Recommendations for HIV Prevention with Adults and Adolescents with HIV in the United States, 2014

December 11, 2014









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Centers for Disease Control and Prevention

Health Resources and Services Administration

National Institutes of Health

American Academy of HIV Medicine

Association of Nurses in AIDS Care

International Association of Providers of AIDS Care

National Minority AIDS Council

Urban Coalition for HIV/AIDS Prevention Services

Correspondence Email: <u>dhapguideline@cdc.gov</u>.

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The contributors to this report (<u>Appendix C</u>) declared no interests regarding the commercial products discussed herein. The report describes the use of certain drugs, tests, and procedures for some indications that do not reflect labeling approved by the U.S. Food and Drug Administration (FDA) at the time of publication. Information about such drugs, tests, or procedures is noted in the relevant sections.

What's New in the Recommendations?

The December 11, 2014, version of *Recommendations for HIV Prevention with Adults and Adolescents with HIV in the United States, 2014*, and its companion summaries have been amended in December 2016 to correct errata, outdated or broken hyperlinks, and missing references or footnotes.

Contents

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Abbreviations

- AAHIVM—American Academy of HIV Medicine
- ACA-Patient Protection and Affordable Care Act
- ACOG—American College of Obstetricians and Gynecologists
- ADA—Americans with Disabilities Act
- ADAP—AIDS Drug Assistance Program
- AIDS-acquired immunodeficiency syndrome
- ANAC—Association of Nurses in AIDS Care
- ART-antiretroviral treatment or antiretroviral therapy
- ARTAS—Antiretroviral Treatment and Access to Services Study
- BUP-buprenorphine treatment
- CBO-community-based organization
- CDC-Centers for Disease Control and Prevention

CI-confidence interval

- CLIA—Clinical Laboratory Improvement Act
- CMS—Centers for Medicare and Medicaid Services
- CROI-Conference on Retroviruses and Opportunistic Infections
- CYFU-couple-years of follow-up
- DAART-directly administered antiretroviral therapy or treatment
- EBI-evidence-based intervention
- EMR-electronic medical record
- FDA—U.S. Food and Drug Administration
- FOA—funding opportunity announcement
- FQHC-federally qualified health centers
- HAB-HIV/AIDS Bureau of the Health Resources and Services Administration
- HHS-U.S. Department of Health and Human Services
- HIPAA—Health Insurance Portability and Accountability Act
- HIV-human immunodeficiency virus
- HIVMA-HIV Medicine Association of the Infectious Diseases Society of America
- HRSA-Health Resources and Services Administration
- HSV-2—herpes simplex virus type 2
- IAPAC-International Association of Providers of AIDS Care
- IAS—International Antiviral Society

- IDSA—Infectious Diseases Society of America
- IOM—Institute of Medicine
- IUD—intrauterine contraceptive device
- M&E-program monitoring and evaluation
- MeSH—Medical Subject Headings
- MSM—gay, bisexual, and other men who have sex with men
- NAAT-nucleic acid amplification test
- NAPWA-National Association of People with AIDS
- NHAS—National HIV/AIDS Strategy
- NHSS—National HIV Surveillance System
- NIH—National Institutes of Health
- NMAC—National Minority AIDS Council
- nPEP-nonoccupational postexposure prophylaxis
- OR-odds ratio
- PrEP—preexposure prophylaxis
- PRS—Prevention Research Synthesis
- PWID—persons who inject drugs
- QI-quality improvement
- RCT—randomized clinical trial
- RNA-ribonucleic acid
- SAMHSA—Substance Abuse and Mental Health Services Administration
- SSPs—syringe services programs
- STD-sexually transmitted disease
- STI-sexually transmitted infection
- UCHAPS—Urban Coalition for HIV/AIDS Prevention Services
- WHO-World Health Organization
- *Note.* Technical terms defined in the Glossary (Appendix B) are in *italics* the first time they appear in the text of each section.

Summary

The goals of HIV prevention, care, and treatment in the United States are to prevent new HIV infections, increase the proportion of persons with HIV who are aware of their infection, prevent HIV-related illness and death, and reduce HIV-related health disparities.¹ The context of HIV prevention in the United States has changed because of recent advances in biomedical, behavioral, and structural prevention strategies, changes in health care delivery, and new national HIV prevention strategies.^{1,2} For example, early initiation of *antiretroviral treatment (ART)* has recently been shown to improve health, suppress HIV *viral load*, and reduce the risk of transmitting HIV to others.³ Offering HIV treatment shortly after diagnosis can also hasten use of other biomedical, behavioral and structural interventions that can reduce the risk of transmitting this expanded set of interventions, health care providers, nonclinical HIV prevention specialists, and health departments and *HIV planning groups* can promote the health of persons with HIV, prevent HIV transmission to their sex and *drug-injection partners* and offspring, and contribute to community well-being.

In response to the new context of HIV prevention and care, the Centers for Disease Control and Prevention (CDC), the Health Resources and Services Administration (HRSA), and the National Institutes of Health (NIH) collaborated with several nongovernmental organizations to update and expand their 2003 recommendations to prevent HIV transmission from persons with HIV, *Recommendations for Incorporating HIV Prevention into the Medical Care of Persons Living with HIV* (hereafter abbreviated as the 2003 *Recommendations*).⁴ These nongovernmental organizations included the American Academy of HIV Medicine (AAHIVM), the Association of Nurses in AIDS Care (ANAC), the International Association of Providers of AIDS Care (IAPAC), the National Association for HIV/AIDS Prevention Services (UCHAPS).

This report updates and expands recommendations on the four topics covered by the 2003 *Recommendations*:

- Screening for behaviors that could transmit HIV and *behavioral interventions* to reduce the risk of transmission
- STD screening, treatment, and other sexual health services that may reduce the risk of HIV transmission
- Services for sex partners and drug-injection partners of persons with HIV (known as HIV *partner* services[†])

^{*} This organization disbanded during late stages of development of these recommendations.

Partner services include an array of voluntary services for persons with HIV or STD and their sex and drug-injection partners that are intended to reduce HIV transmission: interviewing persons with HIV to obtain information to contact or locate their sex and drug-injection partners; notifying partners of possible HIV exposure; offering testing for HIV, sexually transmitted diseases, and other infections; providing condoms, prevention information, and counseling; and providing help in obtaining risk-reduction services, HIV medical care, and other medical and social services.

Referral[‡] for other medical and social services that influence HIV transmission or use of HIV prevention and care services

This report also includes recommendations on seven topics that were not described in detail in the 2003 *Recommendations*:

- Individual, social, structural, ethical, legal, policy, and programmatic factors that influence HIV transmission and use of HIV prevention and care services
- Linkage[§] to and retention in HIV medical care
- Use of antiretroviral treatment (ART) for improving health and for preventing HIV transmission
- Methods to achieve sustained high *adherence* to ART to reduce infectiousness
- Reproductive health care for women and men to reduce the risk of sexual HIV transmission when attempting conception or unintended pregnancy (thereby reducing the risk of perinatal HIV transmission)
- Pregnancy-related services to reduce the risk of sexual or perinatal transmission during recognized pregnancy
- Methods to monitor, evaluate, and improve the quality of HIV prevention and care services and programs for persons with HIV

Although this report consolidates a large number of recommendations about interventions to prevent HIV transmission, it *does not provide comprehensive guidance on all prevention and care services for persons with HIV*. This report does not address

- comprehensive primary care for persons with HIV⁵
- the prevention, diagnosis, and treatment of infections that are relatively common in persons with HIV but are not known to facilitate HIV transmission, such as viral hepatitis, some STDs, and most opportunistic infections^{5,6}
- prevention of HIV transmission from infants or young children^{7,8}

The 2003 *Recommendations* were directed to health care providers who serve persons with HIV. In contrast, the recommendations in this report are directed to a broader audience of *clinical providers* and *nonclinical providers*^{**} who serve persons with HIV and staff of health departments and HIV planning groups who provide population-level HIV prevention and care services. The recommendations may also be of interest to persons with HIV; partners of persons with HIV; specialists in HIV planning and service delivery who work for medical assistance programs, health insurance plans, or health systems; and specialists in HIV policy who develop HIV-related programs, legislation, and regulations.

^{**} In this report, clinical providers are defined as persons who work in health care facilities and who provide risk assessments, health education, counseling, screening, diagnosis, treatment, and other health-related services. These providers include physicians, registered nurses, advance practice nurses, physician assistants, dentists, mental health providers, pharmacists, health educators, case managers, social workers, and counselors. Some may be employees or contractors of health departments. Nonclinical providers are defined as persons who work in community-based organizations or health departments operating outside of health care facilities and who provide HIV testing, health education, risk-reduction interventions, partner services, case management, or assistance with linkage or referral to medical and social services. These persons include HIV testing providers, peer and professional health educators, counselors, service linkage facilitators, partner services specialists, case managers, and social workers.



[‡] Referral is a process to help persons identify and access needed services by offering the service provider's address, phone number, directions, hours of operation, and other basic information.

[§] Linkage to care is the process of helping persons with HIV to obtain HIV medical care and prevention or social services through active methods (e.g., appointment scheduling, reminders, transportation to appointments).

A specially convened Project Workgroup comprised of HIV experts from CDC and HRSA consolidated longstanding recommendations from current federal guidance that were based on scientific evidence, program experience, and/or expert opinion published through July 2014. The Workgroup also developed new recommendations which were based on scientific evidence, program experience, laws, regulations, and expert opinion.

Some highlights of the recommendations include the following:

- Engaging clinical providers, nonclinical providers, health departments, and HIV planning groups to use their expertise, professional authorities, and collaborative relationships to serve individuals or populations of persons with HIV
- Creating a spirit of partnership among persons with HIV and the providers who serve them in
 order to achieve both individual HIV prevention and care goals and public health benefits
- Using evidence-based strategies^{††} to promptly link persons with newly diagnosed HIV infection to HIV medical care and promote their long-term retention in care
- Using HIV clinical and *surveillance* data to promote linkage to and retention in care of individuals or populations with HIV, if allowed by the laws or regulations of the jurisdiction
- Informing all persons with HIV (regardless of their CD4 cell count) about the role of effective ART in promoting their health and reducing HIV transmission and offering ART regimens recommended by the U.S. Department of Health and Human Services
- Supporting sustained high adherence to ART using evidence-based interventions
- Using both biomedical factors, such as HIV viral load and recently diagnosed STDs, and HIV risk behaviors^{‡‡} to assess a person's risk of HIV transmission
- Supporting safer sexual and drug-use behaviors using effective, evidence-based interventions
- Supporting persons with HIV to selectively disclose their HIV infection status and notify partners of possible HIV exposure using methods that minimize the risk of stigma, discrimination, prosecution, and other negative consequences
- Expediting HIV partner services to persons with *acute HIV infection^{§§}* or high viral load who are most infectious
- Informing persons with HIV about the availability of *preexposure prophylaxis* (PrEP)*** or nonoccupational postexposure prophylaxis (nPEP)^{†††} for HIV-uninfected partners when clinically indicated to reduce their risk of HIV acquisition
- Screening persons with HIV with the most sensitive STD tests, including tests for rectal and oropharyngeal specimens from gay, bisexual, and other men who have sex with men (MSM), and treating infected persons with the most effective STD treatment, as recommended by the latest CDC guidance

⁺⁺⁺⁺ nPEP is the use of selected antiretroviral medications by HIV-uninfected persons within 72 hours after isolated, nonoccupational exposures to body fluids potentially containing HIV, such as after unprotected sexual intercourse or condom breakage, in order to reduce the risk of HIV acquisition.¹⁰



^{††} Evidence-based interventions, strategies, guidelines, and recommendations are based on sound scientific research, testing, or program evaluation.

^{‡‡} Risk behaviors are behaviors that can result in transmitting HIV to others or acquiring HIV through sexual contact, drug use, or during pregnancy (e.g., anal or vaginal intercourse without a barrier, sharing nonsterile drug-injection equipment).

Acute HIV infection is the period between initial HIV infection and the expression of HIV antibodies that can be detected by HIV antibody tests. This period is characterized by high levels of HIV in the blood and a vigorous immune response.

^{***} PrEP is the daily, continuous use of a select regimen of antiretroviral medications for a period of time by an HIV-uninfected person to achieve levels of drug in the blood and anal and genital mucosa sufficient to reduce the risk of HIV acquisition.⁹

- Providing women and men with HIV who are of reproductive age with contraceptive services, reproductive health counseling, and information and access to special conception methods that can reduce the risk of HIV transmission, as recommended by the latest federal guidance
- Providing women with HIV who are pregnant and HIV-uninfected pregnant women with HIVinfected partners various biomedical and behavioral interventions that prevent sexual or perinatal HIV transmission during pregnancy, as recommended by the latest federal guidance
- Helping persons with HIV obtain other medical and social services that support long-term HIV care and high adherence to ART, encourage safer behaviors, and prevent HIV transmission, such as mental health and *substance use* treatment, stable housing, and transportation to health-related visits
- Applying *quality improvement*^{‡‡‡} strategies and *program monitoring and evaluation*^{§§§} to improve the effectiveness and efficiency of HIV prevention and care services

This report is published with 3 shorter summaries that list the subset of recommendations pertaining to a specific audience: clinical providers,¹¹ nonclinical providers,¹² and staff of health departments and HIV planning groups who provide population-level HIV prevention and care services.¹³ A companion Web site includes dozens of practical decision-support tools and training aids and is regularly updated as new materials become available: <u>http://www.cdc.gov/hiv/prevention/programs/pwp/resources.html</u>

Because these recommendations are both numerous and ambitious, health professionals and organizations must focus on the interventions that are most feasible given their professional authority, skills, and resources and are most important for their *clients*, patients, and communities. This report's broad audience highlights both the unique and shared roles of different provider types who offer interventions as well as opportunities for *collaboration* across clinical, nonclinical, and public health organizations. Collaboration is important at a time when the number and longevity of persons with HIV in the United States is increasing, more effective interventions are available, and shortages of trained HIV care and prevention providers persist.^{14,15} Finally, these recommendations can help mobilize support, policies, resources, and quality improvement for HIV prevention activities in communities and health systems that will ensure that "prevention with persons with HIV" is a cornerstone of HIV prevention in the United States.

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Monitoring and evaluation is a process that involves the repeated, ongoing collection and review of information about program activities, characteristics, and outcomes in order to assess program implementation, coverage, acceptability, cost, and effectiveness.



^{‡‡‡} Quality improvement is an approach to the continuous study and improvement of the processes of providing services that meet or exceed established professional standards and user expectations.

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Section 1. Introduction

More than 1 million people are living with HIV in the United States, an increase of 60% over the previous 15 years.¹ The number of newly infected persons exceeds the number of deaths among HIV-infected persons, which results in a net increase of about 30,000 persons with HIV each year.^{2,3} In 2012, about 64% of infections in adults and adolescents were diagnosed among gay, bisexual, and other men who have sex with men (MSM) and about 10% in *persons who inject drugs*. Nearly 26% of infections were diagnosed in heterosexual persons, of whom about 67% were women.² Persons diagnosed with HIV are disproportionately black/African-American and Hispanic/Latino and residents of selected states of the Southeast and Mid-Atlantic regions, Puerto Rico, the U.S. Virgin Islands, and about a dozen of the largest U.S. cities.

The growing number of persons living with HIV challenges delivery of prevention and care services and demands more effective methods to prevent HIV transmission to others.⁴ Some persons with HIV have taken steps to reduce the risk of transmitting HIV by starting HIV care shortly after diagnosis, using ART to reduce infectiousness, or undergoing STD screening and treatment. Many practice safer sexual and drug-use behaviors, notify *partners* of possible HIV exposure, or use reproductive health services and *substance use* treatment to lower their *transmission risk*.⁵⁻⁸ Nevertheless, national data indicate that many persons with HIV do not benefit from the full range of biomedical, behavioral, and structural interventions that can reduce infectiousness and the risk of exposing others to HIV.⁹ Of the more than 1 million HIV-infected individuals living in the United States in 2009, only about

- 82% of persons with HIV were aware of their HIV infection status
- 66% of persons with diagnosed HIV were linked to care
- 37% of those who entered care were retained in care
- 33% were prescribed *antiretroviral treatment (ART)*
- 25% had a suppressed *viral load*, which reduces infectiousness⁹ (see Figure 1-1)

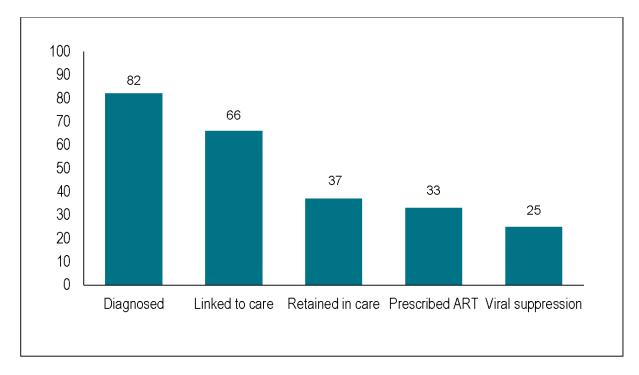


Figure 1-1. Percentage of persons with HIV living in the United States in 2009 who were engaged in selected stages of the continuum of HIV care

Nationally representative data also indicate that only about 45% of persons receiving outpatient HIV medical care reported receiving HIV prevention counseling* from a health care provider during the preceding year.¹⁰ This may be due to time constraints, competing clinical priorities, lack of training in sexual health or injection-drug use, uncertainty that counseling will motivate behavior change, and other factors.^{11,12} Many persons with HIV do not receive routine screening for sexually transmitted diseases (STDs) that may facilitate HIV transmission or services to notify partners of possible HIV exposure.^{6,13} Personal choice to defer safer behaviors also contributes to HIV transmission. Studies conducted in the United States when ART was routinely initiated at CD4 cell counts below 350 per mm³ of blood show that some adolescents and adults with HIV who are aware of their infection status did not practice safe sex and drug-injection behaviors.¹⁴ In 2011, an estimated 13% of MSM with HIV reported engaging in sex without a condom with male partners who were HIV-uninfected or whose infection status was unknown.¹⁵ A review of several U.S. studies of condom use in female adolescents infected with HIV through perinatal exposure, sexual activity, or drug use found that about 40%-60% of adolescents reported engaging in *unprotected sex*.¹⁶ One 2001 study found that adolescent girls who disclosed their HIV infection to partners were more likely to report consistent condom use than adolescent girls who did not disclose their infection.¹⁷

The 2010 National HIV/AIDS Strategy highlighted the need to accelerate HIV prevention and to increase health equity through several approaches. These include reducing the HIV transmission rate; increasing

^{*} HIV prevention counseling is an interactive process between client or patient and counselor aimed at reducing sexual, drug-use, and reproductive behaviors that pose a risk of HIV transmission or acquisition.



