, intravenous administration of ZDV to the mother during labor and delivery, and administration of oral ZDV to the infant during the first 6 weeks of life (1).

Data from several sources demonstrated rapid implementation of the recommendations for ZDV prophylaxis by health-care providers and use of ZDV by HIV-infected pregnant women. One study analyzed approximately 6,800 perinatally exposed and infected children born during 1993–1998 in 32 states that reported HIV infection (51). Among those whose mothers were tested for HIV before or at birth of the infant, the percentage of infants receiving any component of the recommended ZDV regimen increased from 37% in 1994 to approximately 85% during 1996–1998. In a supplemental study of women diagnosed before delivery in four states, the proportion offered prenatal ZDV increased from 27% in 1993 to 85% in 1996, the proportion offered intrapartum ZDV increased from 5% to 75%, and the proportion offered neonatal ZDV increased from 5% to 76% (5). Fewer than 5% of women refused ZDV.

Abbreviated Antiretroviral Regimens

Given the complexity and cost of the PACTG 076 regimen, particularly for the developing world, other effective strategies to reduce the risk for perinatal HIV transmission have been identified. Results of randomized clinical trials in developing countries and observational data from the United States indicated that abbreviated perinatal antiretroviral regimens (20,52–54), regimens that begin as late as the onset of labor (11), and possibly antiretroviral chemoprophylaxis given only to the newborn (47) are effective in reducing the risk for perinatal transmission.

Abbreviated antiretroviral regimens have also proved effective in reducing the risk for transmission in resource-poor countries. In nonbreast-feeding women, a short antepartum/intrapartum regimen of ZDV reduced transmission by 50% (20); a similar regimen in breast-feeding populations was also effective, although efficacy was lower (52–54). Two other intrapartum/postpartum antiretroviral regimens were effective in reducing transmission in clinical trials among breast-feeding African women. One regimen was nevirapine given as a single dose to the woman in labor and to the infant at age 48 hours, and the other was ZDV plus lamivudine (3TC) given orally intrapartum and to the infant and mother for 1 week postpartum (11,36,55). Observational data and animal studies indicated that newborn prophylaxis alone offered some protection (24,56). Updated recommendations for use of these regimens in the United States, including for pregnant women who do not receive health care until near the time of delivery are available at the HIV/AIDS Treatment Information Service (ATIS) website at <<http://www.hivatis.org>> (57).

Other Strategies to Prevent Perinatal Transmission

Reducing exposure of the infant to maternal blood and secretions during the intrapartum period can prevent perinatal HIV transmission. Cesarean delivery performed before onset of labor and membrane rupture lowers the risk for HIV transmission compared with vaginal delivery in certain populations of women. Cesarean delivery resulted in a 50% reduction in perinatal HIV transmission overall among HIV-infected women who had cesarean deliveries compared with women delivering vaginally (28). A randomized clinical trial in Europe (27) demonstrated a benefit of elective cesarean section before onset of labor for both untreated HIV-infected women and infected women on

antiretroviral therapy. However, cesarean delivery is associated with greater morbidity than vaginal delivery among both HIV-infected and noninfected women (58). In 1999 and 2000, the American College of Obstetricians and Gynecologists (ACOG) recommended offering scheduled cesarean delivery at 38 weeks gestation to reduce the risk for vertical transmission of HIV infection (57,59). Other intrapartum interventions alone (e.g., vaginal disinfection during labor and cleansing of the newborn) have not proven effective (60).

Follow-Up Care for Infected Women and Perinatally Exposed Infants

Providing mothers and their infants with ongoing HIV-related care can maximize the benefits of prevention interventions. The medical care of HIV-infected women is a complicated task requiring use of potent combinations of antiretroviral drugs, monitoring of viral load and drug resistance, treatment and prophylaxis of opportunistic infections, and monitoring of immune status. In addition to conditions (e.g., *Pneumocystis carinii* pneumonia [PCP]) for which all immunocompromised HIV-infected persons are at risk, women experience specific manifestations of HIV disease (e.g., aggressive pelvic inflammatory disease and persistent and difficult-to-treat vaginal yeast infections requiring frequent screening and treatment) (61,62). HIV-infected women are also at increased risk for cervical dysplasia, which can result in cancer (63). With early detection and appropriate treatment, many of these complications can be prevented and treated. Improved health outcomes resulting from advances in HIV management and treatment depend not only on access to medical care but also on access to prevention and psychosocial support services. In the United States, most mothers and children with HIV/AIDS live in areas where poverty, illicit drug use, poor housing, and limited access to and use of medical care and social services add to the challenges of HIV disease (4,9). Women with HIV infection often have difficulty gaining access to health care and frequently are responsible for caring for children and other family members who might also be HIV-infected (64). They often lack social support and face other challenges that could interfere with their ability to gain access to and adhere to complicated treatment regimens. The complex medical and social problems of families affected by HIV are best managed by multidisciplinary case-management teams that integrate specialty medical care with prevention, psychosocial, and other HIV-related services (see *Revised Guidelines for HIV Counseling, Testing, and Referral*).

Postnatal evaluation of infants at risk for HIV infection that begins immediately after birth is the key to early diagnosis and optimal medical management of infected children. PCP is the most common opportunistic infection in children with AIDS and is often fatal (65). Because PCP occurs most often in perinatally infected children at ages 3–6 months (65), effective prevention requires that children born to HIV-infected mothers be identified promptly, preferably through maternal testing, so that PCP prophylactic therapy can be initiated at age 6 weeks. In 1995, CDC published revised guidelines recommending PCP prophylaxis for all perinatally exposed infants at ages 4–6 weeks until their infection status was determined (66). Perinatal screening can identify HIV-exposed infants early, making it possible to follow infected children closely and promptly diagnose other potentially treatable, HIV-related conditions (e.g., severe bacterial infections). This also allows antiretroviral treatment to be initiated as soon as indicated to prevent morbidity, prolong survival, and reduce the need for hospitalization (67).

Follow-up of infants, both infected and uninfected, who are exposed to antiretroviral drugs is critical to identifying potential short- and long-term toxicities. Data on the risks of antiretroviral drugs during pregnancy are summarized and updated regularly (57).

Summary of IOM Recommendations

In 1996, Congress charged IOM with evaluating the extent to which state efforts had been effective in reducing perinatal HIV transmission and analyzing barriers to further reduction in such transmission. In 1999, IOM published its results, which addressed ways to increase prenatal testing, improve therapy for HIV-infected women and children, and generally reduce perinatal HIV infections (9).

Despite sharp reductions in perinatally transmitted AIDS cases that resulted from widespread implementation of the 1994 and 1995 PHS guidelines, IOM reported that the number of children born with HIV infection exceeded achievable prevention levels. Prenatal HIV testing was not universal, and many HIV-infected women were inadequately treated because they did not seek prenatal care, were not tested for HIV, or received treatment that did not reflect current standards. Even in settings where most prenatal-care providers agreed that HIV tests should be offered to all pregnant women, some reported that they did not offer the test to all women in their practices, mainly because pretest counseling recommended by CDC and promulgated in some state policies were too burdensome (9). Citing lack of time and skills for counseling, providers based testing decisions on their own, often inaccurate, assessments of maternal risk.

IOM recommended that the United States adopt a goal that all pregnant women be tested for HIV and all infected women receive optimal treatment for themselves and their children. To help meet this goal, IOM recommended that the United States adopt a policy of universal HIV testing, with patient notification, as a routine component of prenatal care (i.e., all pregnant women should be offered testing regardless of their risk factors or the prevalence rates where they live). Early diagnosis of HIV infection allows pregnant women to receive effective antiretroviral therapy for their own health and reduce the risk for transmitting HIV to their infants. Universal testing avoids stereotyping or stigmatizing any socioeconomic or ethnic group. Women should be told they are being tested for HIV and told of their right to refuse testing. Patient notification allows women to decline testing if they feel it is not in their best interest and simplifies the testing process by eliminating the need for extensive pretest counseling.

Legal Considerations

IOM's recommendations prompted reconsideration of the focus, implementation, and impact of PHS's guidelines for HIV screening of pregnant women. These guidelines recommended counseling all pregnant women regarding the risk for HIV infection, benefits of HIV testing, and voluntary testing. This approach was endorsed by most professional organizations representing prenatal, obstetrical, and perinatal-care providers. States quickly implemented the guidelines, but with substantial variability in strategy (68). Most states responded with policies on HIV counseling and testing of pregnant women; approximately 50% also enacted laws or regulations. Most policies and statutes are directed at pregnant women rather than newborns and focus on education, counseling, and consensual testing. New York and Connecticut are the only states that mandate newborn testing. No evidence exists to indicate that any legal approach is more successful than others in preventing perinatal transmission. No states require mandatory testing

of pregnant women. In considering adopting the IOM guidelines, some states have implemented or are considering requiring some form of pretest counseling, routine testing with right of refusal, or universal or selective newborn screening. IOM's recommendation is for universal HIV testing with patient notification. As states consider implementing the IOM recommendations, other important considerations include availability of care and treatment for HIV-infected mothers and their infants, provider training needs, and confidentiality laws to protect positive test results reported to public health surveillance. States should consult with public health officials, health-care providers, and representatives of affected communities during this process.

For the individual woman, the substantial benefits of HIV testing must be weighed against the possible risks. Potential negative consequences of a diagnosis of HIV infection can include loss of confidentiality, job- or health-care-related discrimination and stigmatization, loss of relationships, domestic violence, and adverse psychological reactions (69). Providing HIV-infected women with or referring them to psychological, social, and legal services could help minimize these risks and allow more women to benefit from the health advantages of early HIV diagnosis without adverse consequences. The Americans with Disabilities Act (ADA) of 1990 and other federal, state, and local antidiscrimination provisions aim to protect persons with HIV/AIDS against discrimination in the workplace, housing, public services, and public accommodations (70). A 1998 U.S. Supreme Court decision provided further antidiscrimination protection by ensuring that persons with asymptomatic HIV disease are included under ADA and have access to nondiscriminatory and effective health care (70).

Laboratory Testing Considerations

Testing of women before or during pregnancy is typically conducted according to the standard protocol for detection of antibody to HIV (71). For women with unknown HIV status during active labor, antiretroviral treatment can still be effective when given during labor and delivery, followed by treatment of the newborn (11). This expedited intervention requires the use of rapid diagnostic testing during labor or rapid return of results from standard testing.

Standard Testing Protocol

The HIV testing algorithm recommended by PHS consists of initial screening with an FDA-licensed enzyme immunoassay (EIA) followed by confirmatory testing of repeatedly reactive EIAs with an FDA-licensed supplemental test (e.g., Western blot). Although each test is highly sensitive and specific, using both increases the accuracy of results.

Indeterminate Western blot results can be caused by either incomplete antibody response to HIV in samples from infected persons or nonspecific reactions in samples from uninfected persons (72–74). Incomplete antibody responses that produce negative or indeterminate results on Western blot tests can occur among persons recently infected with HIV who have low levels of detectable antibodies (i.e., seroconversion), persons who have end-stage HIV disease, and perinatally exposed but uninfected infants who are seroreverting (i.e., losing maternal antibody). Nonspecific reactions producing indeterminate results in uninfected persons have occurred more frequently among pregnant or parous women than among other persons (73,74). No large-scale studies have been conducted to estimate the prevalence of indeterminate test results in pregnant women. However, a survey of 1,044,944 neonatal dried-blood specimens tested by EIA

for maternally acquired HIV-1 antibody indicated a relatively low rate of indeterminate Western blot results (<1 in 4,000 specimens tested by EIA) (74). Overall, 2,845 Western blots were performed.

False-positive Western blot results (especially those with a majority of bands) are rare. For example, in a study that used a sensitive culture technique to test approximately 290,000 blood donors, no false-positive Western blot results were detected (75). In a study of the frequency of false-positive diagnoses among military applicants from a low-prevalence population (i.e., <1.5 infections/1,000 population), one false-positive result was detected among 135,187 persons tested (76).

An HIV test should be considered positive only after screening and confirmatory tests are reactive. A confirmed positive test result indicates that a person has been infected with HIV. False-positive results when both screening and confirmatory tests are reactive are rare. However, the possibility of a mislabeled sample or laboratory error must be considered, especially for a client with no identifiable risk for HIV infection. HIV vaccine-induced antibodies may be detected by current tests and may cause a false-positive result. Persons whose test results are HIV-positive and who are identified as vaccine trial participants should be encouraged to contact or return to their trial site or an associated trial site for HIV counseling, testing, and referral (CTR) services.

Incorrect HIV test results occur primarily because of specimen-handling errors, laboratory errors, or failure to follow the recommended testing algorithm (76). However, patients might report incorrect test results because they misunderstood previous test results or misperceived that they were infected (77). Although these occurrences are rare, increased testing of pregnant women will result in additional indeterminate, false-positive, and incorrect results. Because of the significance of an HIV-positive test result, its impact on a woman's reproductive decisions, and the resulting need to consider HIV therapeutic drugs for both a pregnant woman and her infant, previous guidelines have emphasized that HIV test results must be obtained and interpreted correctly. In some circumstances, correct interpretation might require consideration of not only additional testing but also the woman's clinical condition and history of possible exposure to HIV.

Diagnosis of HIV Infection in Newborns

The standard antibody assays used for older children and adults are less useful for diagnosis of infection in children aged <18 months. Nearly all infants born to HIV-infected mothers passively acquire maternal antibody and, in some cases, will test antibody positive until age 18 months regardless of whether they are infected. Definitive diagnosis of HIV infection in early infancy requires other assays, including nucleic acid amplification (e.g., polymerase chain reaction [PCR]) or viral culture. HIV infection is diagnosed by two positive assays (PCR or viral culture) on two separate specimens. Infant HIV testing should be done as soon after birth as possible so appropriate treatment interventions can be implemented quickly (67).

Rapid Tests for Expedited Screening

For certain HIV-infected pregnant women, the labor and delivery setting is the first opportunity for HIV testing and interruption of mother-to-child transmission. Although results of conventional EIAs and Western blots are typically not available for 1–2 weeks, rapid tests for detecting antibody to HIV can produce results in 10–60 minutes (78). The sensitivity and specificity of rapid assays are comparable with EIAs. However, the predictive value of a single screening test varies with the prevalence of HIV infection among

the population tested. Because HIV prevalence is low in most perinatal testing settings, the negative predictive value of a single rapid test (i.e., the probability that a negative test accurately indicates that the person tested is uninfected) is high. A negative rapid test does not require further testing. In contrast, the positive predictive value of a single test (i.e., the probability that a positive test represents true infection) will be low among populations with low prevalence (71). Therefore, a reactive rapid test must be confirmed by a supplemental test (e.g., Western blot). However, necessary peripartum interventions to reduce the risk for perinatal transmission might need to be based on the preliminary results of rapid testing at labor and delivery. Decisions regarding use of antiretroviral drugs to prevent perinatal transmission among women who are repeatedly reactive on a single rapid HIV test require clinical judgment regarding initiation of prophylactic treatment before results of a confirmatory test are available.

Only one FDA-approved rapid HIV test (Abbott Murex Single Use Diagnostic System [SUDS] HIV-1 test, Abbott Laboratories, Inc., Abbott Park, Illinois) is commercially available in the United States, although other rapid tests are being considered for approval. This test can provide definitive negative and preliminary positive test results at the time of testing and identify women who might need antiretroviral treatment and whose infants might benefit from chemoprophylaxis. A careful risk assessment could help make treatment decisions. The predictive value of a reactive rapid test is higher among persons with risk for HIV infection, especially in areas with high HIV prevalence (79). Use of a second screening test (either rapid test or EIA) can also improve the positive predictive value of a single reactive rapid HIV test. In studies conducted outside the United States, specific combinations of ≥ 2 different screening assays provided results as reliable as those from the conventional EIA/Western blot combination (80).

Expedited EIA testing that produces results within a few hours can also aid decisions regarding antiretroviral therapy. Although results from standard testing are not likely to be available during labor and delivery, they could be available within 12 hours of an infant's birth. Because neonatal prophylaxis might be effective in reducing risk for transmission (24), expedited application of the standard testing protocol is another way to reduce mother-to-child infection.

Research and programmatic studies are underway to assess the feasibility of offering voluntary HIV counseling and rapid testing at labor and delivery to women of unknown serostatus in the United States. Implementation of rapid testing and expedited EIA approaches should address several ethical and logistical considerations, including

- acceptability of rapid HIV testing in the labor room,
- difficulty in obtaining informed consent for testing and treatment during labor or soon after birth,
- acceptance of intrapartum and postpartum ZDV prophylaxis for the mother or infant,
- optimal timing of posttest counseling,
- logistical concerns for providers,
- implications of preliminary reactive test results, and
- comprehension of discussions regarding antiretroviral treatment by women who are in labor (81,82).

A CDC-funded, multicenter initiative called Mother-Infant Rapid Intervention at Delivery (MIRIAD) is underway to address these considerations among women with inadequate prenatal care in communities with high HIV seroprevalence among women of childbearing age (81). If successful, this initiative will offer crucial peripartum interventions to reduce the risk for HIV transmission among HIV-infected women first identified at labor and delivery.

