DRAFT

Revised Guidelines for HIV Counseling, Testing, and Referral

DRAFT

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Contents

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Summary

These guidelines revise and replace the previous guidelines, *HIV Counseling, Testing, and Referral Standards and Guidelines* (CDC, 1994). The guidelines contain recommendations for policy developers and service providers of human immunodeficiency virus (HIV) counseling, testing, and referral services. To develop these guidelines, the Centers for Disease Control and Prevention (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 the combined weight of the evidence from all available scientific sources; where evidence is lacking, expert opinion of "best practices" has been used.

Important scientific and programmatic advances in HIV counseling, testing, and referral, as well as advances in prevention and treatment and care of HIV-infected persons, have prompted this revision. With these advances, the need for early detection of HIV infection has become even more compelling, as early detection can benefit infected persons as well as reduce risk of transmission to others. Examples of recent advances include demonstrated efficacy of high-quality HIV prevention counseling models aimed at behavioral risk reduction; effective treatments for HIV infections and opportunistic infections; effective treatment regimens for preventing perinatal transmission; new test technologies; and recognition of the need for systems of referrals to medical, prevention, and psychosocial support services.

Although many aspects of the earlier CDC HIV guidelines remain unchanged (e.g., encouragement of confidential and anonymous HIV testing, informed consent, and provision of high-quality HIV prevention counseling that focuses on the clients' own risks and, whenever possible, is done in association with HIV testing), the current guidelines differ in several respects, including the following:

- They give guidance to all current and potential providers of voluntary HIV counseling, testing, and referral services, not only to those in the public sector.
- They acknowledge the need for flexibility in their use, depending on providers' situations and clients' needs.
- They encourage an easier and more streamlined process for both clients and providers.
- They underscore the importance of making counseling, testing, and referral services more accessible and available.
- They underscore the need to increase the numbers of infected persons who know their HIV status.
- They encourage anonymous testing to be available nationwide.
- They review newly available HIV testing methods and appropriate uses and settings.
- They address ways to improve the quality and provision of HIV prevention counseling.

- They differentiate between “information dissemination” and “prevention counseling” in the context of the counseling session.
- They strengthen the recommendation to identify and meet referral needs.

1.0 About the Guidelines

1.1 Who Should Read the Guidelines

These guidelines have been developed for providers in the many settings that offer voluntary human immunodeficiency virus (HIV) counseling, testing, and referral services—in the public and private sectors, urban and rural areas, and settings with high or low HIV prevalence (Box 1). The guidelines may also be useful for counseling, testing, and referral services in other settings (e.g., insurance, military, blood donation). The U.S. Public Health Service has specific responsibilities for ensuring the quality of services in publicly funded programs, and some aspects of the guidelines focus on these programs.

The guidelines are intended to be used in developing counseling, testing, and referral services and policies. The recommendations should be tailored to fit the needs of clients, communities, and programs within local, state, and federal rules and regulations.

Box 1. HIV Counseling, Testing, and Referral Settings.

Settings that provide HIV counseling, testing, and referral services include but are not limited to the following:

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

1.2 Obtaining Additional Copies of the Guidelines

Single copies of this report can be obtained from (*information to be supplied later*). The guidelines will be updated periodically and posted electronically. Information can be obtained from

- Centers for Disease Control and Prevention (CDC) at www.cdc.gov and 1-800-xxx-xxxx
- HIV/AIDS Treatment Information Service at www.hivatis.org and 1-800-448-0440
- CDC's National Prevention Information Network at www.cdcnpin.org and 1-800-458-5231

1.3 Additional Resources

Additional information on HIV counseling, testing, and referral services can be obtained from

- CDC's National Center for HIV, STD, and TB Prevention at www.cdc.gov/nchstp/od and 1-800-458-5231
- CDC's National Prevention Information Network at www.cdcnpin.org and 1-800-458-5231
- HIV/AIDS Treatment Information Service at www.hivatis.org and 1-800-448-0440
- AIDS Clinical Trials Information Service at www.actis.org and 1-800-874-2572

2.0 HIV Counseling, Testing, and Referral Services: An Overview

2.1 Evolution of the HIV Counseling, Testing, and Referral Guidelines

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

During the last 6 years, several important advances have occurred in the areas of HIV counseling, testing, and referral. The recommendations in this document reflect this new knowledge.

- Controlled trials showed that the high-quality HIV prevention counseling model encouraged by CDC in the 1993 and 1994 guidelines (3,4) is efficacious for changing behavior and reducing the incidence of sexually transmitted diseases (STDs) in HIV-uninfected persons at increased risk (5). Furthermore, mounting evidence supports the efficacy of other counseling models aimed at HIV prevention (5-26).
- Treatment for HIV with antiretroviral therapy (27) and for opportunistic infections (28) has been found to be effective, improving quality and duration of life.
- Medical therapy to dramatically reduce the risk of perinatal HIV transmission has been identified and become available (29,30).
- New testing technologies (e.g., oral fluid, urine, and rapid tests) are increasingly available (31). The flexibility that these tests provide may help increase acceptance of testing and receipt of test results and identify infection earlier (32).
- Guidance on partner counseling and referral services, prevention case management, prevention and control of STDs, and prevention of opportunistic infections (33-36) has been published or updated by CDC.

Because of these advances, CDC, in consultation with multiple partners, revised the 1994 guidelines using an evidence-based approach (37,38) and expanded the target audience to all providers of HIV counseling

and testing services in the United States (37). Where scientific findings were lacking, recommendations were guided by "best practices" from expert opinion. The authors of these guidelines employed a five-step approach to the revision process:

- **Address user needs.** The authors conducted a survey of publicly funded sites to assess user satisfaction with previous (1994) CDC guidelines for HIV counseling, testing and referral. They also consulted with both internal and external content experts on key areas to address in the revised guidance.
- **Review literature.** They screened more than 5,000 abstracts and reviewed and synthesized into Tables of Evidence more than 600 relevant publications (*citations to be posted on the Web site*). In addition, 22 previously published CDC guidelines related to HIV counseling, testing, and referral were summarized.
- **Obtain technical expert opinion.** The authors convened a panel of technical experts from public and private sectors; governmental and nongovernmental agencies; and legal, ethical, and policy fields. This panel reviewed summary recommendations.
- **Obtain user input.** Internal CDC comment, public and private provider assessment, key consultant interviews, broad external review, and public comment through the Federal Register were obtained.
- **Publish electronically and in hard copy.**

The revised guidelines continue to support offering voluntary HIV testing in both confidential and anonymous formats, obtaining informed consent, and providing HIV prevention counseling that is focused on the clients' own risks and, whenever possible, is done in association with HIV testing. These new guidelines expand on or differ from previous guidelines in the following respects:

- Provide guidance for both private and public providers of HIV counseling, testing, and referral services.
- Acknowledge the need for flexibility in implementing the guidelines so that providers can apply them as appropriate for their own circumstances (given their particular client base, prevalence level, and resources) to best meet client needs.
- Provide additional guidance to improve the quality and provision of HIV prevention counseling and describe new information on its proven efficacy in reducing high-risk behaviors and new STDs.
- Strengthen CDC's existing recommendation that anonymous testing be broadly available.
- Revise goals for HIV counseling, testing, and referral to emphasize increasing the numbers of HIV-infected persons who know their HIV infection status and know it early in the course of their infection.

- Provide current information on newly available HIV testing methods and appropriate uses and settings for these new tests.
- Emphasize the importance of ensuring that providers assist clients in accessing needed medical and other support services.
- Describe in greater detail assessment and management of referrals.
- Encourage offering high-quality services in nontraditional settings to facilitate access for those at increased risk for HIV who are not being reached by existing services.
- Strengthen endorsement of the role of quality assurance and evaluation in counseling, testing, and referral services.

2.2 Current Status of HIV and HIV Counseling, Testing, and Referral Services

HIV infection and HIV-related diseases have become a leading cause of illness and death in the United States in the last two decades. As of the end of 1999, it is estimated that more than 430,000 persons have died from HIV/AIDS, and nearly 290,000 persons are living with AIDS (39). Approximately 800,000 to 900,000 persons in the United States are infected with HIV(40); it is estimated that as many as 275,000 of these persons may not know that they are infected (41).

Many types of settings in the United States offer HIV counseling, testing, and referral services. Voluntary testing can be obtained in both public and private medical care settings, such as physicians' offices, hospitals, managed care organizations, and publicly funded clinics (42). Testing is also provided in nontraditional settings (community-based and outreach settings), in which persons at increased risk for HIV are targeted. Sample collection can even be done outside a medical or field facility—through home collection kits (43). Most HIV tests, however, are conducted in the private sector (42).

A substantial number of opportunities for HIV prevention are being missed. In publicly funded sites, at least 70% of persons tested have received their test results and some counseling, but the numbers of persons receiving HIV prevention counseling and receiving referrals are likely much lower. In many potential testing settings (e.g., emergency rooms), HIV prevention counseling and HIV testing are not uniformly offered. Data regarding types and completion of referral are not routinely collected in many settings.

2.3 Goals of HIV Counseling, Testing, and Referral Services

To achieve optimal health for the individual and the public, high-quality HIV counseling, testing, and referral services have the following goals (Box 2). It is essential that these services be easily accessible and available and that the process be easy and streamlined for both clients and providers.

Box 2. Goals of HIV Counseling, Testing, and Referral Services

- Ensure that HIV-infected persons receive high-quality HIV prevention counseling to reduce their risk of transmitting HIV to others; have early knowledge of their HIV status; and have access to appropriate medical, prevention, and psychosocial services.
- Ensure that persons at increased risk for HIV receive high-quality HIV prevention counseling to reduce their risk of acquiring HIV infection; know their HIV status; and have access to appropriate medical, prevention, and psychosocial support services.
- Ensure that persons who are offered or receive HIV testing are provided information about the ways in which HIV is transmitted and can be prevented and about the meaning of the HIV test results.

2.4 Essential Elements of HIV Counseling, Testing, and Referral Services

The following elements are critical in offering high-quality HIV counseling, testing, and referral services:

- **Strictly protect confidentiality for clients who are offered or request and/or who receive HIV services**. Information about a client's use of HIV services should remain private (confidential). Personal information is not to be divulged to others in ways that are inconsistent with the client's original consent.
- **Obtain informed consent before HIV testing**. The provider must obtain informed consent before the HIV test is conducted. 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. In situations where written consent cannot be obtained, documentation of verbal consent or refusal in the client's record may be sufficient.
- **Provide clients the option of anonymous HIV testing.** Anonymous testing (testing information not documented in client's record) has been used widely and effectively and may offer important benefits for the health of individuals and the public, such as earlier entry into

medical care (44). Some persons who would otherwise not have been tested may seek anonymous HIV testing and learn their HIV status. Consistent with current public health best practice, states in which anonymous testing is not available should reconsider their policy. Confidential testing (testing information documented in client's record) is preferred when the client has no clear preference regarding testing format. Confidential testing may facilitate linkage to follow-up counseling and referral for needed services after test results are received.

- **Adhere to local, state, and federal regulations and policies that govern provision of HIV services**. Laws at the local, state, and federal levels may address many aspects of HIV services. Laws may also regulate how services can be provided to particular persons, e.g., minors. In addition, policy, local ordinances, funding source requirements, and planning processes will also affect a provider's decisions about which services to provide and how to provide them.
- **Provide services responsive to client and community needs and priorities**. Providers should work to remove barriers and tailor services to individual and community needs. To help ensure that clients find services accessible, services can be offered in nontraditional settings (e.g., outreach settings); clinic/office hours can be expanded or altered; unnecessary delays can be eliminated through more efficient organization of operations (e.g., integrating counseling and testing for STDs/HIV with counseling and testing for hepatitis); test results can be obtained more -easily (e.g., provided at the time of testing with rapid testing or, in certain situations, by telephone); and less-invasive specimen collection can be used (e.g., oral fluid, urine, finger-stick blood).
- **Provide services that are culturally, linguistically, gender-, and age-appropriate.** The client's culture, language, literacy level, gender, and age may affect how the client seeks, accepts, and understands HIV services. Providers should take these factors into consideration when designing and providing HIV services.
- **Ensure high-quality services.** To ensure that clients receive services of high quality, providers should develop and implement written quality assurance and program evaluation procedures to ensure ongoing effective services that serve client and community needs.

2.5 Routine vs. Targeted HIV Counseling, Testing, and Referral Services

Numerous studies have shown that both in higher-prevalence settings and settings serving clients at increased behavioral risk for HIV infection, targeting clients for HIV testing on the basis of reported risk

factors will not necessarily identify and might not offer services to many HIV-infected clients (45-53).[1] However, in low-prevalence populations, where most clients have minimal risk, targeting clients for HIV testing on the basis of risk screening may be more feasible and cost-effective for identifying small numbers of HIV-infected persons (54).

For these reasons, health-care providers should consider both setting HIV prevalence and behavioral HIV risk of the client population when determining whether to recommend HIV prevention counseling, testing, and referral to all clients or to recommend these services to selected clients. A third factor may also influence this decision: the availability of potentially beneficial treatment for HIV prevention may support routine recommendations for testing, even in low-prevalence or low-risk settings, for example, in HIV-infected pregnant women for prevention of perinatal transmission (see simultaneously published guidelines on preventing perinatal HIV transmission) (30) or persons who have been occupationally exposed to HIV.