Source: Based on data published in Hall HI, et al.9

the percentage of persons with HIV who know their infection status, are promptly linked to HIV care, and remain in continuous care; and increasing the proportion of persons in priority populations (MSM, black/African-American, and Hispanic/Latino) with undetectable HIV viral loads.¹⁸ A prevention strategy that aims to increase access to effective biomedical, behavioral, and structural interventions for the more than 1 million persons with HIV is more likely to decrease HIV transmission than a strategy that attempts to change sexual and drug-injection behaviors of the many millions of persons at risk for infection.^{19,20} Also, many prevention interventions for persons with HIV can capitalize on existing clinical systems and resources because most receive care for HIV or other medical conditions sometime after their HIV diagnosis.

This report updates and expands earlier recommendations about HIV prevention for persons with HIV published by the Centers for Disease Control and Prevention (CDC), the Health Resources and Services Administration (HRSA), the National Institutes of Health (NIH), and the HIV Medicine Association (HIVMA) of the Infectious Diseases Society of America in 2003: *Recommendations for Incorporating HIV Prevention into the Medical Care of Persons Living with HIV.*²¹ Several factors prompted this update, including advances in behavioral, biomedical, and structural interventions, new national HIV prevention goals,¹⁸ and recent changes in public- and private-sector health care delivery and financing in the United States.^{22,23} These recommendations also incorporated perspectives of additional stakeholders, including persons with HIV, *HIV medical care* providers, nonclinical HIV prevention providers, health department HIV/AIDS program managers, and experts in HIV policy and legal issues (see <u>Section 2, Methods</u>).

This report consolidates a large number of federal recommendations about effective biomedical, behavioral, and structural interventions that can reduce the infectiousness of adults and adolescents with HIV and behaviors that can transmit HIV. The recommendations relate to 11 topics, which correspond to the 11 main sections of this report:

- Individual, social, structural, ethical, legal, policy, and programmatic factors that influence HIV transmission and use of *prevention services*[†] (referred to as the Context of HIV prevention)
- $Linkage^{\ddagger}$ to and retention in HIV medical care
- Use of ART for improving health and for preventing HIV transmission
- Methods to achieve sustained, high *adherence* to ART to reduce infectiousness
- Screening for behavioral, biomedical, and structural factors that increase risk of HIV transmission and risk-reduction interventions that promote health and reduce the risk of HIV transmission
- Services for sex partners and *drug-injection partners* of persons with HIV (referred to as HIV partner services[§])
- STD screening, treatment, and other sexual health services that may reduce the risk of HIV transmission

Partner services include an array of voluntary services for persons with HIV or STD and their sex and drug-injection partners that are intended to reduce HIV transmission: interviewing persons with HIV to obtain information to contact or locate their sex and drug-injection partners; notifying partners of possible HIV exposure; offering testing for HIV, sexually transmitted diseases, and other infections; providing condoms, prevention information, and counseling; and providing help in obtaining risk-reduction services, HIV medical care, and other medical and social services.



[†] Prevention services include interventions, strategies, policies, and structures designed to reduce the transmission of HIV infection.

[‡] Linkage to care is the process of helping persons with HIV to obtain HIV medical care and prevention or social services through active methods (e.g., appointment scheduling, reminders, transportation to appointments).

- Reproductive health care for women and men to reduce the risk of sexual HIV transmission when attempting conception or unintended pregnancy (thereby reducing the risk of perinatal HIV transmission)
- Pregnancy-related services to reduce the risk of sexual or perinatal transmission during recognized pregnancy
- Other medical and social services that influence HIV transmission or use of HIV prevention and care services
- Methods to monitor, evaluate, and improve the quality of HIV prevention and care services and programs for persons with HIV

The vast majority of recommendations in this report pertain to persons with HIV, but a few relate to interventions for HIV-uninfected, sex or drug-injection partners of persons with HIV, and these interventions may be used by the partners to reduce their risk of acquiring HIV.

The recommendations consolidate

- the latest guidance from several federal agencies published through May 2014
- new evidence that supports this federal guidance
- several entirely new recommendations and their supporting rationale

Section 2, Methods, describes the methods used to consolidate this federal guidance, to identify new evidence supporting this guidance, and to develop new recommendations based on scientific evidence, program experience, and expert opinion.

This report does not include recommendations about

- comprehensive primary care for persons with HIV²⁴
- the prevention, diagnosis, and treatment of infections that are relatively common in persons with HIV but are not known to facilitate HIV transmission, such as viral hepatitis, some STDs, and most opportunistic infections^{24,25}
- prevention of HIV transmission from infants or young children²⁶⁻²⁸

The primary audiences for this report include the following:

- Clinical providers working in health care facilities and who provide risk assessments, health education, counseling, screening, diagnosis, treatment, and other health-related services. These providers include physicians, registered nurses, advance practice nurses, physician assistants, dentists, mental health providers, pharmacists, health educators, case managers, social workers, and counselors. Some may be employees or contractors of health departments.
- Nonclinical providers working in community-based organizations or health departments outside of health care facilities and who provide HIV testing, health education, risk-reduction interventions, partner services, *case management*, or assistance with linkage or *referral*^{**} to

^{*} Referral is a process to help persons identify and access needed services by offering the service provider's address, phone number, directions, hours of operation, and other basic information.



medical and social services. These providers include HIV testing providers, peer and professional health educators, counselors, service *linkage facilitators*,^{††} *partner services specialists*,^{‡‡} case managers, and social workers.

Staff of health departments and HIV planning groups who provide population-level HIV prevention and care services, such as HIV surveillance or coordination of state and local HIV prevention and care resources.

Secondary audiences for this report include persons with HIV, partners of persons with HIV, specialists in HIV/AIDS policy and law, funding, and service coverage and reimbursement for public and private sector health systems and community-based programs. These also include developers of HIV-related policies, government regulations, and legislation and managers of health insurance plans, medical assistance programs, and private and public health care systems that serve persons with HIV.

By directing these recommendations to a wide range of health professionals and organizations, this report highlights both their unique and shared roles in carrying out individual- and population-level HIV prevention and care strategies. It also underscores opportunities for *collaboration* across clinical, nonclinical, and public health organizations. Collaboration and task sharing are especially needed as the number and lifespans of persons with HIV increases, more effective interventions are available, and shortages of trained HIV care and prevention providers persist.^{1,29} Linkage to HIV medical care provides an example: health department HIV surveillance programs can identify populations or individuals with newly diagnosed HIV who may warrant help linking to HIV medical care, nonclinical HIV testing providers can help newly diagnosed *clients* schedule their first HIV care appointments, health care providers can request expedited scheduling, and HIV planning groups can promote HIV training for primary care physicians, physician assistants, and nurses.

Sections 4 through 12 summarize each intervention topic using a similar format: background that defines the intervention and how it is delivered; a list of recommendations that are specific to provider type; examples of operational strategies, methods, or best practices to implement the recommendations; a summary of how the recommendations differ from previous federal guidance on this topic; methods used to assess federal guidance, published literature, or other sources of evidence used when developing the recommendations; a summary of evidence supporting the recommendations; a summary of issues that influence implementation of the recommendations; a link to a Web site that includes decision-support tools and other implementation resources (http://www.cdc.gov/hiv/prevention/programs/pwp/ resources.html); and references. Section 13 describes *quality improvement*§§ and program *monitoring and evaluation*^{***} methods that can determine if interventions are implemented as intended, yield the expected outcomes, or warrant changes in delivery methods. This report is published with 3 shorter summary documents that list the subset of recommendations for clinical providers,³⁰ nonclinical

^{***} Monitoring and evaluation is a process that involves the repeated, ongoing collection and review of information about program activities, characteristics, and outcomes in order to assess program implementation, coverage, acceptability, cost, and effectiveness.



^{††} Linkage facilitators assist persons with HIV to access HIV medical care and other medical and social services through active methods (e.g., help with making appointments, providing transportation to appointments).

Partner services specialists include specially trained disease investigation specialists, public health investigators, or communicable disease investigators who work in health departments and staff of other agencies who are trained and authorized to provide partner services.

^{§§} Quality improvement is an approach to the continuous study and improvement of the processes of providing services that meet or exceed established professional standards and user expectations.

providers,³¹ and staff of health departments and HIV planning groups who provide population-level HIV prevention and care services.³²

Together these recommendations and implementation resources provide a national action plan to promote HIV prevention with persons with HIV. They can guide the daily work of clinical providers, nonclinical providers, and staff of health departments and HIV planning groups. They can inform HIV prevention policies, quality improvement initiatives, and resource allocation decisions. By galvanizing support and collaboration for HIV prevention activities across health systems, community organizations, and government agencies, these recommendations can reaffirm that prevention with persons with HIV is a cornerstone of HIV prevention in the United States.

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Section 2. Methods

These recommendations were developed in several phases. First, in 2010, HIV prevention and care experts from the Centers for Disease Control and Prevention (CDC) Division of HIV/AIDS Prevention and the Health Resources and Services Administration (HRSA) HIV/AIDS Bureau convened a Project Workgroup to develop a logic model that illustrated how various interventions could lower a person's risk of transmitting HIV by reducing infectiousness or the likelihood of exposing others to HIV (see <u>Appendix A</u>).

Second, CDC and HRSA sought input from several organizations on the proposed scope, audiences, and development methods for the recommendations through teleconferences from 2010–2011: the National Institutes of Health (NIH), including the Office of AIDS Research, the National Institute of Allergy and Infectious Diseases, the National Institute of Drug Abuse, and the National Institute of Mental Health; the American Academy of HIV Medicine; the Association of Nurses in AIDS Care; the HIV Medicine Association of the Infectious Disease Society of America; the International Association of Providers of AIDS Care; the National Association of People with AIDS,* the National Minority AIDS Council; and the Urban Coalition for HIV/AIDS Prevention Services. Based on this input, the Project Workgroup selected the 11 topics described in the Introduction.

Third, writing groups were convened to draft sections for each topic. The section writing groups included staff of CDC's Divisions of HIV/AIDS Prevention, STD Prevention, and Reproductive Health, and HRSA's Bureaus of HIV/AIDS, Primary Health Care, Maternal and Child Health, and Health Workforce. Writing groups had expertise in HIV-related public health; epidemiology; clinical medicine; behavioral and social science; health education; statistics; laboratory science; health policy; health equity; clinical *quality improvement*;[†] clinical and nonclinical interventions; program implementation, *evaluation*, and *monitoring*; and guideline development. Each member was required to be free of financial or intellectual interests that might pose a conflict regarding federal guidance about commercial products.

Each writing group used a slightly different approach in evaluating federal government guidance (hereafter called "source guidance") or other evidence that might support recommendations because the extent of source guidance and primary scientific evidence varied by topic. Three CDC HIV specialists and two HIV information specialists conducted searches of published literature for nine of the eleven topics (all except the topics on context of HIV prevention and quality improvement and program monitoring). The searches were expanded to include guidance from federal agencies (CDC, HRSA, NIH, and the U.S. Department of Health and Human Services [HHS]) and two federally-sponsored organizations: the U.S. Preventive Services Task Force and the Community Preventive Services Task Force.

The above systematic reviews were published in English from 2000 to 2011 and were included in the CDC HIV/AIDS Prevention Research Synthesis (PRS) Project's cumulative HIV/AIDS/STD prevention

[†] Quality improvement is an approach to the continuous study and improvement of the processes of providing services that meet or exceed established professional standards and user expectations.



^{*} This organization disbanded during late stages of development of these recommendations.

database. This database includes articles without language restriction that are indexed in EMBASE, MEDLINE, PsycINFO, Sociological Abstracts, and CINAHL. The information specialists searched articles indexed by MeSH terms or keywords related to three domains: disease (HIV, AIDS, or STD); study type (prevention, intervention, education, or evaluation); and outcome (behavior or other outcomes); details on the search terms are described in other documents.^{1,2} The information specialists also searched systematic reviews published through 2009 that were cited in the Cochrane Database of Systematic Reviews and indexed with the following terms found in the title, abstract or keywords: (*HIV infection* OR *Acquired Immunodeficiency Syndrome* OR *Sexually Transmitted Diseases*) AND (*Prevention* OR *Intervention*).³

The information specialists classified each identified article by one of the nine intervention topics. Each writing group sought additional information through narrative literature reviews that yielded guidelines from nongovernmental organizations in the United States, peer-reviewed journal articles, abstracts from HIV conferences, program evaluation reports, unpublished data from CDC, and policy and legal documents that had been published from 2000 to as late as July 2014. The Methods topic of each section describes these sources.

Fourth, all 11 writing groups drafted recommendations that were based on the latest federal source guidance, recommendations, laws, regulations, or policies published through May 2014 and/or sources of scientific evidence, program experience, and/or expert opinion that were available through July 2014. Most recommendations simply restated the latest relevant source guidance that was based on scientific evidence, program experience, and/or expert opinion. Although some writing groups did not reexamine the evidence supporting recommendations in the source guidance, all groups evaluated evidence that had accumulated since publication of the source guidance to determine if the latest published recommendations warranted reconsideration. The writing groups consolidated and restated the recommendations from the source guidance instead of excerpting them verbatim. This rephrasing enabled use of a standard format that explicitly defined the recommendation's audiences and beneficiaries (that some source guidance had only implied). For example, "Recommendations for clinical providers: Advise patients to take antiretroviral treatment (ART) as prescribed." Roman numerals indicate the source guidance for each recommendation. Some writing groups also drafted new recommendations that extended a recommendation in the source guidance that was directed to one provider type to another provider type; this occurred when published evidence, program experience, or expert opinion indicated that another provider type could become authorized for and proficient at providing this service. For example, the section writing group on ART extended to nonclinical providers the current federal recommendation for *clinical providers* to inform patients that ART can reduce the risk of transmitting HIV because several experts and programs have found that nonclinical providers in *community-based* HIV service organizations and health departments can become proficient at providing this information. All recommendations that were extended from one provider type to another provider type are labeled with alphabetic superscripts.

Some writing groups drafted new recommendations (which did not simply restate or extend recommendations from source guidance) when they identified scientific evidence with generally consistent findings, statistically significant differences between intervention groups and comparison groups; appreciable effect size; and/or consistent or extensive program experience. The writing groups did not combine primary data from more than one study using meta-analyses, direct comparison of effect

sizes, or other quantitative methods, and they did not formally rate the quality of evidence. Some groups also considered information on the cost-effectiveness of interventions and expert opinions expressed in published literature or during the April 2011 consultation (described below).

Writing groups used an informal consensus process without voting when developing new recommendations.⁴ In general, recommendations about *biomedical interventions* (e.g., ART, STD screening), *behavioral interventions* (e.g., *adherence*, risk-reduction interventions), and structural interventions (e.g., *referral*[‡] to supportive housing services) were more likely to be based on evidence from controlled or observational studies, clinical case reports or series, or program evaluation data. Recommendations about program design, operations, or infrastructure (e.g., use of appointment reminders, collaboration agreements) were often based on program evaluations or expert opinion. Writing groups did not grade the strength of recommendations for two reasons: 1) many recommendations derived from source guidance had not been rated for strength or did not specify the supporting evidence; and 2) no single system was well-suited to rate a diverse set of recommendations pertaining to medical evaluation, drugs, devices, counseling messages, and program operations that were based on highly varied types of supporting evidence.

All recommendations are listed in boxes with titles that include "recommendations" or "recommended." Some recommendations are linked to supplemental boxes that list operational strategies, implementation methods, or discussion topics. For example, the recommendation to screen for HIV *risk behaviors* is linked to a supplemental box that lists possible screening topics. Each section also includes information from systematic or narrative reviews regarding 1) progress, challenges, and opportunities in implementing the recommendations; 2) policy, legal, and ethical considerations; 3) implementation issues for special populations; and 4) a link to a Web site that includes decision-support tools and other resources to facilitate implementation of the recommendations (<u>http://www.cdc.gov/hiv/prevention/programs/</u><u>pwp/resources.html</u>). The report does not include recommendations about future research needs because NIH's national HIV research agenda recently addressed many HIV prevention topics.⁵

Fifth, the Project Workgroup solicited oral and written input on the draft recommendations and supporting evidence on many occasions from 2011 through September 2014. Reviewers included 1) participants at a 3-day consultation in April 2011 attended by 103 representatives of 31 federal agencies, nongovernmental organizations, HIV clinical providers, nonclinical community-based organizations, health departments, or HIV advocacy organizations; 2) participants of listening sessions at the 2010 HIV Prevention Leadership Summit, the 2011 National HIV Prevention Conference, and the United States Conferences on AIDS convened in 2011, 2013, and 2014; 3) representatives of HRSA, NIH, and the 5 nongovernmental cosponsor organizations (see <u>Appendix C</u>); 4) 6 nongovernmental experts on HIV prevention and care (as required by the federal Office of Management and Budget for highly influential scientific assessments)⁶ and 5 representatives of clinical, nonclinical and health department subject matter experts to further vet the guideline development process and recommendations; and 5) representatives of several federal agencies (the Center for Medicare and Medicaid Services; the

[‡] Referral is a process to help persons identify and access needed services by offering the service provider's address, phone number, directions, hours of operation, and other basic information.