RECOMMENDATIONS

The following revised recommendations for HIV screening of pregnant women are based on scientific and clinical advances in preventing perinatally acquired HIV and caring for HIV-infected women, recommendations from IOM, consultations with specialists in the field, and public opinion. They reflect the need for universal HIV testing of all pregnant women and simplification of the pretest process so that operational procedures do not impede women from benefitting from proven measures to prevent perinatal transmission and from other advances in the care and treatment of HIV disease. Although universal testing is recommended, testing should remain a voluntary decision by the pregnant woman.

Screening for HIV in Pregnant Women and Their Infants

- PHS recommends that all pregnant women in the United States be tested for HIV infection. All health-care providers should recommend HIV testing to all of their pregnant patients, pointing out the substantial benefit of knowledge of HIV status for the health of women and their infants. HIV screening should be a routine part of prenatal care for all women.
- HIV testing should be voluntary and free of coercion. Informed consent before HIV testing is essential. Information regarding consent can be presented orally or in writing and should use language the client understands. Accepting or refusing testing must not have detrimental consequences to the quality of prenatal care offered. Documentation of informed consent should be in writing, preferably with the client's signature. State or local laws and regulations governing HIV testing should be followed. HIV testing should be presented universally as part of routine services to pregnant women, and confidential informed consent should be maintained (see *Revised Guidelines for HIV Counseling, Testing, and Referral*).
- Although HIV testing is recommended, women should be allowed to refuse testing. Women should not be tested without their knowledge. Women who refuse testing should not be coerced into testing, denied care for themselves or their infants, or threatened with loss of custody of their infants or other negative consequences. Discussing and addressing reasons for refusal (e.g., lack of awareness of risk or fear of the disease, partner violence, potential stigma, or discrimination) could promote health education and trust-building and allow some women to accept testing at a later date. Women who refuse testing because of a previous history of a negative HIV test should be informed of the importance of retesting during pregnancy. All logistical reasons for not testing (e.g., scheduling) should be addressed as well. Health-care providers should remember that some women

who initially refuse testing might accept at a later date, particularly if their concerns are discussed. Some women who refuse confidential testing might be willing to obtain anonymous testing. However, they should be informed that if they choose anonymous testing, no documentation of the results will be recorded in the medical chart, and their providers might have to retest them, potentially delaying provision of antiretroviral drugs for therapy or perinatal prophylaxis. Some women will continue to refuse testing, and their decisions should be respected.

- Before HIV testing, health-care providers should provide the following minimum information. Although a face-to-face counseling session is ideal, other methods can be used (e.g., brochure, pamphlet, or video) if they are culturally and linguistically appropriate.
 - HIV is the virus that causes AIDS. HIV is spread through unprotected sexual contact and injection-drug use. Approximately 25% of HIV-infected pregnant women who are not treated during pregnancy can transmit HIV to their infants during pregnancy, during labor and delivery, or through breast-feeding.
 - A woman might be at risk for HIV infection and not know it, even if she has had only one sex partner.
 - Effective interventions (e.g., highly active combination antiretrovirals) for HIV-infected pregnant women can protect their infants from acquiring HIV and can prolong the survival and improve the health of these mothers and their children.
 - For these reasons, HIV testing is recommended for all pregnant women.
 - Services are available to help women reduce their risk for HIV and to provide medical care and other assistance to those who are infected.
 - Women who decline testing will not be denied care for themselves or their infants.
- Health-care providers should perform HIV testing in consenting women as early as possible during pregnancy to promote informed and timely therapeutic decisions. Retesting in the third trimester, preferably before 36 weeks of gestation, is recommended for women known to be at high risk for acquiring HIV (e.g., those who have a history of sexually transmitted diseases [STDs], who exchange sex for money or drugs, who have multiple sex partners during pregnancy, who use illicit drugs, who have sex partner[s] known to be HIV-positive or at high risk, and who have signs and symptoms of seroconversion). Routine universal retesting in the third trimester may be considered in health-care facilities with high HIV seroprevalence among women of childbearing age. Retesting for syphilis during the third trimester and again at delivery also is recommended for pregnant women at high risk (83). Some states mandate syphilis screening at delivery for all pregnant women.
- Women admitted for labor and delivery with unknown or undocumented HIV status should be assessed promptly for HIV infection to allow for timely prophylactic treatment. Expedited testing by either rapid return of results from standard testing

or use of rapid testing (with confirmation by a second licensed test when available) is recommended for these women. The goal is to identify HIV-infected women or their infants as soon as possible because the efficacy of prophylactic therapy is greatest if given during or as soon after exposure as possible (i.e., within 12 hours of birth). Informed consent is essential for women tested prenatally, and women in labor with unknown status should be allowed to refuse testing without undue consequences. After delivery, standard confirmatory testing should be done for women with positive rapid test results.

- Some women might not a) receive testing during labor and delivery, b) choose to be tested for HIV, or c) retain custody of their infants. If the mother has not been tested for HIV, she should be informed that knowing her infant's infection status has benefits for the infant's health and that HIV testing is recommended for her infant. Providers should ensure that the mother understands that a positive HIV antibody test for her infant indicates infection in herself. For infants whose HIV infection status is unknown and who are in foster care, the person legally authorized to provide consent should be informed that HIV testing is recommended for infants whose biological mothers have not been tested. Testing should be performed in accordance with the policies of the organization legally responsible for the child and with prevailing legal requirements for HIV testing of children.
- Regulations, laws, and policies regarding HIV screening of pregnant women and infants are not standardized throughout all states and U.S. territories. Health-care providers should be familiar with and adhere to state/local laws, regulations, and policies concerning HIV screening of pregnant women and infants.

Education and Prevention Counseling of Pregnant Women Regarding HIV

When the pretest process is simplified to providing essential information, the value of prevention counseling should not be lost. For some women, the prenatal care period could be an ideal opportunity for HIV prevention and subsequent behavior change to reduce risk for acquiring HIV infection. Thus, the following steps are recommended:

- Information regarding HIV and assessment of risks for HIV infection (i.e., risk screening) should be provided to all pregnant women as part of routine health education. Reluctance to provide HIV prevention counseling should never be a barrier to HIV testing. Similarly, a focus on increased HIV testing should not be a barrier to providing effective HIV prevention counseling for persons determined to be at increased risk for acquiring or transmitting HIV (see *Revised Guidelines for HIV Counseling, Testing, and Referral*).
- Pregnant women found to have behaviors that place them at high risk for acquiring HIV infection (e.g., multiple sex partners, current diagnosis or history of STDs, exchange of sex for money or drugs, substance abuse) or who want more intensive client-centered HIV prevention counseling should be provided with or referred to HIV risk-reduction services (e.g., drug treatment, STD treatment, HIV centers with personnel trained in HIV counseling).

Interpretation of HIV Test Results

- HIV antibody testing should be performed according to the recommended algorithm, which includes an EIA to test for antibody to HIV and confirmatory testing with a more specific assay (e.g., Western blot). All assays should be performed according to manufacturers' instructions and state and federal laboratory guidelines.
- HIV infection (as indicated by the presence of antibody to HIV) is defined as a repeatedly reactive EIA and a positive confirmatory supplemental test. Confirmation or exclusion of HIV infection in a person with indeterminate test results should be based on HIV antibody test results, consideration of the person's medical and behavioral history, results from additional virologic and immunologic tests when performed, and clinical follow-up (see *Revised Guidelines for HIV Counseling, Testing, and Referral*). Whenever possible, uncertainties regarding HIV infection status, including laboratory test results, should be resolved before final decisions are made regarding reproductive options, antiretroviral therapy, cesarean delivery, or other interventions.
- Pregnant women who have repeatedly reactive EIAs and indeterminate supplemental tests should be retested for HIV antibody to distinguish between recent seroconversion and a negative test result. Almost all nonpregnant HIV-infected persons with indeterminate Western Blot will develop detectable HIV antibody within 1 month of exposure to the virus; relevant data are not available for pregnant women. Although viral DNA/RNA assays can be helpful, they are not FDA-approved for diagnostic use.
- Women who have negative EIA or rapid test results and those who have repeatedly reactive EIAs but negative supplemental tests should be considered uninfected unless they have had a recent HIV exposure. A negative test result provides information regarding the woman's status, but does not ensure that a sexual or needle-sharing partner is uninfected.
- As additional rapid assays become licensed and available in the United States, specific combinations of ≥ 2 different rapid HIV tests for diagnosis of HIV infection in women who do not receive health care until labor might be useful because combinations of rapid tests have provided results as reliable as those from the EIA/Western blot combination (78). Until other rapid assays are available, some women who are reactive on a single rapid test might consider prophylactic treatment until HIV infection is ruled out. Confirmatory standard testing should be done after delivery for women with a positive rapid test result.

Recommendations for HIV-Infected Pregnant Women

- HIV-infected pregnant women should receive HIV prevention counseling as recommended (see *Revised Guidelines for HIV Counseling, Testing, and Referral*). This counseling should include discussion of the risk for perinatal HIV transmission, ways to reduce this risk, and the prognosis for infants who become infected. HIV-infected pregnant women should also be told the clinical implications of a

positive HIV antibody test result and the need for and benefit of HIV-related medical and other early intervention services, including how to access these services.

- HIV-infected pregnant women should be counseled regarding antiretroviral therapy during pregnancy to improve their health (84) and prevent perinatal transmission (57). Medical care and management of HIV-infected persons, especially pregnant women, can be complicated because of the need for combination therapy with multiple drugs, management of common side effects, careful monitoring of viral load and drug resistance, prophylaxis for and treatment of opportunistic infections, and monitoring of immune status. Health-care providers who are not experienced in the care of pregnant HIV-infected women are encouraged to obtain referral for specialty care from providers who are knowledgeable in this area.

Although pregnancy is not an adequate reason to defer therapy for HIV infection, unique considerations exist regarding use of antiretroviral drugs during pregnancy, including the potential need to alter dosing because of physiologic changes associated with pregnancy, the potential for adverse short- or long-term effects on the fetus and infant, and the effectiveness in reducing the risk for perinatal transmission (57).

- Obstetric providers should adhere to best obstetric practices, including offering scheduled cesarean section at 38 weeks to reduce risk for perinatal HIV transmission (60,85).
- HIV-infected pregnant women should receive information regarding all reproductive options. Reproductive counseling should be nondirective. Health-care providers should be aware of the complex concerns that HIV-infected women must consider when making decisions regarding their reproductive options and should be supportive of any decision.
- To eliminate the risk for postnatal transmission, HIV-infected women in the United States should not breast-feed. Support services for use of appropriate breast milk substitutes should be provided when necessary. UNAIDS and World Health Organization recommendations for HIV and breast-feeding should be followed in international settings (86).
- To optimize medical management, positive and negative HIV test results should be available to a woman's health-care provider and included on her confidential medical records and those of her infant. After informing the mother, maternal health-care providers should notify the pediatric-care providers of the impending birth of an HIV-exposed infant and any anticipated complications. If HIV is first diagnosed in the infant, health-care providers should discuss the implications for the mother's health and help her obtain care. Women should also be encouraged to have their other children tested for HIV. Children can be infected with HIV for many years before complications occur. Providers are encouraged to build supportive health-care relationships that promote discussion of pertinent health information. Confidential HIV-related information should be disclosed or shared only in accordance with prevailing legal requirements.

- After receiving their test results, HIV-infected pregnant women should receive counseling, including assessment of the potential for negative effects (e.g., discrimination, domestic violence, psychological difficulties). Counseling should also include information on how to minimize these consequences, assistance in identifying supportive persons in their own social networks, and referral to appropriate psychological, social, and legal services. HIV-infected women should be counseled regarding the risk for transmission to others and ways to decrease this risk. They also should be told that discrimination based on HIV status or AIDS in housing, employment, state programs, and public accommodations (including physicians' offices and hospitals) is illegal.
- Health-care providers should thoroughly assess the prevention service needs of HIV-infected women (e.g., substance abuse, STD treatment, partner referral, or family planning services) and develop a plan to promote access to and use of these services (see *Revised Guidelines for HIV Counseling, Testing, and Referral*).
- Health-care providers should follow the Public Health Service Task Force recommendations for using antiretroviral drugs to treat pregnant HIV-1 infected women and reduce perinatal HIV-1 transmission in the United States, which address treating pregnant women who do not receive health care until near the time of delivery. These recommendations are available at the HIV/AIDS Treatment Information Service (ATIS) website at <<http://www.hivatis.org>> (57).

Recommendations for Postpartum Follow-Up of Infected Women and Perinatally Exposed Children

- HIV-infected women should receive ongoing HIV-related medical care, including immune-function monitoring, recommended therapy, and prophylaxis for and treatment of opportunistic infections and other HIV-related conditions (84,87). HIV-infected women should receive gynecologic care, including regular Pap smears, reproductive counseling, information on how to prevent sexual and drug-related transmission of HIV, and treatment of gynecologic conditions according to published recommendations (87). Obstetrical providers should ensure that HIV-infected women are introduced or referred to another provider to continue their care after pregnancy.
- HIV-infected women (or their children's guardians) should be informed of the importance of follow-up for their children. Children whose HIV infection status is unknown require early diagnostic testing and prophylactic therapy to prevent PCP pending determination of their status.
 - Infected children require follow-up care to determine the need for prophylactic therapy and antiretroviral treatment and to monitor disorders in growth and development that often occur before age 24 months.
 - Uninfected children who are exposed to antiretroviral therapy should be assessed for potential short- and long-term side effects.
- Identification of an HIV-infected mother indicates that her family needs or will need medical and social services as her disease progresses. Thus, health-care providers should ensure that referrals to services address the needs of the entire family.

CONCLUSION

Because of recent advances in both antiretroviral and obstetrical interventions, pregnant women infected with HIV who know their status prenatally can reduce their risk for transmitting HIV to their infants to $\leq 2\%$. The guidelines in this report are intended to reduce barriers to voluntary HIV testing for all pregnant women in the United States and to make the voluntary counseling and testing process simple and routine in prenatal settings. The recommendations underscore the importance of HIV-infected pregnant women (and their health-care providers) knowing their status to protect their own health and reduce the risk for transmitting HIV to their infants.

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References

1. Connor EM, Sealing RS, Gelber R, et al. Reduction of maternal-infant transmission of human immunodeficiency virus type 1 with zidovudine treatment. *N Engl J Med* 1994;331:1173–80.
2. CDC. Recommendations of the U.S. Public Health Service Task Force on use of zidovudine to reduce perinatal transmission of human immunodeficiency virus. *MMWR* 1994;43(No. RR-11):1–21.
3. CDC. US Public Health Service recommendations for human immunodeficiency virus counseling and voluntary testing for pregnant women. *MMWR* 1995;44(No. RR-7):1–14.
4. CDC. Update: perinatally acquired HIV/AIDS—United States, 1997. *MMWR* 1997;46:1086–92.
5. CDC. Success in implementing Public Health Service guidelines to reduce perinatal transmission of HIV—Louisiana, Michigan, New Jersey, and South Carolina, 1993, 1995, and 1996. *MMWR* 1998;47:688–91.
6. Fiscus SA, Adimora AA, Schoenback VJ, et al. Trends in human immunodeficiency virus (HIV) counseling, testing, and antiretroviral treatment of HIV-infected women and perinatal transmission in North Carolina. *J Infect Dis* 1999;180:99–105.
7. Lindegren ML, Byers RH, Thomas P, et al. Trends in perinatal transmission of HIV/AIDS in the United States. *JAMA* 1999;282:531–8.
8. Cooper ER, Nugent RP, Diaz C, et al. After AIDS clinical trial 076: the changing pattern of zidovudine use during pregnancy, and the subsequent reduction in the vertical transmission of human immunodeficiency virus in a cohort of infected women and their infants. *J Infect Dis* 1996;174:1207–11.
9. Institute of Medicine, National Research Council. Reducing the odds: preventing perinatal transmission of HIV in the United States. Washington, DC: National Academy Press, 1999.
10. Moore RD, Chaisson RE. Natural history of HIV infection in the era of combination antiretroviral therapy. *AIDS* 1999;13:1933–42.
11. Guay LA, Musoke P, Fleming T, et al. Intrapartum and neonatal single-dose nevirapine compared with zidovudine for prevention of mother-to-child transmission of HIV-1 in Kampala, Uganda: HIVNET 012 randomised trial. *Lancet* 1999;354:795–802.
12. Mofenson LM, Lambert JS, Stiehler ER, et al. Risk factors for perinatal transmission of human immunodeficiency virus type 1 in women treated with zidovudine. *N Engl J Med* 1999;341:385–93.
13. Mock PA, Shaffer N, Bhadrakom C, et al. Maternal viral load and timing of mother-to-child HIV transmission, Bangkok, Thailand. *AIDS* 1999;13:407–14.