Although HIV counseling, testing, and referral are naturally linked services, these guidelines acknowledge public and private providers' needs for flexibility. Therefore, the guidelines recognize, for example, that a provider may offer prevention counseling services without being able to offer an HIV test or a provider may be able to offer the test without being able to offer prevention counseling services. In either case, providers should always give referrals to accompany counseling or testing.

2.5.1 Routinely Recommended Counseling, Testing, and Referral Services

HIV prevention counseling, testing, and referral are routinely recommended for all clients in settings where the client population is generally at increased behavioral risk of acquiring or transmitting HIV infection (see below), regardless of setting prevalence.

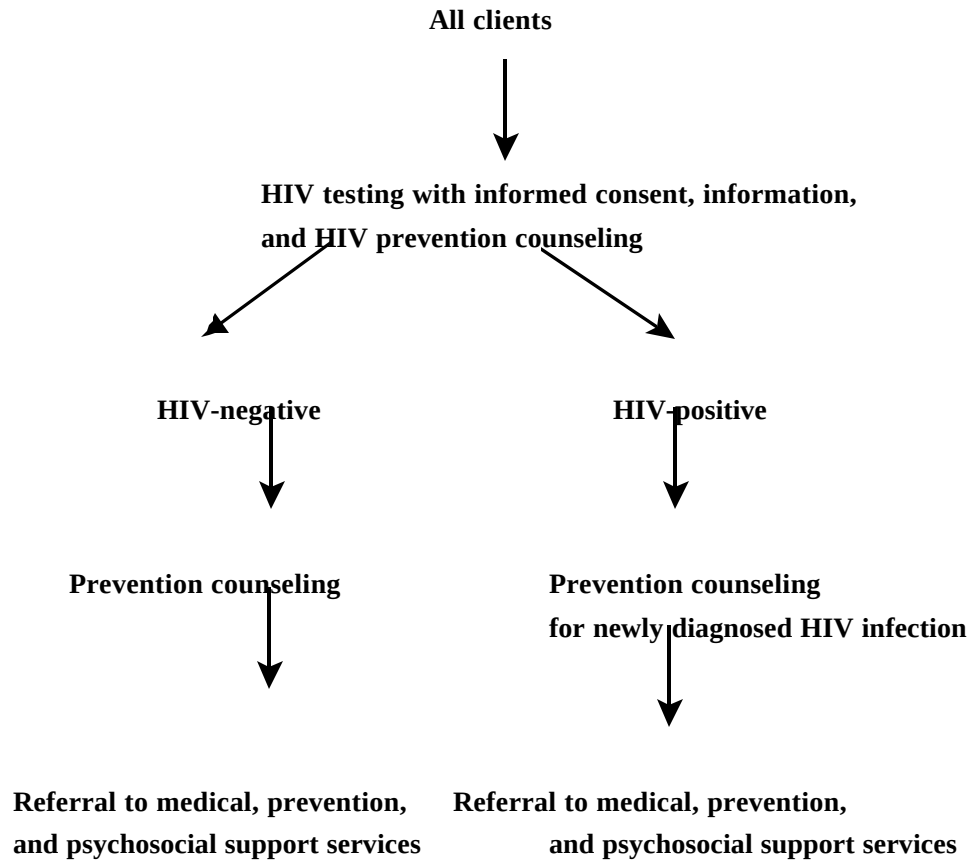
In the settings described above, providers should recommend HIV prevention counseling, testing, and referral for all clients (Figure 1) and provide these services on site.

Examples of settings that may serve client populations at generally increased behavioral risk for HIV are STD clinics, adolescent health clinics with high STD rates, clinics serving men who have sex with men, drug or alcohol prevention and treatment programs, freestanding HIV test sites, homeless shelters, correctional facilities, juvenile detention centers, outreach programs (e.g., syringe exchange programs),

[1]Even in high prevalence settings, HIV testing need not be routinely recommended to clients at minimal risk (e.g., persons not sexually active). In addition to age and behavioral parameters, other local factors could be considered. Providers could consult local health departments.

prisons, and tuberculosis (TB) clinics.

Figure 1. Counseling, testing, and referral for settings where the entire client population is at increased behavioral risk for HIV*, regardless of setting prevalence.



* Such settings might include sexually transmitted disease clinics, drug treatment centers, and needle exchange programs.

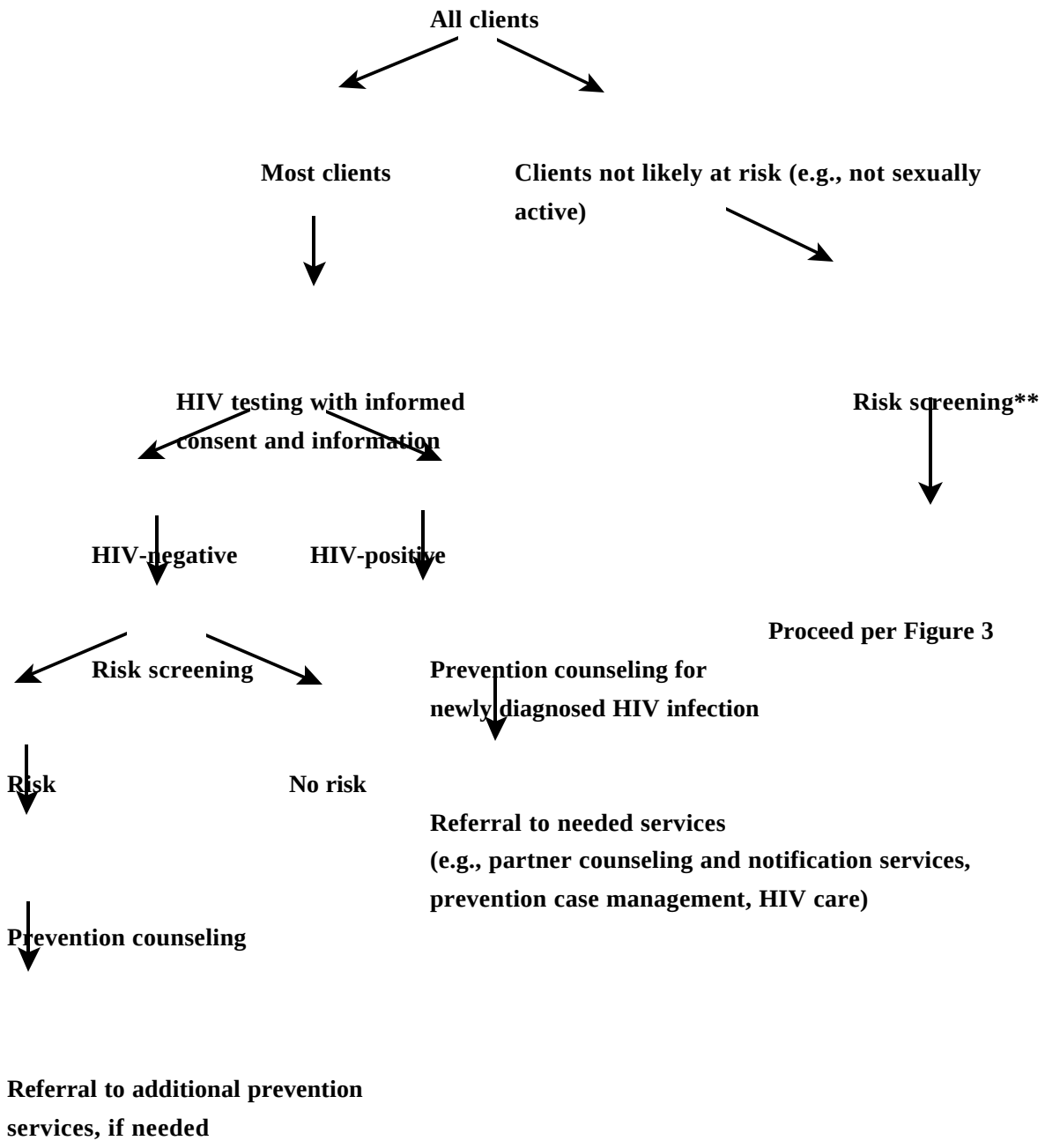
2.5.2 Routinely Recommended Voluntary Testing and Targeted Counseling, Testing, and Referral Services

In settings where HIV prevalence is high (e.g., ≥1%, see 2.5.5), voluntary HIV testing is routinely recommended for most persons. For persons not likely to be at increased risk (e.g., persons not sexually active and who do not inject drugs), risk screening should be conducted, and clients found to be at increased risk should be tested and receive prevention counseling, as well as referral to any needed services.

In high prevalence settings (e.g., ≥1%, see 2.5.5), it is desirable that most clients be recommended HIV testing. However, in these settings, some clients are only at minimal risk (e.g., because of lack of sexual activity).[2] Services should be routinely offered to most clients (see Figure 2), but for those outside specific behavioral or age parameters, services could be targeted based on risk screening. Methods of determining who should not be screened are limited. Evidence suggests that locally applicable factors may be important to consider. Providers may benefit from consulting their local health departments or, through local health departments, local HIV community planning groups to determine if other factors should be considered. Counseling and referral are recommended even if HIV testing is declined.

[2]In many settings, persons older than 54 years of age may also be considered not likely to be at increased risk for HIV.

Figure 2. Counseling, testing, and referral for settings where HIV prevalence is high*.



* ≥1% prevalence in the setting or higher prevalence than other settings in the community (see 2.5.5).

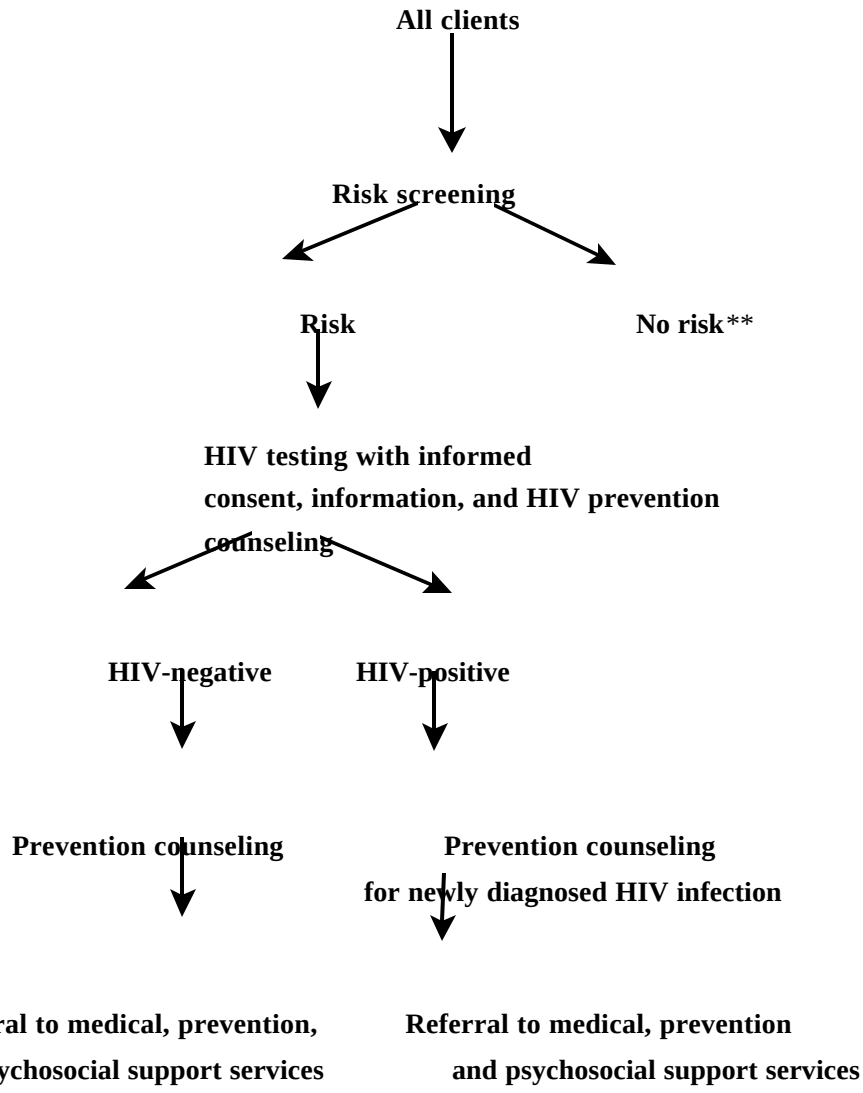
**A client who requests a test or has clinical symptoms suggestive of HIV should be given an HIV

2.5.3 Targeted Counseling, Testing, and Referral Services

In settings where both HIV prevalence is low (e.g., <1%, see 2.5.5) and the client population is generally not at increased behavioral risk of acquiring or transmitting HIV infection, HIV prevention counseling, testing, and referral services should be targeted on the basis of risk screening (see 2.5.6)

Low-prevalence settings where the client population is not at increased risk likely represent the majority of health-care settings. In these settings, if risk screening (see 2.5.6), which assesses an individual client's behavioral and clinical risks for HIV, indicates that a client is at increased risk for HIV, prevention counseling, testing, and referral are recommended (Figure 3). Prevention counseling and referral are recommended even if HIV testing is declined.