Office of the Assistant Secretary of Health of the Department of Health and Human Services; the Substance Abuse and Mental Health Services Administration; and the Department of Veterans Affairs.

This report will be revised periodically as needed.

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Section 3. The Context of Prevention with Persons with HIV: Essential Considerations for Providers

Background

Several broad, contextual issues shape the lives of persons with HIV and their ability to use HIV prevention and care services and adopt HIV prevention strategies. These include individual, social, structural, ethical, legal, and policy issues that influence access to, use of, and delivery of HIV prevention and care services.¹

Service providers who understand these contextual issues are better prepared to

- share responsibility and decision making for HIV prevention with persons with HIV
- communicate in a sensitive, respectful, and *culturally appropriate* manner
- motivate persons with HIV to adopt realistic, *evidence-based** prevention strategies
- help persons with HIV obtain essential medical and social services
- endorse the strategy of "treatment as prevention," in which services for persons with HIV contribute to community well-being
- recognize how contextual factors influence HIV transmission in their communities
- promote the development of community resources that offer prevention and care services

This section makes general recommendations about these contextual issues. In Sections 4 through 12, the Issues that Influence Implementation of the Recommendations topic describes contextual issues related to specific interventions. *Quality improvement*[†] and program *monitoring and evaluation*[‡] can determine if the interventions described in this section are implemented as intended, yield the expected outcomes, or warrant changes in delivery methods (see Section 13, Quality Improvement).

[‡] Monitoring and evaluation is a process that involves the repeated, ongoing collection and review of information about program activities, characteristics, and outcomes in order to assess program implementation, coverage, acceptability, cost, and effectiveness.



^{*} Evidence-based interventions, strategies, guidelines, and recommendations are based on sound scientific research, testing, or program evaluation.

[†] Quality improvement is an approach to the continuous study and improvement of the processes of providing services that meet or exceed established professional standards and user expectations.

Recommendations

BOX 3. RECOMMENDATIONS—CONTEXTUAL ISSUES

For nonclinical providers, clinical providers, and health department staff who serve clients, patients, or populations with HIV

- Become familiar with
 - social and structural determinants of health that influence use of HIV prevention and care services (i, ii, iii, iv) (see <u>Table 3-1</u>)
 - federal, state, and local laws and policies that regulate the following issues (ii, iii, iv, v, vi, vii, viii):
 - rights, responsibilities, and protections of persons with HIV regarding disclosure of their HIV-infection status and the unintentional or intentional exposure of others to HIV
 - provider responsibilities regarding HIV case reporting, protecting confidentiality, obtaining informed consent for HIV services, avoiding discrimination, and any requirements to inform persons about possible HIV exposure
 - governmental and nongovernmental agencies that serve persons with HIV with various insurance and income characteristics and coverage and reimbursement policies (iii, v, ix) (see <u>Table 3-2</u>)
- Support
 - partnerships between persons with HIV and their service providers that foster collaboration, communication, and a spirit of shared responsibility for HIV prevention and care that benefits individuals and the community (iii, v)
 - enrollment of persons with HIV in long-term health care coverage to hasten access to HIV treatment and prevention services^a and to reduce health disparities (i, iii, x, xi)
 - the development of a skilled workforce and organization infrastructure to deliver, coordinate, and finance HIV prevention and care services (i, iii, v) (see <u>Box 3-A</u>)
 - strategies that reduce HIV health disparities and improve access to HIV prevention and care services (i, iii, ix) (see <u>Box 3-A)</u>
 - protection of confidential health information (i, ii, iii, iv, vi, vii, xii) (see <u>Box 3-B</u>)
- Encourage
 - communication that does not stigmatize or negatively judge persons with HIV or their gender identity, sexual orientation, sexual and drug-use behaviors, and medical or social characteristics (i, ii, iii, iv, v, vi)
 - provision of information about rights and responsibilities of persons with HIV regarding confidentiality, privacy, protection from discrimination, and partner notification^b (i, ii, iii, iv, xii)
 - planning by persons with HIV to notify exposed sex and drug-injection partners through partner notification assistance or self-disclosure that reflects an understanding of the benefits and risks of HIV disclosure in the jurisdiction (vi)
 - access to services and devices that improve the knowledge, ability, and motivation of persons with HIV to improve their health, protect the health of partners, and reduce transmission of HIV (i, ii, iii, vi)

BOX 3. RECOMMENDATIONS—CONTEXTUAL ISSUES (cont)

Note. In this report, *nonclinical providers* are defined as persons who work in community-based organizations or health departments operating outside of health care facilities and who provide HIV testing, health education, risk-reduction interventions, partner services, case management, or assistance with linkage or referral to medical and social services. These persons include HIV testing providers, peer and professional health educators, counselors, service linkage facilitators, partner services specialists, case managers, and social workers. *Clinical providers* are defined as persons who work in health care facilities and who provide risk assessments, health education, counseling, screening, diagnosis, treatment, and other health-related services. These persons include physicians, registered nurses, advance practice nurses, physician assistants, dentists, mental health providers, pharmacists, health educators, case managers, social workers, and counselors. Some may be employees or contractors of health departments. Some of the federal guidelines cited in the Recommendation boxes of each chapter may have been updated. For current federal recommendations, please refer to <u>http://www.cdc.gov/hiv/guidelines/</u>.

^a Prevention services include interventions, strategies, policies, and structures designed to reduce the transmission of HIV infection.
 ^b Partner notification is a step of voluntary, confidential partner services that involves locating and confidentially notifying sex and drug-injection partners of persons infected with HIV or STD of possible exposure to HIV or STD.

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Box 3-A. Recommended strategies to improve the infrastructure for delivering, coordinating, and financing HIV prevention and care services

For nonclinical and clinical providers (including health department staff who provide individual-level services to persons with HIV)

- Periodically assess staff and organizational capacity to deliver services, to create a "medical home" in clinical settings, and/or to provide linkage or referral to other providers^{a,b} (i, ii)
- Build organizational capacity to deliver HIV services through staff recruitment, training, retention, and task sharing (iii, iv)
- Participate in comprehensive networks of providers, organizations, and health departments that serve persons with HIV (iii)
- Collaborate with HIV service providers and community organizations to support adequate coverage for HIV
 prevention and care services (i, iv)

Box 3-A. Recommended strategies to improve the infrastructure for delivering, coordinating, and financing HIV prevention and care services *(cont)*

For staff of health departments and HIV planning groups who provide population-level HIV prevention and care services

- Make available online directories of organizations and providers in public and private sectors that offer HIV prevention and care services or other medical and social services that influence HIV transmission^a (iii, iv, v)
- Recruit new providers into HIV service networks and establish agreements that describe their services, reimbursement mechanisms, referral and linkage procedures, exchanging health information, and monitoring prevention outcomes^a (iii)
- Promote HIV training for non-HIV specialists and task sharing as authorized in the jurisdiction (e.g., training physicians, nurses, pharmacists, and health educators to provide adherence support) (vi, vii)
- Promote initiatives to expand access to HIV prevention and care, particularly health insurance or medical assistance programs that offer primary care and skilled provider networks (vi, vii)
- Monitor population-level data on
 - access, use, and quality of HIV prevention and care services in the continuum of HIV care, and identify
 opportunities to improve services and health outcomes^c (viii)
 - coverage and reimbursement for HIV prevention and care services provided by public and private sectors, and identify opportunities to improve coverage^a (vi)
- Evaluate strategies to coordinate and deliver services across the continuum of care that are provided by health systems, community organizations, and health departments^a (vi)
- Participate in evaluations of how laws about criminalizing HIV exposure, same-sex marriage, possession of drug paraphernalia, and other issues might influence disclosure, transmission, and use of HIV services, and apply findings (vi)
- ^a Information described in the <u>Governmental and Nongovernmental Policies and Programs that Provide or Fund Prevention Services to</u> <u>Persons with HIV</u> topic in this section supports this recommendation statement.
- ² Clinical settings are health care facilities in which medical diagnostic, treatment, and disease prevention services are routinely provided. Linkage to care is the process of helping persons with HIV to obtain HIV medical care and prevention or social services through active methods (e.g., appointment scheduling, reminders, transportation to appointments. Referral is a process to help persons identify and access needed services by offering the service provider's address, phone number, directions, hours of operation, and other basic information.
 ² See Section 1, Introduction, for description of the continuum of care.

Sources

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Box 3-B. Recommended strategies to protect the confidentiality and security of personal health information of persons with HIV

For nonclinical and clinical providers (including health department staff who provide individual-level services to persons with HIV)

- Adhere to federal, state, and local laws and regulations related to informed consent, privacy, confidentiality, and security of health information when
 - providing HIV and STD testing, prevention, and care services (i, ii, iii)
 - reporting HIV and STD cases to public health authorities (i, ii, iii)
 - exchanging a person's health information with other providers (i, ii, iii)
 - serving special populations (e.g., minors, pregnant women, persons with mental illness, prisoners, and undocumented immigrants)^a (iii, iv)
- Inform persons with HIV about measures that have been taken to protect confidential health information^a (iii)

For staff of health departments who provide population-level HIV prevention and care services

- Develop and disseminate state and local HIV surveillance data release policies and practices that define and assure providers and persons with HIV about legitimate uses of surveillance data to monitor HIV prevention and care (e.g., to identify individuals with HIV who warrant being offered assistance with linkage to HIV care)^{b,c} (ii, iii, v, vi, vii)
- ^a Information described in the <u>Laws</u>, <u>Regulations</u>, <u>Policies</u>, <u>and Programs that Promote Delivery of HIV Prevention and Care Services</u> topic in this section supports this recommendation statement.
- ² The Centers for Disease Control and Prevention (CDC), states, and local jurisdictions issue recommendations and/or regulations about HIV surveillance.
- The Health Insurance Portability and Accountability Act (HIPAA) allows use of HIV surveillance data for public health purposes.

Sources

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Methods

The section writing group based these recommendations on a narrative literature review of two sources: 1) reports in peer-reviewed journals published in English from December 2000–March 2014 that pertained to the United States and were indexed by using combinations of these terms: *HIV, disclosure, privacy, confidentiality, Health Insurance Portability and Accountability Act (HIPAA), workforce, capacity, prevention, stigma, discrimination, barriers, structural issues, gender, poverty, social issues, ethics, collaboration, coordination, uninsured, and underinsured*; and 2) reports, policy statements, and legal information about the above topics published on the Web sites of governmental and nongovernmental health organizations during this same period. This review included recent reports and

recommendations of the Centers for Disease Control and Prevention (CDC), the Health Resources and Services Administration (HRSA), and the Institute of Medicine (IOM) about contextual issues influencing persons with HIV; laws and policies that affect the delivery of HIV prevention and care services; and shortages of HIV prevention and care providers.²⁻¹¹ The writing group also obtained information on state laws, statutes, and regulations (hereafter referred to as "laws"), and legal review articles by searching 1) WestlawNextTM using the terms *HIV*; *human immunodeficiency virus*; *AIDS*; *acquired immunodeficiency syndrome*; *sexual transmit disease*; *sexual transmit infection*; *communicable disease*; *venereal disease*; *CD4*; *T-lymphocyte*; *viral load*; and *nucleic acid*; 2) the public Web site of a national HIV legal advocacy organization;¹² and 3) a 2014 systematic search of state HIV-specific criminal laws.¹³

Individual, Social, and Structural Issues that Influence Access to and Use of HIV Prevention and Care Services

The central role of persons with HIV

Since the HIV epidemic was first recognized in the United States more than 30 years ago, persons with HIV have played an unprecedented role in drawing attention to the health and social burden of HIV, advocating for HIV prevention and care services, and mobilizing social and legal reforms. This commitment has served as a role model for personal empowerment and shared decision making that has improved access to and quality of services for HIV and other diseases.¹⁴ Persons with HIV and the providers and public health organizations that serve them can create mutually beneficial partnerships that foster shared responsibility for HIV prevention and a common understanding that high quality patient care promotes both individual health and community well-being.^{15,16}

At the individual level, the concept of "prevention *with* persons with HIV" recognizes the rights and responsibilities of persons with HIV to make informed decisions about personal behaviors, to use HIV prevention and care services, and to set prevention goals that incorporate attitudes about infectiousness that do not imply blame. This concept encourages providers to listen to and respect the knowledge, beliefs, values, and cultural background of persons with HIV, to share information that is affirming and practical, and to engage in shared decision making. For example, providers serving persons with HIV who desire complete viral suppression prescribe the most effective ART *adherence* strategies, while providers may refer *persons who inject drugs* (PWID) but decline *substance use* treatment to legal *syringe services programs*[§] (SSPs). "Prevention *with* persons with HIV" may also focus on couples who jointly set HIV prevention goals, such as using condoms or supporting high adherence to ART.

At the community level, "prevention *with* persons with HIV" encourages persons with HIV, health systems, health departments, community-based organizations (CBOs), and *HIV planning groups* to jointly design, implement, and evaluate HIV prevention and care services.¹⁷ In recent years, persons with HIV have led many health, legal, financial, and social reforms that promote HIV prevention and care. These include developing a "patient bill of rights" that describes essential HIV prevention and care services for local health systems and education campaigns that champion "treatment as prevention," the use of ART to reduce the risk of transmission.¹⁸ Working with health and social justice advocates, persons with HIV

[§] Programs that provide free, new, sterile syringes and needles in exchange for used syringes and needles to reduce transmission of bloodborne pathogens among people who inject drugs. May be called syringe exchange programs or needle exchange programs.



have mobilized supportive housing and peer education programs for persons with HIV; advocated for protection of confidential health information; and promoted legal unions of same-sex couples.¹⁸⁻²¹

Individual, social, and structural factors

In the United States, several populations bear a disproportionate burden of HIV infection:

- Gay, bisexual and other men who have sex with men (MSM)
- Black and Hispanic/Latino males and females
- Adolescents and young adults, including those leaving foster care
- Males and females using drugs, especially PWID
- Males and females living in communities with high HIV *prevalence*
- People who live in poverty or lack stable housing
- Transgender females (persons whose assigned sex at birth was male but whose gender expression or identity is female)^{22,23}

The social and structural determinants of HIV infection are complex. They include poverty; unemployment; inadequate health care and health literacy; lack of affordable permanent housing; and stigma, inequality, and discrimination related to race, *ethnicity*, and *sexual orientation*.²⁴ These factors drive disparities in the burden of HIV and other health conditions and in the access, utilization, and quality of many prevention, care, and social services (see <u>Table 3-1</u>). For instance,

- some persons who are poor or suffer from mental illness cannot find stable, affordable housing that fosters high adherence to ART
- some transgender persons fear being stigmatized by their health care providers
- some minors are not aware they can receive services for HIV, *sexually transmitted diseases* (STDs), family planning, or substance use treatment without parental consent
- some inmates who do not receive pre-release transition planning return to the community without an established HIV health care provider or adequate ART supply
- some rural residents cannot find nearby health care providers who are skilled in treating HIV or substance use

The 2010 National HIV/AIDS Strategy stressed the need for HIV prevention and care services for populations that bear the highest burden of HIV infection and for individuals with comorbidities and unique social needs.²³ Many governmental health and welfare agencies, health systems, and individual providers have developed programs and services that are directed to populations heavily affected by HIV.²⁵ Section 12, Other Medical and Social Services, describes services that can mitigate individual, social, and structural factors that impair use of HIV prevention and care services.