14. Ioannidis JPA, Abrams EJ, Ammann A, et al. Perinatal transmission of human immunodeficiency virus type 1 by pregnant women with RNA virus loads <1000 copies/ml. *J Infect Dis* 2001;183:539–45.
15. CDC. U.S. HIV and AIDS cases reported through June 2000: midyear edition. *HIVAIDS surveillance report* 2000;12(No.1):1–41.
16. Karon JM, Rosenberg PS, McQuillan G, Khare M, Gwinn M, Petersen LR. Prevalence of HIV infection in the United States, 1984 to 1992. *JAMA* 1996;276:126–31.
17. Dunn DT, Peckham CS, Semprini AE, Pardi G. Vertical transmission of HIV-1: maternal immune status and obstetric factors. *The European Collaborative Study. AIDS* 1996;10:1675.
18. Pitt J, Brambilla D, Reichelderfer P, et al. Maternal and immunologic and virologic risk factors for infant human immunodeficiency virus type 1 infection: Findings from the Women and Infants Transmission Study. *J Infect Dis* 1997;175:567–75.
19. Simonds RJ, Steketee R, Nesheim S, et al. Impact of zidovudine use on risk and risk factors for perinatal transmission of HIV. *Perinatal AIDS Collaborative Transmission Studies. AIDS* 1998;12:301–8.
20. Shaffer N, Chuachoowong R, Mock PA, et al. Short-course zidovudine for perinatal HIV-1 transmission in Bangkok, Thailand: a randomised controlled trial. *Lancet* 1999;353:773–80.
21. Dabis F, Msellati P, Dunn D, et al. Estimating the rate of mother-to-child transmission of HIV. Report of a workshop on methodological issues: Ghent (Belgium), 17–20 February 1992. *AIDS* 1993;7:1139–48.
22. De Cock KM, Fowler MG, Mercier E, et al. Prevention of mother-to-child HIV transmission in resource-poor countries: translating research into policy and practice. *JAMA* 2000;283:1175–82.
23. Van Dyke RB, Korber BT, Popek E, et al. The Ariel project: a prospective cohort study of maternal-child transmission of human immunodeficiency virus type 1 in the era of maternal antiretroviral therapy. *J Infect Dis* 1999;179:319–28.
24. Wade NA, Birkhead GS, Warren BL, et al. Abbreviated regimens of zidovudine prophylaxis and perinatal transmission of the human immunodeficiency virus. *N Engl J Med* 1998;339:1409–14.
25. Garcia PM, Kalish LA, Pitt J, et al. Maternal levels of plasma human immunodeficiency virus type 1 RNA and the risk of perinatal transmission. *N Engl J Med* 1999;341:394–402.
26. Dorenbaum A for the PACTG 316 Study Team. Report of results of PACTG 316: an international phase III trial of standard antiretroviral (ARV) prophylaxis plus nevirapine (NVP) for prevention of perinatal HIV transmission [Abstract LB7]. In: *Programs and abstracts of the 8th Conference on Retroviruses and Opportunistic Infections*. Alexandria, VA: Foundation for Retrovirology and Human Health, 2001:277.
27. The European Mode of Delivery Collaboration. Elective caesarean-section versus vaginal delivery in prevention of vertical HIV-1 transmission: a randomised clinical trial. *Lancet* 1999;353:1035–9.
28. The International Perinatal HIV Group. The mode of delivery and the risk of vertical transmission of human immunodeficiency virus type 1. *N Engl J Med* 1999;340:977–87.
29. Mandelbrot L, Le Chenadec J, Berrebi A, et al, for the French Perinatal Cohort. Perinatal HIV-1 transmission: interaction between zidovudine prophylaxis and mode of delivery in the French perinatal cohort. *JAMA* 1998;280:55–60.
30. CDC. Prenatal discussion of HIV testing and maternal HIV testing—14 states, 1996–1997. *MMWR* 1999;48:401–4.
31. Anonymous. Surveillance of pediatric HIV infection. *American Academy of Pediatrics. Pediatrics* 1998;101:315–9.
32. Fowler MG, Simonds RJ, Roongpisuthipong A. Update on perinatal HIV transmission. *Pediatr Clin North Am* 2000;47:21–38.

33. Bertolli J, St Louis ME, Simonds RJ, et al. Estimating the timing of mother-to-child transmission of human immunodeficiency virus in a breast-feeding population in Kinshasa, Zaire. *J Infect Dis* 1996;174:722–6.
34. Nduati R, John G, Mbori-Ngacha D, et al. Effect of breastfeeding and formula feeding on transmission of HIV-1: a randomized clinical trial. *JAMA* 2000;283:1167–74.
35. Miotti PG, Taha TE, Kumwenda NI, et al. HIV transmission through breastfeeding: a study in Malawi. *JAMA* 1999;282:744–9.
36. Moodley D. The SAINT trial: nevirapine (NVP) versus zidovudine (ZDV)+lamivudine (3TC) in prevention of peripartum HIV transmission [Abstract LB0r10]. In: Program and abstracts of the XIIIth International AIDS Conference. Durban, South Africa: International AIDS Society, 2000.
37. Semba RD, Kumwenda N, Hoover DR, et al. Human immunodeficiency virus load in breast milk, mastitis, and mother-to-child transmission of human immunodeficiency virus type 1. *J Infect Dis* 1999;180:93–8.
38. Pillay K, Coutoudis A, York D, Kuhn L, Coovadia HM. Cell-free virus in breast milk of HIV-1-seropositive women. *J Acquir Immune Defic Syndr* 2000;24:350–6.
39. Embree JE, Njenga S, Datta P, et al. Risk factors for postnatal mother-child transmission of HIV-1. *AIDS* 2000;14:2535–41.
40. John GC, Nduati RW, Mbori-Ngacha DA, et al. Correlates of mother-to-child human immunodeficiency virus type 1 (HIV-1) transmission: association with maternal plasma HIV-1 RNA load, genital HIV-1 DNA shedding, and breast infections. *J Infect Dis* 2001;183:206–12.
41. Dunn DT, Newell ML, Ades AE, Peckham CS. Risk of human immunodeficiency virus type 1 transmission through breast feeding. *Lancet* 1992;340:585–8.
42. Shaffer N, Roongpisuthipong A, Siriwasin W, et al. Maternal virus load and perinatal human immunodeficiency virus type 1 subtype E transmission, Thailand. *J Infect Dis* 1999;179:590–9.
43. The International Perinatal HIV Group. Duration of ruptured membranes and vertical transmission of HIV-1: a meta-analysis from 15 prospective cohort studies. *AIDS* 2001;15:357–68.
44. Landesman SH, Kalish LA, Burns DN, et al. Obstetrical factors and the transmission of human immunodeficiency virus type 1 from mother to child. *N Engl J Med* 1996;334:1617–23.
45. Mandelbrot L, Mayaux M-J, Bongain A, et al, and The French Pediatric HIV Infection Study Group. Obstetric factors and mother-to-child transmission of human immunodeficiency virus type 1: the French perinatal cohorts. *Am J Obstet Gynecol* 1996;175:661–7.
46. St. Louis ME, Kamenga M, Brown C, et al. Risk for perinatal HIV-1 transmission according to maternal immunologic, virologic, and placental factors. *JAMA* 1993;269:2853–9.
47. Wade N, Birkhead G, Gourlay-Doyle M, et al. Perinatal HIV transmission rates among HIV-infected pregnant women in New York State (NYS) [Abstract 708]. In: Program and abstracts of the 7th Conference on Retroviruses and Opportunistic Infections. Alexandria, VA: Foundation for Retrovirology and Human Health, 2000.
48. Fernandez MI, Wilson TE, Ethier KA, Walter EB, Gay CL, Moore J, for the Perinatal Guidelines Evaluation Project. Acceptance of HIV testing during prenatal care. *Public Health Rep* 2000;15:460–8.
49. Royce RA, Walter EB, Fernandez MI, Wilson TE, Ickovics JR, Simonds RJ, for the Perinatal Guidelines Evaluation Project. Barriers to universal prenatal HIV testing in 4 US locations in 1997. *Am J Public Health* 2001;91:727–33.
50. Mills WA, Martin DL, Bertrand JR, Belongia EA. Physicians' practices and opinions regarding prenatal screening for human immunodeficiency virus and other sexually transmitted diseases. *Sex Transm Dis* 1998;25:169–75.
51. Lindegren ML, Steinberg S, Byers RH. Epidemiology of HIV/AIDS in children. *Pediatr Clin North Am* 2000;47:1–20.

52. Wiktor SZ, Ekpini E, Karon JM, et al. Short-course oral zidovudine for prevention of mother-to-child transmission of HIV-1 in Abidjan, Côte d'Ivoire: a randomised trial. *Lancet* 1999;353:781-5.
53. Dabis F, Msellati P, Meda N, et al, for the DITRAME Study Group. 6-month efficacy, tolerance, and acceptability of a short regimen of oral zidovudine to reduce vertical transmission of HIV in breastfed children in Côte d'Ivoire and Burkina Faso: a double-blind placebo-controlled multicentre trial. *Lancet* 1999;353:786-92.
54. Wiktor SZ, Leroy V, Ekpini ER, et al. 24-month efficacy of short-course maternal zidovudine for the prevention of mother-to-child HIV-1 transmission in a breast feeding population: a pooled analysis of two randomized clinical trials in West Africa [Abstract TuOrB3542]. In: Program and abstracts of the XIII International AIDS Conference. Durban, South Africa: International AIDS Society, 2000:329.
55. Gray G. The PETRA study: early and late efficacy of three short ZDV/3TC combination regimens to prevent mother-to-child transmission of HIV-1. In: Programme supplement of the XIII International AIDS Conference. Durban, South Africa: International AIDS Society, 2000:17.
56. Thomas P, Bornschlegel K. Short courses of zidovudine and perinatal transmission of HIV. [Letter]. *N Engl J Med* 1999;340:1041.
57. Public Health Service Task Force recommendations for the use of antiretroviral drugs in pregnant women infected with HIV-1 for maternal health and for reducing perinatal HIV-1 transmission in the United States. HIV/AIDS Treatment Information Service (ATIS) website at <<http://www.hivatis.org>>. Accessed August 2, 2001.
58. Watts DH, Lambert JS, Stiehm ER, et al, for the Pediatric AIDS Clinical Trials Study Group 185 Team. Complications according to mode of delivery among human immunodeficiency virus-infected women with CD4 lymphocyte counts of $\leq 500/\mu\text{L}$. *Am J Obstet Gynecol* 2000;183:100-7.
59. American College of Obstetricians and Gynecologists. Committee opinion: scheduled cesarean delivery and the prevention of vertical transmission of HIV infection. No. 234, May 2000.
60. Biggar RJ, Miotti PG, Taha TE, et al. Perinatal intervention trial in Africa: effect of a birth canal cleansing intervention to prevent HIV transmission. *Lancet* 1996;347:1647-50.
61. Irwin KL, Moorman AC, O'Sullivan MJ, et al, for the PID-HIV Infection Study Group. Influence of human immunodeficiency virus infection in pelvic inflammatory disease. *Obstet Gynecol* 2000;95:525-34.
62. Duerr A, Sierra MF, Feldman J, Clarke SM, Ehrlich I, DeHovitz J. Immune compromise and prevalence of *Candida* vulvovaginitis in human immunodeficiency virus-infected women. *Obstet Gynecol* 1997;90:252-6.
63. Ellerbrock TV, Chiasson MA, Bush TJ, et al. Incidence of cervical squamous intraepithelial lesions in HIV-infected women. *JAMA* 2000;283:1031-7.
64. Schable B, Diaz T, Chu SY, et al. Who are the primary caretakers of children born to HIV-infected mothers? Results from a multisite surveillance project. *Pediatric* 1995;95:511-5.
65. Simonds RJ, Oxtoby MJ, Caldwell MB, Gwinn ML, Rogers MF. *Pneumocystis carinii* pneumonia among US children with perinatally acquired HIV infection. *JAMA* 1993;270:470-3.
66. CDC. 1995 revised guidelines for prophylaxis against *Pneumocystis carinii* pneumonia for children infected with or perinatally exposed to human immunodeficiency virus. *MMWR* 1995;44(No. RR-4):1-11.
67. Guidelines for the use of antiretroviral agents in pediatric HIV infection. HIV/AIDS Treatment Information Service (ATIS) website at <<http://www.hivatis.org>>. Accessed August 2, 2001.
68. Lazzarini Z, Gostin LO, Ward JW, Fleming PL, Nesland V. State efforts to reduce perinatal HIV transmission [Abstract 44105]. In: Program and abstracts of the 12th World AIDS Conference. Geneva, Switzerland, 1998:959.

69. Koenig LJ, Moore J. Women, violence, and HIV: a critical evaluation with implications for HIV services. *Matern Child Health J* 2000;4:103-9.
70. Americans with Disabilities Act. 42 USC section 12101 et seq. Available at <<http://www.usdoj.gov/crt/ada/adahom1.htm>>. Accessed August 2, 2001.
71. George JR, Schochetman G. Detection of HIV infection using serologic techniques. In: Schochetman G, George JR, eds. *AIDS testing: a comprehensive guide to technical, medical, social, legal, and management issues*. 2 ed. New York, NY: Springer-Verlag, 1994.
72. Celum CL, Coombs RW, Lafferty W, et al. Indeterminate human immunodeficiency virus type 1 Western blots: seroconversion risk, specificity of supplemental tests, and an algorithm for evaluation. *J Infect Dis* 1991;164:656-64.
73. Celum CL, Coombs RW, Jones M, et al. Risk factors for repeatedly reactive HIV-1 EIA and indeterminate Western blots: a population-based case-control study. *Arch Intern Med* 1994;154:1129-37.
74. Gwinn M, Redus MA, Granade TC, Hannon WH, George JR. HIV-1 serologic test results for one million newborn dried-blood specimens: assay performance and implications for screening. *J Acquir Immune Defic Syndr* 1992;5:505-12.
75. MacDonald KL, Jackson JB, Bowman RJ, et al. Performance characteristics of serologic tests for human immunodeficiency virus type 1 (HIV-1) antibody among Minnesota blood donors: public health and clinical implications. *Ann Intern Med* 1989;110:617-21.
76. Burke DS, Brundage JF, Redfield RR, et al. Measurement of the false positive rate in a screening program for human immunodeficiency virus infections. *N Engl J Med* 1988;319:961-4.
77. Sheon AR, Fox HE, Alexander G, et al. Misdiagnosed HIV infection in pregnant women: implications for clinical care. *Public Health Rep* 1994;109:694-9.
78. Branson BM. Rapid tests for HIV antibody. *AIDS Rev* 2000;2:76-83.
79. Irwin K, Olivo N, Schable CA, Weber T, Janssen R, Ernst J, and the CDC-Bronx-Lebanon HIV Serosurvey Team. Performance characteristics of a rapid HIV antibody assay in a hospital with a high prevalence of HIV infection. *Ann Intern Med* 1996;125:471-5.
80. Stetler HC, Granade TC, Nunez CA, et al. Field evaluation of rapid HIV serologic tests for screening and confirming HIV-1 infection in Honduras. *AIDS* 1997;11:369-75.
81. Bulterys M, Fowler MG. Prevention of HIV infection in children. *Pediatr Clin North Am* 2000;47:241-60.
82. Minkoff H, O'Sullivan MJ. The case for rapid HIV testing during labor. *JAMA* 1998;279:1743-4.
83. CDC. 1998 guidelines for treatment of sexually transmitted diseases. *MMWR* 1998;47(No. RR-1):1-118.
84. Guidelines for the use of antiretroviral agents in HIV-infected adults and adolescents. January 2000. HIV/AIDS Treatment Information Service (ATIS) website at <www.hivatis.org>. Accessed August 10, 2001.
85. American College of Obstetricians and Gynecologists. Human immunodeficiency virus screening. Joint statement of the American Academy of Pediatrics and the American College of Obstetricians and Gynecologists. *Pediatrics* 1999;104:128.
86. WHO Technical Consultation on Behalf of the UNFPA/UNICEF/WHO/UNAIDS Inter-Agency Task Team on Mother-to-Child Transmission of HIV. New data on the prevention of mother-to-child transmission of HIV and their policy implications. October 2000. Available at <<http://www.unaids.org/publications/documents/mtct/index.html>>. Accessed August 16, 2001.
87. CDC. 1999 USPHS/IDSA guidelines for the prevention of opportunistic infections in persons infected with human immunodeficiency virus. *MMWR* 1999;48(No. RR-10):1-66.

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3. Indicate whether you are registering for CME, CEU, or CNE credit.
4. Select your answers to the questions, and mark the corresponding letters on the response form. To receive continuing education credit, you must answer all of the questions. Questions with more than one correct answer will instruct you to "Indicate all that apply."
5. Sign and date the response form or a photocopy of the form and send no later than **November 9, 2004**, to

Fax: 404-639-4198

Mail: MMWR CE Credit
Office of Scientific and Health Communications
Epidemiology Program Office, MS C-08
Centers for Disease Control and Prevention
1600 Clifton Rd, N.E.
Atlanta, GA 30333

6. Your Certificate of Completion will be mailed to you within 30 days.

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GOAL AND OBJECTIVES

This *MMWR* provides recommendations regarding the screening of pregnant women for human immunodeficiency virus (HIV) infection. These recommendations were prepared by the U.S. Public Health Service based on public health and obstetric practice guidelines and input from a panel of specialists. The goal of this report is to provide guidance to public- and private-sector policy makers and clinical providers on HIV screening during pregnancy. Upon completion of this continuing education activity, the reader should be able to a) describe the recommended HIV counseling and testing strategy for pregnant women, b) identify risk factors for perinatal HIV transmission, c) identify barriers to HIV testing among pregnant women, and d) describe the information that pregnant women should receive before HIV testing.