Figure 3. Counseling, testing, and referral for settings where HIV prevalence is low* and the client population is generally not at increased behavioral risk for HIV.



* <1% prevalence or lower than other settings in the community (see 2.5.5).

**A client who requests a test should be given an HIV test, information, and HIV prevention counseling.

2.5.4 Recommended Counseling, Testing, and Referral Services for Clients with Prevention Treatment Potential

Effective treatment that may reduce the risk for HIV transmission and acquisition exists in a limited number of situations: perinatal transmission, acute occupational exposure, and possibly acute nonoccupational (high-risk sexual or needle-sharing) exposure.

Given the availability of such treatment, voluntary HIV testing should be

- routinely recommended for all pregnant women (30)
- routinely recommended for clients with acute occupational exposure (55)
- routinely recommended for clients with acute nonoccupational exposure (e.g., high-risk sexual or needle-sharing)(56)

HIV prevention counseling and referral should be

- targeted to pregnant women on the basis of risk screening (30)
- routinely recommended to clients with acute occupational exposure (55)
- routinely recommended to clients with acute nonoccupational exposure (56)

For further information, consult the respective guidelines (30,55,56).

2.5.5 Determining Whether a Setting Has "High" or "Low" Prevalence and Setting Service Priorities

Limited data exist with which to formulate a general definition for "high" and "low" HIV prevalence and describe how such a definition could assist in developing and prioritizing HIV counseling, testing, and referral services. However, research from the early 1990s for acute care hospitals with $\geq$ 1% HIV prevalence suggests that routine HIV testing of all patients ages 15-54 years identifies a large proportion of HIV-infected patients in a cost-effective manner (57). This 1% prevalence figure and age range may be used as *very general guidance* for whether or not to routinely recommend HIV counseling and testing.

The threshold of HIV prevalence that should lead to routine recommendations for HIV testing of all clients within a setting may vary markedly within and across settings and should be made in consideration of available resources. If need be, services could target settings with HIV prevalence rates <1% but higher than other settings in the community, according to U.S. prevalence data (42,54). If HIV prevalence data are outdated or unknown, providers should consult their local or state health department for assistance in determining appropriate HIV testing, counseling, and referral strategies. In situations where

prevalence data are known, providers may also base decisions in part on the behavioral HIV risk of the client population.

2.5.6 Determining Individual Client Risk Through Risk Screening[3]

Determination of a client's HIV risk through risk screening for the purpose of targeting counseling, testing, and referral services is based on both the client's self-reported behavioral risk and clinical signs or symptoms (e.g., STDs) suggesting increased risk for HIV infection or other signs or symptoms (e.g., opportunistic infections) suggesting the presence of HIV infection (Box 4). Behavioral risks include, for example, injection drug use or unprotected intercourse with someone at increased risk for HIV.

Most primary health-care providers do not ask clients about HIV or other STD risks (58-61), assuming that their clients have less HIV and STD risk than they actually do (62) and thus missing opportunities for HIV counseling and testing or referral for those services. Although risk screening will not identify all HIV-infected persons or persons at increased risk for infection, the use of strategies to identify clients at increased risk (Box 3) could identify many who might otherwise have been missed in low-prevalence settings. Available data do not support the efficacy of any one behavioral risk screening strategy over others (e.g., face-to-face discussion or interviews, self-administered questionnaires, computer-assisted interviews, provider use of simple open-ended questions) (45,54). Because client HIV risk may not always be identified by provider or client, any client who requests a test should be offered one.

[3] "Risk screening" differs from "risk assessment," which is a part of HIV prevention counseling (see 3.4.3 and 3.4.4).

Box 3. Examples of Strategies to Elicit Client-Reported HIV Risk

- 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 (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 (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 an STD or hepatitis, or has had multiple sex partners)?
  - had unprotected vaginal or anal intercourse with more than one sex partner?
  - been diagnosed or treated for an STD or hepatitis?
  - had a positive TB skin test?
  - had a fever or illness of unknown cause?
  - been told you have an infection related to a weak immune system?"

Box 4. Clients Who Should Receive HIV Prevention Counseling, Testing, and Referral

- All clients with acute occupational or known sexual or needle-sharing exposure to an HIV-infected person. See guidelines (55,56).
- All clients seeking services in settings with a client population having ≥1%* HIV prevalence See 2.5.2.
- All clients seeking services in settings serving client populations at increased behavioral HIV risk (regardless of setting HIV prevalence).
- Individual clients seeking services in settings with <1%** HIV prevalence (see 2.5.3) who
  - specifically request an HIV test;
  - have clinical symptoms suggesting HIV (e.g., fever or illness of unknown origin, positive Mantoux [TB skin] test, opportunistic infection [including TB] without known reason for immune suppression) or suggesting increased risk for HIV (e.g., another STD or bloodborne infection); or
  - self-report HIV risks (Box 3)
- All pregnant women should be tested for HIV regardless of setting prevalence or behavioral risk and should receive HIV prevention counseling and referral on the basis of risk screening (see 2.5.6). See guidelines (30).

* Or higher than other settings in the community.

**Or lower than other settings in the community.

3.0 HIV Counseling

3.1 Background

Since 1985, the recommended HIV counseling model used in the context of HIV testing has evolved from a technical discussion about the HIV test to an interactive counseling approach aimed at reducing clients' personal risk for acquiring or transmitting HIV. The current guidelines continue to recommend providing up-to-date information about HIV prevention and the test whenever HIV testing is done but focus on interactive HIV prevention counseling approaches aimed at personal risk reduction for HIV-infected persons and for uninfected persons at increased HIV risk.

The body of scientific evidence provides convincing support that personalized HIV prevention counseling (i.e., counseling aimed at ways a specific client can reduce his or her own risks) can reduce HIV acquisition among high-risk persons with negative or unknown HIV status (5-26) and transmission from HIV-infected persons (24-26,63-67). In addition, several large trials have found interactive counseling approaches that fully engage the client in the sessions are more effective than purely informational approaches (5,9,18,19). Effective counseling approaches also tend to be directed at clients' personal risks and situations in which those risks occur and at helping clients commit to realistic, concrete steps to reduce those risks (5,7,20). Given limited provider time, a practical question is whether such counseling approaches aimed at personal risk reduction are needed whenever HIV testing is done. Although the body of research strongly supports that HIV prevention counseling can lead to risk reduction among HIV-infected persons (63-67) and uninfected persons with increased HIV risk (5-26), little evidence supports the utility or cost-effectiveness of this type of counseling in uninfected persons with low or no HIV risk.

3.2 Goals

HIV counseling seeks to reduce HIV acquisition and transmission through

- *Information dissemination*: Providing information about HIV transmission and prevention and the meaning of HIV test results (see 3.3)
- *HIV prevention counseling*: Helping clients identify the specific behaviors putting them at risk for acquiring or transmitting HIV and commit to steps to reduce their HIV risks (see 3.4).

3.3 Information Dissemination

All clients who are offered or receive HIV testing should be given information about ways in which HIV is transmitted, the importance of obtaining test results, and the meaning of HIV test results, even if the test is declined.

Whenever an HIV test is offered, the following information could be provided in a culturally, linguistically, gender-, and age-appropriate manner by means of pamphlets, brochures and/or videos, rather than face-to-face.

- Information and benefits about the HIV test
- Risks for HIV transmission and means by which HIV can be prevented
- The importance of obtaining the test results and clear procedures for doing this
- The meaning of the test results in clear understandable language*
- Where to obtain further information or, if applicable, HIV prevention counseling services

*An example of such language would be "A negative test means no HIV was found. But if you were exposed to HIV recently–in the last 1-2 months–this test was not able to pick that up." (See 4.7.2)

In addition, in many settings where HIV testing is offered, the following information is useful:

- Descriptions or demonstrations of how to use condoms correctly
- Information about risk-free and "safer" sex options (68)
- Information about other sexually transmitted and bloodborne diseases
- Descriptions about the effectiveness of using clean needles, syringes, cotton, water, and other drug paraphernalia
- Information about drug treatment

For efficiency, this information could be provided in a pamphlet, brochure, and/or video rather than in a face-to-face encounter with a counselor. This allows face-to-face provider-client interactions to focus on proven-effective prevention counseling approaches (see 3.4). Information should be provided in a manner appropriate for the client's culture, language, gender, and age (see 2.4), and technical discussions (e.g., about antibodies or the window period) should be avoided. Certain informational videos and large-group presentations providing explicit information about how to use condoms correctly have been found effective in reducing new STDs (21-23,69). For additional information, contact CDC's National Prevention Information Network (NPIN) at 1-800-458-5231 or www.cdcnpin.org.

3.4 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 that would reduce his or her chance of acquiring or transmitting HIV.

3.4.1 Definition

"HIV prevention counseling" is a process that is aimed at personal HIV risk reduction—that is, a type of counseling with the explicit goal of helping the client identify and commit to a specific behavior change step that will help prevent acquisition or transmission of HIV. HIV prevention counseling engages the client in the session. It is usually, but not always, done in the context of HIV testing.

In "client-centered[4] HIV prevention counseling" (see 3.4.3), sessions are fairly brief (4,5,70); other counseling models are longer or have more sessions (5-12,14-20,71). Regardless of the model used, inherent in HIV prevention counseling is its focus on the client's personal risks or circumstances and on helping the client set and reach a specific, realistic, risk-reduction goal.

3.4.2 Who Should Receive Prevention Counseling?

Routine HIV prevention counseling is recommended for all clients in settings where the client population is generally at increased behavioral risk for HIV infection, regardless of HIV prevalence in the setting. Counseling should be provided on site.

In these settings, clients with ongoing risk behaviors should be linked to additional HIV prevention services, as appropriate. HIV-infected clients should receive ongoing HIV prevention counseling that is applicable to their personal situation.

Targeted HIV prevention counseling is recommended in settings where HIV prevalence is high (see 2.5.5) and thus most clients are routinely recommended HIV testing. Results of risk screening (see 2.5.6) can be used to determine which clients should be recommended HIV prevention counseling.

[4]The term "client-centered" is used here to mean that the counseling sessions are focused on the client's own unique risk circumstances, risk behaviors, and prevention needs. It should not be confused with the more intensive client-centered approach advocated by psychologist Carl Rogers, although some skills and strategies that involve the client in the prevention counseling process may be similar.

In these settings, clients with ongoing risk behaviors identified on risk screening should be linked to additional HIV prevention services, as appropriate. Counseling should be provided on site whenever possible. If counseling cannot be provided on site, clients should be referred to facilities that can provide HIV prevention counseling.

Targeted HIV prevention counseling is recommended for clients in settings where HIV prevalence is low (see 2.5.5) and for clients in settings where the client population is not at increased behavioral risk for HIV infection. Results of risk screening (see 2.5.6) can be used to determine which clients should be recommended HIV prevention counseling.

In low-prevalence settings where the client population is not at increased HIV risk, if HIV prevention counseling and/or testing does not occur on site, a clear referral system should be established and maintained for clients at increased risk.

In addition to HIV testing, risk screening (see 2.5.6) is recommended for all pregnant women. For women identified as having increased HIV risk, HIV prevention counseling is recommended and ideally should be done at the testing site. However, in settings where such counseling is not available, referral should be offered.

Counseling should not be a barrier to HIV testing. Similarly, a focus on increased HIV testing should not be a barrier to providing effective HIV counseling services for clients determined to be at increased risk for acquiring or transmitting HIV.

Knowledge of HIV status is a critical HIV prevention strategy. Lengthy counseling sessions should not impede a client's decision to have an HIV test. However, because evidence is strong that effective counseling can reduce high-risk behaviors leading to HIV acquisition (5-26), the opportunity to apply high-quality HIV prevention counseling when HIV testing is offered to persons at increased risk for HIV should not be missed.

3.4.3 Prevention Counseling Models

Several models for HIV prevention counseling done with testing have been developed, evaluated in controlled studies, and found efficacious in changing behavior or reducing sexually transmitted infections. These have included individual face-to-face counseling (5,13), large- and small-group counseling with a facilitator (7,18,20,71), and video-based counseling (21). Many of the counseling protocols are available

for use by counselors. (For additional information about interventions, see The Compendium of HIV Prevention Interventions with Evidence of Effectiveness, http://www.cdc.gov/nchstp/hiv_aids/pubs/hivcompendium.pdf).

Client-centered HIV prevention counseling. Since 1993, CDC has recommended one interactive counseling approach, client-centered HIV prevention counseling (3,4). Client-centered HIV prevention counseling involves two face-to-face sessions with a provider or counselor (3-5,70,72,73). First recommended for use in publicly funded HIV clinics in 1993, this model takes advantage of a two-step HIV testing approach in which clients are physically present at a setting for the HIV test (pretest counseling) and then return for HIV test results (posttest counseling). Sessions may require 15 to 20 minutes (including testing and referral) for clients at increased risk for HIV, but could take only a few minutes for clients at lower risk. In the first session, a personalized risk assessment[5] encourages clients to identify, understand, and acknowledge their own behaviors and circumstances that put them at increased risk for acquiring HIV. The session includes an exploration of previous attempts to reduce risk and identification of successes and challenges in previous risk reduction. This in-depth exploration of risk behaviors (risk assessment) allows the counselor to help clients consider ways to reduce their personal risk and commit to a single, explicit step to reduce risk. In the second session, which occurs when HIV test results are provided, the counselor discusses the test results, asks the client to describe the risk-reduction step attempted (acknowledging positive steps made), helps the client identify and commit to additional behavioral steps, and provides appropriate referrals.