Table 3-1. Factors that influence health, quality of life, HIV transmission, and use of HIV prevention, medical, and social services among persons with HIV

Factor(s)	Possible effect on health, quality of life, HIV transmission, and use of services
Real or perceived alienation, discrimination, or stigma due to HIV infection, sexual orientation, sexual practices, drug use, race, ethnicity, age, gender, or other factors	 Factors may impair access to medical care, housing, or employment that can promote use of HIV prevention and care services cause physical and mental health problems, which can increase risk behaviors, substance use, or immunosuppression limit social support that can foster retention in HIV medical care, adherence to ART, transportation, housing, and use of other medical and social services that influence HIV transmission cause gay, lesbian, or transgender persons to defer HIV testing, prevention, or care services
Poverty, unemployment, food insecurity, or unstable housing	 Factors may lead to behaviors that can increase the risk of HIV transmission (e.g., exchanging sex for housing and money, sharing drug-injection equipment) hinder access to health insurance, medical care, ART, support for adherence to ART, risk-reduction interventions (e.g., condoms and sterile drug-injection equipment), and other medical and social services Malnutrition and inconsistent access to food may also weaken immune function and impair adherence to and absorption of ART, which may influence viral load and infectiousness Unstable housing or reliance on temporary shelter may hinder the security and storage of ART and prevention devices (e.g., sterile drug-injection equipment and condoms) complicate adherence to ART
Inadequate health insurance or access to affordable health care services	 Factors may impair access to HIV medical care, ART, support for adherence to ART, risk-reduction interventions, condoms, sterile drug-injection equipment, and other medical and social services
Limited education and health literacy	 Factor may impair understanding of the biologic or social basis for HIV transmission, prevention, and care impair understanding of educational materials about HIV prevention, care, and medications impair navigation of complex health systems and social service providers

Table 3-1. Factors that influence health, quality of life, HIV transmission, and use of HIV prevention, medical, and social services among persons with HIV (cont)

Factor(s)	Possible effect on health, quality of life, HIV transmission, and use of services
Recreational substance and alcohol use and dependence, including drug injection	 Substance use may impair judgment, cause disinhibition, and increase sexual and drug-injection risk behaviors contribute to unstable and unstructured lifestyles, which can complicate regular HIV care and adherence to ART lead to social isolation, which can hinder recruiting of family and friends to support safe behaviors and adherence to ART cause mental illness and immunosuppression Sharing nonsterile drug-injection equipment may transmit HIV and other bloodborne infections
Fear or risk of physical or verbal abuse, including domestic and intimate partner violence	 Factors may impair ability to negotiate safer sexual and drug-use behaviors impair ability to retain stable housing and financial resources that foster retention in HIV care and adherence to ART
Commercial sex work, sexual coercion, and sexual assault	 Factors may result in inability to negotiate consistent condom use result in trauma that may result in bloodborne HIV exposure
Mental illness and psychological conditions, including depression, emotional distress, anxiety, and social isolation	 Factors may coexist with substance use hinder willingness or ability to seek prevention services or use prevention strategies impair judgment and increase sexual and drug-injection risk behaviors that can expose others to HIV lead to unstable and unstructured lifestyles, which can hinder regular HIV care and adherence to ART lead to social isolation, which can hinder recruitment of family and friends to support safe behaviors and adherence to ART
Legal issues, including incarceration and laws criminalizing sex work, drug possession, and intentional HIV exposure	 Criminalization laws may deter possession or use of condoms and sterile syringes deter voluntary HIV disclosure and use of HIV care and other services that promote ART use and safe behaviors Incarceration may result in exposure to sexual violence lead to sharing of drug-injection equipment interrupt HIV care, ART use, substance use treatment, and other HIV-related services during incarceration or after release

Factor(s)	Possible effect on health, quality of life, HIV transmission, and use of services
Immigration status	 Factor may deter HIV disclosure or prompt fear of arrest, detainment, or deportation that may delay HIV services prohibit HIV care, ART use, and prevention services if person cannot provide documentation to confirm eligibility for services
Cultural and linguistic background, gender identification, and sexual orientation	 Factors may cause stigma or discrimination hinder ability to find service providers who have common language skills cause resistance to unfamiliar treatment or prevention strategies, including ART hinder ability to find providers who understand cultural norms about HIV prevention and care, or have experience in health care for gay, lesbian, and transgender persons
Lack of transportation or childcare	 Factors may hinder access to regular HIV medical care that enables use of ART and reinforces safer behaviors cause missed visits for HIV prevention and care services
Residence in rural and urban areas with limited medical and social services	 Factor may require traveling long distances to skilled service providers cause reliance on local providers who lack HIV prevention and care experience increase risk for confidentiality violations that may hinder HIV disclosure to supportive providers, partners, family, and friends
Adolescence and legal minor status	 Factors may hinder access to HIV services because of lack of awareness about ability to access services without parental consent or concern about confidentiality of medical records preclude having an established health care provider, having experience navigating HIV services, or having documents to confirm eligibility for HIV services (e.g., family income) hinder access to age-appropriate specialty services (youth-friendly services) hinder HIV disclosure because of fear of parental abuse, loss of financial support or housing, or stigma about sexual or drug activity
Advanced age	 Factor may lead to cognitive decline, comorbid health conditions, and social isolation that may impair ART adherence loss of longstanding sex partners or sexual function that may lead to new or casual partners use of sexual performance devices that may cause genital trauma use of erectile dysfunction medication that may increase sexual behavior that may increase the risk of HIV transmission

Note. For evidence supporting the factors listed in this table, see <u>Section 7, Risk Screening and Risk Reduction</u> and <u>Section 12, Other</u> <u>Medical and Social Services</u>. For an expanded version of this table that includes specialty services that address these factors, see <u>Table 12-1</u>.

Ethical and legal issues that influence access to and use of HIV prevention and care services

Since the early 1980s, federal and state governments have enacted several laws intended to protect the confidentiality, rights, and autonomy of persons with HIV; promote access to HIV prevention and care services; or prevent HIV transmission. Many relate to

- authorized and unauthorized disclosure of HIV status
- discrimination protections
- autonomy in health decisions and rights to access prevention and care services

Providers who are aware of these issues are better equipped to affirm the rights and responsibilities of persons with HIV, encourage safer sexual and drug-use behaviors, and fulfill their own legal and ethical obligations. These providers are also more likely to direct patients and *clients* to appropriate services, support public health practice, and foster mutual respect and cooperation between persons with HIV, their service providers, and their communities.

Authorized and unauthorized disclosure of HIV status by providers of prevention and care services

Several federal and state laws protect the *privacy* and confidentiality of persons with HIV. These laws have taken on greater importance as health information and delivery of care have become more collaborative, integrated, and networked and as teams are more frequently used to manage the care of a person with HIV or other complex, chronic conditions.

All 50 states and the District of Columbia require name-based reporting of HIV cases and laboratory test results that confirm HIV infection to health departments for HIV *surveillance* purposes. Most persons with HIV are legitimately sensitive about case reporting because of the risk of stigma, discrimination, and other adverse consequences of unintended HIV disclosure as well as reported cases of inadvertent and intended breaches of confidentiality. To protect confidentiality, all jurisdictions require health departments to collect, store, use, and transmit identifiable HIV-related information in a secure manner consistent with HIPAA and state laws.^{26,27}

CDC has issued standards for handling HIV surveillance data that minimize uses that might reveal the identity of persons with HIV (see <u>Box 3-B</u>).⁵ This includes situations in which health departments use surveillance data to identify populations or individuals with HIV who have unmet HIV prevention needs. For example, HIV surveillance programs that track cases of HIV infection that are not followed by reported *CD4 cell count* test results (a marker of receiving HIV medical care) can identify populations that may warrant being offered assistance with *linkage to HIV care*, ** if allowed by the jurisdiction.^{28,29} In jurisdictions in which surveillance data are used to support an individual's health care, case reports may prompt health department disease investigation specialists to help HIV testing providers link case-persons to HIV medical care.²⁹⁻³¹ Also, in states that require reporting of a person's sequential CD4 cell count and *viral load* test results, health departments can identify persons who have declining CD4 cell

^{**} Linkage to care is the process of helping persons with HIV to obtain HIV medical care and prevention or social services through active methods (e.g., appointment scheduling, reminders, transportation to appointments).



counts or increasing viral load levels and may warrant being offered more effective treatment or adherence support.³² (See Sections 4, 6, 8, and 11 for recommendations about using HIV surveillance data to assess unmet HIV prevention needs.) A CDC toolkit describes strategies that HIV surveillance programs and health departments can use to promote HIV prevention and care, including ethical considerations when using confidential surveillance data.^{33,34} HIPAA specifies standards to protect the confidentiality of individual-level, identifiable health information for electronic transactions initiated by health care providers, health plans, and health care clearinghouses.³⁵ These protections are especially important for persons with HIV because they

- enable informed choices about how health information is used and shared
- set boundaries on the use and release of health records
- impose civil and criminal penalties on persons who violate patient confidentiality

Since widespread implementation of HIPAA in 2003, many persons with HIV and their providers have reported greater trust in and acceptance of the security protections for HIV-related health information.³⁶

In some jurisdictions, health care providers, health plans, and health care clearinghouses covered by HIPAA may be required to disclose some confidential health information without an individual's authorization for a few specific purposes, including³⁵

- conducting HIV-related surveillance, investigations, or interventions reporting abuse, neglect, or domestic violence that may involve HIV exposure
- enforcing federal, tribal, state, or local laws and judicial and administrative proceedings related to HIV exposure

In many states, additional regulations govern the transfer of HIV-related information from the patient's treating health care provider to another health care provider serving that patient; some state regulations are more stringent than those prescribed by HIPAA.³⁵ Additional federal laws also govern privacy protection of mental health and drug and alcohol treatment records. If state law and federal law conflict on matters of confidentiality, the law that best protects confidentiality applies.

Use of confidential *electronic medical records* (EMRs)^{††} for managing patients with HIV has grown as a result of the Patient Protection and Affordable Care Act (ACA) and technology innovations. Once stripped of confidential information, data from these record systems can also be used for legitimate quality improvement and monitoring purposes, such as revealing gaps in the continuum of HIV care within medical practices and health systems. However, some providers who are not familiar with regulations that protect the confidentiality of paper-based and electronic records may be overly cautious about sharing or withholding information. In some cases, this may delay important care and *prevention services*,^{‡‡} including initiation of ART.³⁷ For example, in some states, results of HIV tests conducted in 2 health care facilities that share EMRs are not accessible to patients' providers unless they work inside the facility that ordered the test. In other states, a quality improvement program in one health system

^{‡‡} Prevention services include interventions, strategies, policies, and structures designed to reduce the transmission of HIV infection.



An electronic medical record (EMR) is a patient record that is maintained using computer software. The record should include patient history, including diagnoses, treatments, prescribed medications, drug allergies, and self-reported problems; patient demographics; physician clinical notes; and laboratory and imaging results.

cannot access HIV viral load results from one of its clinics, thereby precluding using viral load to estimate treatment effectiveness.³⁸

Some states have "duty-to-inform" laws that obligate or permit providers who know that a person has exposed another person to HIV to notify the exposed person.^{39,40} Providers may also be required or permitted to disclose HIV-related information to law enforcement authorities when required for legal proceedings.

Voluntary disclosure by persons with HIV

State laws about HIV disclosure vary in scope and degree of enforcement. Many require that persons with HIV notify their sex or *drug-injection partners*, including spouses, after they have received an HIV diagnosis. *Partner services specialists* in many health departments offer voluntary, confidential assistance to persons who want help notifying their partners.⁴¹

Voluntary disclosure of HIV infection status to providers has many potential benefits. It can foster open communication and well-informed, shared decision making about HIV prevention and care goals, and facilitate access to medical and social services that can improve health and reduce HIV transmission.¹⁶ Disclosure to partners may enhance intimacy and psychosocial well-being and prompt frank discussion about using condoms, contraception, or sterile drug-injection equipment. Disclosure to family and friends can engage support for ART adherence or managing psychosocial problems.⁴² Disclosure can also empower persons with HIV to openly collaborate with organizations that seek input from persons with HIV¹⁷ (see Section 7, Risk Screening and Risk Reduction, and Section 8, Partner Services, for recommendations about HIV disclosure to partners.) However, disclosure can also lead to negative outcomes, such as physical or verbal abuse, dissolution of relationships, criminal or civil sanctions for HIV exposure, or job discrimination for health care providers with HIV.⁴³

Providers can take several steps to help patients and clients support safe, selective disclosure. They can review the health and psychosocial benefits of self-disclosure and describe effective disclosure strategies, such as choosing a safe, secure place to make the disclosure; offering partners information about where to obtain HIV testing; and anticipating and managing negative reactions.³⁷ They can also help persons engage *partner notification*^{§§} assistance from health department specialists who are trained to assess risk of partner physical or verbal abuse. They can also provide information about local laws on voluntary disclosure and make *referrals**** to legal professionals who can understand specific legal consequences of disclosure in the jurisdiction⁴⁴ (see Section 8, Partner Services).

Discrimination protections for persons with HIV

The Americans with Disabilities Act (ADA) protects HIV-infected persons, including those without *AIDS*-defining conditions, from discrimination in employment, housing, education, health care, and other settings.⁴⁵ By guarding against discrimination in housing and employment, the ADA can foster more

^{***} Referral is a process to help persons identify and access needed services by offering the service provider's address, phone number, directions, hours of operation, and other basic information.



^{§§} Partner notification is a step of voluntary, confidential partner services that involves locating and confidentially notifying sex and druginjection partners of persons infected with HIV or STD of possible exposure to HIV or STD.

stable housing, income, and lifestyles that encourage safe behaviors and sustained access to HIV medical care and ART.⁴⁵

Despite the privacy, confidentiality, and discrimination protections promised by ADA, HIPAA, and other regulations, many persons with HIV choose not to disclose their infection to others or forbid others to disclose this information because they fear stigma, abuse, prejudice, discrimination, deportation or criminal prosecution.^{42,46} Although experts have long known that HIV cannot be transmitted through casual contact, concerns that persist even among health care personnel can provoke negative reactions.⁴⁷ HIV-related stigma can compound stigma related to sexuality ("homophobia" or "transphobia"), substance abuse, race, ethnicity, and other characteristics that many populations heavily affected by HIV already face.

Prejudice may manifest as anger, physical or verbal abuse, offensive nonverbal cues, or social marginalization that devalues or discredits persons with HIV.⁴⁷ This may cause psychological distress, depression, and other mental health problems that may erode safe behaviors, encourage substance abuse, or lead to immunosuppression.^{48,49} Social isolation may make it difficult to engage friends and family in supporting risk-reduction or ART adherence goals. Some persons who wish to avoid real or perceived stigma or discrimination may defer HIV testing, care, and prevention services.^{49,50} Other persons with HIV may be denied medical or dental care, experience indifferent or substandard health care, or face housing or employment discrimination.⁴⁷ Yet others may decline to carry sterile drug-using equipment or condoms in public settings if they fear that possession may increase the risk of charges of illegal drug use or commercial sex work.^{51,52}

Implications of not disclosing HIV infection status

Between 1986 and 2011, 33 states enacted HIV-specific laws that could be used to impose criminal penalties on persons who knowingly expose others to HIV.^{13,53} These laws are controversial and have been subject to intense public debate. Most were passed before 2000, a period when the use of ART to reduce HIV-related disease and HIV transmission was less prevalent. Of these 33 states, 27 specifically criminalize behaviors that pose a high risk of HIV transmission, including anal or vaginal sex, prostitution, and donating blood, tissue, or body fluids. Additionally, 25 states have laws that criminalize behaviors that pose negligible or no risk of HIV transmission, such as spitting or biting. Many of the 33 states specifically criminalize behaviors when persons have not disclosed their HIV infection to sex partners (24 states) or drug-injection partners (14 states). Few of these laws allow defendants to claim use of ART, condoms, or other prevention measures in their defense against criminal liability.¹³ In 28 of these 33 states, violations of HIV-specific criminal laws are classified as felonies and prison sentences can range from 1 to 20 years.¹³ In 3 states that do not impose criminal sanctions for HIV exposure, a person's infection status may increase the severity of sentencing or be considered an aggravating factor if the person is prosecuted for a related crime.¹³ Some states have also used general criminal laws (e.g., assault, battery, reckless endangerment, or communicable disease laws) to prosecute persons accused of exposing others to HIV.^{53,54}

National databases cannot readily estimate the number of state-level prosecution, arrests, or plea agreements related to these HIV-specific criminal laws. However, one evaluation of 186 arrests or prosecutions related to HIV from 2008 to January 2014 found that about 80% occurred under such laws.⁵⁵ Many HIV criminalization laws were enacted with the expectation that awareness of these laws would

encourage persons with HIV to disclose their infection status and avoid behaviors that would result in HIV exposure.¹³ However, studies have shown that many persons with HIV are unaware of HIV disclosure requirements and exposure laws until they are notified by a provider⁵⁶ and that 25%–50% of persons with HIV served by community-based organizations may not be aware of HIV criminalization laws in their state.^{57,58} Health professionals and staff of health departments can play a valuable role in informing persons with HIV about legal requirements about disclosure and referring clients and patients to legal resources if prosecution is possible; however, they cannot provide legal counsel.²⁶ These professionals can also help persons to engage health department partner notification assistance (especially if physical or verbal abuse is possible) and to prevent exposing others to HIV in the future.

The impact of HIV criminalization laws on HIV disclosure, use of health department *partner services*,^{†††} or HIV transmission is not known. However, several studies have concluded that these laws may not deter HIV *risk behaviors*^{‡‡‡} and may cause significant or unintended harms. Harms may include resistance to HIV testing and self-disclosure or forcing persons to choose between the risk of prosecution for undisclosed sexual HIV exposure and the risk of intimate partner violence after disclosing their HIV infection.⁵⁹⁻⁶¹ For these reasons, the 2010 National HIV/AIDS Strategy (NHAS) stated that it may be appropriate for legislators to consider if existing criminalization laws in their jurisdictions advance the public's interest and health.²³ Some health policy experts have proposed revising these laws to limit prosecution to persons in whom intent to harm (e.g., sexual assault) or high risk of intentional transmission has been demonstrated (e.g., practicing prostitution without using condoms).^{53,54,61,62}

Autonomy in health decisions and rights to access prevention and care services

The principles of autonomy in health care decisions and *informed consent* are fundamental to providing HIV prevention and care. Persons with HIV have the right to accept and decline prevention and care services, even if these services might lower their risk of exposing others to HIV or their infectiousness. For example, the U.S. Department of Health and Human Services (HHS) recommends that ART be offered to all persons with HIV to treat and prevent HIV-related disease and to reduce the risk of HIV transmission but only be prescribed to those who are ready and willing to adhere to the regimen on a long-term basis.⁶³ Health department partner notification services are also strictly voluntary.³ In most states, minors may consent to HIV-related services, STD testing, and reproductive health services without parental consent.^{41,64}

Many low income persons with HIV obtain free or subsidized care through Medicare, Medicaid, and the Ryan White HIV/AIDS Program based on income, disability, or other characteristics. Increases in insurance coverage prompted by the ACA, increased eligibility for Medicaid for low-income persons in many states, and continued funding of flagship HIV care programs, such as the Ryan White HIV/AIDS Program (described below), are expected to improve access to HIV prevention and care services.⁶⁵ However, demand for government-funded services may outstrip available resources in the short-term as the number of persons living with HIV increases, more effective treatment increases their lifespans, and

^{‡‡‡} Risk behaviors are behaviors that can result in transmitting HIV to others or acquiring HIV through sexual contact, drug use, or during pregnancy (e.g., anal or vaginal intercourse without a barrier, sharing nonsterile drug-injection equipment).



