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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
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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.

Technical Expert Panel Review of CDC 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 ≥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 ≥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.

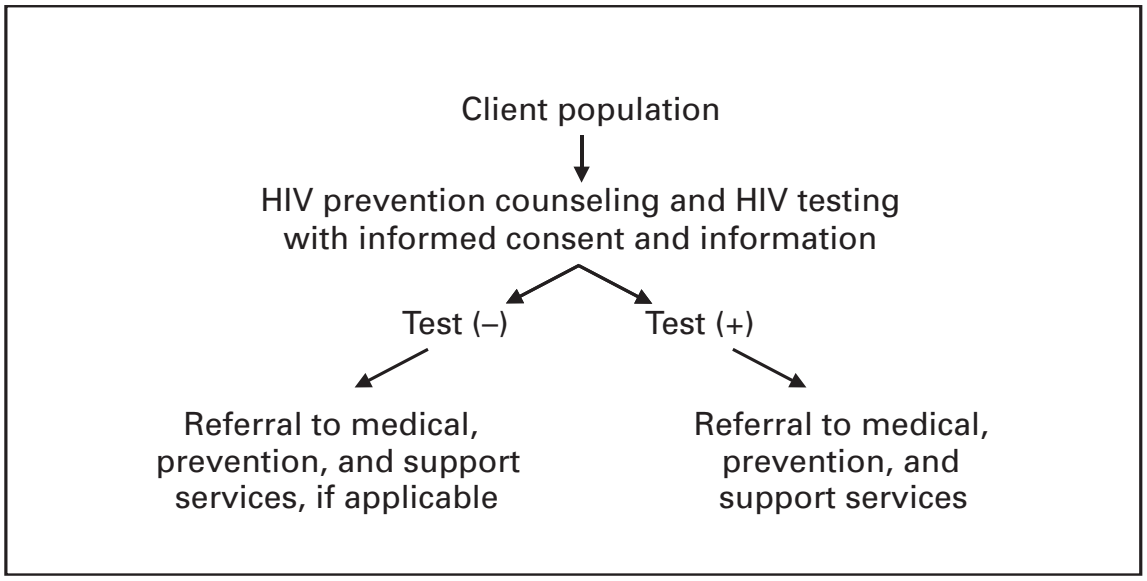
* Or lower than other settings in the community.
† Constitutes risk screening; see Determining Individual HIV Risk Through Risk Screening.
§ Or higher than other settings in the community.
¶ Clients should be routinely recommended testing, and if risk is identified during risk screening, they should 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)
- Clinics serving men who have sex with men
- Correctional facilities, prisons, juvenile detention centers
- Drug or alcohol prevention and treatment programs
- Freestanding HIV test sites
- Homeless shelters
- Outreach programs (e.g., syringe exchange 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., ≥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