Client-centered HIV prevention counseling has been shown to be effective at reducing high-risk sex behaviors and new STDs in a large randomized trial evaluating HIV counseling (5). The model has been found to be feasible to use even in busy publicly funded clinics; acceptable to clients, counselors, and health-care providers (72); and cost-effective at preventing STDs in persons with sexual risk behaviors (74-76). The approach appears to be especially effective among adolescents and persons with ongoing sexual risk behaviors (e.g., newly diagnosed STDs) (5). Although the benefits of this model in reducing high-risk drug behaviors are as yet unknown, similar counseling approaches engaging clients in personal exploration of risks and setting concrete risk-reduction goals appear to be effective in reducing risky drug use behaviors (24-26,77).

[5]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(s) for HIV. Risk assessment is not synonymous with risk screening, which helps determine which individual clients in a population require HIV prevention services.

Observational studies and reviews of programs suggest that many counselors are still unfamiliar with the specific goals of the client-centered HIV prevention counseling model (70,73,78). The term "client-centered" is sometimes misinterpreted to mean "face-to-face," and thus in many HIV test sites, the provider delivers a face-to-face informational message in response to a check-list risk assessment. In this document, this type of "counseling" is considered to be "information dissemination" and "data collection." It tends not to encourage client participation or discussion of personal risk and seldom focuses on personal goal setting. The term "client-centered" is also sometimes misinterpreted to mean the counselor should avoid directing the session. Although attentive listening and respect for clients' concerns are important elements of good counseling, the primary goal of client-centered HIV prevention counseling is risk reduction. In client-centered counseling, risk reduction is brought about through an in-depth, personalized risk assessment and negotiation of a risk-reduction step that is concrete, acceptable, and achievable. HIV prevention counseling will usually require provider training and support and ongoing quality assurance to achieve optimal benefit (see 3.4.8). Providers can contact their state health department HIV/AIDS program office for information on local training opportunities or NPIN (www.cdcnpin.org; 1-800-458-5231) for training materials.

3.4.4 Elements of HIV Prevention Counseling

Regardless of the specific HIV prevention counseling model used, some counseling components have been repeatedly used in effective interventions and are recognized by many experts as critical in counseling success (Expert Panel Meeting, Atlanta, Georgia, February 1999).

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 unrelated to the client's situation or allowing the session to be distracted by the client's additional problems unrelated to HIV. Counseling techniques such as use of open-ended questions (Box 5) and role-play scenarios, attentive listening, and maintaining a nonjudgmental and supportive approach can encourage the client to remain focused on personal HIV risk reduction.

Include an in-depth, personalized risk assessment. This risk assessment allows the counselor and client to identify, acknowledge, and understand the specific details of the client's own HIV risks and the context in which risks occur (19,79,80). Keeping the risk assessment personal, as opposed to global, will help the client identify concrete and 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 may be important to explore include

intoxicant or substance abuse preceding sexual activity, underestimation of personal risk, perception that precautionary changes are not an accepted peer norm, limited perceived self-efficacy for success in change efforts, high reinforcement value associated with frequent unsafe practices (e.g., a negative HIV test result in the face of clear HIV risk behaviors), and a perception that vulnerability is associated with "luck" or "fate" (79-82).

Clarify important misconceptions about HIV transmission risks. The counselor should address any misconceptions about HIV transmission that arise in the client's discussion of personal risk. For example, as applicable, the counselor can clarify for the client that oral sex is not a risk-free behavior or that HIV can be transmitted through the "cooker, cotton, or water" used by several persons sharing drugs and discuss lower-risk alternatives (68). For HIV-infected clients, the counselor should discuss HIV transmission risks associated with specific sexual or drug-use activities, even those in which the client may not currently be engaged. However, for most clients, the counselor should focus on reducing clients' current risks and avoid lengthy, global discussion about HIV transmission modes and the meaning of the HIV test results, as this information can be more efficiently provided in other ways (see 3.3).

Negotiate one concrete, achievable behavior change step that will reduce HIV risk. Although the optimal goal may be to entirely eliminate HIV risk behaviors, even 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 the client focus on reducing the most important risk that he or she is willing to commit to changing. The step need not be entirely personal. For many people, knowledge of a partner's recent HIV status (and thus talking with the partner about getting an HIV test) may be more critical than personal behavior changes. In any case, the step should be explicit and achievable rather than general (Box 6). Identifying the barriers and facilitators to achieving a step, through interactive discussion, role-play modeling, recognizing positive social supports, or other methods will enhance the likelihood of success (83). Writing down the agreed-upon goal may be useful. *For clients with ongoing risk behaviors, referral to additional prevention services is encouraged.*

Acknowledge and provide support for positive steps that have already been 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 client's beliefs that he or she can successfully perform further HIV risk-reduction steps. For some clients, agreeing to have an HIV test is an important step in reducing risk (5,70).

Seek flexibility in the prevention approach and counseling process. Counselors should avoid a "one size fits all" prevention message. Specific behaviors that are safe for one person may be risky for another (84). For example, unprotected vaginal intercourse may 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., counseling adolescents may require more time than adults).

Provide skills-building exercises. Depending on client needs, the counselor can model or ask the client to demonstrate proper use of male latex condoms, by using different brands on a penis model; proper use of female condoms, by using female anatomy pictures; cleaning injection equipment if clean syringes are unavailable; communicating safer sex commitments to new sex partners; or other problem-solving strategies (79,85-87).

Be clear when providing test results. Test results should be provided at the beginning of the posttest session. Counselors should never ask clients to "guess" their test results. Technical information about the test can be provided in a brochure or other means so that the session can focus on personal HIV risk reduction. In-depth, technical discussions of the "window period" (see 3.3, the meaning of the test results) should be avoided, as these may confuse clients and diffuse the importance of the HIV prevention message. Counselors should be clear that negative test results do not mean no HIV risk and should work with the client to reconsider ongoing HIV risk behaviors and the importance of taking steps to reduce those risks. Clients with ongoing risk behaviors should not be given a false sense of the safety of those behaviors (i.e., avoid statements such as "Whatever you were doing seems to be safe" or "Continue to do whatever you are doing now").

Box 5. Examples of Directed vs. Open-Ended Questions

Directed questions that may not facilitate client-centered HIV prevention counseling:	Open-ended questions that facilitate client-centered HIV prevention counseling:
Have you ever injected drugs?	What are you doing that you think many be putting you at risk for HIV infection?
Have you ever had sex with a man (bisexual man)?	What are the riskiest things that you are doing?
	If you are HIV-infected, how do you think you may have become infected?
	When was the last time that 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 drugs or alcohol influence your HIV risk?
Do you (always) use condoms when you have sex?	How often do you use condoms when you have sex?
Can you always 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?
Can you always use clean syringe and works when you inject?	How risky are your sex/needle-sharing partners? For example, have they been recently tested for HIV?
	Tell me about specific situations when you have reduced your HIV risk. What was going on that made that possible?

Box 6. Examples of Global vs. Specific Risk-Reduction Steps for HIV Prevention Counseling

In HIV prevention counseling, counselors work with clients to commit to a specific risk-reduction step relevant to reducing the clients' own risk. The risk-reduction step should be a small, explicit, and achievable goal, as opposed to a global goal.

Global risk-reduction steps	Specific risk-reduction steps
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 nightstand 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 STDs.
Stop injecting drugs.	Obtain a clean syringe, clean works tomorrow so I have them before I use next time.

In addition to the above counseling components considered necessary in conducting high-quality counseling, many experts (Expert Panel, Atlanta, Georgia, February 1999) suggested that the following

elements be adopted:

Return 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 have tended to use the same counselor for all sessions. (See The Compendium of HIV Prevention Interventions with Evidence of Effectiveness, http://www.cdc.gov/nchstp/hiv_aids/pubs/hivcompendium.pdf)

Use a written protocol (a counselor's guide to conducting an effective session) (73,88).

Ensure ongoing support of supervisors and administrators. Supervisory support is essential for effective prevention programs. Training in HIV counseling approaches that focus on personal risk reduction is recommended for anyone supervising counselors. Staff appraisals should prioritize completion of critical counseling components over simply professionalism and completion of paperwork.

Avoid using counseling sessions as a time for data collection. If required, paperwork should be completed at the end of the counseling session or done by staff who are not counseling. Check-list risk assessments driven by data collection forms are a detriment to effective counseling because they can encourage even skilled counselors to use directed questions, limit eye contact, and miss critical verbal and nonverbal cues. The relevance of any routinely collected data should be periodically assessed.

Avoid providing extraneous excessive information. An emphasis on providing information may prompt counselors to miss critical HIV prevention opportunities and clients to lose interest. Discussion about theoretical HIV risks (e.g., sex with a person who has hemophilia, needle exposures through tattoos) tends to shift the focus of the counseling away from the client's actual HIV risk situations to "comfortable" but irrelevant topics.

3.4.5 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 components (see 3.4.4) (5,72). Advanced degrees or extensive experience are not necessary for effective HIV prevention counseling (72). Training in counseling is available (see 3.4.3). In situations where primary health-care providers (e.g., physicians) may not be able to provide prevention counseling, auxiliary health professionals trained in HIV prevention counseling models may be more practical providers of this service.

Although peer counseling has been successful in certain situations (20), research does not support a clear risk-reduction need or benefit to match clients with counselors on the basis of the same or similar backgrounds, gender, ethnicity, age, or peer group for intervention efficacy (89-91). However, the following skills and counselor characteristics have been identified by an expert panel (Atlanta, Georgia, February 1999) as important for effective HIV prevention counseling:

- 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 directed 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
- Ability to maintain client confidentiality
- Interest in learning new counseling and skills-building techniques
- Being informed about specific HIV transmission risks (68)
- Comfort in discussing specific HIV risk activities (i.e., explicit sex or drug activities)
- Ability to remain focused on risk-reduction goals
- Being supportive of routine, periodic quality assurance measures (see 7.1)

3.4.6 Additional Counseling Considerations in Special Situations

HIV prevention counseling in the following situations entails special considerations.

Health-care workers following an occupational exposure. Although HIV infection following occupational exposure occurs infrequently, health-care workers should be counseled after an occupational exposure to use measures to prevent transmission during the follow-up period (see guidelines that address acute occupational exposure) (55). HIV-exposed health-care workers should be advised to abstain from sex or use condoms and to avoid pregnancy; not to donate blood, plasma, organs, tissue, or semen; and, if the exposed health-care worker is breastfeeding, to consider discontinuation of breastfeeding, especially following high-risk exposures (55). The worker should also be told about the rationale for postexposure prophylaxis, the risk for occupationally acquired HIV infection due to 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.

Persons with a single, recent nonoccupational HIV exposure. After a reported sexual, injecting drug use, or other nonoccupational exposure to HIV (see guidelines that address acute nonoccupational exposure) (56), health-care providers should provide their clients with referral to promptly initiate evaluation, counseling, and follow-up services. Although early postexposure prophylaxis may reduce a

person's likelihood of becoming infected with HIV, the efficacy of early treatment in preventing new infection after acute nonoccupational HIV exposure is still unclear.

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 (one person HIV-infected and one uninfected) should receive counseling aimed at preventing HIV transmission from the infected to the uninfected partner, including explicit discussion and clarification of any misconceptions about HIV transmission risks associated with specific sexual and/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 (33,92-94).

Little evidence exists to conclusively support or refute whether simultaneous infection with two or more strains of HIV is likely to occur or, if it does, whether it is associated with more aggressive or resistant disease (95). Experts remain divided on the value of recommending consistent condom use to prevent HIV sequelae for mutually monogamous, HIV-infected partners.

Persons with newly identified HIV infection. For persons who have recently learned that they are HIV-infected, the next 3 to 6 months are important for them to access medical and other support services, which can help them obtain treatment for their infection and establish and maintain behavior changes that reduce the likelihood of their transmitting the virus to others. HIV prevention counseling should receive the same high priority as referral for medical care and counseling for sex and needle-sharing partners. As part of HIV prevention counseling, counselors should explicitly discuss and clarify any misconceptions about the HIV transmission risk associated with specific sexual and/or needle-sharing activities. For sexually active clients who are not in mutually monogamous partnerships, counselors 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, cytomegalovirus). A follow-up appointment after 3 to 6 months is recommended by some experts (96) to assess whether clients were able to initiate medical care, minimize transmission risks to uninfected partners, and access other needed services such as partner counseling and referral. See guidance on partner counseling and referral (33) and prevention case management (34).

Persons seeking repeat HIV testing. In addition to brief prevention counseling sessions, ongoing HIV prevention counseling aimed at personal risk reduction may be useful for persons seeking repeated HIV testing who have continued HIV risk. Because repeated testing in the absence of other behavior changes is an ineffective personal risk-reduction strategy, clients should be encouraged to explore alternative prevention strategies and helped to identify and commit to additional risk-reduction steps. Clients with ongoing risk behaviors may benefit from referral to other HIV prevention services, as they may be experiencing reinforcement of their current risky behavior through repeated negative HIV test results or viewing an HIV test as protective (97). See also 4.9.3 and guidance on prevention case management (34).