To receive continuing education credit, please answer all of the following questions.

- 1. The recommended testing strategy for pregnant women can best be described as**
 - A. universal counseling and voluntary HIV testing.
 - B. routine counseling and targeted testing.
 - C. voluntary counseling and testing.
 - D. targeted counseling and testing.

- 2. The new guidelines differ from the 1995 guidelines for HIV counseling and testing for pregnant women in all of the following ways except**
 - A. making the consent process more flexible.
 - B. strengthening the recommendation that all pregnant women be tested for HIV.
 - C. placing more emphasis on HIV testing and treatment at the time of delivery.
 - D. recommending simplification of the testing process.
 - E. none of the above.

- 3. All of the following factors have been associated with increased risk for perinatal HIV transmission except**
 - A. advanced maternal HIV disease.
 - B. prolonged rupture of membranes.
 - C. scheduled cesarean delivery.
 - D. preterm delivery.
 - E. maternal infection with another sexually transmitted disease (STD).

- 4. All of the following are reasons commonly cited by women for declining HIV testing except**
 - A. no perceived risk.
 - B. financial constraints.
 - C. administrative scheduling difficulties.
 - D. lack of provider endorsement.
 - E. history of previous testing.

5. **Which of the following are included as one of the components of the recommended Pediatric AIDS Clinical Trials Group protocol 076 regimen for administration of zidovudine (ZDV)?**
- A. Administration of oral ZDV to the infant for the first 8 weeks of life.
 - B. Administration of oral ZDV to the mother beginning during the first trimester.
 - C. Administration of intravenous ZDV to the infant at time of birth.
 - D. Administration of intravenous ZDV during labor and delivery.
6. **All of the following information should be provided to pregnant women before HIV testing except**
- A. Effective interventions can help protect infants from becoming infected.
 - B. Services are available to help women reduce their risk for HIV.
 - C. A woman might be at risk for HIV and not know it.
 - D. Repeat HIV testing is not recommended for women tested within the year.
 - E. HIV can be transmitted through breast-feeding.
7. **Retesting for HIV in the third trimester is recommended for**
- A. women with a history of STDs.
 - B. women with multiple sex partners during pregnancy.
 - C. A and B.
 - D. none of the above.
8. **Informed consent before HIV testing is**
- A. optional.
 - B. mandated by federal law.
 - C. essential.
 - D. required by most states.
9. **Indicate your work setting.**
- A. State/local health department.
 - B. Other public health setting.
 - C. Hospital clinic/private practice.
 - D. Managed care organizations.
 - E. Academic institution.
 - F. Other.
10. **Which best describes your professional activities?**
- A. Patient care — emergency/urgent care department.
 - B. Patient care — inpatient.
 - C. Patient care — primary-care clinic or office.
 - D. Laboratory/pharmacy.
 - E. Public health.
 - F. Other.

- 11. I plan to use these recommendations as the basis for . . . (Indicate all that apply.)**
- A. health education materials.
 - B. insurance reimbursement policies.
 - C. local practice guidelines.
 - D. public policy.
 - E. other.
- 12. Each month, approximately how many pregnant patients/clients do you see?**
- A. None.
 - B. 1-10.
 - C. 11-30.
 - D. 30-50.
 - E. >50.
- 13. How much time did you spend reading this report and completing the exam?**
- A. Fewer than 1.5 hours.
 - B. More than 1.5 hours but fewer than 2 hours.
 - C. 1-1.5 hours.
 - D. More than 2.5 hours but fewer than 3 hours.
 - E. 3 hours or more.
- 14. After reading this report, I am confident I can describe the recommended HIV counseling and testing strategy for pregnant women.**
- A. Strongly agree.
 - B. Agree.
 - C. Neither agree nor disagree.
 - D. Disagree.
 - E. Strongly disagree.
- 15. After reading this report, I am confident I can identify risk factors for perinatal HIV transmission.**
- A. Strongly agree.
 - B. Agree.
 - C. Neither agree nor disagree.
 - D. Disagree.
 - E. Strongly disagree.

- 16. After reading this report, I am confident I can identify barriers to HIV testing among pregnant women.**
- A. Strongly agree.
 - B. Agree.
 - C. Neither agree nor disagree.
 - D. Disagree.
 - E. Strongly disagree.
- 17. After reading this report, I am confident I can describe the information that pregnant women should receive before HIV testing.**
- A. Strongly agree.
 - B. Agree.
 - C. Neither agree nor disagree.
 - D. Disagree.
 - E. Strongly disagree.
- 18. The objectives are relevant to the goal of this report.**
- A. Strongly agree.
 - B. Agree.
 - C. Neither agree nor disagree.
 - D. Disagree.
 - E. Strongly disagree.
- 19. Overall, the presentation of the report enhanced my ability to understand the material.**
- A. Strongly agree.
 - B. Agree.
 - C. Neither agree nor disagree.
 - D. Disagree.
 - E. Strongly disagree.
- 20. The recommendations will affect my practice.**
- A. Strongly agree.
 - B. Agree.
 - C. Neither agree nor disagree.
 - D. Disagree.
 - E. Strongly disagree.

21. How did you learn about this continuing education activity?

- A. Internet.
- B. Advertisement (e.g., fact sheet, *MMWR* cover, newsletter, or journal).
- C. Coworker/supervisor.
- D. Conference presentation.
- E. *MMWR* subscription.
- F. Other.

Correct answers for questions 1-8
1. A; 2. E; 3. C; 4. B; 5. D; 6. D; 7. C; 8. C.

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November 9, 2001/Vol. 50/No. RR-19a2**

**Revised Recommendations for HIV Screening
for Pregnant Women**

To receive continuing education credit, you must
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- 4. []A []B []C []D []E
- 5. []A []B []C []D
- 6. []A []B []C []D []E
- 7. []A []B []C []D
- 8. []A []B []C []D
- 9. []A []B []C []D []E []F
- 10. []A []B []C []D []E []F
- 11. []A []B []C []D []E
- 12. []A []B []C []D []E
- 13. []A []B []C []D []E
- 14. []A []B []C []D []E
- 15. []A []B []C []D []E
- 16. []A []B []C []D []E
- 17. []A []B []C []D []E
- 18. []A []B []C []D []E
- 19. []A []B []C []D []E
- 20. []A []B []C []D []E
- 21. []A []B []C []D []E []F

Signature

Date I Completed Exam

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MMWR

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**Appendix D:
Quality Assurance of
HIV Prevention
Counseling in a
Multicenter,
Randomized Controlled
Trial (Research Paper)**

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

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.

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

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	

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 participant'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)

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	Exceeded
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

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-

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.

Appendix E: Partner Counseling and Referral Services Guidelines

HIV Partner Counseling and Referral Services

Guidance

December 30, 1998



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service • Centers for Disease Control and Prevention •
National Center for HIV, STD, and TB Prevention • Divisions of HIV/AIDS Prevention



Preface

This guidance is intended to assist state and local health department HIV prevention cooperative agreement grantees and HIV prevention community planning groups in planning, implementing, and evaluating the services provided to persons living with HIV and their sex and needle-sharing partners. External consultants and CDC staff collaborated in the development of this guidance, which is intended to supplement current CDC cooperative agreement guidance for HIV prevention programs. The development process included input based on reviews of the relevant scientific literature, actual program experience, and expert recommendations from within and outside CDC.

This guidance uses new terminology to label the process of reaching and serving sex and needle-sharing partners. As opposed to *contact tracing* and *partner notification*, the term *partner counseling and referral services* (PCRS) is used in this document because it better reflects the type and range of public health services that are recommended for sex and needle-sharing partners. These services are vital to any community's HIV prevention efforts. This guidance should assist in developing programs, planning services, or prioritizing resource allocation for PCRS, and state and local programs supported with CDC funds should adapt it to meet their local policies, needs, and circumstances.

The principles listed on the following pages constitute the basis for PCRS and are applied to issues discussed throughout this document. Principles 1–11 apply to partner counseling and referral services associated with partner services for all sexually transmitted diseases, including HIV. Principles 12–13 apply to partner counseling and referral services associated with HIV in particular.

The reader can refer to Appendix B, “Glossary of Terms Associated with PCRS,” for clarification on how some terms are used in this document. For example, the term ***PCRS provider*** is used to refer to any qualified health care personnel, including physicians, nurses, counselors, or disease intervention specialists, who might be involved in serving HIV-infected clients, their partners, and affected communities. Guidance in this document assumes and strongly recommends that PCRS providers be specifically trained in delivering these services.

For technical assistance or inquiries, PCRS providers should contact their state health department. State health departments should contact their CDC project officers.

Principles Associated with Providing PCRS for All Sexually Transmitted Diseases, Including HIV

1. **Voluntary.** PCRS is voluntary on the part of the infected person and his or her partners.
2. **Confidential.** Every part of PCRS is confidential.
3. **Science-Based.** PCRS activities are science-based and require knowledge, skill, and training.
4. **Culturally Appropriate.** PCRS is to be delivered in a nonjudgmental, culturally appropriate, and sensitive manner.
5. **A Component of a Comprehensive Prevention System.** PCRS is one of a number of public health strategies to control and prevent the spread of HIV and STDs. Other strategies include access to clinical services, outreach to and targeted screenings of at-risk populations, behavioral interventions, and educational programs.
6. **Diverse Referral Approaches.** PCRS may be delivered through two basic approaches: provider referral, whereby the PCRS provider locates and informs sex or needle-sharing partners of their exposure, and client referral, whereby the infected person takes responsibility for informing his or her partners. Sometimes a combination of these approaches is used.
7. **Support Services and Referral.** PCRS is delivered in a continuum of care that includes the capacity to refer sex and needle-sharing partners to HIV counseling, testing, and treatment, as well as other services, e.g., STD treatment, family planning, violence prevention, drug treatment, social support, housing.
8. **Analysis and Use of PCRS Data.** PCRS program managers should collect data on services provided and use the data for evaluating and improving program efficiency, effectiveness, and quality.
9. **Counseling and Support for Those Who Choose To Notify Their Own Partners.** Counseling and support for those who choose to notify their own partners is an essential element of PCRS. Such efforts can assist in ultimately reaching more partners and minimizing unintended consequences of notification. Assistance to clients in deciding if, how, to whom, where, and when to disclose their infection can help them avoid stigmatization, discrimination, and other potential negative effects. Working with a client to think through what it means to notify a partner and creating a specific plan to ensure he or she successfully accomplishes the notification is a vital role of the provider.
10. **Client-Centered Counseling.** Providing client-centered counseling for HIV-infected individuals and their partners can reduce behavioral risks for acquiring or transmitting HIV infection. In addition, client-centered counseling will help the provider understand the readiness of the client to notify partners. This will allow the provider to offer services to assist the client in successfully notifying partners without adverse consequence.
11. **Increased Importance as New Technologies Emerge.** As new technologies emerge, such as rapid diagnostic tests, vaccines, behavioral interventions, and even more effective therapies, PCRS will become an increasingly important prevention tool.

***Principles Associated with Providing PCRS,
Particularly for HIV***

12. Ongoing Access to PCRS for HIV-Infected Individuals and Partners.

PCRS should not be a one-time service. It should be offered as soon as an HIV-infected individual learns his or her serostatus and made available throughout that person's counseling and treatment. If new partners are exposed in the future, PCRS should be made available again. HIV-infected individuals should have the ability to access PCRS whenever needed.

13. Assistance in Accessing Medical Evaluation and Treatment To Prolong Life.

Sex and needle-sharing partners might already be HIV-infected but be unaware of or deny their risks. They can be assisted through PCRS in learning their status, and in obtaining earlier medical evaluation and treatment for HIV disease and opportunistic infections. PCRS provides an opportunity for HIV primary prevention interventions for those partners not infected with HIV and an opportunity for secondary prevention for those partners living with HIV.

How To Use This Document

The standards and guidance in this document describe the core elements that are essential for successful PCRS programs at publicly funded sites. Even though HIV and STD programs share many common goals, policies, and activities, PCRS is designed specifically for HIV prevention programs. It is not intended to replace or modify CDC guidance for partner notification for other STDs.

The two levels of recommendations in this document are **Standards** and **Guidance**:

Standards. Specific standards are provided in several sections and are intended to be applied consistently. **Standards must be followed by CDC grantees in virtually all cases where CDC funds are used to support services.** To assist the reader, each standard is set apart from the other text in

reverse type on a black background.

In addition, Appendix A is a concise listing of all the PCRS standards in the order discussed in the main part of the document.

Guidance. The main text of this document provides overall guidance for PCRS programs. **This guidance *should* be followed in most cases, but can be tailored to fit the individuals and affected communities being served as well as the program needs.** Providers are urged to follow this guidance but have flexibility to modify or adapt based on state or local needs, policies, or circumstances.

Other organizations providing PCRS or other HIV prevention service providers might also find this document a useful guide. CDC recommends that the guidance be shared with providers and consumers of services in local areas. Managers of PCRS programs are urged to work closely with STD prevention, violence prevention, drug treatment, reproductive health, and other state agencies in planning, implementing, and evaluating their program and services.

CONTENTS

PREFACE	i
Principles Associated with Providing PCRS for All Sexually Transmitted Diseases, Including HIV	ii
Principles Associated with Providing PCRS, Particularly for HIV	iii
How To Use This Document	iv
1.0 PARTNER COUNSELING AND REFERRAL SERVICES FOR HIV PREVENTION – AN OVERVIEW	1
1.1 How HIV PCRS Has Evolved	1
1.2 What Are the Goals of PCRS?	1
1.3 Is PCRS Cost-effective?	2
1.4 Who Benefits from PCRS?	2
1.5 What Activities Are Involved in PCRS?	3
2.0 AVAILABILITY OF PCRS	4
2.1 Making Services Available to All HIV-infected Persons	4
2.1.1 Services for Those Persons Tested Anonymously	5
2.1.2 Inability to Pay	5
2.2 Accommodating Requests from Other Health Jurisdictions	6
3.0 DECIDING ON A PCRS PLAN AND SETTING PRIORITIES	6
3.1 Encouraging Client Participation	6
3.1.1 Fully Informing and Reassuring Clients	6
3.1.2 Developing an Atmosphere of Trust	6
3.1.3 Introducing PCRS	7
3.2 Formulating a PCRS Plan	7
3.2.1 Taking a Closer Look at Client Referral	8
3.2.2 Taking a Closer Look at Provider Referral	9
3.2.3 Taking a Closer Look at Combined Referral Approaches	10
3.3 Setting Priorities for Reaching Partners	10
3.4 Considering Other Options and Special Circumstances	12
3.4.1 Other Persons Who Might Need To Be Contacted	12
3.4.2 “But, I Do Not Want My Partner To Be Contacted!”	13
3.4.3 PCRS for Needle-sharing Partners	13

Contents (continued)

4.0 LOCATING AND NOTIFYING PARTNERS 14

4.1 Preparing the PCRS Provider 14

4.2 Setting Activities in Motion 15

4.3 Maintaining Confidentiality 15

4.4 Helping Partners Access Services 16

4.5 Addressing Community Concerns 16

5.0 COLLECTING, ANALYZING, AND USING PCRS DATA 17

5.1 Why Collect Program Data? 17

5.2 What Data Should Be Collected? 17

6.0 ENSURING THE QUALITY OF PCRS 18

6.1 Training 18

6.2 Quality Assurance and Evaluation 18

6.3 How Can CDC Help? 19

REFERENCES 20

APPENDICES 22

A. PCRS Programmatic Standards 22

B. Glossary of Terms Associated with PCRS 24

ACKNOWLEDGMENTS 26

1.0 PARTNER COUNSELING AND REFERRAL SERVICES FOR HIV PREVENTION

AN OVERVIEW

1.1. *How HIV PCRS Has Evolved*

Once known as “contact tracing,” outreach activities for finding, diagnosing, and treating partners of persons infected with sexually transmitted diseases (STDs) have long been used by public health workers as a prevention activity. In the 1930s, U.S. Surgeon General Thomas Parran advocated the use of contact tracing to help “prevent new chains of [syphilis] infection” (Parran, 1937). Contact tracing was later expanded to include partners of persons infected with gonorrhea and other STDs, including the human immunodeficiency virus (HIV), and came to be known in the 1980s as “partner notification” (West and Stark, 1997).

In the 1980s, when public health workers were first being confronted with the rapid spread of HIV, the virus that causes acquired immunodeficiency syndrome (AIDS), informing persons of their possible exposure to HIV and offering counseling, testing, and referral services were already recognized as an important disease prevention effort that could help stem the tide of HIV infection. As HIV prevention activities have evolved, so has the terminology for informing the HIV-infected person’s sex and needle-sharing partners of their possible exposure to the virus. Today, the term *HIV partner counseling and referral services (PCRS)* more accurately reflects the range of services available to HIV-infected persons, their partners, and affected communities through this public health activity.

Of necessity, PCRS for HIV differs from partner services for other STDs because the “epidemiological, biological, and clinical characteristics of HIV are different” (West and

Stark, 1997). Despite recent advances in treatment, we do not yet have a cure for AIDS, so HIV remains a lifelong issue for those infected. Furthermore, because society frequently stigmatizes and sometimes discriminates against HIV-infected persons and their families and friends, the affected communities may be concerned about the potential negative impact of PCRS. HIV prevention programs need affected communities to be involved in and understand PCRS for the overall prevention efforts to be accepted and effective.