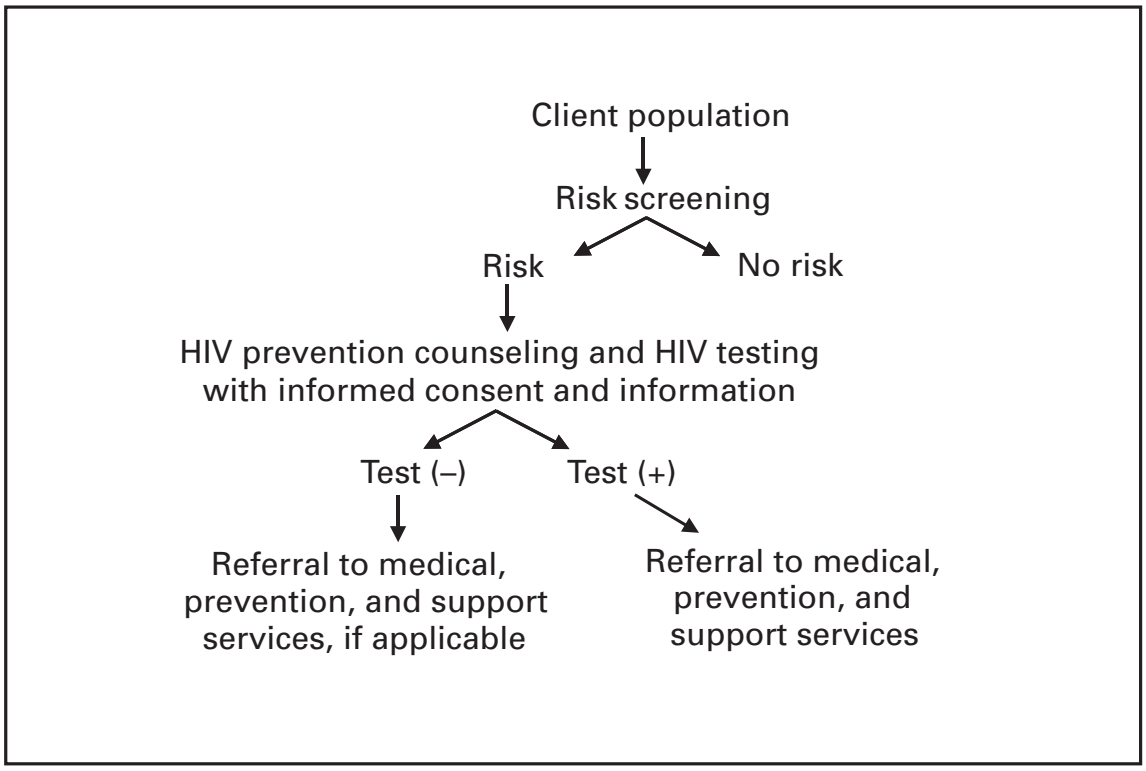
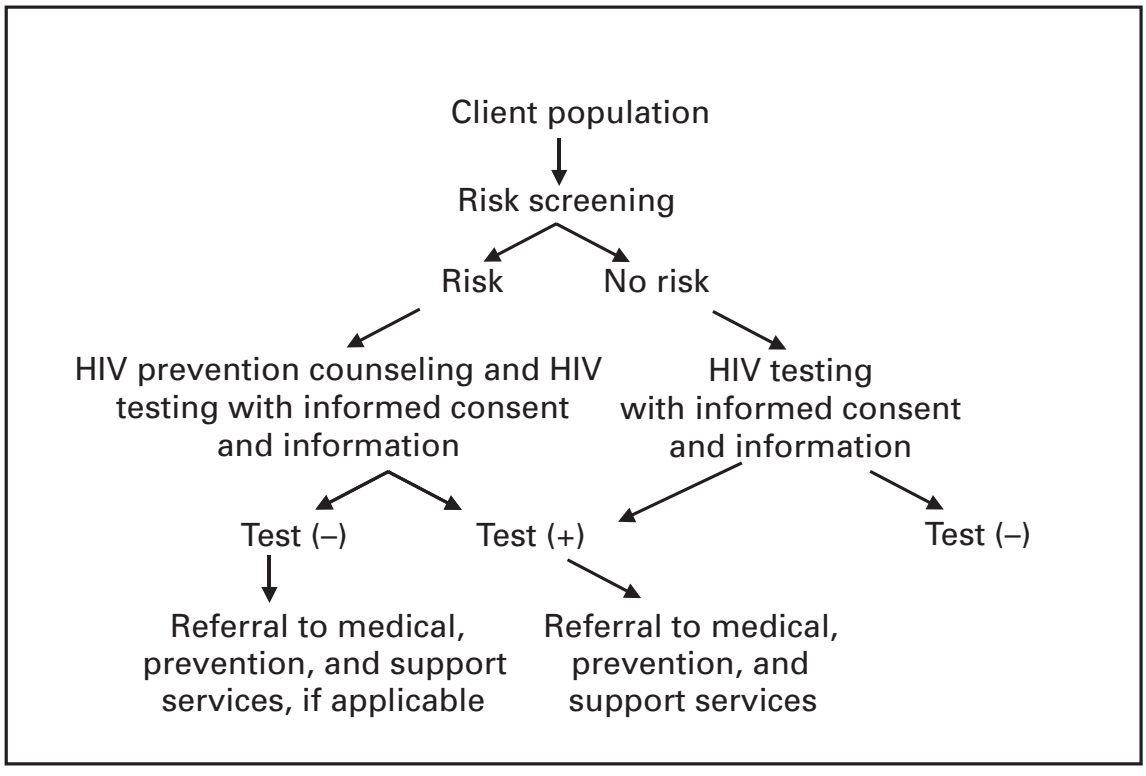