Partner services includes an array of voluntary services for persons with HIV or STD and their sex and drug-injection partners that are intended to reduce HIV transmission: interviewing persons with HIV to obtain information to contact or locate their sex and drug-injection partners; notifying partners of possible HIV exposure; offering testing for HIV, sexually transmitted diseases, and other infections; providing condoms, prevention information, and counseling; and providing help in obtaining risk-reduction services, HIV medical care, and other medical and social services.

socioeconomic disparities in the burden of HIV persist. This situation raises ethical questions about rights to health care if persons with HIV do not receive basic prevention and care services or receive them only after harmful delays. For example, until 2014, many states were unable to provide subsidized ART to all eligible persons due to long waiting lists for the AIDS Drug Assistance Program (ADAP).⁶⁶ Some *clinical settings*^{§§§} are unable to promptly offer HIV medical care to all recently diagnosed persons because of appointment backlogs, lack of qualified health care providers, or delays in patient *enrollment* in health insurance or medical assistance programs.⁶⁷⁻⁷⁰ Some health departments that handle a high volume of HIV case reports cannot promptly offer *partner services* to all newly diagnosed persons when staffing for this core public health service declines.⁷¹

Laws, Regulations, Policies, and Programs that Promote Delivery of HIV Prevention and Care Services

Several federal and state laws, regulations, policies, and programs promote delivery of prevention, care, or social services to persons with HIV. Providers who are familiar with these issues are better equipped to help their clients and patients navigate a complex patchwork of service providers and leverage resources to secure needed services.

Governmental and nongovernmental policies and programs that provide or fund prevention and care services for persons with HIV

Many governmental and nongovernmental policies and programs determine the funding or infrastructure for delivering HIV prevention and care services. The NHAS described several essential elements of HIV prevention and care that favor more holistic, comprehensive care, reduce gaps in the continuum of HIV care, and reduce the burden of HIV in the communities where the infection is most prevalent.²³ The NHAS encourages HIV prevention and care providers to use evidence-based strategies to provide services, including the following:

- Early detection of HIV infection
- Prompt linkage to high quality HIV care that enables initiation of ART
- Support for sustained high adherence to ART
- Access to *behavioral* and *biomedical interventions* that reduce the risk of HIV transmission from persons with HIV
- Screening and treatment for other medical conditions that may influence HIV transmission or are common comorbid conditions (e.g., STDs that facilitate HIV transmission, substance use, and mental illness)
- Assessment and services for social conditions that may influence HIV transmission (e.g., unstable housing that may impair ART adherence)
- Services to notify recent sex and drug-use partners of possible HIV exposure and facilitate their access to behavioral and biomedical interventions that can reduce their risk of HIV acquisition

Government-funded programs that directly deliver or cover the costs of HIV prevention and care services have been crucial in expanding services to the many persons with HIV who are not covered by private

⁸⁸⁸ Clinical settings are health care facilities in which medical diagnostic, treatment, and disease prevention services are routinely provided.

health insurance. According to a nationally representative study, only about 30% of persons with HIV who received HIV health care in 2009 had some type of private health insurance.⁷² However, recent implementation of the ACA has increased access to HIV care through private health insurance, Medicaid, and other federal and state medical assistance programs.⁷³ As of early 2014, most HIV prevention, treatment, and care services were funded by federal sources (see <u>Table 3-2</u>). Many persons with HIV also receive services through programs that are jointly funded or administered by federal and state governments, such as Medicaid and ADAP. In some states, state funds support prerelease medical transition planning for prisoners, SSPs, and HIV education programs (see <u>Table 3-2</u>).^{9,74} Many nongovernmental programs provide information about HIV; distribute condoms and new, sterile drug-injection equipment; offer HIV testing, *risk screening*, risk-reduction interventions; assist with linkage to *HIV medical care*; provide affordable HIV care; and provide subsidized ART (see <u>Table 3-2</u>).

Table 3-2. Selected governmental and nongovernmental organizations that deliver or cover costs of HIV prevention and care services for persons with HIV

Organization—examples of HIV prevention and care services provided or covered

Centers for Medicare and Medicaid Services (CMS)—cover services^a for the following:

- HIV and STD testing and treatment
- Risk assessment and risk-reduction counseling
- Family planning services
- Mental health services
- Substance use treatment
- HIV care during pregnancy

Health Resources and Services Administration Ryan White HIV/AIDS Program (HRSA HIV/AIDS Bureau) funds clinics and providers to deliver the same services as CMS (see above) and the following:

- Case management
- Transportation to medical visits
- Subsidized ART through the AIDS Drug Assistance Program (ADAP)
- Support services (e.g., transportation, housing, food vouchers)
- Services for undocumented immigrants

Health Resources and Services Administration Maternal and Child Health Title V Maternal and Child Health programs (HRSA Maternal and Child Health Bureau)—fund health agencies that provide the following:

- Comprehensive prenatal and postnatal care to women (especially low-income and at-risk women)
- HIV and STD testing, counseling, and treatment

Federally qualified health centers (FQHC)—deliver the same services as CMS (see above) and the following:

- Translation and health education services
- Case management
- Transportation to community and migrant health centers
- Health care programs for homeless persons and residents of public housing facilities
- Primary care services in public housing facilities

Department of Veterans Affairs—delivers the same services as CMS (see above)

Table 3-2. Selected governmental and nongovernmental organizations that deliver or cover costs of HIV prevention and care services for persons with HIV (cont)

Organization—examples of HIV prevention and care services provided or covered

Federal Bureau of Prisons—covers some of the same services as CMS (see above)

Substance Abuse and Mental Health Services Administration (SAMHSA)—funds facilities offering the following:

- Drug and alcohol use counseling and treatment
- Mental health services
- HIV testing
- Assistance with linkage to HIV medical care

Centers for Disease Control and Prevention (CDC)—funds state and local health departments and communitybased organizations (CBOs) that provide the following:

- HIV and STD testing, education, and risk-reduction services
- Condoms
- Partner services
- Linkage to and retention in HIV care services
- HIV and STD surveillance that may activate prevention services
- Development of HIV prevention and care polices

Office of Population Affairs Title X Family Planning—funds health care facilities that provide low-income or uninsured persons with the following:

- HIV and STD education, counseling, testing, and referral
- Family planning services for women and men
- Pregnancy services

U.S. Department of Housing and Urban Development—funds state and local governments to support housing for low-income persons with HIV and their families (e.g., Housing Opportunities for Persons with HIV/AIDS program)

State and local governmental agencies—fund health care facilities, health departments, STD clinics, and CBOs that provide the following:

- Nonreimbursed clinical and preventive services
- HIV and STD testing, risk-reduction services, partner services, and linkage to medical and social services
- Condom and sterile syringe distribution^b
- State contributions to Medicaid programs
- Administration of federally funded ADAP (see above)

Table 3-2. Selected governmental and nongovernmental organizations that deliver or cover costs of HIV prevention and care services for persons with HIV (cont)

Organization—examples of HIV prevention and care services provided or covered

Nongovernmental organizations—fund health care facilities and programs that provide the following:

- Nonreimbursed clinical and preventive services, including services to undocumented immigrants
- HIV and STD testing, education, risk-reduction services, partner services, and HIV disclosure assistance
- ART adherence support and programs that subsidize ART
- Case management, peer support, and linkage to medical and social services
- Housing, nutritional, and legal services
- Condoms and syringe services programs^b
- Private insurance that covers HIV and STD testing, treatment, medication, and in some cases, counseling, substance abuse, and mental health services

Note. This list only includes examples and is not comprehensive.

^a The range of services covered by Medicaid varies by state.

Unfortunately, many persons with HIV are not aware of these prevention and care resources. As a critical first step to improve awareness, case managers, *navigation assistants*, peer educators, and other professionals can help persons with HIV enroll in private health insurance or governmental and nongovernmental assistance programs.¹¹ Health departments, HIV advocacy organizations, HIV planning groups, and public and private sector health systems can also facilitate access to HIV prevention and care services through cross-sector collaborations and coordination.⁹ For instance, to expedite the start of HIV medical care, HIV surveillance programs can identify community-based HIV testing sites where many newly diagnosed clients lack evidence of starting HIV medical care (e.g., no reported CD4 cell count test results); these testing sites can help clients schedule their first HIV medical appointments; health care providers can prioritize scheduling of these appointments; and health systems can evaluate the health outcomes and costs of this expedited approach.

Anticipated impact of the ACA on prevention services for persons with HIV

Over the next decade, the implementation of the ACA will dramatically change the scope, delivery, and funding of prevention services for many persons with HIV by

- providing federal funding to assist low-income populations in accessing health insurance
- expanding coverage for preventive and clinical services through Medicaid or private health plans offered through state *health insurance marketplaces*****
- reducing the ability of health plans to discriminate due to HIV and other preexisting conditions⁷³

^{****} Health insurance marketplaces were created by the Patient Protection and Affordable Care Act (ACA) for individuals and small employers to directly compare available private health insurance options on the basis of price, quality, and other factors.



^b Syringe services programs provide free, new, sterile syringes and needles in exchange for used syringes and needles to reduce transmission of bloodborne pathogens among people who inject drugs. As of fiscal year 2012, states that authorize syringe services programs can no longer use federal funds to support staff who distribute needles or syringes; related delivery infrastructure, such as vehicles or rent for fixed sites used to distribute needles or syringes; and purchase of needles or syringes. For more information, see "Dear Colleague" letter: http://www.nastad.org/Docs/102846 OHAP ECOPY EXCHANGE 03282012-103554.CPY.pdf.⁷⁵

Under ACA reforms, more low-income persons who have received free services in clinics directly funded by the Ryan White HIV/AIDS program can now receive care from providers who are reimbursed by Medicaid or private insurance plans.⁷⁶ Reforms of the ACA have increased the number of providers working in Ryan White-funded clinics who can bill Medicaid, other medical assistance programs, or private health insurance for HIV-related services.⁷⁷ Medicaid and private insurance plans can also cover costs of HIV medications for persons who now receive subsidized medications through ADAP.

The Centers for Medicare and Medicaid Services (CMS) and HRSA are working at the federal level to provide technical assistance to Medicaid agencies and Ryan White HIV/AIDS Programs to increase access to HIV care for low-income persons with HIV and to increase the number of Medicaid providers who are skilled in HIV care.⁷⁷ The ACA encourages states to enroll persons with HIV and other chronic conditions who are eligible for Medicaid into "medical homes" that use teams of providers to coordinate comprehensive care and engage patient support services.^{73,78,79} This approach is intended to increase attention to primary care and prevention, communication and service coordination between providers, financial efficiencies, adoption of standards of care, and use of integrated EMRs.^{73,78-80} HRSA is seeking to expand the successful "HIV medical home" used in Ryan White-funded clinics by offering training in HIV care, treatment, prevention, HIV-related mental health, and cultural competency to health centers without this expertise.⁸¹ Several states have recently specifically expanded opportunities for "medical homes" for persons with HIV.⁸² Many *state and local health agencies* and HIV planning groups are monitoring HIV service delivery, health outcomes, and coverage policies in their jurisdictions to identify coverage gaps during this transition and advocating for relevant coverage expansion.⁸⁰

Despite anticipated improvements in HIV services due to ACA implementation, several troubling gaps in access to HIV prevention and care services persist and may delay implementation of recommendations in this report.^{73,78,83} As of early 2014, some states deferred expansion of state Medicaid programs to many low-income persons. This may impair access to HIV medical care, particularly in Southern states where many low-income persons with HIV reside.⁸⁴ More persons with HIV will receive care from the growing cadre of primary care providers working outside HIV specialty clinics who serve new enrollees of Medicaid or private insurance. Many of these providers have not yet had extensive HIV training and experience or lack established relationships with other professionals proficient in risk reduction, case management, and other services that comprise a comprehensive "medical home." Medicaid and private insurance plans may not cover many valuable services now covered by the Ryan White HIV/AIDS Program or other special HIV programs. These include assistance with linkage to and retention in HIV care; case management; some types of ART adherence support; substance use and mental health treatment; and support for transportation, housing, and employment. Medicaid and private insurance do not cover some core public health activities, such as partner notification, that can prevent HIV transmission. Some antiretroviral medications covered by ADAP may not be covered by or included in drug formularies of private health insurance plans or have prohibitive copays. Finally, immigrants who are not yet United States citizens are only eligible to receive HIV care through Medicaid or health insurance plans if they have lived in the United States at least five years.^{73,85} Immigrants who are not citizens and do not meet these residency requirements can receive care through other federal and state HIV assistance programs that do not specify eligibility requirements related to immigration status if they can provide required enrollment documentation.⁸⁶ Until these many gaps are closed, the Ryan White HIV/AIDS Program, ADAP, and other "safety net" programs will continue to provide essential HIV services and cover the cost of copays, deductibles, and other noncovered expenses for many persons with HIV.

Strategies to expand the HIV prevention and care workforce

The demand for skilled HIV prevention and care providers in clinical settings and *nonclinical settings*^{††††} will grow over the next decade as the number and lifespan of persons with HIV increase, persons with HIV seek services in new settings, and options for prevention and care services expand.²³ The IOM recently cautioned about the national shortage of skilled HIV prevention providers and called for¹⁰

- training primary care medical providers, including those who will provide HIV services under ACA-related Medicaid expansion, in HIV prevention and care services
- developing a new cadre of HIV medical specialists who can replace retiring specialists
- aligning health department resources to maximize HIV prevention and care services after recent budget cuts

In the face of these challenges, the IOM recommended that health departments, primary care providers, and others advocate to increase the number of HIV providers and to train non-HIV specialists in HIV care and treatment. IOM also recommended shifting some tasks across provider levels, e.g., physicians could share some ART adherence support functions with physician assistants, advance practice nurses, registered nurses, pharmacists, and health educators.⁸⁷ Multidisciplinary clinical teams can form within a single practice or health system or within networks of service providers who practice locally or through remote, *telemedicine services*.^{‡‡‡‡88} The Ryan White HIV/AIDS Program's experience with comprehensive HIV services through "medical homes" provides valuable lessons about provider networks that other prevention and care providers could apply. Use of effective and cost-effective interventions and evaluation processes that monitor intervention delivery and outcomes may also encourage more judicious use of providers' time. To build the capacity of health care providers serving persons with HIV, HRSA and CDC support regional training centers across the U.S. that offer training in the prevention, diagnosis, and management of HIV and STD.^{89,90}

Nonclinical HIV prevention providers in community-based organizations and health departments will continue to lead crucial HIV prevention and care programs. These organizations have provided HIV testing, risk-reduction interventions, and partner services for decades; many are now helping persons with HIV to engage in HIV medical care and support ART adherence with funding from CDC and other sources.⁶ For example, one state health department is tracking case-specific CD4 cell counts and viral load measures reported to HIV surveillance as a means to identify persons who have had lapses in HIV medical care and may warrant help to resume care.³¹ HIV planning groups can foster the development of a skilled HIV prevention and care workforce by supporting training programs, adequate provider reimbursement for HIV services, and use of the most effective and cost-effective interventions.⁹¹

Implementation Resources

Additional information and practical resources to support implementation of these recommendations can be found at <u>http://www.cdc.gov/hiv/guidelines/implementationresources.html</u>.

Telemedicine services involve the use of telecommunications technology to provide, enhance, or expedite health care services or to provide consultation, training, and mentoring to health care professionals.



^{****} Nonclinical settings are facilities that provide prevention, education, screening and interventions for risk behaviors, and referrals for medical and social services. Some nonclinical settings may also provide health promotion services and screening for HIV and some STD.

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Section 4. Linkage to and Retention in HIV Medical Care Background

A growing body of evidence indicates that early initiation of *HIV medical care* and *antiretroviral treatment (ART)* and sustained high *adherence* to ART improve health outcomes and survival rates and can prevent HIV transmission¹⁻⁸ (see Section 5, Treatment). Starting HIV medical care shortly after diagnosis and sustaining long-term care also provides opportunities to offer risk-reduction interventions, partner services,* sexually transmitted disease (STD) services, and other services to prevent HIV transmission.⁹⁻¹⁹ Some studies show that persons who stay in care during their first year of outpatient HIV medical care are more likely to start ART than persons with early lapses in care, have high adherence to ART, achieve virologic suppression, and practice safer sexual behaviors.^{3,7,20,21}

A meta-analysis of studies published from 1996–2009 found that about 25% of persons who tested positive for HIV did not start HIV medical care within 6 months after their first positive test result. This analysis also revealed limited *retention in care*: only 69% of persons who tested positive had two or more visits during the 6 months after diagnosis; only 61% had at least one visit every 6 months during the 18– 24 months after diagnosis; and only 26% had at least one visit per year during the 3–5 years after diagnosis.²² These findings prompted the National HIV/AIDS Strategy for the United States and several federal agencies to prioritize proactive methods to help persons start HIV medical care shortly after diagnosis (termed *linkage to care[†]*), attend scheduled follow-up HIV medical visits (*retention in care[‡]*), and resume HIV medical care after a lapse in care (*reengagement in care[§]*)^{1,6,8,23} (see Figure 4-1).