Federal and state legislative mandates in the 1990s have underscored the importance of notifying sex and needle-sharing partners of their possible exposure to HIV. Recent examples include the federal requirement to notify spouses of HIV-infected persons (Public Law 104-146, Section 8[a] of the Ryan White CARE Reauthorization Act of 1996) and state legislation to require health departments to offer HIV partner notification services to newly reported HIV-infected persons (National Council of State Legislators, 1998). Legal and ethical concepts such as the rights of individuals to know their risk of infection, to learn their HIV status anonymously or confidentially, and to be protected against discrimination if HIV-infected, will continue to drive public health policies and legislative action on HIV PCRS (West and Stark, 1997). Public health policies and legislative actions related to the above concepts will determine, at least in part, how PCRS is conducted.

1.2 *What Are the Goals of PCRS?*

PCRS is a prevention activity with the following goals:

1. Providing services to HIV-infected persons and their sex and needle-sharing partners so they can avoid infection or, if already infected, can prevent transmission to others.
2. Helping partners gain earlier access to individualized counseling, HIV testing,

medical evaluation, treatment, and other prevention services.

Through PCRS, persons – many of whom are unsuspecting of their risk – are informed of their exposure or possible exposure to HIV. Notified partners can choose whether to be tested, and if not tested or if found to be uninfected, can receive counseling about practicing safer behaviors to avoid future exposure to HIV. If, however, they are found to be infected, they can seek early medical treatment and practice behaviors that help prevent transmission of HIV to others and reduce the risk of becoming infected with other STDs.

PCRS can be instrumental in identifying sexual and drug-injecting networks at high risk for transmission of HIV or other sexually transmitted diseases (Fenton and Peterman, 1997; West and Stark, 1997). These networks are made up of individuals who share social relationships involving sex or drug use. Such networks can be identified and described at least partly through information obtained by PCRS activities (West and Stark, 1997). Future prevention interventions can then be more effectively directed, and the HIV risks within the network(s) potentially reduced. Network research, combined with new methods of virus typing and identification of recently infected persons (Janssen, *et al.*, 1998), will contribute to a greater understanding of HIV transmission (Fenton and Peterman, 1997).

1.3 Is PCRS Cost-effective?

Some have raised concerns about the high potential cost of PCRS and have questioned on these grounds whether or not it should be supported. In fact, although the relative investment per person reached might be greater than other public health activities, PCRS is likely to be highly cost-effective. A simple threshold analysis illustrates the probable cost-effectiveness of PCRS to society.

Assuming an estimated current \$154,402 lifetime cost in the United States of a person acquiring HIV infection and eventually dying from HIV-related illness (Holtgrave and Pinkerton, 1997) and a conservatively estimated average \$3,205 cost of PCRS to reach one infected person (Toomey *et al.*, 1998), PCRS must prevent 1 infection out of every 51 HIV-infected partners reached through PCRS to be cost-effective. As PCRS links HIV-infected partners to client-centered counseling and other interventions proven or likely to be effective, this appears to be a threshold relatively easy to achieve by programs. Greater effectiveness, such as preventing only 2–3 infections for every 51 HIV-infected partners reached through PCRS, would convey substantial cost savings to society.

1.4 Who Benefits from PCRS?

Clearly, three distinct beneficiaries of PCRS are (1) persons with HIV infection; (2) their spouses and other sex and/or needle-sharing partners; and (3) affected communities (Fenton and Peterman, 1997). Through a client-centered approach, HIV-infected persons can receive counseling about their risk behavior and be offered a range of choices and support in informing their partners of the possibilities of exposure to HIV (CDC, 1994). Studies have shown that a client-centered counseling approach can result in behavior change, thereby decreasing the likelihood of HIV transmission to others (Kamb *et al.*, 1998 and Fenton and Peterman, 1997). HIV-infected persons can also benefit from referrals to other social and medical services, such as couples counseling, prevention case management, and antiretroviral therapy.

For the partners of HIV-infected persons, one basic benefit comes from being informed that they are at risk. This will be particularly helpful information for those who do not even suspect that they might have been exposed. Once informed, the partner can decide to access available HIV prevention counseling

and testing services. If not infected with HIV, partners can be assisted in changing their risk behavior, thus reducing the likelihood of acquiring the virus. Or, if already HIV-infected, the partner's prognosis can be improved through earlier diagnosis and treatment.

The role of PCRS, earlier diagnosis, and prevention and treatment services might have prevention benefits at the community level in reducing future rates of HIV transmission.

Evidence is accumulating that antiretroviral therapy reduces the amount of HIV in genital secretions and fluids and thus might reduce the infectivity of HIV (Gupta P, *et al.*, 1997; Vernazza PL, *et al.*, 1997; Vernazza PL, *et al.*, 1997; Musicco M, *et al.*, 1994). However, concern may be well justified that some might misinterpret antiretroviral therapy as a cure for HIV and thus be less concerned about adopting safe behaviors or exposing others (Kalichman SC, *et al.*, 1998; Kelly JA, *et al.*, 1998; Remien RH, *et al.*, 1998; Remien RH, *et al.*, 1998). Efforts to link HIV-infected persons to treatment must also continue to emphasize safe behavior during the course of treatment. Effective PCRS also can improve disease surveillance, identify social sexual networks at high risk that can then be targeted for prevention (Fenton and Peterman, 1997), and potentially assist a comprehensive program in lowering the transmission rate of HIV. In addition, PCRS can benefit service providers in the community by increasing their access to individuals in need of their services, especially people who would not come to them on their own.

1.5 What Activities Are Involved in PCRS?

PCRS should be introduced at the point an individual seeks HIV prevention counseling and testing. A brief overview of the activities associated with PCRS is included in this section, but more detailed discussions are provided throughout the remainder of this document.

- ◆ **Person Seeks HIV Prevention Counseling and Testing.** PCRS begins when persons seek, either through private care providers or publicly funded programs, HIV prevention counseling and testing. As they enter services, they should be assisted first, ideally through client-centered counseling techniques, in –

1. assessing their risks of acquiring or transmitting HIV, and
2. negotiating a realistic and incremental plan for reducing risk.

During the initial counseling and testing session, the provider should also explain (1) how HIV testing will be conducted if the client does choose to be tested, and (2) all the available options for PCRS. The provider must assist clients in understanding their responsibility, if their HIV test results are positive, for ensuring that their partners are informed of their possible exposure, and referring those partners to HIV prevention counseling, testing, and other support services (CDC, 1994).

- ◆ **Client Tests Positive and Chooses To Participate in PCRS.** Once a client's test results are confirmed positive, that person should be provided the earliest appropriate opportunity to receive partner counseling and referral services. Reactions to learning one is infected with HIV vary, and personal circumstances differ among individuals. PCRS providers need to recognize and accommodate those clients who need other issues resolved before being ready to participate in PCRS. This might mean, for some individuals, scheduling a follow-up appointment to discuss PCRS issues more thoroughly.
- ◆ **PCRS Provider and Client Together Formulate a Plan and Set Priorities.** The PCRS provider (who might not be the counseling and testing provider) counsels the client on if, how, and when

specific partners should be informed of their risk of exposure. The provider should present partner referral options (Section 3.2). Then, the client and PCRS provider together can develop a plan for reaching partners that uses one or more of the referral options. The plan should be one that will result in each partner being (1) informed of possible exposure to HIV; (2) provided with accurate information about HIV transmission and prevention; (3) informed of benefits of knowing one's serostatus; (4) assisted in accessing counseling, testing, and other support services; and (5) cautioned about the possible negative consequences of revealing their own or others' serostatus to anyone else. As the individualized plan is developed, the PCRS provider and client prioritize which partners should be reached first (Section 3.0 provides a discussion of how priorities are set).

- ♦ **HIV-Infected Client Voluntarily Discloses Information About Partners.** The HIV-infected client is encouraged to voluntarily and confidentially disclose the identifying, locating, and exposure information for each sex or needle-sharing partner that the PCRS provider or the client will attempt to inform.
- ♦ **Client and/or Provider Informs Each Partner of Possible Exposure to HIV.** The client and/or the PCRS provider informs each sex or needle-sharing partner who can be located of his or her possible exposure to HIV. Ideally, the partner is always informed confidentially face-to-face, but this cannot necessarily be ensured when the client chooses to inform the partner without the provider's assistance.
- ♦ **Client and/or Provider Assists Partner in Accessing Counseling, Testing, and Other Support Services.** At the core of PCRS is referring the now-informed partner to counseling, testing, and needed

social and medical services. If on-the-spot counseling and/or testing for HIV and other STDs is not practical or not desired at this time, each partner should receive, immediately upon being informed of possible exposure to HIV, a specific referral for obtaining client-centered counseling and testing. Some partners will also need immediate referrals for medical evaluation, substance abuse treatment, mental health, or other support services to enhance or sustain risk-reducing behaviors.

How each PCRS activity is conducted might have a direct impact on how communities perceive the value of such efforts to themselves and to public health. Quality assurance for services provided, routine staff and program evaluations, and network analysis are, therefore, necessary components of PCRS. For example, ensuring that strict confidentiality is maintained for all persons involved in PCRS will encourage community support and involvement. (See Sections 4.3, 4.5, and 6.2)

2.0 AVAILABILITY OF PCRS

2.1 Making Services Available to All HIV-infected Persons

All CDC-funded HIV prevention counseling and testing sites, both confidential and anonymous, must make PCRS available to all HIV-infected persons.

People can learn that they are HIV-infected through a variety of sources, including confidential and anonymous testing sites, private care physicians, or home collection kits. However, regardless of where and how persons have been tested, PCRS must be made easily accessible to all HIV-infected persons.

For example, an HIV-infected person who has been tested by a private provider might seek services from a CDC-funded provider.

Although verified evidence of HIV infection should always be presented to the PCRS provider before partners are contacted, PCRS must be made available to the HIV-infected person.

The client who has just been informed of being HIV-infected will, of course, need to have PCRS offered at the earliest appropriate time, but the PCRS provider will encounter many others to whom services should be offered. For example, those persons could include a previously identified HIV-infected –

- ◆ client who in the past was not offered PCRS;
- ◆ sex or needle-sharing partner who the PCRS provider learns is continuing to have unprotected sex and who has partners other than the original HIV-infected client;
- ◆ client who now has new sex or needle-sharing partners;
- ◆ client who is now seeking additional STD or family planning services or substance abuse treatment; or
- ◆ client who in the past refused or only partially participated in PCRS but has now decided to participate fully.

Health department HIV prevention program staff should ensure that health care and prevention providers in the community and HIV-infected persons in the area are aware that PCRS is available at publicly funded sites and are aware of how to access those services. Furthermore, health departments can expand access to PCRS by developing agreements with private providers. These agreements could specify that the private providers will deliver PCRS to their HIV-infected clients. In such situations, these providers should be given

relevant information, training, and support to successfully deliver the services.

2.1.1 Services for Those Persons Tested Anonymously

CDC-funded programs must provide access to PCRS for persons testing anonymously without requiring that the infected client disclose his or her identity.

Opportunities to access PCRS must be provided to HIV-infected clients who have been tested anonymously and choose to remain anonymous. Program experience has indicated that PCRS can be conducted in an anonymous setting (Hoffman, *et al.*, 1995). CDC requires that, unless prohibited by state law or regulation, grantees must provide reasonable opportunities for anonymous testing. Clients who test HIV-positive in anonymous settings must be counseled on how to enter a confidential system and be strongly encouraged to do so. This will assist them in receiving medical care and other services, including PCRS.

Recent reports show that persons who enter anonymous HIV testing programs do so earlier in their HIV infection and are more likely to begin medical care while still comparatively well (Bindman *et al.*, 1998; Nakashima *et al.*, 1998). CDC currently recommends that persons initially testing positive for HIV in an anonymous setting be counseled and informed about how to enter a confidential medical care system.

2.1.2 Inability To Pay

CDC-funded PCRS programs must provide access to PCRS regardless of clients' or partners' ability to pay (CDC, 1993).

2.2 Accommodating Requests from Other Health Jurisdictions

Requests for PCRS from other health jurisdictions must be accommodated whenever practical.

PCRS providers might sometimes be asked to contact the partner of an HIV-infected person residing in another health jurisdiction. Such contacts with other jurisdictions is the role of the state

health department. For example, a PCRS provider might request that the staff in a neighboring state health department assist in locating and informing a previous partner or former spouse of an HIV-infected client. A **reasonable** effort must be made to accommodate that request if it complies with state and local regulations and policies, and confidentiality is maintained.

3.0 DECIDING ON A PCRS PLAN AND SETTING PRIORITIES

3.1 Encouraging Client Participation

3.1.1 Fully Informing and Reassuring Clients

PCRS providers must ensure that clients are aware that all information disclosed by them will be kept strictly confidential and that participation is always voluntary.

The PCRS provider should explain the purpose and process of PCRS before PCRS activities can begin. The HIV-infected person serves as the “gate-keeper” to his or her partners. Program experience indicates that once a person understands the benefits both to themselves and their partners, they willingly participate in PCRS. Therefore,

ensuring that the HIV-infected person fully understands the PCRS process and its benefits is important.

Providers should create an environment that is private, confidential, and comfortable enough so that clients are encouraged to participate in PCRS without feeling fearful or coerced. Reminders of the voluntary nature of PCRS and explanations of how privacy will be maintained for clients and partners alike will be necessary before some individuals feel secure enough to participate.

Each interaction a counseling and testing or health care provider has with an HIV-infected client is a potential opportunity to discuss the importance of informing that person’s sex or needle-sharing partners of their possible exposure to HIV. Prevention counseling, prevention case management, and medical follow-up sessions while clients are in treatment, all provide opportunities to stress the importance of getting partners involved in PCRS. Community-level interventions provide other opportunities to reach out to partners.

3.1.2 Developing an Atmosphere of Trust

To foster an atmosphere of trust, PCRS providers must treat all HIV-infected clients and their partners with respect.

The success of the PCRS process hinges on the trust and cooperation of the persons infected with HIV and their partners. How well the provider fosters an atmosphere of trust, respect, and rapport with the HIV-infected individual will have a significant impact on PCRS. Client-centered counseling techniques (CDC, 1994) are highly recommended for developing this relationship, not only with original clients but also with their partners. The ability to develop trust and rapport will also enhance the PCRS provider’s effectiveness when working in the community.

3.1.3 Introducing PCRS

Persons entering CDC-funded HIV prevention counseling and testing programs must be counseled at the earliest opportunity about PCRS and options for informing sex and needle-sharing partners of possible exposure to HIV.

During the first visit, the health care provider, using a client-centered approach (CDC, 1994), should begin discussions with the client on the risks to his or her partners. This visit

would typically be for HIV counseling and testing. When clients choose to be tested and the results are positive, then the provider must offer, at the earliest appropriate opportunity, to assist in formulating an individualized PCRS plan. That plan is always based on the personal circumstances of the HIV-infected client and each of his or her partners.

When the provider demonstrates genuine concern for the overall well-being of clients and their partners during discussions about PCRS, the provider encourages greater client participation. Clients' reactions vary significantly to learning that their HIV test results are positive; therefore, the provider must gauge the appropriate point at which to initiate the discussion about the PCRS plan. In fact, other critical issues might need to be resolved first. For example, the client might express suicidal ideation or a fear of a violent reaction from a partner. Because potentially violent situations might be encountered, collaboration between the PCRS program and the appropriate state or local violence prevention programs is important. Such collaboration will help in developing plans and protocols for such situations and provide opportunities for the PCRS provider to learn about relevant services.

3.2 Formulating a PCRS Plan

The PCRS provider must explain to the HIV-infected client the options for serving partners and then assist that client in deciding on the best plan for reaching each partner confidentially and referring him or her to counseling, testing, and other support services.

HIV prevention programs use two basic approaches for reaching partners (West and Stark, 1997). In this document, the term *client referral* is used when HIV-infected individuals choose

to inform their partners themselves and refer those partners to counseling and testing (see Section 3.2.1). (NOTE: The terms *patient referral* and *self-referral* are sometimes used instead of *client referral*.) The term *provider referral* is used in this document when the PCRS provider, with the consent of the HIV-infected client, takes the responsibility for contacting the partners and referring them to counseling, testing, and other support services (see Section 3.2.2).

Sometimes a combination of the two approaches is used. With the *dual-referral* approach, the HIV-infected client informs the partner of his/her serostatus in the presence of the PCRS provider. By having a professional counselor present, this approach supports the client and reduces other potential risks. In such situations the PCRS provider must not reveal the client's serostatus to the partners without prior informed consent. With the *contract-referral* approach, the PCRS provider does the informing only if the client does not notify the partner within a negotiated time period (see Section 3.2.3).

The PCRS provider should explain to clients all available options for reaching their partners, including the advantages and disadvantages of each approach. Then, together they

can formulate a plan that can result in each partner being confidentially informed and encouraged to access counseling and testing or other social or medical services. Some HIV-infected individuals will be reluctant to participate in PCRS. Client-centered counseling techniques and reassurances of confidentiality can encourage better participation. Resolving problems through role-playing, for example, might help clients overcome barriers to participating in PCRS and help them better prepare for their part in those activities. No matter which approach is chosen, the PCRS provider should ensure the partners are actually informed of the exposure.