FIGURE 3. An example of HIV counseling, testing, and referral in high prevalence settings



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. DeGroff, 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 Have you (for a male client) ever had sex with a man? OR Have you (for a female client) ever had sex with a bisexual man?	What are you doing that you think may be putting you at risk for HIV infection? What are the riskiest things that you are doing?
	If your test comes back positive, how do you think you may have become infected?
	When was the last time you put yourself at risk for HIV? What was happening then?
Have you ever had sex when you were under the influence of alcohol or drugs?	How often do you use drugs or alcohol?
	How do you think drugs or alcohol influence your HIV risk?
Do you (always) use condoms when you have sex? OR Can you always use condoms when you have sex?	How often do you use condoms when you have sex? When/with whom do you have sex without a condom? When with a condom?
	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?
Can you always use clean works (i.e., needles, syringes, cottons, or cookers*) when you inject?	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 $\geq$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 $\geq$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 $\geq$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	• High sensitivity • Rare false-positives • High-volume processing • Utility for testing for other conditions (e.g., sexually transmitted diseases [STDs])	• 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	• Convenience • Increased receipt of test results • Use in urgent medical circumstances (e.g., postexposure prophylaxis)	• 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	• Convenience • Anonymity • Privacy • Conservation of public resources	• 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	• Noninvasive • Nontechnical collection • No venipuncture • Decreased infectious hazard • Utility in nonclinical settings	• 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	• Noninvasive • Nontechnical collection • No venipuncture • Decreased infectious hazard • Utility in nonclinical settings • Utility for testing for other conditions (e.g., STDs)	• 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/lymphandenopathy-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. DiGuiseppi 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, Hessol 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, Schecter 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, 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.
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 multidiagnosed 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 nonoccupational 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.

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MMWR
MORBIDITY AND MORTALITY
WEEKLY REPORT

November 9, 2001 / Vol. 50 / No. RR-19a1

Recommendations and Reports

Continuing Education Activity Sponsored by CDC

Revised Guidelines for HIV Counseling, Testing, and Referral

EXPIRATION — November 9, 2004

You must complete and return the response form electronically or by mail by **November 9, 2004,** to receive continuing education credit. If you answer all of the questions, you will receive an award letter for 2.75 hours Continuing Medical Education (CME) credit, 0.25 hour Continuing Education Units (CEUs), or 3.1 hours Continuing Nursing Education (CNE) credit. If you return the form electronically, you will receive educational credit immediately. If you mail the form, you will receive educational credit in approximately 30 days. No fees are charged for participating in this continuing education activity.

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.
4. Fill out and submit the registration form.
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.
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
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6. Your Certificate of Completion will be mailed to you within 30 days.

ACCREDITATION

Continuing Medical Education (CME). CDC is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians. CDC designates this educational activity for a maximum of 2.75 hours in category 1 credit toward the AMA Physician's Recognition Award. Each physician should claim only those hours of credit that he/she actually spent in the educational activity.

Continuing Education Unit (CEU). CDC has been approved as an authorized provider of continuing education and training programs by the International Association for Continuing Education and Training and awards 0.25 hour Continuing Education Units (CEUs).