Several types of providers can assist with linkage to, retention in, and reengagement in care. They include staff of nonclinical and clinical HIV testing sites, such as prevention specialists, health care providers, case managers, *linkage facilitators*,** *navigation assistants*,^{††} *outreach* specialists, and clinic administrators. They also include disease investigation specialists, *partner services specialists*,^{‡‡} or other health department staff. Proactive linkage and retention services typically require a more intense or sustained level of effort than traditional *referral*^{§§} strategies (e.g., providing clinic contact information)

Referral is a process to help persons identify and access needed services by offering the service provider's address, phone number, directions, hours of operation, and other basic information.



^{*} Partner services include an array of voluntary services for persons with HIV or STD and their sex and drug-injection partners that are intended to reduce HIV transmission: interviewing persons with HIV to obtain information to contact or locate their sex and drug-injection partners; notifying partners of possible HIV exposure; offering testing for HIV, sexually transmitted diseases, and other infections; providing condoms, prevention information, and counseling; and providing help in obtaining risk-reduction services, HIV medical care, and other medical and social services.

[†] Linkage to care is a process to help persons with HIV obtain HIV medical care and prevention or social services through active methods (e.g., appointment scheduling, reminders, and transport to visits).

Retention in care is a process to help persons with HIV continue to attend scheduled HIV medical appointments after their initial HIV medical appointment.

Reengagement in care is a process to help persons with HIV resume HIV medical care and continue to attend scheduled HIV medical appointments after a lapse in care.

^{**} Linkage facilitators assist persons with HIV to access HIV medical care and other medical and social services through active methods (e.g., help with making appointments, providing transportation to appointments).

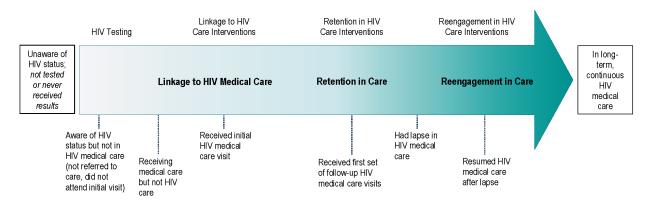
^{††} Navigation assistance is the process of helping persons obtain timely and appropriate medical or social services given their preferences about providers, insurance status, scheduling issues, and other factors that may complicate access to or utilization of services.

^{‡‡} Partner services specialists include specially trained disease investigation specialists, public health investigators, or communicable disease investigators who work in health departments and staff of other agencies who are trained and authorized to provide partner services.

and often involve tracking outcomes, such as completion of scheduled visits.²⁴ Linkage strategies can operate at the patient, facility, or system level and often require formal *coordination**** and *collaboration*^{†††} among *nonclinical providers*, *clinical providers*, health systems, and health departments that provide HIV testing or other HIV services.^{25,26}

This section describes interventions to promote linkage to, retention in, and reengagement in HIV medical care. *Quality improvement*^{‡‡‡} and program *monitoring and evaluation*^{§§§} methods can determine if the interventions described in this section are implemented as intended, yield the expected outcomes, or warrant changes in delivery methods (see Section 13, Quality Improvement). Sections 5 through 12 also describe interventions that can be offered to persons with HIV who are linked or referred to other clinical providers, or health departments.

Figure 4-1. The continuum of engagement in HIV medical care



Note. The headings above the arrow refer to interventions that promote engagement in care. The text blocks below the arrow indicate events that some persons with HIV may experience. The arrow points to the desired outcome of long-term, continuous HIV medical care. Adapted from Cheever LW.¹

^{§§§} Monitoring and evaluation is a process that involves the repeated, ongoing collection and review of information about program activities, characteristics, and outcomes in order to assess program implementation, coverage, acceptability, cost, and effectiveness.



^{***} Coordination is a process of creating more client-centered, streamlined, and nonduplicative systems that clarify communication methods, staff roles, use of health information, and reimbursement policies and procedures.

⁺⁺⁺ Collaboration is working with another person, organization, or group for mutual benefit by exchanging information, sharing resources, or enhancing the other's capacity, often to achieve a common goal or purpose.

^{****} Quality improvement is an approach to the continuous study and improvement of the processes of providing services that meet or exceed established professional standards and user expectations.

Recommendations

BOX 4. RECOMMENDATIONS—LINKAGE TO AND RETENTION IN HIV MEDICAL CARE

For nonclinical and clinical providers (including health department staff who provide individual-level services to persons with HIV)

- Establish infrastructure to support starting HIV care (within 3 months after diagnosis), long-term retention in care, and resuming care after a lapse^{a,b} (i, ii, iii, iv, v, vi) (see <u>Box 4-A</u>)
- Inform persons about the benefits of starting HIV care and antiretroviral treatment (ART) early (even when feeling well) and staying in care for personal health and to prevent HIV transmission, before HIV testing is offered and when providing preliminary or confirmatory HIV positive test results (v, vi, vii)
- Assess possible facilitators and barriers to linkage and retention and provide or make referrals for other medical and social services that may improve linkage and retention^a (ii, iii, iv, v, vi, viii) (see <u>Box 4-B</u>)
- Help persons enroll in health insurance or medical assistance programs that provide HIV care or cover costs of care (ii, vi, vii, ix, x)
- Provide immediate, active, and, if necessary, repeated, linkage services to persons with a preliminary positive HIV test result or a confirmed HIV diagnosis, striving to start care within 3 months after diagnosis^{a,c,d} (i, iii, v, xi, xii) (see <u>Box 4-C</u>)
- Collaborate with other health care providers, case managers, navigation assistants, nonclinical communitybased organizations, and health departments to provide services that promote prompt linkage to and retention in care (ii, iii, vi, xiii, xiv, xv) (see <u>Box 4-A</u>)
- Track outcomes of linkage and retention services and provide follow-up assistance, if allowed by jurisdiction, to
 persons who have not started HIV medical care within 3 months after diagnosis or who have lapses in care^{a,d} (i,
 v, xv) (see <u>Box 4-C</u>)

For staff of health departments and HIV planning groups who provide population-level HIV prevention and care services

- Support efforts to increase assistance with linkage, retention, and reengagement services, and affordable ART through
 - direct interventions provided by staff, contractors, and programs^e (ii) (see <u>Box 4-A</u>, <u>Box 4-B</u>, <u>Box 4-C</u>)
 - partnerships with public- and private-sector health systems (ii, iii, ix, x, xiii, xiv, xvi, xvii) (see <u>Box 4-A</u>, <u>Box 4-B</u>, Box 4-C)

Note. In this report, *nonclinical providers* are defined as persons who work in community-based organizations or health departments operating outside of health care facilities and who provide HIV testing, health education, risk-reduction interventions, partner services, case management, or assistance with linkage or referral to medical and social services. These persons include HIV testing providers, peer and professional health educators, counselors, service linkage facilitators, partner services specialists, case managers, and social workers. *Clinical providers* are defined as persons who work in health care facilities and who provide risk assessments, health education, counseling, screening, diagnosis, treatment, and other health-related services. These providers, health educators, case managers, social workers, and counselors. Some may be employees or contractors of health departments. Some of the federal guidelines cited in the Recommendation boxes of each chapter may have been updated. For current federal recommendations, please refer to http://www.cdc.gov/hiv/guidelines/.

- ^a Information described in the <u>Evidence</u> topic in this section supports this recommendation statement.
- ^b Existing source guidance does not address methods to establish infrastructure for retention in care.
- ^c Existing source guidance does not address methods to provide repeated linkage assistance.
- ^d Existing source guidance does not specify optimal time frames for linkage to care, such as 3 months.
- ^e The Centers for Disease Control and Prevention has compiled examples of best practices for health departments to track linkage and retention outcomes and to provide linkage and retention assistance.^{23,27}



BOX 4. RECOMMENDATIONS—LINKAGE TO AND RETENTION IN HIV MEDICAL CARE (cont)

Sources

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Box 4-A. Examples of strategies to establish infrastructure that supports linkage to, retention in, and reengagement in HIV medical care by setting

Nonclinical and clinical settings, including health departments that provide individual-level services to persons with HIV

- Establish procedures to promptly provide confirmatory HIV testing to all persons with preliminary positive HIV test results
- Develop written agreements between HIV testing providers and HIV health care providers that define roles and responsibilities for linking persons to HIV care and for supporting retention in care
- Train staff to
 - provide linkage, retention, and reengagement services or engage other professionals, community
 organizations, or health departments that provide these services (see <u>Box 4-C</u>)
 - comply with laws, policies, and procedures to protect patient confidentiality when exchanging personal, health, or financial information used for linkage, retention, and reengagement services
- Establish protocols to monitor individual-level outcomes of linkage, retention and reengagement services (see Box 4-C)
- Provide staff training and tools to increase competence in serving patients with differing ages, sexes, gender identities, sexual orientations, cultural backgrounds, education levels, and health literacy levels

Box 4-A. Examples of strategies to establish infrastructure that supports linkage to, retention in, and reengagement in HIV medical care by setting *(cont)*

HIV medical care settings (in addition to above recommendations)

- Train clinical providers about the most recent U.S. Department of Health and Human Services guidelines that advise offering ART to all persons (regardless of CD4 cell count) for health benefits and preventing HIV transmission.
- Develop protocols to update patient contact information at each visit (e.g., residence, phone number(s), payment method)
- Develop procedures to routinely assess factors that enable or hinder attending visits (see <u>Box 4-B</u>)
- Establish procedures to identify patients at risk for lapses in care and services that support their continued care
- Establish methods to monitor timing and completion of each patient's scheduled medical visits

Health departments that provide population-level HIV prevention and care services

- Make available online directories of HIV testing and health care providers who provide HIV care in the public and private sectors^a
- Develop and implement protocols and data-sharing agreements to use HIV surveillance and other data to monitor linkage to and retention in HIV medical care at the individual, provider, facility, and community level, if allowed by the jurisdiction^b
- Promote the use of evidence-based intervention^c models for linkage to or retention in care that are suited to the jurisdiction
- Encourage and train health department staff to collaborate with HIV testing and health care providers to help persons with HIV start or resume HIV medical care, if allowed by the jurisdiction
- Collaborate with corrections facilities to establish policies and procedures that link inmates to health care facilities in the community that provide HIV medical care after their release and provide follow-up until HIV care has resumed
- *Note.* Nonclinical settings are facilities that provide prevention, education, screening and interventions for risk behaviors, and referrals for medical and social services. Some nonclinical settings may also provide health promotion services and screening for HIV and some STD. Clinical settings are health care facilities in which medical diagnostic, treatment, and disease prevention services are routinely provided.
- ^a Several organizations maintain national directories of HIV medical care providers that are searchable by name, location, languages, insurance types accepted, and/or services provided: The American Academy of HIV Medicine (<u>http://www.aahivm.org/ReferralLink/exec/frmAdvSearch.aspx</u>, accessed January 1, 2014); the HIV Medicine Association (<u>http://www.hivma.org/directory/</u>, accessed July 17, 2014); and the HRSA Ryan White HIV/AIDS Program (<u>http://findhivcare.hrsa.gov/Search_HAB.aspx</u>, accessed July 17, 2014).
- ^b Sources of data that might be used in conjunction with HIV surveillance data vary by jurisdiction. They may include HIV testing sites; laboratories that conduct testing for HIV, CD4 cell counts, and viral load; Medicaid and Medicare benefit programs; AIDS Drug Assistance Programs (ADAP); clinics funded by the Ryan White HIV/AIDS Program; large HIV clinics; and other health systems.
- ^c Evidence-based interventions are individual-, group-, or population-level interventions that have been shown to promote safer behaviors or reduce HIV or STD transmission in research studies, program evaluations, or theory-based intervention experience.

Box 4-B. Barriers to linkage to, retention in, and reengagement in HIV medical care and components of multifaceted interventions that may overcome barriers, as identified in evidence review

Linkage to care

Barriers for persons with HIV

- Feeling well
- Feeling stigmatized
- Lack of health insurance and/or misperception that HIV care requires health insurance
- Negative perceptions of the health care system
- Discomfort with clinical providers
- Competing priorities (e.g., job, child care)
- Substance use
- Mental illness
- Limited social support to engage in HIV medical care
- Unstable housing

Barriers related to community infrastructure

- Limited health insurance or medical assistance options
- Few trained HIV health care providers
- Lack of health facilities with convenient locations and/or hours
- Limited transportation or child care services
- Limited sources of affordable, stable housing that enable consistent contact information and proximity to health care facilities

Barriers for health care facilities

- Inability to schedule visits promptly or at convenient times
- Lack of staff or resources to engage new patients

Components of multifaceted interventions that may overcome barriers

- Providing assistance at HIV testing sites
- Linking persons tested in clinical sites to HIV medical care in the same health system
- Multiple case management^a sessions
- Motivational counseling
- Navigation assistance,^b specifically
 - help enrolling in health insurance or medical assistance programs
 - transportation services to the health care facility
- Providing or linking to other medical or social services (e.g., substance abuse treatment, mental health services, child care)
- Maintaining relationship with a consistent care team

Box 4-B. Barriers to linkage to, retention in, and reengagement in HIV medical care and components of multifaceted interventions that may overcome barriers, as identified in evidence review *(cont)*

Retention and reengagement in care

Barriers for persons with HIV

- Same as linkage noted previously, plus barriers associated with
 - Younger age
 - Female gender
 - Being a member of a sexual, racial, or ethnic minority group

Barriers related to community infrastructure

- Same as linkage noted previously, plus
 - Fragmented HIV prevention and care services

Barriers for health care facilities

- Inability to schedule visits at appropriate intervals or convenient times
- Lack of routine monitoring of past and future visits
- Visit times too short to build rapport or trust or to answer patients' questions
- Health care providers have limited expertise in HIV medical care
- Health care providers have limited experience with patients with diverse sexual, linguistic, or cultural characteristics

Components of multifaceted interventions that may overcome barriers

- Providing assistance at HIV clinical sites
- Multiple case management^a sessions
- Motivational counseling
- Navigation assistance,^b specifically
 - reminders for follow-up visits
 - help enrolling in health insurance or medical assistance programs
 - transportation services to the health care facility
- Providing or linking to other medical or social services (e.g., substance abuse treatment, mental health services, child care)
- Maintaining relationship with a consistent care team
- Experience in serving culturally diverse patients

Note. The <u>Methods</u> topic in this section describes the sources of evidence that identified these barriers and intervention components.

^a Case management is a service generally provided through an ongoing relationship with a client or patient that includes comprehensive assessment of medical and psychosocial support needs, development of a formal plan to address needs, provision of assistance and advocacy in accessing services, and monitoring of service delivery.

Navigation assistance is the process of helping persons obtain timely and appropriate medical or social services given their preferences about providers, insurance status, scheduling issues, and other factors that may complicate access to or utilization of services.

Box 4-C. Selected steps and strategies to support early linkage to and retention and reengagement in HIV medical care

Linkage to care

(the process of assisting persons with HIV to begin HIV medical care)

For nonclinical and clinical providers who provide HIV testing and education but not HIV medical care

- Assess the person's readiness to start care, and barriers and facilitators to starting care (see Box 4-B)
- Help schedule the first HIV medical visit, seeking same-day or priority appointments when possible, especially for newly diagnosed persons
- Provide transportation assistance to the first visit, when possible
- Verify attendance at first visit by contacting the person or the HIV health care provider
- If the first visit was not completed, provide additional linkage assistance until visit is completed or no longer required

For HIV medical care providers

- Assess the person's readiness to start care, and barriers and facilitators to starting care (see <u>Box 4-B</u>)
- Offer convenient scheduling whenever possible (e.g., same-day or priority appointments, extended hours)
- Maintain a patient-friendly environment that welcomes and respects new patients
- Provide reminder for first appointment, using the patient's preferred contact method
- Offer patient navigation assistance and support to encourage attendance (e.g., directions, transportation advice)

For staff of health departments who conduct HIV surveillance or provide disease intervention services

- Use HIV testing, CD4 cell count, and viral load data to identify populations or individuals who may need linkage assistance, if allowed by the jurisdiction
- Engage staff to provide linkage assistance in nonclinical and clinical HIV testing sites, if allowed by the jurisdiction
- Make available online information about HIV medical care sources in the community to HIV testing and service organizations

Retention in care

(the process of assisting persons with HIV to attend scheduled follow-up HIV medical appointments after they have started HIV medical care)

For nonclinical and clinical providers who provide HIV testing and education but not HIV medical care

- Help schedule follow-up HIV medical care visits
- Provide reminders for all visits, using the person's preferred method of contact
- Offer navigation assistance and encourage person to complete the visit
- Reinforce the benefits of regular HIV care for improving health and preventing HIV transmission to others during in-person encounters or outreach by phone, email, or other methods
- Periodically assess facilitators and barriers to retention and motivate the person to overcome the barriers (see <u>Box 4-B</u>)
- Verify if the person attended follow-up visits, even when the patient was seen in another clinical setting

Box 4-C. Selected steps and strategies to support early linkage to and retention and reengagement in HIV medical care

For HIV medical care providers (in addition to above strategies)

- Offer convenient scheduling of follow-up visits (e.g., evening or extended hours), when possible
- Implement clinical decision-support tools or systems that alert providers about patients with suboptimal follow-up, increasing viral load, or decreasing CD4 cell counts

Box 4-C. Selected steps and strategies to support early linkage to and retention and reengagement in HIV medical care *(cont)*

For staff of health departments who conduct HIV surveillance or provide disease prevention services

- Use CD4 cell count and viral load data to identify populations or individuals who lack evidence of retention in care, if allowed by the jurisdiction
- Engage staff to provide retention assistance in nonclinical and clinical settings that provide HIV testing and education, if allowed by the jurisdiction
- Provide information about HIV medical care options in the community to HIV testing sites and organizations that serve persons with HIV

Reengagement in care

(the process of assisting persons with HIV to resume continuous HIV medical care, after a lapse in care)

Same as retention in care but provided to persons who have had a lapse in care (e.g., 6 or more months)

Note. This box includes only selected steps and strategies among many that may be available. See the <u>Evidence</u> topic in this section for more information.