3.2.1 Taking a Closer Look at Client Referral

When HIV-infected clients choose to inform their partners themselves, they usually need some assistance to succeed. Although the majority of clients do not experience negative consequences when notifying partners, the PCRS provider can help the client minimize any potentially negative consequences. The provider should, therefore, be prepared to assess the situation and ability of the HIV-infected client to make successful notification and referrals. Based on this information, clients might need to be coached on:

1. the best ways to inform each partner;
2. how to deal with the psychological and social impact of disclosing one's HIV status to others;
3. how to respond to a partner's reactions, including the possibility of personal violence directed toward the client or others; and
4. how and where each partner can access HIV prevention counseling and testing.

Despite the provider's coaching, however, the client's lack of counseling skills and experience might result in unsuccessful or ineffective PCRS. Another disadvantage of the client-referral approach is that the client might

unintentionally convey incorrect information about HIV transmission, available support services, confidentiality protections, or other issues. The client also forfeits anonymity to partners, increasing the potential for disclosure of serostatus to third parties, subsequent discrimination, or partner repercussion. The findings of Landis *et al.* (1992) clearly indicate that fewer partners are actually informed of their possible exposure to HIV when the client-referral approach is used. However, because PCRS is a voluntary process, clients should be able to choose this approach. The PCRS program needs reasonable systems for monitoring whether partners are actually reached (see "Contract Referral" in Section 3.2.3). Also, more support to the client in notifying their partners will enhance the effectiveness of notifying partners.

For anonymous test sites, the client-referral approach poses a slightly different problem because some clients might be less likely to give the provider information about partners. Under these circumstances the provider will be less likely to determine whether PCRS has been successful. Although PCRS can be provided to anonymous clients, CDC currently recommends providers encourage the client to voluntarily enter a confidential setting for PCRS and additional medical follow-up. Here again, an appropriately detailed discussion with anonymous clients of how confidentiality will be maintained for themselves and their partners can ease the transition of anonymous clients to a confidential setting. That transition will also be eased if clients are not required to take another HIV test. If the anonymous and confidential test sites are at separate facilities, reciprocal agreements between the two might be necessary so that the client's confirmed positive test result can easily be transferred to the confidential setting.

At confidential test sites, PCRS providers should make every reasonable effort to follow up with each HIV-infected client to assess how

well he or she has progressed with PCRS. Whenever feasible, careful and confidential monitoring of which of the client's partners actually do access counseling and testing services can greatly enhance quality assurance and program evaluation. This also will help ensure that partners have actually been reached.

Despite its drawbacks, client referral is the approach frequently chosen, and it can have some advantages. Because the client is usually more familiar with the identity and location of the partner, this approach can allow some partners to be referred for counseling and testing more promptly. Also, some clients choose this approach because they feel the best way to preserve a current relationship is by informing the partner themselves rather than having a third party – the provider – do it. Finally, when client referral is conducted successfully, fewer staff are used and fewer resources are consumed than with the provider-referral approach, so the financial burden for HIV prevention programs is reduced.

3.2.2 Taking a Closer Look at Provider Referral

When the client chooses provider referral, the provider will also need to assess the situation regarding each partner, including the best ways to inform them, how to locate and contact them, suggestions on how to approach them, how to predict the psychosocial impact of their learning their HIV serostatus, and how to respond to partners' reactions. Research indicates that provider referral is more effective in serving partners than client referral (Landis *et al.*, 1992). The following are some of the advantages of using the provider-referral approach:

1. The PCRS provider is able to readily verify that partners have been confidentially informed and have received client-centered counseling and testing services.
2. The PCRS provider can better ensure the HIV-infected client's anonymity since no information about the client is disclosed to his or her partners.
3. A well-trained PCRS provider is better able to defuse the partner's potential anger and blame reactions as well as accurately and more comprehensively respond to the partner's questions and concerns.
4. Provider referral better facilitates learning about sexual and drug-injection networks, thus potentially enhancing overall HIV prevention efforts in affected communities.
5. In many cases, the PCRS provider can deliver on-site HIV testing to the partner.

Among the disadvantages of the provider-referral approach is the fact that PCRS providers are not always able to readily locate and identify the partners. Because the provider is less familiar with how to reach the partners, actually locating them to discuss their possible exposure to HIV can be more difficult. The provider-referral approach also entails substantial financial costs and causes some ethical concerns among leaders of affected communities (Fenton and Peterman, 1997; West and Stark, 1997). For example, Fenton and Peterman (1997) found that financial costs for provider referral are between \$33 and \$373 per partner notified and between \$810 and \$3,205 per infected partner notified. This program expense, however, is greatly offset in the long run because PCRS frequently reaches persons who do not suspect they have been exposed to HIV and is likely cost-effective (see Section 1.3). Once informed, they can access prevention counseling and testing, and if HIV-infected, they can enter treatment earlier. It is important to note that some infected people who choose provider referral might still notify some partners about their serostatus and will thus need relevant counseling.

3.2.3 Taking a Closer Look at Combined Referral Approaches

Two variations on provider and client referral are the dual- and contract-referral approaches. Potentially, combinations of these approaches can enhance the advantages of both approaches for the client while reducing the disadvantages.

Dual Referral. Some HIV-infected clients feel that they and their partners would be best served by having both the client and the provider present when the partner is informed. The dual-referral approach can work well for these clients. The dual approach allows the client to receive direct support in the notification process. The PCRS provider is available to render immediate counseling, answer questions, address concerns, provide referrals to other services, and in some cases potentially minimize partner repercussions. Being present also enables the provider to know which partners have in fact been served, and to some extent, learn about sexual and drug-injecting networks. Whether the client or provider will take the lead in informing the partner should be worked out in advance of the notification.

The provider still needs to coach and support the client as with the client-referral approach. The provider and the HIV-infected client need to consider, in particular, the partner's possible concerns about having his or her relationship with the client revealed to the provider. By considering this issue in advance, the client and the provider can anticipate the partner's possible reactions and discuss how to respond appropriately.

Contract Referral. The other variation on provider and client referral, the contract-referral approach, might require more negotiation skill on the PCRS provider's part. In the contract-referral approach, the provider and client decide on a time frame during which the client will contact and refer the partners. If the client is unable to complete the task within

that agreed-upon time period, the PCRS provider then has the permission and information necessary to serve the partner. The provider must also have agreement with the client about how to confirm that partners were notified and what follow-up is required for situations where the client does not make the notification. Negotiation skill and a relationship of trust are needed so that the provider will have the identifying and locating information immediately available if the client does not inform the partner before the time limit expires.

When the contract-referral approach is used, the PCRS provider should also negotiate a provision with the client whereby the partner confirms in some way (e.g., telephone call, appointment for services) to the provider that he or she has been informed of being at risk. Otherwise, the provider may have difficulty knowing which partners have been informed and whether or not provider referral or some other assistance is now needed.

3.3 Setting Priorities for Reaching Partners

The PCRS provider and HIV-infected client must prioritize reaching partners based on who is most likely to transmit infection to others and who is most likely to become infected.

The PCRS plan must include prioritizing which sex or needle-sharing partners need to be reached first, based on each client's and partner's circumstances. Ideally, all partners should be reached, but limited program resources usually dictate that priorities have to be set. Priorities are determined by deciding (1) which partners are most likely to be already infected and to transmit infection to others; (2) which partners are most likely to become infected; and (3) which partners can be located. Priority is also affected by federal and state laws. For example, **federal legislation requires that a**

good-faith effort be made to notify “any individual who is the marriage partner of an HIV-infected patient, or who has been the marriage partner of that patient at any time within the 10-year period prior to the diagnosis of HIV infection.” (Public Law 104-146, Section 8[a] of the Ryan White CARE Reauthorization Act of 1996.)

A number of factors influence how the PCRS provider and client decide which partners need to be reached first. Obviously, if the client has had only one partner during his or her lifetime, that partner is likely to be infected. When the client has had more than one partner, other factors then have to be considered, such as the following:

- ◆ **Possible Transmission of HIV to Others.** The partner who is most likely to transmit HIV to others must receive highest priority. A partner who is a pregnant woman should be reached as soon as possible for counseling, testing, and referral to medical treatment if infected, to avoid perinatal transmission. Likewise, the partner who the client knows has multiple other sex and needle-sharing partners needs to be reached as soon as possible to reduce the potential for transmission of HIV to others.
- ◆ **Partners of a Recently Infected Client.** If, for example, the client had a negative HIV test result 6 months ago, but now the test result is positive, partners within that 6-month time period or in the potential “window period” that preceded the negative test would receive priority. These partners are more likely to have acquired or been exposed to HIV than any of the client’s partners during the period before the client’s HIV negative test. Other evidence of a recently infected person might be indicated by the exposure history of the client, e.g., client with a history of negative test results, findings from less sensitive EIA or serologic

testing algorithm for recent HIV seroconversion, or other evidence of recent infection.

- ◆ **Likelihood of the Partner Being Unaware of Exposure to HIV.** Some individuals are less likely than others to suspect a risk for HIV infection or to understand what being “at risk” means. For example, many heterosexual women might be less aware of their HIV risk and therefore less likely to access counseling, testing, or other prevention services without PCRS.
- ◆ **Partners at Continued Risk.** Reaching the client’s current, recurring, or recent partners is a high priority because those partners might be at continued risk of becoming infected with HIV, if not already infected.
- ◆ **History of Other STDs.** Either the client’s or partner’s history of other STD infections is an important factor in setting priorities. For example, if a partner was treated for another STD, that partner is more likely to also be infected with HIV and, additionally, more likely to transmit HIV to others. If the HIV-infected client has a recent history of other STD infection, then his or her sex partners are more likely to have been HIV-infected, especially those exposed during the STD infection (Wasserheit, 1992).
- ◆ **Transmission of Strains of HIV That Are Resistant to Antiretroviral Therapies.** If information or evidence exists that the client is infected with a strain of HIV resistant to antiretroviral therapies, partners of this client would have high priority for PCRS services.

The PCRS provider and client should begin by noting current or recent partners and the details of their exposure. Next, working back in time, they should consider any other partners who need to be contacted. By briefly

noting the circumstances for each partner and then moving quickly on to the next one, the provider will be better able to stimulate the client's memory. Then, together, they can determine the priorities for reaching as many partners as program resources might permit. Because determining when a client was actually infected or the circumstances associated with individual partners is often difficult or impossible, some HIV prevention programs routinely attempt to locate and counsel all partners from a defined time period. This time period, often 1-2 years, frequently is based on availability of resources for PCRS. Programs with greater amounts of resources, those with lower morbidity, or those that give higher priority to PCRS frequently attempt to reach and counsel partners exposed over a longer time period.

Once the provider and client have established which partners are to be reached, they can begin discussing a plan for reaching these partners. For those partners the provider will be contacting, exact locating information, plus the dates, types, and frequency of exposure should be noted (See Section 4.2). During this phase, new information about partners might come to light that necessitates adjustments in the priorities previously established.

In addition to the factors listed previously, the PCRS provider must also consider federal legislation and relevant state laws that require a *good-faith effort* be made in notifying current spouses or persons who have been spouses of a known HIV-infected person during the 10 years prior to the client's diagnosis of HIV infection. Both the program policies of PCRS and the efforts of individual providers contribute to the required good-faith effort.

PCRS providers can satisfy the requirement of a good-faith effort by (1) asking all HIV-infected clients if they have a current or past marriage partner(s), (2) notifying these part-

ners of their possible exposure to HIV, except in situations when, in the judgment of public health officials, there has been no sexual exposure of a spouse to the known HIV-infected individual during the relevant time frame; (3) referring them to appropriate prevention services; and (4) documenting these efforts. Programs need to have or develop policies to guide providers in situations in which the HIV-infected client does not give consent and will not allow the provider to notify his or her current or past marriage partner(s).

3.4 Considering Other Options and Special Circumstances

3.4.1 Other Persons Who Might Need To Be Contacted

While the PCRS plan is being developed and priorities are being set for reaching partners, the provider should take special note of any other persons being mentioned who might be at risk. For example, during interviews or counseling sessions, the HIV-infected client might discuss other persons who are not sex partners but are involved in a sexual or drug-injection network with high risks of HIV transmission. Another example is children or newborns who might have been exposed perinatally or through breast-feeding. Although not direct sex or needle-sharing partners of the HIV-infected client, these other persons should be offered HIV prevention counseling and testing, if resources and program policies permit. General information obtained through PCRS, not just a person's name, can be used to identify high-risk places and venues where PCRS programs can provide outreach services. CDC encourages such efforts to identify and lower risks of HIV and other STDs within sexual or drug-injection networks and is interested in working with state and local health authorities to develop methods and more detailed guidance on network identification, analysis, and intervention.

3.4.2 “But, I Do Not Want My Partner To Be Contacted!”

CDC-funded PCRS providers must review with the HIV-infected client in appropriate detail the legal and ethical reasons for informing sex and needle-sharing partners of their possible exposure to HIV.

Unfortunately, in some cases HIV-infected clients initially will simply not want their partners notified. For example, they might fear loss of anonymity, the breakup of a relationship, or other adverse consequences. Clients might say that partners have already been informed about

their risks or that partners would not be interested in counseling, testing, or other support services. Providers can encourage a client’s participation by explaining that the partner benefits by knowing his or her HIV status and being able to seek immediate treatment if infected. Also, if infected, the partner can avoid transmitting the virus to others. However, when a client is determined not to disclose partner names, the PCRS provider should counsel the client as if he or she has chosen the client-referral approach.

Sometimes a client might not want his or her partner notified because of fear of a violent reaction from the partner. It is not uncommon for persons receiving public health services to report having experienced violence in their lives (Maher, 1998). Therefore, providers should be aware of the potential for partner violence and should be prepared to make appropriate referrals. If the provider has indication of a potentially violent situation for the client or others, the provider must make an assessment prior to notifying the partner and seek expert consultation before proceeding. States have varying legal requirements about reporting situations such as those involving violence or child abuse. The PCRS program must comply with relevant state laws and local regulations.

In some cases, the provider knows of a partner at risk even though the client has not identified that partner. Whether or not a legal “duty to warn” such partners (or identified partners that the client did not want notified [see Appendix B]) exists is best determined by reviewing applicable state laws or regulations, especially regarding spousal notification. All states must have a policy established to guide health department staff in situations in which an HIV-infected client indicates he or she does not plan to notify known partners and will not provide the information necessary for the health department staff to make the notification.

The Association of State and Territorial Health Officials recommends in its 1988 *Guide to Public Health Practice: HIV Partner Notification Strategies* that a health care provider may invoke his or her “privilege to disclose” (see Appendix B) when that provider knows of an identifiable at-risk partner who has not been named by the HIV-infected person. State and local HIV prevention program managers should consider the ASTHO recommendations and their own relevant laws when developing policies and procedures.

3.4.3 PCRS for Needle-sharing Partners

Sharing of needles, syringes, and other paraphernalia used for injection drug use (e.g., illicit drugs, steroids) carries high risk for transmission of HIV. Throughout this document, the importance of providing partner counseling and referral services to HIV-infected clients with needle-sharing partners is emphasized. CDC recognizes that some HIV prevention programs have relatively limited experience in working with needle-sharing partners and that special issues exist relating to clients disclosing information about such partners, reaching such partners, deciding which prevention interventions should be provided, and referring them for needed services.

Some state and local HIV prevention programs have already gained considerable experience in reaching and serving needle-sharing partners and report that such services are feasible and likely to be effective. For example, Levy and Fox (1998) reported that injection drug users infected with HIV want to notify their sex and needle-sharing partners and are willing to participate in the PCRS process. Information provided by HIV-infected clients who are injection drug users may help HIV prevention program managers gain insight into the extent and types of prevention service needs of injection drug users and how best to deliver and target such services.

CDC will provide expanded guidance on PCRS for needle-sharing partners in future versions of this guidance.

4.0 LOCATING AND NOTIFYING PARTNERS

4.1 Preparing the PCRS Provider

Program managers and supervisors must ensure that each PCRS provider has the appropriate training and skills to effectively serve HIV-infected clients and their partners.

In large part, the manner in which PCRS is provided to and perceived by the affected communities determines how successful HIV

prevention programs will be (see Section 4.5). Therefore, program managers and supervisors should ensure that PCRS staff –

- ◆ are skilled and competent in providing PCRS;
- ◆ are culturally competent and demonstrate respect for the community to be served;
- ◆ are knowledgeable about HIV infection, transmission, and treatment;

- ◆ are knowledgeable in local, state, and federal laws regarding HIV and other relevant issues of providing health care, especially the right to privacy and confidentiality;
- ◆ receive updated information and periodic retraining as appropriate;
- ◆ have standards, objectives, and specific guidelines for performance;
- ◆ are appropriately supervised and given written and oral feedback about their performance on a regular basis; and
- ◆ have appropriate problem-solving skills to deal with situations that might be encountered in a field setting, e.g., personal safety, violence to others.

In addition to receiving formal training, such as CDC’s training course on PCRS, an inexperienced PCRS provider should complete an internship by being teamed with a more experienced provider for a period of time before conducting PCRS alone (see Section 6.1). Another way to enhance a provider’s performance is through routine peer review of selected cases.