Persons with indeterminate HIV test results. Until follow-up test results are available, persons with an indeterminate test result should be provided information about the meaning of the test results (see 4.7.3). However, HIV prevention counseling should be approached in the same manner as for a person with newly identified HIV infection (see above). 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 at least 1 month apart are not HIV-infected and can be counseled in the same way as clients with negative test results, unless recent HIV exposure is suspected (see 4.7.3).

Persons who use drugs. Persons who inject or use illicit drugs in other ways may be at increased risk for acquiring HIV through unprotected sex with an HIV-infected partner (98-100). For injection drug users, intervention studies suggest that personalized, interactive prevention counseling models using goal-setting strategies may be effective in reducing both injecting drug and sexual risk behaviors (24-26,77). In addition, mounting evidence supports the efficacy of community strategies such as methadone maintenance programs, outreach programs, and syringe exchange in reducing new HIV infections among injection drug users (101-105). Experts advocate recommending such strategies, in addition to individual HIV prevention counseling, to persons who inject drugs.

3.4.7 Addressing Barriers to HIV Prevention Counseling

Several factors may prevent provision of high-quality HIV prevention counseling for clients at increased HIV risk, such as unavailability of trained prevention counselors on site at the HIV test facility, client reluctance, and low rates of client return for test results. Recommended strategies for addressing these common barriers are to provide counseling services on site rather than referring clients for counseling services, enhance client acceptance of counseling through examination and improvement of services, and consider the use of alternate methods of providing counseling.

- **Provide On-Site Counseling**

  Cost, lack, or turnover of trained staff and space constraints are barriers to providing HIV prevention counseling services (106). However, given the proven efficacy of prevention counseling models, in settings where HIV prevalence or frequency of HIV risk behaviors among clients is higher (e.g., some primary care or emergency room settings), the ability to provide such counseling on site is a high priority. Efforts should be made to address and remove barriers to providing HIV prevention counseling on site. Health educators or other auxiliary staff trained to discuss preventive services 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 referral systems should be arranged 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 Section 5). Until prevention counseling can be provided on site, an alternative such as home sample collection, in which test results and counseling are available by telephone, may be considered.

- **Enhance Client Acceptance of HIV Prevention Counseling**

  Clients who agree to HIV testing and who decline HIV counseling often report they lack time or already know about HIV transmission modes. However, counseling experts assert that a major reason that counseling is refused is that clients do not perceive the service to be personally useful. Most clients agreeing to an HIV test are concerned about a specific risk and are willing to explore their personal risks. In settings where many clients decline counseling, the type of counseling being provided, the manner in which counseling is recommended, and the setting should be examined. Counseling may provide information only and may not address clients' personal risk. The setting may inhibit honest and open discussion of risk. Counselors may not offer services that are linguistically, culturally, gender-, or age-appropriate. Counseling skills (e.g., attentive listening, use of open-ended questions) that allow clients to participate may have been overlooked. Even when a client at increased risk refuses counseling, use of one or two open-ended questions that urge the client to examine his or her personal situation may begin the process of personal exploration of risk (e.g, "What were your concerns that led you to decide to get tested today?").

- **Consider the Use of Alternative Methods to Provide HIV Prevention Counseling**

  Proven-effective HIV prevention counseling models thus far have used face-to-face (individual or group) encounters between counselor and client and have involved at least two brief sessions; face-to-face prevention counseling is still preferred for clients at increased HIV risk. At this time, most HIV test sites use an enzyme immunoassay (EIA) and a confirmatory test algorithm that requires several days for final test results. The return visit for the 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), clients do not return for their results (107-110). In such settings, counseling programs may elect to adopt strategies that increase clients' receipt of their test results, and counseling strategies may need to be adapted (111).

Telephone counseling. Limited studies among lower-risk STD clinic clients indicate that substantially more clients learn their HIV infection status when negative test results are provided by telephone rather than in person (13,112). 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 number of new HIV infections has not been demonstrated. In addition, at least one study suggests that telephone notification of positive results is associated with delay in linkage to care (113). However, not learning positive test results at all is a guaranteed "delay" in linkage to care. Many experts recommend that provision of HIV test results and prevention counseling by telephone be limited to clients whose results are negative (Expert Panel Meeting, Atlanta, Georgia, February 1999). In addition, given the known risk-reduction benefits of face-to-face counseling and lack of efficacy data on telephone counseling, these experts recommend limiting telephone counseling to clients without known ongoing HIV risk behaviors (e.g., unprotected sex or needle-sharing with an HIV-infected [or status unknown] partner). See also 4.8.1.

Single-session prevention counseling with rapid testing. Rapid tests, which are increasingly being adopted, allow clients to receive their HIV test results on the same day the test is done (see 4.6 and 4.8.2). 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. Some single-session counseling protocols have been successfully implemented in busy clinics and are well accepted by most clients; however, how well a single counseling session reduces risky behaviors or number of new HIV infections is unknown. For one counseling protocol developed for use with a rapid test and currently under study, see www.cdc.gov/hiv/projects/respect-2 . For clients with identified risk behaviors, referral or rescheduling for return for ongoing counseling should be considered.

3.4.8 Ensuring High-Quality HIV Prevention Counseling

Routine, periodic assessments should be conducted by all providers of counseling, testing, and referral services to ensure that the counseling being conducted includes the recommended, essential counseling elements.

Experts concur that routine quality assurance is essential for high-quality HIV prevention counseling and

should always be done regardless of who offers the counseling or where the counseling occurs (Expert Panel Meeting, Atlanta, Georgia, February 1999). High-quality counseling requires that supervisors are aware of HIV prevention counseling goals and necessary counselor skills. Supervisor and administrator support of HIV counseling models focused on personal risk reduction (distinct from information dissemination) is critical to provision of effective services.

Quality assurance for counseling optimally contains the following elements:

- **Training and Continuing Education.** Basic training in the use of one or more of the interactive HIV prevention counseling models aimed at personal risk reduction is recommended for counselors and supervisors. In addition, counselors may benefit from formal training about transmission and prevention of HIV and other sexually transmitted and bloodborne diseases, the natural history of HIV, recognition and treatment of opportunistic infections, new therapeutic agents used to treat HIV and AIDS, partner counseling and referral services, prevention case management, and other HIV prevention services available in their community (e.g., regarding substance abuse assessment, cultural competence, adolescent issues, domestic abuse, health concerns for gay or lesbian clients). Additional training in specific counseling skills is also warranted. For example, counselors conducting group sessions can benefit from training in facilitating groups. For training opportunities, providers or supervisors can contact their state HIV office.

- **Supervisor Observation and Immediate Feedback to Counselors**. Direct observation of counseling sessions can help ensure that counseling objectives are being met (72). This may be done periodically by a supervisor (after first obtaining client consent). Sessions may also be audio-taped (after first obtaining 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 rather than punitive. Supervisors should support positive elements of the prevention counseling session and provide specific, constructive comments about content areas that could be improved. Observation and feedback should be conducted on a regular basis as part of “routine” counseling. Staff discomfort with observation typically wanes over time; many counselors find the sessions useful in enhancing skills. When observation is presented as a matter of routine course, 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 of performing HIV counseling services, monthly for the second 6 months, and quarterly for counselors with more than one year of experience.

After observation, supervisors should provide feedback to counselors quickly, preferably during the same week. Templates of observation and feedback forms that have been used in research studies of client-centered HIV prevention counseling can be obtained at www.cdc.gov/nchstp/hiv_aids/projects/RESPECT and www.cdc.gov/hiv/projects/respect-2.

- **Periodic Evaluation of Physical Space, Client Flow, and Time Issues.** Counseling sessions should be done in a private space where discussion cannot be overheard. Optimally, clients should not wait for long periods between testing and counseling. Any waiting times could be used for information dissemination through videos or other means. Periodic time-flow analyses or client surveys can be used to evaluate adequacy of space and client flow and whether waiting periods are excessive.

- **Periodic Counselor and/or Client Satisfaction Evaluations**. Evaluations of client satisfaction can ensure that services meet client needs. In addition, these evaluations can provide important feedback to counselors who otherwise may not see the benefits of what they do. Evaluations can be brief. However, surveys should optimally address whether specific counseling goals were met, for example, 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?"). Methods that allow linking of client and counselor descriptions of a particular session may be useful. Conducting such evaluations only occasionally (e.g., for one or two weeks once or twice a year) decreases the programmatic burden and is probably sufficient to identify problems. Program evaluation of overall counseling, testing, and referral services is described in Section 7.0.

- **Case Conferences.** Regularly scheduled meetings of counselors allow supervisors to understand counselors' skills and areas for improvement and can help counselors learn techniques from their colleagues. Case conferences are an opportunity for counselors to bring up questions being asked by clients so that providers are better aware of the issues facing those at increased risk or those HIV-infected in their facility. Some programs report case conferences help with counselor fatigue and "burn out" by providing a positive outlet for dealing with difficult situations. Discussion may focus on a full session with a hard-to-address client or only on simple components (e.g., developing an acceptable and practical risk-reduction plan with a client who denies the magnitude of his or her HIV risks). Frequency of case conferences should be balanced with client volume, with efforts made to meet, at a minimum, on a monthly basis.

4.0 HIV Testing

4.1 Background

During the past decade, the demonstrated medical benefits of antiretroviral therapy have underscored the importance of expanding voluntary HIV testing services to facilitate early diagnosis and treatment of HIV-infected persons. Early knowledge of HIV infection can also result in public health benefits by decreasing risk behaviors that could transmit HIV to uninfected persons (152). Uninfected persons may benefit from HIV testing if knowing their HIV status assists them in modifying or reducing risk behavior. In particular, knowledge of both one's own HIV status and one's partner's HIV status may be the most critically important factor for preventing acquisition of HIV (114).

The past decade has seen a marked expansion in the array of HIV test technologies. In addition to venipuncture, specimens can be collected for HIV testing through U.S. Food and Drug Administration (FDA)-approved oral fluid, urine, and finger-stick methods (31). These methods can help simplify testing procedures and may increase the proportion of clients at increased risk who accept HIV testing. The availability of rapid HIV testing permits test results to be provided to clients at the time of testing (see 4.8.2) and is particularly useful in settings where clients do not routinely return for their HIV test results and follow-up is difficult (115). HIV testing may also be conducted using commercially available, FDA-approved home sample collection devices, for which HIV test results are available to clients by telephone after a blood specimen collected by the client is sent to a laboratory for testing (43)(see 4.6, Table).

The decision to adopt a particular test technology in a clinic or nonclinic setting should be based on several factors, including accuracy of the test, client preferences and acceptability, likelihood of client receiving test results, cost and mechanism for provider reimbursement, ease of sample collection, complexity of laboratory services required for the test, availability of trained personnel, and FDA licensure of the test.

4.2 Goals

HIV testing seeks to

- Ensure early knowledge of HIV infection status among HIV-infected persons
- Ensure knowledge of HIV infection status among persons at increased risk for HIV infection

4.3 Who Should Offer Testing?

Health-care providers in a wide variety of settings should offer voluntary HIV testing with informed consent to clients at increased risk for HIV infection.

Given the medical and public health benefits of early HIV diagnosis (116), health-care providers in a wide variety of settings (Box 1) should offer voluntary HIV testing services to clients at risk for HIV infection, either on site or through referral to other providers.

The decision to offer HIV testing is facilitated when the provider believes that testing is beneficial to clients for early diagnosis and prevention purposes (106). The decision is also influenced by constraints on finances, time, and other resources. Providers who serve clients at increased risk for HIV infection but who have limited capacity for offering counseling and testing services should maintain clear and appropriate methods of referral to services elsewhere (see section 5). To optimize client referral, providers who do offer HIV counseling and testing services should establish collaborative relationships with providers serving populations at increased risk for HIV who may not offer such services.

4.4 Who Should Be Tested?

Routine voluntary HIV testing is recommended for all clients in settings where the client population is generally at increased behavioral risk for HIV infection, regardless of setting HIV prevalence. Routine voluntary HIV testing is recommended for most clients in settings where HIV prevalence is high (e.g., ≥1%, see 2.5). Routine voluntary HIV testing is also recommended for all pregnant women because treatment is available for prevention of perinatal transmission (30).

Targeted voluntary HIV testing is recommended for clients in settings where both HIV prevalence is low (see 2.5.5) and where the client population is not at increased behavioral risk for HIV infection. Results of risk screening (2.5.6) can be used to determine which clients should be recommended HIV testing.

The decision to routinely recommend voluntary HIV testing to most or all clients within a setting or to target HIV testing to selected clients at increased risk for HIV infection on the basis of risk screening

should be based on setting HIV prevalence, behavioral HIV risk of the client population, and the availability of potentially beneficial treatments to prevent HIV infection (e.g., prevention of perinatal HIV transmission)(30). See 2.5.