How These Recommendations Differ from Previous Recommendations

These recommendations are consistent with guidance from the Centers for Disease Control and Prevention (CDC), the Health Resources and Services Administration (HRSA), and the U.S. Department of Health and Human Services (HHS) that recommend that persons be linked to services shortly after a positive HIV test.^{6,11,26,28-37} However, the recommendations in this section provide

- greater emphasis on proactive linkage and retention strategies instead of passive referral methods
- greater emphasis on starting care within 3 months after diagnosis because of the benefits of starting ART regardless of *CD4 cell count*
- strategies for health departments to establish infrastructure and services that support linkage to and retention in care, if allowed by their jurisdictions (e.g., use of *surveillance* data)
- more detailed guidance on *evidence-based* methods to support linkage to, retention in, and reengagement in HIV medical care

The recommendations are also generally consistent with the latest comparable recommendations about linkage to and retention in care of these nongovernmental organizations: the International Association of Physicians in AIDS Care;³⁸ the HIV Medicine Association of the Infectious Diseases Society of America;³⁹ and the International Antiviral Society-USA Panel.^{4,15}

Methods

The section writing group based these recommendations on several sources of federal guidance, scientific evidence, and programmatic experience:

- Previously published CDC and HRSA guidance that was based on reviews of scientific evidence and expert opinion.^{6,10,28,29,32-35}
- A systematic review of U.S. studies (published from 1996–2011) about interventions to promote linkage to HIV medical care.⁴⁰ Studies included in the review 1) had linkage to HIV medical care as a main study outcome; 2) evaluated intervention effects using descriptive data or comparative data that applied tests of statistical significance; and 3) included sufficient details about the linkage interventions.
- A systematic review of U.S. studies (published from 1996–2012) about interventions to promote retention in HIV medical care.⁴¹ Studies included in the review 1) focused on multifaceted interventions to improve retention in HIV medical care as the main or secondary outcome;
 2) evaluated intervention effects using descriptive data or comparative data that applied tests of statistical significance; and 3) defined retention in care as attending multiple HIV medical visits over varying time intervals.
- A compendium of U.S. studies (published from 1996–2014) about interventions to promote linkage to or retention in HIV medical care (hereafter called the Best Practices Compendium) that were identified through a systematic process and met *a priori* criteria for the quality of study design, implementation, and analysis, and statistically significant intervention effect.⁴²
- A modeling study that assessed the health impact and cost-effectiveness of linkage and retention interventions in which data on health care outcomes and per-client costs were based on a randomized controlled trial (RCT) of linkage and retention interventions in the United States (i.e., the Antiretroviral Treatment Access Study [ARTAS]⁴³ described in the Evidence topic below).⁴⁴

Evidence Supporting the Recommendations

Linkage to HIV medical care

Barriers to linkage to care

The systematic review⁴⁰ and other studies⁴⁵⁻⁵⁶ identified several barriers to linkage to care (see <u>Box 4-B</u>).

Interventions to promote linkage to care

Evidence from the systematic literature review

This review identified 6 studies that reported linkage to care outcomes.⁴⁰ Five studies evaluated linkage assistance for persons diagnosed with HIV during the previous 12 months in health departments, clinics, and community-based programs in large cities.^{43,57-60} All 5 found that 78%–92% of participants had their first HIV care visit within 3–6 months after receiving linkage assistance. Four intervention components significantly improved linkage to care (as compared with the reference group) or were likely to result in initiation of care (for observational studies). These components included: 1) motivational and strengths-based counseling tailored to a person's strengths, barriers, and needs; 2) assistance in navigating the

health care system; 3) linkage to an HIV care site at the same location where the HIV diagnosis was made or transportation assistance to the care site; and 4) other medical or social services, such as *substance use treatment*, mental health services, child care, food vouchers, or emergency financial assistance.⁴⁰

- One of these 5 studies was ARTAS, an RCT conducted in 4 cities from 2001–2003.⁴³ Participants recruited from health department testing sites, STD clinics, hospitals, and community-based organizations were randomized to receive 1) one to five motivational, strengths-based *case management* sessions over 90 days that allowed time to build rapport and that focused on identifying personal motivations for starting HIV care (e.g., desire to protect health) and overcoming barriers to starting care (e.g., helping to make appointments, accompanying at the first visit, providing transportation assistance, or helping to enroll in health insurance); or 2) information about local sources of HIV medical care. Participants who received the case management sessions were significantly more likely to attend at least 1 visit within 6 months after *enrollment* than participants who received information only (78% vs. 60%; adjusted relative risk 1.36, p=0.0005).⁴³
- Four observational studies evaluated the outcomes of various types of linkage assistance.⁵⁷⁻⁶⁰ Most newly diagnosed persons started HIV care within 3–6 months after receiving assistance:
 - 79% of persons who received motivational, strengths-based case management sessions (as described by ARTAS study above) in clinical, nonclinical, or health department settings.⁵⁸
 - 87% of African American or Hispanic gay, bisexual, or other men who reported sex with men (MSM) aged 13–24 years and who received the following services from staff of health departments, community-based organizations, or universities: counseling and psychosocial support, appointment reminders, and transportation to visits.⁵⁹
 - 90% of persons who received the following services from peer and nonpeer outreach workers, case managers, or nurses: counseling tailored to their individual barriers; riskreduction information; rapport-building phone calls and meetings; coordinating and accompanying at visits; and coordinating and making referrals for other medical and social services.⁵⁷
 - ◆ 92% of persons who received brief sessions led by linkage facilitators that addressed psychosocial, financial and structural barriers to starting HIV care, and provided information on HIV, HIV-related stigmatization, and how to obtain health insurance and housing.⁶⁰
- The sixth study in the systematic review evaluated linkage services at community-based, HIV education and testing sites in California where outreach workers encountered persons with HIV who did not report receiving HIV medical care.⁶¹ On average, clients were offered linkage assistance 18 months after HIV diagnosis. Only 29% started HIV care within 15 months after receiving linkage assistance. Of those who started HIV care, clients had their first visit an average of 33 months after diagnosis. The low linkage rates in this study contrast with the high linkage rates in the 5 studies described above that offered linkage assistance within 6–12 months after diagnosis.

Evidence from the Best Practices Compendium

Two studies met criteria for "best practices": the ARTAS study⁴³ described above and Project Connect from Birmingham, Alabama⁵⁴ (the study was published in 2008 in a journal that was not included in the systematic review). In Project Connect, linkage facilitators invited persons with newly diagnosed HIV to

an orientation visit at an HIV outpatient clinic. Facilitators aimed to build rapport with patients, gathered information about patients through semi-structured interviews and psychosocial assessments, collected laboratory test specimens, and initiated referrals for conditions that might deter HIV care (e.g., substance abuse and mental health services). A significantly higher proportion of patients attended a comprehensive HIV care visit within the next 6 months compared with the period before the clinic had implemented this program (81% vs. 69%, p<0.01).

Evidence from modeling study

A cost-effectiveness study compared the effectiveness of linkage interventions with the prevailing standard of providing contact information for local HIV clinics using data on per-client costs from the ARTAS intervention.⁴³ It found that the linkage interventions to prevent HIV transmission were cost-saving compared with the prevailing standard⁴⁴ and that the intervention cost per new case of HIV averted (~\$270,000) was substantially lower than the lifetime cost of HIV treatment (>\$400,000).⁶²

Retention and reengagement in HIV medical care

Barriers to retention in care

The systematic review⁴¹ and other studies⁴⁵⁻⁵⁰ identified several barriers to retention (see <u>Box 4-B</u>).

Interventions to promote retention in care

Evidence from the systematic literature review

This review qualitatively examined 13 multifaceted interventions.⁴¹ Four studies were RCTs, 7 compared retention before and after receipt of retention assistance, and 2 observed retention in care after assistance was offered.

The review found that persons who received multifaceted interventions were more likely to stay in care than those not receiving assistance, but none of the studies assessed the independent effect of specific intervention components.⁴¹ Ten of the 13 studies identified intervention components that were associated with increased retention in care: strengths-based case management, navigation assistance (e.g., appointment coordination), accompanying persons at visits, transportation assistance, *colocating***** HIV medical care and social services in the same facility, bilingual/bicultural health care teams (for Hispanic/Latino patients), messages about the importance of retention in care during medical visits, HIV-related posters and brochures in clinics, regular reminder calls, and tailored HIV education and support through phone calls, home visits, or other outreach methods.

Of the 4 RCTs in this systematic review, only the one that used strengths-based case management showed a strong effect on retention.⁵⁸ One RCT found that motivational interviewing provided by peer outreach workers (who had similar demographic characteristics to their clients) working in community sites or clinics yielded similar retention outcomes as motivational interviewing provided by health care providers.⁶³ However, an RCT that evaluated rental housing assistance for persons without stable

^{****} Colocating is the provision of more than one type of HIV service in the same physical space, such as providing substance use treatment in an HIV medical clinic or providing HIV partner services in an HIV testing site.



housing⁶⁴ and an RCT that evaluated peer mentoring for *persons who inject drugs* (PWID) through group discussion and video presentations did not appreciably improve retention in care.⁶⁵

Evidence from the Best Practices Compendium

Eight intervention studies met criteria for "best practices" for improving retention in care: four were RCTs and four compared retention outcomes before and after the intervention was implemented. Five of these studies were included in the systematic review of retention interventions,⁴¹ of which one was an RCT (ARTAS,⁴³ described above) and four used "before-after" comparison designs.⁶⁶⁻⁶⁹

The 4 RCTs were the following:

- An RCT evaluated retention outcomes in 4 clinics during 2001–2003. Participants who received motivational, strengths-based counseling from a case manager were significantly more likely to continue HIV care (defined as at least 2 visits over 12 months) than participants who only received information about where to obtain HIV care (64% vs. 49%, adjusted relative risk 1.41, p=0.006).⁴³
- An RCT in 6 HIV clinics evaluated retention of patients who received 1 of 3 interventions:

 enhanced contact (brief face-to-face meeting with clinic staff when returning for care, appointment reminders, phone calls between scheduled visits, and calls about missed visits);
 enhanced contact (as described above) plus skills building in organization (e.g., appointment calendars), problem solving, and communicating with health care providers; or 3) the clinic's prevailing standard of appointment reminders provided by staff or audio recordings. Patients who received enhanced contact or enhanced contact plus skills building had a 22% higher number of visits attended and 6%–8% relative improvement in visits attended over 12 months, when compared with patients who received only appointment reminders.⁷⁰
- An RCT evaluated a clinical decision-support system in a large HIV clinic practice that generated alerts in *electronic medical records* (EMRs)^{††††} that notified HIV care providers of gaps in follow up visits, laboratory evidence of *virologic failure*, and adverse events. Alerts on the EMR home page, patient-specific EMR, and biweekly emails included key clinical information and expedited ordering of lab tests and scheduling follow-up visits. Over the 12 month follow-up period, patients of providers who received alerts had a lower rate of suboptimal retention in care over 6 months than patients of providers who did not receive alerts (20.6 vs. 30.1 events per 100 patient-years, p=0.022).⁷¹
- A buprenorphine treatment study evaluated opioid-dependent patients in an HIV primary care clinic. Intervention patients received directly observed buprenorphine treatment (BUP) 3 times a week and supplies to last until their next visit, individual counseling, and urine drug testing. Control patients were referred for community-based opioid replacement therapy and intensive case management services. Over the 12-month follow-up period, patients who received directly observed BUP had significantly more HIV care visits than control patients (median, 3.5 vs. 3 visits, p=0.047).⁷²

⁺⁺⁺⁺ An electronic medical record (EMR) is a patient record that is maintained using computer software. The record should include patient history, including diagnoses, treatments, prescribed medications, drug allergies, and self-reported problems; patient demographics; physician clinical notes; and laboratory and imaging results.



The 4 interventions that used "before-after" comparison designs were the following:

- The Bilingual/Bicultural Care Team intervention was directed to Hispanic/Latino patients in HIV clinics funded by the Ryan White HIV/AIDS Program. A team included a Spanish-speaking Hispanic/Latino nurse practitioner, Ryan White case manager, and a peer educator. Team members assessed ART adherence barriers, provided information about HIV disease progression using culturally and linguistically appropriate materials, helped with clinic registration, acted as liaisons with health care providers, and made home visits and referrals to social services in the community. Patients who received the intervention attended a higher mean number of scheduled visits during the 12 months after the intervention started than during the 12 months before receiving the intervention (5.3 visits vs. 2.8 visits [t=6.29, p<0.05]).⁶⁷
- The Centralized HIV Services intervention was directed to young black/African American and Hispanic/Latino HIV clinic patients aged 13–23 years in an adolescent clinic. Case managers and social workers used motivational interviewing to improve patient self-efficacy, health care navigation skills, and encourage HIV disease management. Clinic patients who received care after this intervention started (March 2004–March 2007) were more likely to have attended a significantly higher number of visits than did clinic patients who received care before this intervention started (January 2002–February 2004) (56.7% vs. 30.6%, unadjusted OR=2.94, 95% CI=1.30, 6.67).⁶⁶
- The Strength through Youth Livin' Empowered (STYLE) multifaceted intervention was directed to black/African American and Hispanic/Latino young MSM aged 17–24 years who had been recently diagnosed with HIV but were not engaged in HIV care. After the men were reengaged in HIV medical care, social workers and case managers used several methods to promote retention. They assessed individual barriers to retention in care; offered weekly support group meetings; provided information and counseling by phone, text or in-person about medical issues, prevention, substance use, and mental health; and helped to schedule appointments. Patients who received the intervention (during June 2006–August 2009) attended a significantly greater proportion of scheduled HIV visits than patients who received care before the intervention started (during January 2003–January 2005) (80% vs. 67%, p=0.03).⁶⁹
- Stay Connected was a clinic-wide intervention to motivate patients to continue HIV care. Patients received brochures and saw clinic posters that stressed the health benefits of staying in care and taking personal responsibility for health and included clinic contact information. Health care providers also stressed the health benefits of staying in care and praised patients for attending scheduled visits. Patients who received the intervention were significantly more likely to attend 2 consecutive scheduled visits in the following 12 months than patients who received care before the intervention started (52.7% vs. 49.3%; adjusted % relative improvement: 7%, p<0.001).⁶⁸

Evidence from a modeling study

A cost-effectiveness study compared the effectiveness of retention interventions with the prevailing standard of scheduling follow-up appointments, using data on per-client costs from the ARTAS trial.⁴³ It found that retention interventions to prevent HIV transmission had a cost per quality-adjusted life-year gained of \$13,460 when compared with scheduling follow-up appointments.⁴⁴ It also estimated that the intervention cost per new case of HIV averted (~\$478,000) was similar to the lifetime cost of HIV treatment (>\$400,000).⁶²

Issues that Influence Implementation of the Recommendations Implementation progress, challenges, and opportunities

Data on linkage to and retention in care collected through 2009 (described in the <u>Background</u> topic above) may not reflect patterns of care since 2012, the year HHS recommended starting ART regardless of CD4 cell count and when the Patient Protection and Affordable Care Act (ACA) expanded health insurance options for persons for HIV.⁷³ Linkage and retention rates are likely to improve as more persons with HIV become aware of the health and prevention benefits of early ART and become enrolled in health insurance or medical assistance programs. Improving linkage and retention will also require a cadre of trained professionals and peers to provide linkage and retention assistance; this assistance can be particularly beneficial for populations that are uninsured or live in communities with limited or fragmented HIV medical services (see <u>Box 4-A</u> and <u>Section 3</u>, <u>Context of Prevention</u>). Enabling billing and reimbursement for linkage and retention services can encourage providers to offer these services. Some health systems and health departments are exploring strategies for third-party reimbursement for these services.⁷⁴

Policy, legal, and ethical considerations

Providing linkage and retention services usually requires sharing HIV test results and other identifiable health information between agencies; this process must protect the *confidentiality* of persons with HIV and comply with health information security standards, including the *Health Insurance Portability and Accountability Act*⁷⁵⁻⁷⁷ (see Section 3, Context of Prevention). CDC provides guidance on how health departments might use HIV surveillance data (e.g., dates of HIV diagnosis, first and follow-up CD4 cell count test results and *viral load* test results) to identify persons who might benefit from linkage or retention assistance, if allowed in their jurisdictions.^{23,27,75,76,78}

Special populations

Many individual and contextual factors may impair the use of HIV medical care (see barriers noted in <u>Box 4-B</u>). Interventions to promote linkage may have less impact for persons who use drugs or suffer from depression⁷⁹ and retention interventions may be less effective for patients who are young,⁸⁰⁻⁸² lack health insurance,^{50,83} are homeless,⁸⁴ or use drugs.⁸⁵ Linkage and retention services that are tailored to such special circumstances may be more acceptable and effective. Examples include the following:

- Adolescents concerned about stigma, inability to access confidential HIV care if uninsured or insured by parents, or unwanted *disclosure* of HIV infection status to parents can benefit from linkage to providers who do not require parental consent and who provide free or low cost services and reassurance about the confidentiality of HIV services⁴⁸
- Transgender persons can benefit from linkage to providers who are familiar with the unique medical and psychosocial concerns of these individuals^{49,86,87}
- Substance users can benefit from enrolling in treatment programs that encourage structured lifestyles that foster attendance at scheduled visits⁸⁸⁻⁹³
- Immigrants can benefit from help to secure documents needed to start care (e.g., employment verification, Social Security number); linkage to providers who serve immigrants under ACA-approved insurance plans, the Ryan White HIV/AIDS Program, medical assistance programs, or

specialty clinics;^{73,94} and information about whether seeking HIV care may threaten job security or prompt deportation or legal actions

- Inmates can benefit from reentry planning to enable continuous HIV care after release⁹⁵⁻⁹⁷
- Women of reproductive age can benefit from information and *reproductive health counseling* about ART regimens that are safe and tolerable during and after pregnancy, and options for free, subsidized, or otherwise affordable ART⁴⁵⁻⁴⁷

Implementation Resources

Examples of best practices for linkage, retention, and reengagement and materials to support implementation of these recommendations are found at

http://www.cdc.gov/hiv/guidelines/implementationresources.html.