Providers of successful PCRS programs regularly go outside the clinic or office setting to reach partners. The inexperienced provider will need training in deciding when to deliver PCRS outside the office or clinic and when to postpone PCRS. Benefits of delivering PCRS in a partner’s home might include providing the partner with a familiar environment and helping the provider better understand the personal circumstances of that partner.

Whether or not to do PCRS outside the clinic or office, or whether it is best postponed until an adverse situation can be resolved, must be decided on a case-by-case basis. In addition, training in avoiding confrontations, diffusing anger, and mediating disputes will better prepare any provider for handling potentially violent situations.

4.2 Setting Activities in Motion

Locating and notifying activities must begin promptly once the PCRS plan has been formulated and the priorities set for reaching partners.

For those partners the provider will be contacting, the first step the provider should take is to verify the identifying and locating information

given by the HIV-infected client. Locating and notifying partners should begin as soon as possible after the provider and HIV-infected client have decided on the best approach to use for each partner and priorities have been set for reaching partners. If the client will be informing partners, the client should be well-coached on how to do so and should be provided opportunities to obtain additional counseling, assistance, or other support during the process.

4.3 Maintaining Confidentiality

While conducting PCRS activities in the community, providers must continue to maintain confidentiality for all HIV-infected clients and their partners.

Confidentiality for all persons involved in PCRS must continue to be maintained. All attempts to make contact with a sex or needle-sharing partner should be confidential. This is often difficult because other community

members might ask the purpose of the provider's visit and why he or she is attempting to make contact. Nevertheless, providers should not, for example, reveal to others why they are trying to find a particular person. Likewise, providers should never leave a note or message that mentions HIV exposure as the reason for attempting to make contact. In addition, no other information should be revealed that might lead to others learning the reason for the contact or that might otherwise

lead to disclosure of sensitive information or to a breach of confidentiality. As each partner is located, he or she should be informed privately and face-to-face, if at all possible. However, if the person refuses to meet with the provider, informing a partner by telephone might become necessary. In such situations, only limited information should be provided to the partner, and the goal still should be to arrange a face-to-face meeting if at all possible. Informing a partner by telephone should only be done as determined by state and local jurisdictions and after every step has been taken to ensure that the correct person has been located, is on the telephone, and others are not listening. Further attempts should be made to arrange a meeting in person.

The original HIV-infected client will sometimes inquire about the results of the PCRS provider's activities regarding his or her partners. The provider, when requested, can reveal whether a particular partner has been informed of his or her exposure to HIV, but must not reveal any confidential information about that partner, including whether the partner decided to be tested or whether he or she is HIV-infected.

Of equal importance is not revealing any identifying information about the original client to the partner, including the person's sex, name or physical description, or time, type, or frequency of exposure. Although the PCRS provider will need to document the results of his or her activities in a thorough, concise, and timely manner, confidentiality must still be maintained for all persons involved. Information that identifies partners should be kept locked in a secure location. Client and partner information, other than the official record (as determined by state practice), should be destroyed when current PCRS activities are concluded.

State or local areas should establish PCRS record-keeping policies and procedures, and

client and partner information should be maintained in accordance with these policies. Many public health programs have developed policies and procedures to safeguard sensitive client or partner information. One example can be found in CDC's *Guidelines for HIV/AIDS Surveillance*, Appendix C, Security and Confidentiality (as revised October 1998). In developing their policies, PCRS managers can choose to review and adapt the policies and procedures in this document or those of other public health programs.

4.4 *Helping Partners Access Services*

As each partner is informed of possible exposure to HIV, the PCRS provider must be prepared to assist that person with immediate counseling and referrals for more intensive counseling as well as testing and other support services.

The PCRS provider must be well prepared to handle the initial reactions of the person who is being informed of possible exposure to HIV. That person will undoubtedly need immediate counseling, followed by referral to additional HIV prevention counseling. The provider must be prepared

to answer the questions and concerns of each partner without revealing any identifying information about the original HIV-infected client.

As described earlier, referring partners to needed prevention, treatment, and other relevant services is a goal of PCRS. Testing is a very important issue to persons who have just learned of possible exposure. The provider must be prepared to, at a minimum, refer them to counseling and testing services. For many years, providers have taken blood specimens of those who consent at the time of notification, which requires specialized training. With the

current availability of oral fluid and urine collection kits, and rapid testing systems, program managers are encouraged to consider providing on-the-spot collection of specimens for HIV testing as each partner is informed. If the partner has previously been tested, and those results were negative, the PCRS provider should stress the need to follow up with another test if exposure history indicates it is warranted.

However, many partners will need referrals for other kinds of social and medical support services beyond counseling and testing. The PCRS provider should already have agreements in place and an up-to-date resource guide so that immediate referrals can be made to services such as substance abuse treatment, family planning assistance, other STD treatment, domestic violence prevention, mental health counseling, or housing assistance (CDC, 1993). Having agreements in place for collaboration between PCRS providers and referral sources will help ensure that those services can be successfully accessed. PCRS providers should then follow up with each partner contacted to ensure that test results and other referral services have in fact been received. If providers in another health jurisdiction have been asked to contact a partner, health departments should follow up with that provider to determine that services have been received.

4.5 *Addressing Community Concerns*

The potential exists for PCRS to have a negative impact on HIV-infected individuals, their partners, or affected communities (Rothenberg and Paskey, 1995; West and Stark, 1997). Some community leaders view these kinds of activities with suspicion and are apprehensive about such issues as –

- ♦ whether disclosure of partner names is done voluntarily;
- ♦ possible denial of health care or other services if the HIV-infected client refuses

to reveal partner names or otherwise refuses to cooperate with the provider;

- ◆ unintended effects on personal relationships, such as partnership breakup or violence;
- ◆ potential for invasion of privacy or loss of confidentiality for HIV-infected clients and their partners; and
- ◆ possible discrimination if confidential information held by government agencies is ever released, either accidentally or by law.

Although PCRS providers cannot always resolve these issues, they can strive to build relationships of trust between themselves and those they serve, including the leaders of affected communities. Working with HIV prevention community planning groups and others when determining and evaluating priorities, policies, and procedures for PCRS will help increase community support and acceptance. PCRS providers should be prepared, whenever an opportunity arises, to address legitimate concerns and dispel misconceptions about policies and practices (West and Stark, 1997).

5.0 COLLECTING, ANALYZING, AND USING PCRS DATA

5.1 Why Collect Program Data?

PCRS data must be collected and used (1) to assess the behavioral risks for sex and needle-sharing partners of HIV-infected persons; (2) to evaluate the effectiveness of the PCRS program as part of the overall HIV prevention effort; and (3) to improve how other HIV prevention activities, interventions, and services are implemented.

Accurate and consistent data collection is a critical component for evaluating how effective the PCRS program is, as well as how well it enhances the overall HIV prevention inter-

vention (CDC, 1994). Moreover, PCRS data enable providers to better focus prevention efforts on those persons most at risk. When the data reveal information about networks of people who are having sex or injecting drugs, the dynamics of HIV transmission can be better analyzed (Fenton and Peterman, 1997), and more intensive prevention and education efforts can be applied for specific high-risk groups (West and Stark, 1997). To do all this, however, the collected data must be relevant to behavioral risks, HIV/AIDS prevalence, and the demographics of affected communities. With accurate and consistent data, the staff of health departments and community-based organizations and members of HIV prevention community planning groups can establish an effective mix of prevention strategies.

5.2 What Data Should Be Collected?

CDC-funded PCRS providers must collect data that help answer key questions about how well the PCRS program is functioning, the extent and quality of services being provided, the degree to which clients and their partners accept and are satisfied with services, and how PCRS and other prevention services can be enhanced.

CDC-funded PCRS providers must use standardized data collection tools throughout the program that maintain the privacy or confidentiality of the original HIV-infected client and his or her partners.

Any data collection tool used in a PCRS program should be designed so that certain core information can be ascertained, including answers to the following:

- ◆ What proportion of HIV-infected clients is offered PCRS?

- ♦ What are the reasons those clients either reject or accept PCRS?
- ♦ What is the range of PCRS services (e.g., client referral, provider referral, combinations of referral approaches) offered to and accepted by each client?
- ♦ How many sex or needle-sharing partners are identified?
- ♦ What is the percentage of partners actually reached through PCRS, and how many of those partners are HIV-infected? Of those partners who are HIV-infected, how many are being informed of their infection for the first time?
- ♦ What are the demographics (e.g., marital status, age, sex, race/ethnicity) of the clients and partners actually served?
- ♦ How many partners are offered referral services? How many receive these services? In what time frame do they receive referral services?

And, perhaps most importantly, PCRS program managers should routinely assess what all of this information means in regard to how well PCRS is working for HIV-infected clients, their partners, and the community at large. Are clients served well? Are partners gaining access to services that might not be otherwise available? Are communities becoming more supportive of public health efforts? Does evidence exist that risks are being reduced? Are other prevention program services better targeted to communities in need?

The HIV prevention program managers in each health jurisdiction should decide how best to collect, analyze, and use PCRS data. This should be done in a manner that is consistent with the policies and procedures that they have developed to safeguard the security of the data and the confidentiality of the client or partner (see Section 4.3). Those managers should keep in mind that misconceptions about the collection and use of HIV data, in addition to a general mistrust of publicly

funded agencies, are two of the biggest barriers to HIV prevention efforts in affected communities. CDC plans to work with state and local HIV prevention and STD prevention and treatment programs to develop proposals for standardizing the collection and analysis of PCRS data.

6.0 ENSURING THE QUALITY OF PCRS

PCRS providers must be well trained to provide effective PCRS services.

6.1 Training

Of all the resources necessary for the successful operation of PCRS programs, training is perhaps the most critical (Fenton and Peterman, 1997). Each individual PCRS provider must receive initial basic training plus periodic updates on how to conduct PCRS (including its scientific rationale), provide client-centered counseling, protect individuals' rights to privacy, use scientific information in prioritizing partners, administer HIV tests when appropriate, and defuse potentially violent situations involving clients, partners or staff (see Section 4.1). PCRS providers also need to understand laws regarding confidentiality of medical records.

6.2 Quality Assurance and Evaluation

CDC-funded PCRS programs must have a quality assurance plan.

Quality assurance for PCRS programs entails ensuring that appropriate and standardized methods are used for –

CDC-funded PCRS programs must evaluate their services.

1. counseling HIV-infected clients regarding the notification of their partners;
2. developing a PCRS plan with HIV-infected clients;

3. prioritizing which partners are to be reached;
4. locating and informing those partners of their possible exposure to HIV;
5. providing immediate counseling and testing services to informed partners and/or referring them to other service providers; and
6. collecting, analyzing, using, and storing PCRS data.

Written job descriptions, including minimum performance criteria, and comprehensive procedures for delivering quality PCRS should be developed and copies made available to all personnel. Also, supervisors should directly observe a new PCRS provider until confident that the provider is proficient in serving clients and their partners. Then, through periodic supervisor observation, peer review of selected cases, and “customer” satisfaction surveys, each PCRS provider should be given constructive oral and written feedback.

PCRS programs should include policies relevant to situations in which an HIV-infected

person knowingly exposes others to HIV. These policies must comply with relevant state or local laws.

The overall program should also be regularly evaluated to determine the quality of effort and the success in reaching the PCRS goals (Fenton and Peterman, 1997) (see Section 1.2). Program evaluations should include a comprehensive assessment of all confidentiality procedures that includes, at a minimum, record-keeping.

6.3 How Can CDC Help?

Many types of technical assistance are available for designing, managing, or evaluating PCRS through CDC’s project officers, program consultants, and network of HIV prevention partners. In addition, training is provided through CDC and its contractors that is designed to enhance PCRS providers’ skills regardless of their level of experience. Finally, information on the latest scientific findings about HIV is available through the CDC National Prevention Information Network (toll-free, 800-458-5231).

REFERENCES

- Association of State and Territorial Health Officials (ASTHO). *Guide to Public Health Practice: HIV Partner Notification Strategies*. Public Health Foundation: Washington, D.C., 1988.
- Bindman, Andrew B., *et al.* "Multistate Evaluation of Anonymous HIV Testing and Access to Medical Care." *Journal of the American Medical Association*, Vol. 80, No. 16, October 28, 1998, pp. 1416-1420.
- Centers for Disease Control and Prevention. *Guidelines for HIV/AIDS Surveillance*, Appendix C, Security and Confidentiality, Atlanta, Georgia, revised October 1998.
- Centers for Disease Control and Prevention. *HIV Counseling, Testing, and Referral: Standards and Guidelines*, Atlanta, Georgia, May 1994.
- Centers for Disease Control and Prevention. "Technical Guidance on HIV Counseling." *Morbidity and Mortality Weekly Report; Recommendations and Reports*, Vol. 42, No. RR-2, January 15, 1993, pp. 8-17.
- Centers for Disease Control and Prevention. *HIV Prevention Case Management: Guidance*. Atlanta, Georgia, September 1997.
- Fenton, Kevin A., and Peterman, Thomas A. "HIV Partner Notification: Taking a New Look." *AIDS*, Vol. 11, No. 13, November 1, 1997, pp. 1535-1546.
- Gostin, Lawrence O., and Hodge, Jr., James A. "Piercing the Veil of Secrecy in HIV/AIDS and Other Sexually Transmitted Diseases: Theories of Privacy and Disclosure in Partner Notification." *Duke Journal of Gender Law and Policy*, Vol. 5, No. 1, Spring 1998, pp. 9-88.
- Gupta, P., *et al.* "High Viral Load in Semen of Human Immunodeficiency Virus Type 1 – Infected Men at All Stages of Disease and Its Reduction by Therapy with Protease and Nonnucleoside Reverse Transcriptase Inhibitors." *Journal of Virology* 1997, Vol. 71, pp. 6271-6275.
- Hoffman, R.E., *et al.* "Comparison of Partner Notification at Anonymous and Confidential HIV Test Sites in Colorado." *Journal of Acquired Immune Deficiency Syndromes and Retrovirology* 1995, Vol. 8, No. 4, pp. 406-410.
- Holtgrave, D.R., and Pinkerton, S.D. "Updates of Cost of Illness and Quality of Life Estimates for Use in Economic Evaluations of HIV Prevention Programs." *Journal of Acquired Immune Deficiency Syndromes and Human Retrovirology* 1997, Vol. 16, pp. 54-62.
- Janssen, Robert S., *et al.* "New Testing Strategy to Detect Early HIV-1 Infection for Use in Incidence Estimates and for Clinical and Prevention Purposes." *Journal of the American Medical Association*, Vol. 280, No. 1, pp. 42-48.
- Kalichman, S.C., *et al.* "AIDS Treatment Advances and Behavioral Prevention Setbacks: Preliminary Assessment of Reduced Perceived Threat of HIV/AIDS." *Health Psychology* 1998, Vol. 17, pp. 546-550.
- Kamb, M., *et al.* "Efficacy of Risk-Reduction Counseling to Prevent Human Immunodeficiency Virus and Sexually Transmitted Diseases: A Randomized Controlled Trial. Project RESPECT Study Group." *Journal of the American Medical Association*, October 7, 1998, Vol. 280, No. 13, pp. 1161-1167.
- Kelly, J.A., *et al.* "Protease Inhibitor Combination Therapies and Perceptions of Gay Men Regarding AIDS Severity and the Need to Maintain Safer Sex." *AIDS* 1998, Vol. 12, No. 10, pp. 91-95.
- Landis, S.E., *et al.* "Results of a Randomized Trial of Partner Notification in Cases of HIV Infections in North Carolina." *New England Journal of Medicine*, Vol. 326, No. 2, January 9, 1992, pp. 101-106.
- Levy, Judith A., and Fox, Susan E. "The Outreach-Assisted Model of Partner Notification with IDUs." *Public Health Reports*, Vol. 113, Supplement 1, June 1998, pp. 160-169.