Numerous studies have shown that targeting testing on the basis of self-reported risk factors is not fully effective at identifying HIV-infected clients in settings with high HIV prevalence and settings serving client populations at increased behavioral risk for HIV infection (45-53). Targeted testing may also fail to identify all HIV-infected women who could benefit from treatment to prevent perinatal HIV transmission (117-121).

Routine voluntary testing should thus be recommended to most or all clients in these settings. Targeted testing, however, may be more feasible and cost-effective for identifying small numbers of HIV-infected clients in low-prevalence populations where most clients have minimal risk (54). Regardless of reported or suspected risk in the settings, any client who requests HIV testing should be offered a test to provide knowledge of HIV status.

4.5 Addressing Barriers to HIV Testing

HIV testing should be made as convenient as possible to facilitate client knowledge of HIV infection status.

Reasonable effort should be made to remove or lower barriers to HIV testing services by addressing accessibility and availability; responsiveness to client and community needs and priorities; convenience to client; client preferences; availability of anonymous HIV testing in addition to confidential HIV testing; cultural, linguistic, gender, and age appropriateness; and confidentiality, safety, and privacy (see 2.4).

Providers can facilitate client acceptance of HIV testing by providing an environment that is supportive of anonymous as well as confidential testing and that allows clients to conveniently obtain HIV prevention counseling and testing, HIV test results, and referral to medical and other supportive services.

HIV testing is more likely to be accepted when clients perceive their own HIV risk and acknowledge behaviors placing them at increased risk for HIV (122); voluntary testing is routinely offered to clients rather than relying on client request (106,123); protections for client confidentiality are in place (106,124); anonymous testing is made available (106,125); alternate HIV test technologies are offered to clients (32);

providers recommend testing as part of appropriate medical care (126,127); and both providers (128) and clients (106) perceive HIV counseling and testing to be beneficial.

Acceptance of HIV testing has been shown to be lower when clients have previously been tested and when clients have fears about coping with their test results (95,106).

4.6 Laboratory Characteristics 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 for diagnostic testing.

A variety of HIV test technologies have been approved by the FDA for diagnostic use in the United States. These tests enable testing of different fluids: whole blood, serum, plasma, oral fluid, and urine (Table).

Available FDA-approved HIV test technologies

- Enable specimen collection procedures that are less invasive than venipuncture, thus permitting expansion of HIV testing services into nontraditional settings, such as outreach and community settings (with collection of urine and oral fluids, collection of specimens by finger stick) (31)
- Enable provision of HIV test results during a single clinic visit at the time of testing (with rapid HIV tests) (115)
- Increase the convenience of HIV testing without requiring a clinic visit for testing or receipt of test results (with home sample collection tests) (43).

Home testing vs. home sample collection. Home-use HIV test kits, in which a consumer purchases a test kit, collects a sample in private, and interprets his or her own HIV test results in a few minutes, have not been approved by the FDA. These tests must be distinguished from FDA-approved home sample collection kits, in which a consumer purchases a test kit, collects a sample in private, sends the sample to a laboratory for testing, and telephones for his or her HIV test result, counseling, and referral. The Federal Trade Commission has recently warned that some home-use HIV test kits, many of which are

available on the Internet and in the "gray" market, supply inaccurate results and are not FDA-approved (129).

HIV-2 and HIV-1 group O infections. Although most HIV infections in the United States are of HIV-1 group B subtype, currently approved EIA tests can accurately identify infections with nearly all non-B strains and many infections with group O HIV strains (130). Infections with HIV type 2 (HIV-2) and HIV-1 group O remain very rare in the United States (131,132), and routine screening for these strains is not generally recommended as part of diagnostic testing except in areas where many such infections have been identified. Routine screening for HIV-2 may be appropriate in some populations where potential risk of HIV-2 infection is higher (133). The FDA has recommended routine screening for antibody to HIV-2 since June 1992 (in addition to HIV-1) for all donations made to blood centers (133). Clients who have clinical, epidemiologic, or laboratory history that suggests HIV infection and negative, indeterminate, or inconclusive HIV-1 screening tests should receive further diagnostic testing to rule out HIV infection (130), potentially including testing for HIV-1 non-B (130) and HIV-2 strains (133).

Other test uses. Test technologies may receive approval from the FDA for purposes other than diagnostic use. For example, FDA-approved viral load and HIV-1 p24 antigen assays are not intended for routine diagnostic use but may be used in clinical management of HIV-infected persons in conjunction with clinical signs and symptoms and other laboratory markers of disease progression. The HIV-1 p24 antigen assays have been approved for routine screening in blood and plasma centers and as an aid in diagnosis or prognosis monitoring; however, routine use of HIV-1 p24 assays for diagnosis of HIV infection in other settings has been discouraged because of the relatively low sensitivity and specificity of the assay when used alone (134).

Table. Performance Attributes and Potential Applications of FDA-Approved HIV Test Technologies

	Serum-based EIA	**Rapid EIA or other rapid method**	**Home sample collection**[a]	**Oral fluid**	**Urine-based assay**
Specimen	Serum or plasma	Serum, plasma, whole blood	Dried blood spot	Oral mucosal transudate	Urine
Mode of collection	Phlebotomy	Phlebotomy, finger stick	Finger stick	Oral fluid collection device	Urine cup
CLIA test categorization	High complexity	Moderate complexity[b]	Collection–not CLIA applicable Testing–high complexity	Collection–not CLIA applicable Testing–high complexity	Collection–not CLIA applicable Testing–high complexity
FDA-approved: Screening test Confirmatory test	 EIA Western blot/IFA	 Rapid EIA Western blot/IFA[c]	 EIA Western blot/IFA	 EIA Western blot	 Urine EIA Urine Western blot
Licensure approval[d]	HIV 1/2[e]	HIV-1	HIV-1	HIV-1	HIV-1

1085 1086	Provision of results	HIV(-): Test result at return visit (typically a few days to 1-2 weeks) HIV(+): Confirmed result at return visit	HIV(-): Test result at time of testing (typically 30-60 minutes) HIV(+): Preliminary positive test result at time of testing;[f] confirmed result at return visit	HIV(-): Test result when client telephones (typically 3-7 days) HIV(+): Confirmed result by telephone	HIV(-): Test result at return visit (typically 1-2 weeks) HIV(+): Confirmed result at return visit	HIV(-): Test result at return visit (typically 1-2 weeks) HIV(+): Test result at return visit; requires further confirmation on blood sample because of lower specificity of urine Western blot in comparison with serum-based Western blot/IFA

1087	Advantages	• High sensitivity • Rare false-positives • High-volume processing • Utility for testing for other conditions (e.g., STDs)	• Convenience • Increased receipt of test results • Use in urgent medical circumstances (e.g., postexposure prophylaxis)	• Convenience • Anonymity • Privacy • Conservation of public resources	• Noninvasiveness • Nontechnical collection • No venipuncture • Decreased infectious hazard • Utility in nonclinical settings	• Noninvasiveness • Nontechnical collection • No venipuncture • Decreased infectious hazard • Utility in nonclinical settings • Utility for testing for other conditions (e.g., STDs)
1088	Potential settings	• Blood screening •Wide variety of health-care settings and client populations	• Clinics with low return rates • Perinatal/labor and delivery for prophylaxis • Health-care settings for decisions about postexposure prophylaxis • Rapid EIA requires on- site laboratory testing capability; other rapid tests may not	• Outreach settings • Community-based settings • Syringe exchange programs • Rural areas • Clinics with low-risk populations • Home	• Outreach settings • Community-based settings • Syringe exchange programs • Drug treatment centers	• Outreach settings • Community-based settings • Syringe exchange programs • Drug treatment centers

1089 [a] Home sample collection should be distinguished from home use testing. While home sample collection has been approved by the FDA, no home HIV tests have
1090 received approval or licensing by the FDA (31).

1091 [b] Currently, there is only one licensed rapid test (SUDS) that is classified as a moderate complexity test under CLIA. Rapid tests that are FDA-licensed in the future
1092 may receive different CLIA classifications (e.g., low complexity) depending on the expertise required to perform the test correctly and consistently. All other HIV

tests are classified as high complexity.

[c] As of June 2000, only one rapid test (SUDS) has been licensed for use; however, in the future, a rapid test may be able to be confirmed with a second rapid test to provide high sensitivity, specificity, and predictive value comparable to EIA/Western blot and an immediate test result (135).

[d] While current tests detect most HIV-1 group O infections, few tests detect all HIV-1 group O infections.

[e] All serum EIAs in use for diagnostic screening detect HIV-1, but not all detect HIV-2. EIAs detecting HIV-1 and -2 are required only for blood screening and are recommended only in clinical circumstances where HIV-2 infection is likely.

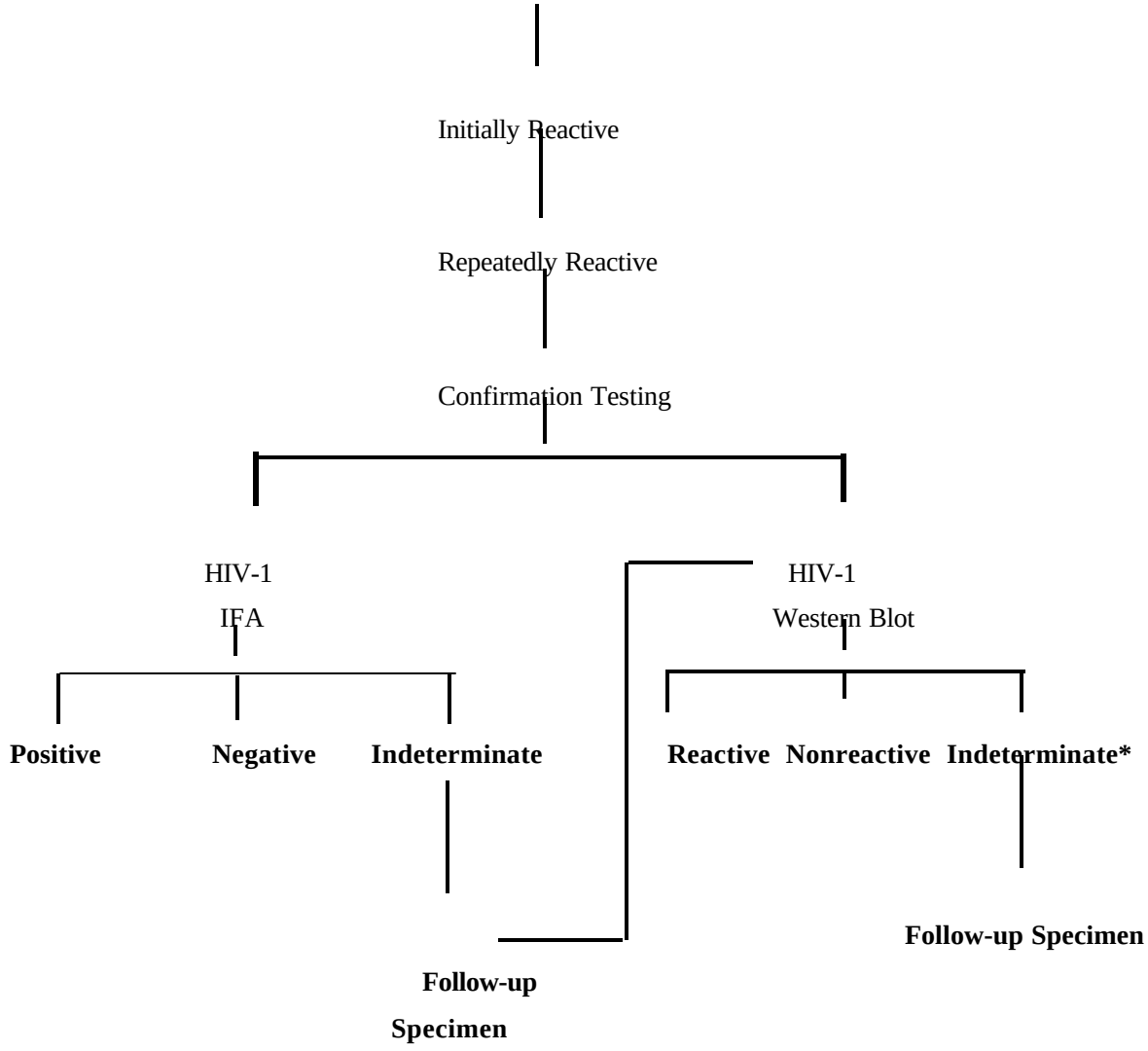
[f] See language for provision of "preliminary" positive test results from a single rapid test (115).

FDA, U.S. Food and Drug Administration; EIA, enzyme immunoassay; CLIA, Clinical Laboratory Improvement Amendments; IFA, immunofluorescence assay.

4.7 Interpreting HIV Test Results

Standard algorithm (Figure 4). HIV-1 testing consists of initial screening with an FDA-licensed EIA to detect antibodies to HIV. Specimens with a nonreactive result from the initial EIA are considered HIV-negative unless recent exposure has been documented (see 4.7.2). 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 FDA-licensed supplemental test such as a Western blot or, less commonly, an immunofluorescence assay (IFA). Only specimens that are repeatedly reactive by EIA and IFA-positive or Western blot-reactive are considered HIV-positive and indicative of HIV infection. Repeatedly EIA-reactive specimens occasionally provide an indeterminate Western blot result, which may represent either an incomplete antibody response to HIV in sera from infected persons or nonspecific reactions in sera from uninfected persons (136). Although IFA can be used to resolve an EIA-reactive Western blot indeterminate sample, this assay is not widely available. It is recommended that a second specimen from persons with indeterminate Western blot results be collected at least 1 month later and retested (see 4.7.3).