Continuing Nursing Education (CNE). This activity for 3.1 contact hours is provided by CDC, which is accredited as a provider of continuing education in nursing by the American Nurses Credentialing Center's Commission on Accreditation.

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

To receive continuing education credit, you must
1. provide your contact information;
2. indicate your choice of CME, CEU, or CNE credit;
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Fill in the appropriate blocks to indicate your answers. Remember, you must answer <u>all</u> of the questions to receive continuing education credit!

1. [ ] A [ ] B [ ] C [ ] D
2. [ ] A [ ] B [ ] C [ ] D
3. [ ] A [ ] B [ ] C [ ] D
4. [ ] A [ ] B [ ] C [ ] D
5. [ ] A [ ] B [ ] C [ ] D
6. [ ] A [ ] B [ ] C [ ] D
7. [ ] A [ ] B [ ] C [ ] D
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9. [ ] A [ ] B [ ] C [ ] D
10. [ ] A [ ] B [ ] C [ ] D [ ] E [ ] F
11. [ ] A [ ] B [ ] C [ ] D [ ] E [ ] F
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21. [ ] A [ ] B [ ] C [ ] D [ ] E
22. [ ] A [ ] B [ ] C [ ] D [ ] E
23. [ ] A [ ] B [ ] C [ ] D [ ] E [ ] F

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 ≤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 ≤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 $\geq$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 antiretoviral 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 $\geq$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 ≤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, Stiehm 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 nevirpine (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 annd 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. Perintal 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, Coutsoudis 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 annd 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 ≤500/µL. 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 an 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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MMWR
MORBIDITY AND MORTALITY
WEEKLY REPORT

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

Recommendations and Reports

Continuing Education Activity Sponsored by CDC

Revised Recommendations for HIV Screening for Pregnant Women

EXPIRATION — November 9, 2004

You must complete and return the response form electronically or by mail by **November 9, 2004,** to receive continuing education credit. If you answer all of the questions, you will receive an award letter for 1.5 hours Continuing Medical Education (CME) credit, 0.1 hour Continuing Education Units (CEUs), or 1.7 hours Continuing Nursing Education (CNE) credit. If you return the form electronically, you will receive educational credit immediately. If you mail the form, you will receive educational credit in approximately 30 days. No fees are charged for participating in this continuing education activity.

INSTRUCTIONS

By Internet

1. Read this *MMWR* (Vol. 50, RR-19, *Revised Recommendations for HIV Screening for Pregnant Women*), 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.
4. Fill out and submit the registration form.
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 **Novemeber 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 Recommendations for HIV Screening for Pregnant Women*), 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.
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
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   Epidemiology Program Office, MS C-08
   Centers for Disease Control and Prevention
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ACCREDITATION

Continuing Medical Education (CME). CDC is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians. CDC designates this educational activity for a maximum of 1.5 hours in category 1 credit toward the AMA Physician's Recognition Award. Each physician should claim only those hours of credit that he/she actually spent in the educational activity.

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Continuing Nursing Education (CNE). This activity for 1.7 contact hours is provided by CDC, which is accredited as a provider of continuing education in nursing by the American Nurses Credentialing Center's Commission on Accreditation.

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.

MMWR Response Form for Continuing Education Credit
November 9, 2001/Vol. 50/No. RR-19a2

Revised Recommendations for HIV Screening for Pregnant Women

To receive continuing education credit, you must
1. provide your contact information;
2. indicate your choice of CME, CEU, or CNE credit;
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Fill in the appropriate blocks to indicate your answers. Remember, you must answer <u>all</u> of the questions to receive continuing education credit!

1. [ ] A [ ] B [ ] C [ ] D
2. [ ] A [ ] B [ ] C [ ] D [ ] E
3. [ ] A [ ] B [ ] C [ ] D [ ] E
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***

All *MMWR* references are available on the Internet at <http://www.cdc.gov/mmwr/>. Use the search function to find specific articles.

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MMWR

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