REFERENCES (Continued)

- Maher, Julie, *et al.* "Partner Violence and Women's Decisions To Have an HIV Test." (Abstract TH.C.43110). *Abstracts of the Twelfth World AIDS Conference*, Vol. 1, p. 869.
- Musicco, M., *et al.* "Antiretroviral Treatment of Men Infected with Human Immunodeficiency Virus Type 1 Reduces the Incidence of Heterosexual Transmission." *Archives of Internal Medicine* 1994; Vol. 154, pp. 1971-1976.
- Nakashima, Allyn K., *et al.* "Effect of HIV Reporting by Name on Use of HIV Testing in Publicly Funded Counseling and Testing Programs." *Journal of the American Medical Association*, Vol. 280, No. 16, pp. 1421-1426.
- National Council of State Legislators. "Partner Notification Programs." *Issue Brief*, July 13, 1998.
- Parran, Thomas. *Shadows on the Land*. New York: Waverly Press, 1937.
- Public Law 104-146, Section 8(a) of the Ryan White CARE Reauthorization Act of 1996.
- Remien, R.H., *et al.* "Perceptions, Attitudes, and Sexual Risk Among HIV-Positive Men with Undetectable Plasma Viral Loads." Poster presented at the XII International Conference on AIDS, June 1998.
- Remien, R.H., *et al.* "HAART, Attitudes, and Risk Behavior Among Serodiscordant Male Couples." Paper presented at the XII International Conference on AIDS, June 1998.
- Rothenberg, Karen H., and Paskey, Stephen J. "The Risk of Domestic Violence and Women with HIV Infection: Implications for Partner Notification, Public Policy, and the Law." *American Journal of Public Health*, Vol. 85, No. 11, November 1995, pp. 1569-1576.
- Toomey, Kathleen E., *et al.* "Human Immunodeficiency Virus Partner Notification: Cost and Effectiveness Data From an Attempted Randomized Controlled Trial." *Journal of the American Sexually Transmitted Diseases Association*, Vol. 25, No. 6, July 1998, pp. 310-316.
- Vernazza, P.L., *et al.* "Quantification of HIV in Semen: Correlation with Antiviral Treatment and Immune Status." *AIDS* 1997, Vol. 11, pp. 987-993.
- Vernazza, P.L., *et al.* "Effect of Antiviral Treatment on the Shedding of HIV-1 in Semen." *AIDS* 1997, Vol. 11, pp. 1249-1254.
- Wasserheit, J.N. "Epidemiological Synergy: Interrelationships between Human Immunodeficiency Virus Infection and Other Sexually Transmitted Diseases." *Sexually Transmitted Diseases*, Vol. 19, No. 2, March-April 1992, pp. 61-77.
- West, Gary R., and Stark, Kathleen A. "Partner Notification for HIV Prevention: A Critical Reexamination." *AIDS Education and Prevention: HIV Counseling and Testing*. Vol. 9, Supplement B, June 1997, pp. 68-78.

APPENDIX A

PCRS PROGRAMMATIC STANDARDS

All PCRS programmatic standards are listed here, followed by a reference to the section of this document where a discussion of that standard and other related guidance can be found.

- ◆ All CDC-funded HIV prevention counseling and testing sites, both confidential and anonymous, must make PCRS available to all HIV-infected persons. (Section 2.1)
- ◆ CDC-funded programs must provide access to PCRS for persons testing anonymously without requiring that the infected client disclose his or her identity. (Section 2.1)
- ◆ Requests for PCRS from other health jurisdictions must be accommodated whenever practical. (Section 2.2)
- ◆ PCRS providers must ensure that clients are aware that all information disclosed by them will be kept strictly confidential and that participation is always voluntary. (Section 3.1)
- ◆ To foster an atmosphere of trust, PCRS providers must treat all HIV-infected clients and their partners with respect. (Section 3.1)
- ◆ Persons entering CDC-funded HIV prevention counseling and testing programs must be counseled at the earliest opportunity about PCRS and options for informing sex and needle-sharing partners of possible exposure to HIV. (Section 3.1)
- ◆ The PCRS provider must explain to the HIV-infected client the options for serving partners and then assist that client in deciding on the best plan for reaching each partner confidentially and referring him or her to counseling, testing, and other support services. (Section 3.2)
- ◆ The PCRS provider and HIV-infected client must prioritize reaching partners based on who is most likely to transmit infection to others and who is most likely to become infected. (Section 3.3)
- ◆ CDC-funded PCRS providers must review with the HIV-infected client in appropriate detail the legal and ethical reasons for informing sex and needle-sharing partners of their possible exposure to HIV. (Section 3.4)
- ◆ Program managers and supervisors must ensure that each PCRS provider has the appropriate training and skills to effectively serve HIV-infected clients and their partners. (Section 4.1)
- ◆ Locating and notifying activities must begin promptly once the PCRS plan has been formulated and the priorities set for reaching partners. (Section 4.2)
- ◆ While conducting PCRS activities in the community, providers must continue to maintain confidentiality for all HIV-infected clients and their partners. (Section 4.3)
- ◆ As each partner is informed of possible exposure to HIV, the PCRS provider must be prepared to assist that person with immediate counseling and referrals for more intensive counseling as well as testing and other support services. (Section 4.4)
- ◆ CDC-funded PCRS providers must collect data that help answer key questions about how well the PCRS program is functioning, the extent and quality of services being provided, the degree to which clients and their partners accept and are satisfied with services, and how PCRS and other prevention services can be enhanced. (Section 5.2)

PCRS PROGRAMMATIC STANDARDS *(Continued)*

- ◆ CDC-funded PCRS providers must use standardized data collection tools throughout the program that maintain the privacy or confidentiality of the original HIV-infected client and his or her partners. (Section 5.2)
- ◆ PCRS providers must be well trained to provide effective PCRS services. (Section 6.1)
- ◆ CDC-funded PCRS programs must have a quality assurance plan. (Section 6.2)
- ◆ CDC-funded PCRS programs must evaluate their services. (Section 6.2)

APPENDIX B

GLOSSARY OF TERMS ASSOCIATED WITH PCRS

Client-Centered Prevention Counseling	Counseling conducted in an interactive manner that is responsive to the individual's needs. This approach requires an understanding of the unique circumstances of the client – behaviors, culture, knowledge, and social and economic status.
Client Referral Approach	A PCRS approach whereby the HIV-infected client informs his or her partners of their possible exposure to HIV and refers them to counseling, testing, and other support services.
Confidential	Requirement that all personally identifying records be kept secure in a locked file and that no information be released to anyone without signed authorization from the client.
Contract Referral Approach	A PCRS approach whereby, if the HIV-infected client is unable to inform a partner within an agreed-upon time, the provider has the permission and information necessary to do so.
Dual Referral Approach	A PCRS approach whereby the HIV-infected client and the provider inform the partner together.
Duty To Warn	A legal concept indicating that a health care provider who learns that an HIV-infected client is likely to transmit the virus to another identifiable person must take steps to warn that person; state laws determine what actually constitutes a “duty to warn.”
Partner	A person who shares sex or drug-injection needles with another.
PCRS	Partner counseling and referral services.
PCRS Provider	A wide variety of qualified, trained health care professionals including physicians, nurses, counselors, disease intervention specialists, and others.
Prevention Counseling	Guiding a client's understanding of his or her perception of risk for becoming infected with HIV and developing a plan for reducing that risk for themselves and their partners.
Privilege To Disclose	Guidance for a PCRS provider who knows the identity of a partner at risk for HIV, whom the infected client is unable or unwilling to inform; usually guided by state laws.
Provider Referral Approach	A PCRS approach whereby, with the permission of the HIV-infected client, the provider informs the partner and refers him or her to counseling, testing, and other support services.

GLOSSARY OF TERMS ASSOCIATED WITH PCRS (Continued)

Spouse

A legal marriage partner as defined by state law (for purposes of the requirements of the Ryan White CARE Act).

Window Period

Period of time in between initial infection of HIV and development of a positive antibody test for HIV. The window period can last anywhere from about 2 weeks to (rarely) a year, although antibodies will usually be detected within 3 to 6 months.

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**Appendix F:
Cost to Implement
RESPECT HIV
Prevention Counseling**

The chart below lists the key personnel necessary to implement RESPECT HIV Prevention Counseling, including the number of staff and the percentage of staff time required for each position. In addition, the position responsibilities and required skills and knowledge are listed. This will assist you in estimating personnel needs and costs.

Table F-1. Personnel (Pay rates vary by community, so have been omitted.)

Position	Number of Staff	Percent Time	Responsibilities	Skills & Knowledge
Program Manager	1	varies	See that program integrity is maintained; supervise staff & debrief them daily; assure that supplies & testing kits are on hand when needed, that peers are trained and encouraged; monitor records; request TA.	Supervisory skills; excellent knowledge of program elements to supervise staff; knowledge of outreach and local community; culturally competent with target community.
Counselors	1–15	100%	Conduct one-on-one counseling, explain HIV testing process, communicate HIV test results; collect client information in a neat and orderly manner; complete legally required paperwork.	Comfort with target populations; verbal communication skills; sensitivity and maturity to communicate HIV positive result; literacy and willingness to read and follow specific protocols.
HIV Testing Staff	1	100%	Draw patient blood and accurately administer a variety of HIV tests. Coordinate transfer of tests to processing facilities and the collection of results. Ensure that individual test results are matched back to appropriate client; administer rapid tests when required.	Basic lab or medical technician training; detail oriented and organized; sensitive and professional demeanor; basic record keeping skills.
Support Staff	1	50%	Maintain program records, including data records (process evaluation and cost records); order and follow up on materials and publications; organize system to remind patients to attend follow-up sessions and pick up test results. Duplicating; maintaining administrative contact with public health department as required by jurisdictional law.	Detail-oriented; good at record keeping & retrieval; can use agency's database program; understands concepts related to project.

Beyond personnel, other costs are listed below:

Basic assumptions: Center is compliant with HIPAA and CLIA regulations regarding the handling of patient information and the management of laboratory services and tests. HIV testing is to be conducted on-site. Larger sites with more than 15 counseling personnel may require more supervisory, HIV testing, and support staff.

Space for individual counseling sessions: Because of the sensitive nature of HIV counseling and testing, spaces allocated should be reasonably private and insulated from outside noise. If individual rooms are not available, larger rooms can be subdivided using floor-to-ceiling noise-resistant dividers. Each space will have to be equipped with at least two chairs, and preferably a table of some sort.

Counselor office space: Individual counselors are likely to require space to prepare and organize patient records and evaluation materials. To minimize costs, counselors may not require individual desks, but should be equipped with filing cabinets and in-boxes or cubbyholes within a larger space with shared desks and tables.

HIV testing space and facilities: HIV testing may take place in the counseling session rooms or in a separate space. HIV testing, including the storage of blood samples and testing equipment, maintaining data confidentiality and the reporting of results to state and local health departments, should conform to the CDC guidelines. Links for HIV testing guidelines are provided.

Guidelines for Standard HIV Testing:

<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5019a1.htm>

HIV testing kits and equipment: RESPECT requires adequate supplies of HIV test kits (one per intervention) and the equipment necessary for kit and sample storage.

RESPECT Training: A certain amount of staff time is needed to train counselors to implement the RESPECT intervention. At a minimum, one half day of labor time per counselor should be budgeted for RESPECT training. Initially most trainings are likely

to also require the supervisor's time. As RESPECT becomes established, veteran counselors can be used to train newer staff.

Accompanying materials: Though RESPECT requires fewer materials than many interventions, it is assumed that RESPECT will be part of a larger prevention effort on the part of the agency. Thus, it requires (and/or assumes) the presence of:

- Equipment such as TVs and VCRs (to review the RESPECT training video).
- Computers.
- Services like phone bills, internet service, cleaning and maintenance.
- Office supplies such as paper, pens, copying fees, and postage.
- Intervention materials: For 2-Session Counseling, this includes counselor cards, risk-reduction step forms, and referral information. For 4-Session Counseling, this includes condoms, male and female genital models, counselor cards, and the games/forms included in the 4-Session RESPECT package.

The incremental cost of RESPECT may vary widely because the costs of labor and space vary widely by region; different centers will have different capacity in terms of existing HIV testing services, administrative support, and unused or underused space; and the size of individual RESPECT programs are likely to vary. However, a close approximation of your costs can be obtained by analyzing your program in terms of the components above and "costing them out" given your region and particular situation.

Appendix G: Quality Assurance Forms

Quality Assurance Form for RESPECT Session 1

Counselor Name _____ Type of QA: Tape Observation

Reviewer Name _____

Date of Observation _____ Session Start Time _____

Client ID _____ Session End Time _____

Session 1 Protocol Activities	Not Achieved	Achieved	N/A
Introduce and orient client to the session			
Introduce yourself to client			
Explain role of counselor			
Indicate the duration of session			
Outline content of session			
Provide referrals			
Discuss activities (lab work) with client			
Address immediate questions and concerns			
Enhance the client's sense of self-risk			
Find out why client has come for HIV testing			
Listen for and identify behaviors that put client at risk			
Assess client's level of concern for getting/having HIV			
Discuss client's HIV test history and prior behavior changes			
Assess whether client is engaging in risky behavior because of previous HIV negative test result			
Direct the client's attention toward risk behavior			
Discuss examples of conflicts between beliefs and behavior			
Explore the specifics of most recent risk incident			
Explore the who, what, when, where, how of recent risk incident			
Assess level of risk acceptable to client			
Assess communication about HIV with partner(s)			
Identify circumstances or situations that contributed to risk incident			
Identify risk vulnerabilities and triggers to the risk behavior incident			
Discuss examples of conflicts between client's beliefs and behavior			
Review previous risk reduction experience(s)			
Assess the client's pattern of risk behavior			
Identify successful attempts at practicing safer sex			
Identify obstacles to risk reduction			
Explore triggers and situations that increase the likelihood of high-risk behavior			
Assess client's communications about risk with friends and partners			
Discuss the client's level of acceptable risk			
Discuss examples of conflicts between client's beliefs and behavior			

Quality Assurance Form for RESPECT Session 1 (cont.)

Session 1 Protocol Activities (cont.)	Not Achieved	Achieved	N/A
Summarize risk incident and risk patterns			
Provide feedback about client's risk for HIV			
Summarize the information the client has provided			
Note the pattern of risk behavior			
Identify triggers and things that make the client vulnerable			
Discuss examples of conflicts between beliefs and behavior			
Convey concern and urgency about the client's risks			
Support and encourage client in addressing risk issues			
Negotiate risk-reduction step			
Prioritize risk-reduction behavior			
Explore behavior(s) that client will be most motivated about or capable of achieving			
Identify a reasonable, yet challenging, step toward changing the behavior			
Break down the risk step into specific, concrete actions			
Problem-solve obstacles to step			
Role-play the step (if applicable)			
Identify support for risk-reduction step			
Confirm with the client that the step is reasonable and acceptable			
Acknowledge that the step is a challenge. Inform client the step will be reviewed/revised at the next session			
Ask client to be aware of strengths and weaknesses in the step			
Document the risk-reduction step, keeping a copy for yourself			
Identify sources of support and provide referrals			
Assess the client's support system			
Address the long-standing or tough-to-manage issues that contribute to risk			
Assessed client's willingness to seek professional help or use a referral			
Evaluate the types of referral the client would be most receptive to			
Provide appropriate referrals			
Close the session			
Review follow-up schedule			
Identify ways for the client to remember follow-up appointment			
Review contact information for the client and the counselor			
Proceed with organization's guidelines to obtain specimen for HIV test			

Quality Assurance Form for RESPECT Session 2: Negative Test Result

Counselor Name _____

Type of QA: Tape Observation

Observer Name _____

Date of Observation _____

Session Start Time _____

Client Number _____

Session End Time _____

Session II Protocol Activities	Not Achieved	Achieved	N/A
Provide negative test result			
Welcome the client back			
State result clearly and simply			
Review meaning of the result			
Assess client's reaction to result			
Note the need to consider test result in terms of the most recent exposure			
Review the risk-reduction step			
Assess client's efforts to try out the risk-reduction step			
Provide encouragement and support for client's risk-reduction efforts			
Identify supports for and barriers to risk-reduction step			
Problem-solve issues with step			
Revise the risk-reduction step			
Revise or develop a new risk-reduction step			
Discuss a more challenging step or revise previous step			
Identify or clarify actions to achieve the step			
Confirm with the client that the step is reasonable and achievable			
Document the revised risk-reduction step and give copy to client			
Identify sources of support for the risk-reduction step			
Emphasize importance of client discussing with a trusted friend/relative the intention and content of step			
Identify a person to whom the client could comfortably disclose the step			
Establish a concrete, specific approach for client to use in sharing the step with friend/relative			
Ask client be aware of strengths/weaknesses when trying it out			
Let client know you have confidence in his or her ability to complete the step			
Provide referral and end session			
If a referral was provided in previous session, follow up on the client's completion			
Address long-standing or hard-to-manage issues that contribute to risk			
Assess the client's willingness to seek professional help and use a referral			
Evaluate types of referral			
Provide appropriate referral			
Provide closure			

Quality Assurance Form for RESPECT Session 2: Positive Test Result

Counselor Name _____ Type of QA: Tape Observation

Observer Name _____

Date of Observation _____

Session Start Time _____

Client Number _____

Session End Time _____

Session II Protocol Activities	Not Achieved	Achieved	N/A
Provide positive test result			
Welcome the client back			
Re-explain confidentiality			
Verify the result belongs to the client			
Assess the client's readiness to receive the result			
Provide the result clearly and simply			
Allow client time to absorb meaning of test result			
Explore client's understanding of the meaning of the result			
Assess how client is coping with result			
Address immediate concerns and fears			
Acknowledge the challenge of dealing with a positive result			
Identify sources of support and provide referrals			
Assess whom client would like to tell about his/her positive test result.			
Identify person, family member or friend to help the client through the process of dealing with HIV (coping and support, planning for the future, medical follow-up)			
Discuss wellness strategies			
Identify current health care resources			
Address the need for health care providers to know client's test result			
Explore client's access to medical services (STD exam, routine medical care, TB screening)			
Identify needed medical referrals			
Assess client's receptiveness to referral			
Help client access referral services			
Address risk-reduction issues			
Refer to client's risk-reduction step.			
Assess client's plan to reduce risk of transmission to current partners			
Explore client's plan for reducing the risk of transmission to future partners			
Address disclosure of HIV status to current and future partners			
Encourage the client to protect others from HIV			
Summarize and close the session			
Validate client feelings			
Summarize key issues addressed			
Review contact information and arrange for follow-up			
Get the client's plans for the next step			
Close session			