Figure 4. The HIV-1 testing algorithm. In settings or for clients where HIV-2 is of concern, persons with a negative or indeterminate confirmatory test could be screened for HIV-2 using the same algorithm. Modified from the figure presented by the Association of State and Territorial Public Health Directors, Eighth Annual Conference on Human Retrovirus Testing, 1993.



*An IFA can be used to resolve an indeterminate Western blot result; however, since IFAs are not widely available, a follow-up specimen should be collected at least one month after the initial indeterminate Western blot

1142 and retested.

Modified testing algorithms are anticipated with the FDA approval of additional rapid HIV tests. If two or more sensitive and specific rapid HIV tests became available, one positive rapid test could be confirmed with a second different rapid test. This combination has been demonstrated to provide positive predictive value comparable to the EIA/Western blot or IFA algorithm above (135). However, at the time of publication of these guidelines, no such algorithms have been adequately assessed for use in the United States.

4.7.1 Positive HIV Test Results

An HIV test should be considered positive only after both screening and confirmatory tests are positive. A confirmed positive test result indicates that a person has been infected with HIV. False-positive results under these testing circumstances are extremely 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 also be detected by current HIV tests and may result in a false-positive test. Persons participating in vaccine trials who desire HIV testing should identify themselves as being in such trials and should be referred to study investigators at their trial site for HIV testing services.

4.7.2 Negative HIV Test Results

A negative test result usually indicates that a person is not infected. With earlier tests using whole virus-lysate EIAs, the estimated median time between exposure and HIV antibody seroconversion was 2.4 months (137). With newer, more sensitive HIV antibody tests, detection of HIV antibody is approximately 20 days earlier than with whole virus lysate EIA (138). Consequently, most infected persons will develop detectable HIV antibody by 3 months after exposure.

Because is it likely that a negative test truly indicates absence of infection (high predictive value negative), a negative test should seldom be repeated in clients in settings with low HIV prevalence. For clients with a recent history of known or possible exposure to HIV who are tested before they develop detectable antibodies, the possibility of HIV infection cannot be definitively excluded without follow-up HIV testing (35)(see 4.9). In addition, a false-negative test result should be considered in persons with a negative HIV-1 test who have clinical symptoms suggestive of HIV infection or AIDS. Additional testing for HIV-2 and HIV-1 group O infections may be appropriate for these persons.

4.7.3 Indeterminate HIV Test Results

Almost all HIV-1-infected persons with initial indeterminate Western blot results will develop detectable HIV antibody within 1 month (136,139,140). Persons with an initial indeterminate Western blot result should be retested for HIV-1 infection at least 1 month later. Persons with continued indeterminate Western blot results after 1 month are highly unlikely to be HIV-infected and should be counseled as though they are not HIV-infected, unless recent

HIV exposure is suspected. The use of viral DNA/RNA assays is not generally recommended to resolve indeterminate test results since these assays have not been approved by FDA for diagnostic use; however, in consultation with clinical and laboratory experts, such testing could be considered.

4.7.4 Inconclusive HIV Test Results

Some HIV tests will result in inconclusive results because of insufficient quantity of specimen for the screening or confirmatory tests. Positive rapid tests should be considered preliminary until confirmatory tests have been completed.

4.8 Informing Clients of Test Results

Providers should take responsibility for ensuring that HIV test results are given to clients. This is particularly important for HIV-infected clients.

The 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 both the receipt of the HIV test and the HIV test result must be maintained, regardless of the method used.

Because low rates of return for test results occur in many settings offering HIV counseling, testing, and referral services, providers should make strong efforts to ensure that clients tested for HIV infection receive their HIV test results, particularly HIV-infected clients who may benefit from earlier entry into care and initiation of antiretroviral therapy. A range of flexible approaches exists to maximize the number and proportion of persons tested for HIV who receive their test results in a timely manner. As necessary, providers should seek the support of their local or state health department for help in providing test results to clients.

4.8.1 Increasing Receipt of HIV Test Results

Because knowledge of HIV status is a critical HIV prevention strategy and essential for entry into care services, providers should stress to clients the importance of returning to receive the test results and establish a plan with the client for how he or she will obtain the results (see section 3.0). Reminder systems may be useful. Using alternate HIV test technologies may 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., telephone) and request clients to return to the clinic to discuss positive test results that may indicate potential life-threatening illnesses. This strategy can also be applied, under certain circumstances, to notify 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 may benefit from HIV prevention counseling and referral to outside sources of care (see also 3.4.7). It may be appropriate to provide HIV-uninfected clients not at increased risk the option of receiving HIV test results and counseling by telephone–with the understanding that assurance of client confidentiality is paramount. Limited research suggests that offering clients the option of contacting the provider by telephone to receive negative HIV results may increase rates of receipt of test results, satisfy client preferences for options, and preserve clinic resources without apparent adverse consequences (43,112). No published research exists regarding the use of telephones for providing positive HIV test results with most HIV test technologies. There is very limited experience regarding the use of telephones in providing HIV-positive test results with home sample collection testing (43).

4.8.2 Current Considerations: Rapid Tests

During the initial visit, the provider can definitively tell a client who has had a single rapid HIV test with negative results that he or she is not infected (115) except where retesting may be indicated because of recent known or possible exposure to HIV (see 4.9). Pending confirmatory testing, the meaning of a reactive rapid HIV test result should be carefully communicated to the client to account for the possibility of a false-positive result.

Since the likelihood that a positive screening test is truly positive (i.e., the client is truly infected with HIV) decreases as HIV prevalence in the tested population gets lower, false-positive HIV test results are more likely to occur 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 such as "a good chance of being infected" or "very likely infected" can be used to indicate the likelihood of HIV infection and qualified on the basis of both the HIV prevalence in the setting and the client's individual risk (115, 153). Further testing is always required to confirm a reactive screening test result.

4.9 Subsequent Testing in HIV-Uninfected Clients

The timing and frequency of subsequent HIV testing should be individualized to client needs.

A negative HIV test usually indicates the absence of HIV infection (35). Because very recent infection cannot be excluded without follow-up testing (see 4.7.2), the appropriate timing and frequency for offering follow-up testing

has been an ongoing question. Although follow-up testing at 6 months after possible exposure has been recommended in the past (4), follow-up testing 6 months after possible exposure is not warranted for most clients who do not have recent HIV exposure.

Providers should consider the factors below 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
- Availability of clinic resources

4.9.1 Recent Exposure

Follow-up testing may be appropriate for clients who have negative test results but who have not had time to develop detectable antibody after a recent documented occupational (55) or nonoccupational (sexual or needle-sharing) (56) exposure to HIV-infected persons or to persons at increased risk for HIV with unknown serostatus. The timing of subsequent testing must address these issues: it should provide "reasonable" assurance that the exposure of concern did not lead to infection; and/or it should be done in a timely manner so that clients identified as HIV-infected can receive appropriate antiretroviral treatment and prevention services as soon as possible.

4.9.2 Single Possible or Known Exposure

For persons with a single exposure, the timing of the exposure should be determined. Most infected persons will have developed detectable HIV antibody within 3 months after exposure (134). If the initial test was negative, repeat testing should be considered at 3 months after exposure to account for the possibility of a false-negative test result. If the follow-up test is nonreactive, the client is very likely not HIV-infected. If the client was exposed to a known HIV-infected person or if provider and/or client concern remains, a second repeat test may be considered at or after 6 months from the exposure. Very rare cases of seroconversion between 6 and 12 months after known exposure have been reported (141). 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 individualized to the particular needs of the client (55).

4.9.3 Ongoing Exposure

Persons with continued HIV risk behavior pose a special challenge in regard to follow-up testing. In some settings, clients with ongoing risk represent a substantial proportion of the clinic population receiving HIV counseling, testing, and referral services. In most circumstances, follow-up HIV testing should be recommended periodically (e.g., every 6 months) for clients with ongoing risk behavior to monitor the client's HIV status, but more importantly, to facilitate continued client contact, opportunities for HIV prevention counseling (see 3.4), and referral to additional prevention and support services.

4.9.4 No Identifiable Risk

In general, persons with no recent identifiable risk for HIV infection should be provided additional HIV prevention counseling (see 3.4) and follow-up testing, when requested. Efforts should be made to understand the reasons these clients are repeatedly seeking follow-up testing. These clients should be considered for in-depth prevention counseling and referral to outside sources of care, where appropriate.

4.9.5 Special Considerations

General recommendations for follow-up testing may not be applicable in all circumstances. In certain circumstances, e.g., when persons are simultaneously exposed to hepatitis C virus and HIV (55) and when persons have received HIV vaccines, guidance should be provided only with expert consultation (55).

4.10 Ensuring High-Quality Testing

Counseling, testing, and referral programs should coordinate activities with state and local laboratories to ensure high-quality HIV testing through proper specimen collection, storage, and transport. 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 (142). Currently, laboratory errors most often occur in the pre-analytic steps of testing (specimen collection, labeling, transporting, processing, and storing) and in the postanalytic steps of testing (results validation and reporting) (143-145).

5.0 Referral

5.1 Background

Referral is a key component of comprehensive HIV prevention services because not all providers can address the variety of medical, prevention, and psychosocial issues that influence a person's ability to initiate and sustain behavioral changes that reduce the risk of acquiring or transmitting HIV.

Most published studies have addressed the effectiveness of referrals in the context of medical case management systems. Few published studies have evaluated the effectiveness of HIV-related referrals in the context of counseling and testing services. These guidelines have been developed on the basis of the scant published literature and expert opinion that identify characteristics, methods, and "best practices" likely to facilitate effective referrals.

5.2 Goals

HIV referral seeks to

- Ensure that HIV-infected persons have access to appropriate medical, prevention, and psychosocial support services
- Ensure that individuals at increased risk for HIV infection have access to appropriate medical, prevention, and psychosocial support services

5.3 Definition

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

When provided in the context of HIV prevention counseling and testing, referral does not include ongoing support or management of the referral. Referral is not intended to replace case management, which 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.

5.4 Who Should Receive Referrals?

Referral services should be offered to all clients who are HIV-infected or at increased risk for HIV.

For HIV-infected clients and those not infected but at increased risk for HIV, linkage with appropriate medical, prevention, and other supportive services increases the likelihood of maintaining health, enhancing longevity and quality of life, and reducing the risk of transmitting or acquiring HIV. Advances in medical treatment and prevention interventions underscore the critical and essential role that referral plays in efforts to decrease illness and death associated with HIV infection and AIDS.

5.5 Typical Referral Needs

Clients should be referred to services that are responsive to their priority needs and that are culturally, linguistically, gender-, and age-appropriate.

- **Medical Evaluation, Care, and Treatment**
  HIV-infected clients should receive or be referred to medical services that address their HIV infection, including treatment or prevention of opportunistic infections and evaluation of immune system function. Prophylaxis for opportunistic infections and related HIV-conditions and medical treatment for TB, STDs, and hepatitis are important for HIV-infected persons.

- **Partner Counseling and Referral Services**
  Persons with HIV-positive test results should receive or be referred to services to assist them in notifying their sex and/or injection drug equipment-sharing partners and/or spouses about their exposure to HIV and how to access counseling, testing, and referral services. See guidelines on partner counseling and referral services (33).

- **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 receive referral to providers who can provide

prevention counseling and education, initiate medical therapy to prevent perinatal transmission, and provide appropriate care pursuant to established treatment guidelines (30).

- **Drug or Alcohol Prevention and Treatment**
  Clients who abuse drugs or alcohol should receive or be referred to substance abuse or alcohol prevention and treatment services.

- **Prevention Case Management**
  Clients with multiple and complex needs that affect their ability to adopt and sustain behaviors to reduce their risk for transmission or acquisition of HIV should receive or be referred to prevention case management services, including ongoing prevention counseling (34).

- **Mental Health Services**
  Clients who have mental illness, developmental disability, or difficulty coping with HIV diagnosis or HIV and HIV-related conditions should receive or be referred to appropriate mental health services.

- **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**
  Clients who are HIV-infected or at increased risk for HIV are at increased risk for acquiring viral hepatitis, particularly hepatitis B and C. Such clients should receive or be referred for vaccination (for hepatitis B), testing for hepatitis B and C, and appropriate medical treatment.

- **Other Services**
  Clients may have multiple needs that can be addressed through a variety of HIV prevention and other support services such as assistance with housing, food, employment, transportation, child care, domestic violence, and legal services. Addressing these needs can assist clients in accessing and accepting medical services and facilitate the adoption and maintenance of behaviors to reduce the risk for transmission/acquisition of HIV. Clients should receive referrals to such services as appropriate to identified needs.

5.6 Implementing and Managing Referral Services

Clients should be provided with assistance in accessing and completing referrals. Completion of referrals should be verified.

In the context of HIV prevention counseling and testing, the following should be considered key elements in the development and delivery of referral services (96).

5.6.1 Assessing Client Referral Needs

In consultation with the client, providers should identify factors that are likely to influence the client's ability to adopt or sustain behaviors to reduce risk for transmission or acquisition of HIV or that 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 not matching client priorities (147). Priority should be placed on ensuring that HIV-infected clients are assessed for referral needs related to clinical management of HIV infection, partner counseling and referral services, and prevention services aimed at reducing the risk for further transmission of HIV.

When a provider does not have the capacity to make appropriate referrals or when client needs are especially complex, referral to a case management system should be made.

5.6.2 Planning the Referral

Referral services should be responsive to the clients' needs and priorities and should be provided in a manner that is appropriate given the client's culture, language, gender, and age. In consultation with the client, providers should assess what factors, if any, may make it difficult for the client to complete the referral (e.g., lack of transportation or child care, client work schedule, cost) and address them. Research suggests that accessibility and convenience of services predict whether a referral will be completed (147).

5.6.3 Facilitating Client Access to Referral Services

Clients should be provided with information necessary to enable them to successfully access the referral service (e.g., contact name, eligibility requirements, location, hours of operation, telephone number). For some clients, however, this may not be sufficient. Research suggests that providing assistance (e.g., setting an appointment, addressing transportation needs) facilitates completion of referrals (62). Where anonymous testing is an option and the client chooses anonymous testing, consent will need to be obtained from the client before sharing identifying information necessary to facilitate the referral.

Outreach workers and peer counselor/educators can serve as an important and effective resource to help clients identify needs and plan successful referrals (148). Multiple contacts with outreach workers predict completed referrals (147).

5.6.4 Documenting 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 not; and 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. Expert opinion suggests that documentation of referrals made, the status of those referrals, and client satisfaction with referrals will assist providers in better meeting 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.

5.7 Ensuring 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 culturally, linguistically, gender-, and age-appropriate manner.

5.7.1 Education and Support of Staff

Staff providing referral services must possess appropriate knowledge of client needs, the skills and resources to address them, and authority to assist the client in procuring services. Providers should develop protocols to ensure that staff receive adequate training and continuing education.

Training and Education. Providers should ensure that staff receive adequate training and continuing education to develop and maintain knowledge, skills, abilities (including competence in providing culturally, linguistically, gender-, and age-appropriate services) essential to implement and manage referrals. Training and education should address what resources are available and methods for managing referrals. Training and education should also 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). Research suggests that a provider's ability to correctly evaluate a client's readiness to adopt risk-reducing behaviors predicts completed referrals (147). Research suggests that cross-training can facilitate fuller knowledge and understanding among providers of

available community resources and suggest gaps in the service array (62).

Authority. Staff providing referrals must have the authority necessary to accomplish a referral. This may relate to 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. In providing referral services, the provider should maintain the confidentiality of client records pursuant to local, state, and federal regulations and established agency policy.

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

5.7.2 Provider Coordination and Collaboration

Providers should develop and maintain strong working relationships with other providers and agencies that may be able to provide needed services. Coordination and collaboration should be formally documented.

Providers who offer HIV prevention counseling and testing services 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. Such coordination and collaboration promotes a shared understanding of the specific medical and psychosocial needs of target populations, current resources available to address these needs, and gaps in resources.

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

5.7.3 Referral Resources

Providers of HIV prevention counseling and testing services should maintain accurate and current information regarding referral services.

Knowledge of available support services is essential to facilitating successful referrals. Some services may not be available locally. A resource guide should be developed and maintained to assist staff in making appropriate referrals (Box 7).

Information about community resources can be obtained from local health planning councils, consortia, and community planning groups. Local, state, and national HIV/AIDS information hotlines and/or Web pages (such as NPIN's), other community-based health and human service providers, and state and local public health departments may also serve as sources for such information.

Box 7. Contents of Referral Resource Guide

For each resource, the referral resource guide should specify

- Name of the provider or agency
- Range of services provided
- Target population(s)
- Service area(s)
- Contact names and telephone and fax numbers, street addresses, e-mail addresses
- Hours of operation
- Location
- Cultural, linguistic, gender, and age competence
- Cost for services
- Eligibility
- Application materials
- Admission policies and procedures
- Directions, transportation information, and accessibility to public transportation
- Client satisfaction with services

6.0 HIV Counseling, Testing, and Referral in Nontraditional Settings

6.1 Background

Counseling, testing, and referral services should be provided in community-based and outreach settings, as well as clinical settings.

Providers of HIV counseling, testing and referral services are strongly encouraged to expand provision of services into nontraditional settings such as community-based organizations and outreach settings. Doing so may facilitate use of these services by persons at increased risk for HIV, according to data from publicly supported counseling, testing, and referral programs. When HIV counseling, testing, and referral services are not readily available, accessible, or acceptable, persons at increased risk for HIV may not take advantage of them.

Expansion of counseling, testing, and referral services into nontraditional settings can be accomplished through

- Partnership with community-based health and human service providers
- Use of new FDA-approved HIV test technologies that offer less invasive sample collection, portability, low complexity sample collection and processing, and reduced bio-hazard

6.2 Ensuring High-Quality Services in Nontraditional Settings

To ensure high-quality services responsive to client needs, agencies should develop and implement written quality assurance protocols and procedures specific to provision of services in nontraditional settings.

Expansion of counseling, testing, and referral into nontraditional settings presents challenges related to providing high-quality services. For example, issues related to client privacy and confidentiality, informed consent, counseling, testing, provision of test results, referral, record keeping, and staff safety must be considered during development of protocols and procedures regarding provision of services in nontraditional settings.

Privacy and Confidentiality. Ensuring clients' privacy and confidentiality during the counseling, testing, and referral process is essential but may 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

- 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 of a facility 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 client return to provider/agency to receive test results and posttest counseling and referral

Informed Consent. Staff providing counseling, testing, and referral services should be sensitive to issues that may interfere with obtaining true informed consent (see 2.4). Such issues include use of alcohol/drugs, mental illness, and peer pressure in venues where people congregate or socialize. Suggested strategies for obtaining informed consent during provision of services in nontraditional settings include

- 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 informed consent to client
- Use verbal prompts to ensure that the client understands consent

Counseling. Staff working in community-based and other nontraditional settings should be familiar with risk screening strategies to determine whether HIV prevention counseling should be offered (see 2.5.6.). Staff should be trained in HIV prevention counseling or other approaches aimed at personal HIV risk reduction. When appropriate (e.g., among injecting drug users), information about other STDs and bloodborne diseases should be incorporated into the counseling sessions (35,149) (see 3.4.6).

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 such as field conditions related to collection, transport, and storage of specimens; worker safety; and the likelihood that clients will receive HIV test results. Providers must fully understand the extent to which "field conditions" may affect specimens (e.g., extreme temperatures, time lapse from collection to processing). Test specimens should be collected, stored, and transported pursuant to

manufacturer instructions.

Provision of Test Results. Clear protocols for provision of test results and prevention counseling should be developed. The following strategies may 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, for receiving results
- Make incentives available (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 working in community-based and other nontraditional settings should receive training in the implementation and management of referrals. Providers should establish appropriate collaborative relationships to facilitate referrals. Arranging for partner counseling and referral services staff and/or case managers to be available to clients at the time test results are provided may facilitate 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

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

Where allowed by state/local statute, clients may elect to be tested for HIV anonymously. Procedures to ensure client's anonymity with respect to HIV testing (i.e., no indication of testing in a client's record and no recording of personal identifying information on laboratory requests) should be developed. Even when staff who provide counseling, testing, and referral services know the client (including names and locating information) from other activities, the client's right to be tested anonymously should be protected.

Staff Safety. Providing services in outreach settings such as bars and parks may compromise staff safety, which must be considered in development of outreach protocols. Appropriate training and precautions, such as working in teams, should be developed in planning for services in nontraditional settings.

7.0 Quality Assurance and Evaluation of HIV Counseling, Testing, and Referral Services

In these guidelines, the role of quality assurance and evaluation has been expanded and strengthened. Quality assurance activities are needed to ensure provision of high-quality services. Evaluation focuses on ways to improve the overall benefit of prevention services.

7.1 Quality Assurance

Written quality assurance protocols should be developed and routinely followed by providers of HIV counseling, testing, and referral services.

Written quality assurance protocols should be developed and made available to all staff providing counseling, testing, and referral services. General components of quality assurance activities follow, and issues specific to ensuring high-quality counseling, testing, and referral services are included in 3.4.8, 4.10, and 5.7, respectively. All staff should receive training and orientation about quality assurance.

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, lubricant)
- Compliance with written protocols for provision of service to an individual client (e.g., appropriate counseling protocols, timely return of HIV test results to clients, referral for services responsive to client's priority needs)
- Cultural, linguistic, gender, and age appropriateness of services and materials
- Staff performance/proficiency (e.g., competence, skills, credentials, and training)
- Supervision of staff, including routine timely feedback to staff
- 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 counseling, testing, and referral services.

7.2 Evaluation

Counseling, testing, and referral services should be regularly evaluated.

Evaluation of public or private counseling, testing, and referral services should be viewed as an essential activity and a continual process to improve services to clients and provide accountability to stakeholders (150,151). Evaluation should be an interactive process involving individuals and organizations affected by the service (150). In public health settings, the goals of the community as described by community health planning processes and other relevant local planning processes could be incorporated into the evaluation process.

Providers need to identify the key relevant, programmatic goals and objectives that reflect provision of services to the program, community, and individual client and determine what data are needed to evaluate those goals and objectives. Information obtained from the evaluation process should be used to plan and prioritize the provision of counseling, testing, and referral services within a setting. For example, information from the HIV Counseling and Testing System (CTS) (42) or other locally available sources could be used during the local community planning process (e.g., the HIV prevention community planning process) to assist in developing or revising an HIV/AIDS prevention plan and/or describing the target population in need of services. Since resources for evaluation may be limited, comprehensive evaluations (including outcome evaluation and impact evaluation, for example) are often not possible. However, even with limited resources, providers can conduct meaningful evaluations by focusing on relevant local outcomes (75).

7.2.1 Data

Data collected should have a clear, anticipated use and should not be the focus of or interfere with the provision of counseling, testing, or referral services.

Data should be used to evaluate the extent to which the goals of counseling, testing, and referral and locally defined service outcomes (e.g., targeted return rates, knowledge of HIV infection status, proportion of successful referrals) are met.

While high-quality 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 counseling, testing, or referral discussions between the provider and the client. Examples of approaches to data collection include having the client complete a questionnaire or intake information form on admission, having a provider complete these forms immediately after a meeting with a client has ended, or combining these two approaches.

Data collection methods should be compatible with the evaluation needs of the counseling, testing, and referral service setting. Data should be collected by using a standard collection instrument throughout the program. Simple data collection instruments (e.g., intake forms, medical record reviews) should be developed so that data can be collected unobtrusively as part of the provision of services.

Publicly funded counseling, testing, and referral sites currently collect data on client demographic characteristics, risk behavior/exposure category, test acceptance, and type of site where service is provided. Most sites record the date of visit, anonymous or confidential test status, previous test result, current test result, and return for current test result from each client encounter. Additional data may be useful for evaluation of services, such as date of previous test, type of current test (e.g., standard, rapid, oral), 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).

7.2.2 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 utilized to ensure that any data gathered and maintained will not compromise client confidentiality.

7.2.3 Ensuring High-Quality Evaluation

- **Monitor.** The system used to collect the information must be monitored periodically to ensure high data quality, which depends on the cooperative efforts of all persons providing counseling, testing, and referral 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.

- **Train.** 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 counseling, testing, and referral services.

- **Expedite.** The information assembled during the evaluation process should be analyzed and reported in a timely fashion to individuals and organizations affected by the service.

- **Apply.** Whenever feasible, the information and feedback gained during the evaluation process should be used to improve the services offered by the site to the client.

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: Without any personally identifying information. With regard to HIV testing, it means that the persons ordering and performing the test do not maintain a record of the name or other personal identifiers of the person whose specimen they are testing.

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, 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 offered or receive HIV counseling, testing, and referral 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 below). A commonly used screening test to detect antibodies to HIV.

ELISA: Enzyme-linked immunosorbent assay. A type of EIA (see above). 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 publicly funded HIV counseling, testing, and referral program. Sometimes referred to as "alternate test site" or "anonymous test site."

HIV: Human immunodeficiency virus, the virus that causes AIDS.

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 period (i.e., the rate of incidence).

inconclusive test result: Test results are inconclusive when nonspecific or insufficient antibody is present.

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

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, the 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 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 to help partners gain earlier access to individualized counseling, HIV testing, medical evaluation, treatment, and other prevention services.

perinatal HIV transmission: Transmission of HIV from the mother to the fetus or infant during pregnancy, delivery, or breastfeeding.

positive test: For HIV, a sample of serum 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 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, and individualized prevention counseling, support, and referral to other needed services.

prevention counseling: See HIV prevention counseling.

quality assurance: An ongoing process for ensuring that the counseling, testing, and referral 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 10-30 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 that portion of a client-centered HIV prevention counseling session in which the client is encouraged to identify and acknowledge his or her personal risk for acquiring or transmitting HIV.

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

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

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 antigens or microorganisms into the host.

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

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

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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