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Section 5. Antiretroviral Treatment for Care and Prevention

Background

Antiretroviral treatment (ART) refers to treatment with highly effective combinations of antiretroviral drugs to suppress HIV replication. Current federal HIV treatment guidelines and other studies recommend ART for all persons with HIV, regardless of *CD4 cell count*,^{*} to improve their health, prolong their lives, and reduce their risk of transmitting HIV to others.¹⁻³ The initial and regular follow-up clinical visits that are required to prescribe and manage ART also provide opportunities to reinforce risk-reduction messages and to provide other care and *prevention services*.[†] To maximize the individual and public health benefits of ART, sustained high *adherence* is essential.³

This section covers several aspects of use of ART for personal health benefits and preventing HIV transmission; *however, it does not provide comprehensive recommendations on managing patients who are eligible for or who are using ART found in other federal guidance*.^{3,4} This section also addresses informing persons with HIV about antiretroviral medications that HIV-uninfected *partners* may take to reduce their risk of HIV acquisition, if clinically indicated; *it does not provide comprehensive recommendations on prophylaxis for HIV-uninfected persons found in other federal guidance*.^{5,6}

Quality improvement[‡] and program *monitoring and evaluation*[§] can determine if the interventions described in this section are implemented as intended, yield the expected outcomes, or warrant changes in delivery methods (see Section 13, Quality Improvement). Section 6, ART Adherence, covers adherence to ART; Section 10, Reproductive Health Care, covers antiretroviral medication use by women using hormonal contraceptives and persons seeking conception; and Section 11, Pregnancy, covers use of ART and prophylaxis during pregnancy and the postpartum period.

^{*} CD4 cell count is the number of CD4+ T-lymphocyte cells per millimeter cubed (mm^3) of blood. It is used to estimate the immune system's capacity to fight infection, assign stage of HIV disease, and guide decisions about the need for treatment to prevent HIV-related diseases.

Prevention services include interventions, strategies, policies, and structures designed to reduce the transmission of HIV infection.
 Quality improvement is an approach to the continuous study and improvement of the processes of providing services that meet or exceed

established professional standards and user expectations.

[§] Monitoring and evaluation is a process that involves the repeated, ongoing collection and review of information about program activities, characteristics, and outcomes in order to assess program implementation, coverage, acceptability, cost, and effectiveness.

Recommendations

BOX 5. RECOMMENDATIONS—ANTIRETROVIRAL TREATMENT FOR CARE AND PREVENTION

For nonclinical and clinical providers (including health department staff who provide individual-level services to persons with HIV)

- Inform all persons with HIV about the following issues regarding antiretroviral treatment (ART) (i.e., treatment with highly effective combinations of antiretroviral drugs to suppress HIV replication)^a (i, ii) (see <u>Box 5-A</u>):
 - The health benefits of early initiation of ART, including
 - improving or maintaining health when compared with later initiation of ART
 - prolonging lifespan
 - reducing risk of HIV transmission to others^b
 - The limitations of ART, including
 - the need for lifelong treatment
 - the need for high adherence
 - potential medication side effects
 - the use of ART substantially reduces, but may not eliminate, the risk of HIV transmission
- Inform all persons with HIV (and any of their HIV-uninfected partners referred for evaluation) about the following HIV prophylaxis issues^{c,d} (iii, iv) (see <u>Box 5-B</u>):
 - The availability of preexposure prophylaxis^e (PrEP) and nonoccupational postexposure prophylaxis^f (nPEP) for HIV-uninfected partners when clinically indicated to reduce their risk of HIV acquisition
 - Names and locations of health care facilities where HIV-uninfected partners can be evaluated for prophylaxis indications, and assisting with accessing these services, when feasible
 - Use of these regimens may reduce, but may not eliminate, the risk of HIV acquisition

Specific to clinical providers (in addition to above recommendations)

- Offer ART (according to U.S. Department of Health and Human Services [HHS] recommendations), regardless
 of patient's CD4 cell count, for the following purposes (i, ii):
 - To treat and prevent HIV-related disease
 - To reduce the risk of transmitting HIV
- When prescribing ART, provide information to ensure that patients understand the following (i, ii):
 - Expected benefits and risks to personal health
 - Expected reduction in HIV transmission risk
 - Need for sustained high adherence to ART, long-term follow-up, and retention in care
 - Importance of committing to initiating or resuming lifelong, uninterrupted ART
 - Hazards of sharing their ART with others (e.g., HIV-uninfected partners seeking antiretroviral medication for prophylaxis)⁹
 - Use of ART is voluntary and patients can decline ART without risk of being denied medical and social services
- For patients who choose to postpone or discontinue treatment, periodically reoffer ART after informing them of the benefits and risks of currently recommended regimens based on experiences of other patients with similar viral load and immune status (i,ii)



BOX 5. RECOMMENDATIONS—ANTIRETROVIRAL TREATMENT FOR CARE AND PREVENTION (cont)

For staff of health departments and HIV planning groups who provide population-level HIV prevention and care services

- Support efforts to increase access to HIV medical care and affordable ART through the following (v, vi, vii, viii, ix) (see Box 5-C):
 - Direct interventions with staff, contractors, and programs
 - Partnerships with public and private sector health systems
- *Note.* In this report, *nonclinical providers* are defined as persons who work in community-based organizations or health departments operating outside of health care facilities and who provide HIV testing, health education, risk-reduction interventions, partner services, case management, or assistance with linkage or referral to medical and social services. These persons include HIV testing providers, peer and professional health educators, counselors, service linkage facilitators, partner services specialists, case managers, and social workers. *Clinical providers* are defined as persons who work in health care facilities and who provide risk assessments, health education, counseling, screening, diagnosis, treatment, and other health-related services. These providers include physicians, registered nurses, advance practice nurses, physician assistants, dentists, mental health providers, pharmacists, health educators, case managers, social workers, and counselors. Some may be employees or contractors of health departments. Some of the recommendations specific to clinical providers apply only to clinical providers with authority for clinical evaluation and examinations, diagnosis, treatment, and prescribing. Some of the federal guidelines cited in the Recommendation boxes may have been updated. For current federal recommendations, please refer to http://www.cdc.gov/hiv/guidelines/personswithhiv.html.
- ^a The cited source guidance that supports this recommendation was intended for health care providers. Based on opinions of the Project Workgroup and recent program experience, the section writing group concluded that it would be beneficial and feasible for other types of providers to implement this recommendation.
- The U.S. Food and Drug Administration (FDA) had approved the use of antiretroviral medication for treating HIV-infected persons. The cited source guidance recommends use of ART for HIV treatment and for reducing the risk of HIV transmission.

² In July 2012, FDA approved one PrEP regimen (tenofovir/emtricitabine) for preventing sexual transmission. Although HHS recommendations in May 2014 advised use of this same regimen for persons who inject drugs, the product label only addresses use for preventing sexual transmission. Use of antiretroviral medication for nPEP does not reflect labeling approved by FDA.

The cited source guidance advises health care providers to inform HIV-uninfected persons about these interventions, but does not address the role of health care providers in informing HIV-infected persons about the use of PrEP or nPEP for their uninfected partners.

PrEP is the daily, continuous use of a select regimen of antiretroviral medications for a period of time by an HIV-uninfected person to achieve levels of drug in the blood and anal and genital mucosa sufficient to reduce the risk of HIV acquisition.⁶

nPEP is the use of selected antiretroviral medications by HIV-uninfected persons within 72 hours after isolated, nonoccupational exposures to body fluids potentially containing HIV, such as after unprotected sexual intercourse or condom breakage, in order to reduce the risk of HIV acquisition.⁵

³ Information described in the <u>Implementation</u> topic in this section supports this statement.

Sources

- i. Panel on Antiretroviral Guidelines for Adults and Adolescents. *Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents*. 2014. http://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-treatment-guidelines/0/. Accessed July 7, 2014.**
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- http://hab.hrsa.gov/sites/default/files/hab/clinical-quality-management/2014guide.pdf. Accessed December 23, 2016.
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^{**} For the current version of Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents and any updated resources and support materials, please visit <u>http://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-treatment guidelines/0/</u>.

Box 5-A. Important counseling points about initiating or resuming ART

- Counsel persons when initiating or resuming ART and regularly thereafter about the importance of (i, ii):
 - long-term monitoring and follow-up visits
 - adhering to the regimen as prescribed^a
 - seeking resources for adherence support^a
 - continuing other HIV prevention measures^b
- Review options to obtain ART and cover and minimize ART costs on a short-term and long-term basis and during any lapses in coverage by insurance or medical assistance programs^c (i)
- Remind persons to tell their health care providers about any current or planned use of prescription, nonprescription, or recreational drugs, alcohol, or dietary supplements because these may impair ART effectiveness or cause toxicity that could impair adherence (ii)
- ^a See <u>Section 6, ART Adherence</u>, for methods to support adherence.
- See Section 7, Risk Screening and Risk Reduction, for details on HIV transmission behaviors and prevention measures.
- Information described in the <u>Implementation</u> topic in this section also supports this statement.

Sources

- i. Panel on Antiretroviral Guidelines for Adults and Adolescents. *Guidelines for the use of antiretroviral agents in HIV-1–infected adults and adolescents*. 2014. <u>http://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-treatment-guidelines/0/</u>. Accessed July 7, 2014.
 ii. HRSA. *Guide for HIV/AIDS Clinical Care—2014 Edition*. U.S. Department of Health and Human Services; 2014.
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Box 5-B. Important points when informing persons with HIV that some HIV-uninfected sex and druginjection partners may have clinical indications for prophylaxis to reduce their risk of HIV acquisition

- PrEP use may be clinically indicated as one method to reduce the risk of HIV acquisition in some HIVuninfected gay, bisexual, and other men who have sex with men (MSM), heterosexual persons, or persons who inject drugs (PWID) who are at substantial risk of acquiring HIV^a (i)
- nPEP use may be clinically indicated for HIV-uninfected persons who have had isolated, inadvertent exposures within the previous 72 hours to body fluids that may contain HIV (ii)
- Use of PrEP and nPEP may reduce, but may not eliminate, the partner's risk of HIV acquisition; partners should therefore use other effective measures to reduce the risk of HIV acquisition, including safer sexual and drug-injection behaviors (i, ii)
- Antiretroviral prophylaxis (PrEP or nPEP) regimens must be prescribed by a health care provider who can assess clinical indications for use and who is licensed to prescribe medications (i, ii)
- Persons considering PrEP or nPEP need an initial clinical and laboratory evaluation to test for established or recent HIV infection (i, ii)
- Person using PrEP or nPEP need regular follow-up evaluations to assess the following (i, ii):
 - HIV infection status through retesting
 - Possible side effects or other reasons to discontinue prophylaxis
 - Adherence to the prescribed regimen
 - Adherence to behaviors that may decrease risk of HIV infection, such as consistent, correct use of latex or polyurethane condoms

Note. The cited source guidance advise health care providers to inform HIV-uninfected persons about these interventions, but does not address the role of health care providers in informing HIV-infected persons about use of PrEP or nPEP for their uninfected partners. Although HHS recommendations in May 2014 advised use of this same regimen for PWID, the product label only addresses use for preventing sexual transmission. Use of antiretroviral medication for nPEP does not reflect labeling approved by FDA.

^a For information on use of PrEP in persons who are attempting conception or are pregnant, see <u>Section 10, Reproductive Health Care</u>, and <u>Section 11, Pregnancy</u>.



Box 5-B. Important points when informing persons with HIV that some HIV-uninfected sex and druginjection partners may have clinical indications for prophylaxis to reduce their risk of HIV acquisition *(cont)*

Sources

- i. CDC, et al. Preexposure prophylaxis for the prevention of HIV infection in the United States—2014: a clinical practice guideline. May 14, 2014. <u>http://stacks.edc.gov/view/cdc/23109</u>. Accessed May 15, 2014.
- ii. CDC. Antiretroviral postexposure prophylaxis after sexual, injection-drug use, or other nonoccupational exposure to HIV in the United States: recommendations from the U.S. Department of Health and Human Services. *MMWR* 2005;54(RR-2). <u>http://stacks.cdc.gov/view/cdc/7303</u>. Accessed November 3, 2014.

Box 5-C. Examples of population-level strategies to improve access to HIV medical care and ART

- Make available online information about
 - private and public sector sources of HIV medical care and drug assistance (e.g., Medicare, Medicaid, Veterans Affairs, Ryan White HIV/AIDS programs, private health insurance, government-sponsored insurance plans, AIDS Drug Assistance Program [ADAP], and state medical and pharmacy assistance programs)
 - HIV medications covered by public sector clinical providers and drug formularies
 - state laws regarding minors' access and consent to HIV medical care
- Foster collaboration and coordination between HIV service providers in the public and private sectors to
 - ensure continuity of HIV services for persons who change health care provider, health care insurance, or medical assistance program
 - establish policies and procedures with correctional facilities (including juvenile detention centers) that enable transition planning and continued HIV services after detainee release
- Support efforts to increase the number of health care providers who are skilled in HIV medical care (e.g., through training, telemedicine, expansion of professional authority, and task sharing)
- Educate clinical and nonclinical HIV prevention providers, including pharmacists and health department partner services specialists, that all persons with HIV should be informed about
 - the benefits of ART, regardless of CD4 cell count, for their own health and for preventing HIV transmission
 - options for covering and minimizing the cost of ART
- Develop protocols and data-sharing agreements with public and private sector entities, if allowed by the jurisdiction, to enable tracking of HIV health care delivery, quality, efficiency, and outcomes
- Support social marketing campaigns for populations with high HIV prevalence that promote the benefits of HIV testing and early initiation of ART

How These Recommendations Differ from Previous Recommendations

These recommendations are consistent with the most recent federal guidance on ART and the prophylactic use of antiretroviral medications to reduce the risk of HIV acquisition by partners of persons with HIV.³⁻⁶ They are also consistent with nearly all of the latest comparable recommendations about using ART for treatment and prevention from the HIV Medicine Association of the Infectious Diseases Society of America;⁷ and the International Antiviral Society-USA Panel.^{8,9}

However, these recommendations differ in several ways from those in the 2003 *Recommendations for Incorporating HIV Prevention into the Medical Care of Persons Living with HIV*.¹⁰ This report recommends that

- *clinical providers* offer ART to all persons with HIV, regardless of CD4 cell count, for both their own health and for reducing the risk of HIV transmission, according to the most recent U.S. Department of Health and Human Services (HHS) treatment recommendations³
- clinical providers and *nonclinical providers* inform persons with HIV about
 - the benefits of ART for their own health, prolonging lifespan, and reducing the risk of HIV transmission
 - the limitations and risks of ART, including that use of effective ART substantially reduces, but may not eliminate, the risk of HIV transmission
 - options to obtain ART and cover and minimize costs of ART
 - the availability of two different prophylactic regimens of antiretroviral medications, preexposure prophylaxis (PrEP)^{††} and nonoccupational postexposure prophylaxis (nPEP),‡‡ for HIV-uninfected partners when clinically indicated to reduce their risk of HIV acquisition^{§§}

Methods

The section writing group based these recommendations on current guidance from HHS³ and the Health Resources and Services Administration (HRSA) on the use of ART^{3,4} and current guidance from HHS on the use of nPEP and PrEP for HIV-uninfected partners of persons with HIV.^{5,6} This federal guidance was based on a large body of scientific evidence, including randomized controlled trials (RCTs) (see the <u>Evidence</u> topic). The writing group also reviewed a systematic review and meta-analysis of the relation of *viral load* and sexual HIV transmission,¹ a meta-analysis of the influence of ART on sexual behavior,¹¹ and the latest nongovernmental recommendations of the International Antiviral Society-USA Panel⁹ and the HIV Medicine Association of the Infectious Diseases Society of America.⁷ The writing group also considered information about the role of ART on HIV transmission, *acute HIV infection*, and ART resistance identified during a narrative literature review of peer-reviewed studies and abstracts of HIV conferences published in English from January 1996 through May 2014. The recommendations to health departments and *HIV planning groups* were based on recent federal guidance about population-level strategies to increase access to *HIV medical care* and ART.¹²⁻¹⁶

Evidence Supporting the Recommendations

Several sources of evidence support the use of ART to reduce the risk of HIV transmission. In untreated adults, the risk of sexual HIV transmission increases with the amount of HIV RNA present in the plasma¹⁷ and genital secretions.^{18,19} ART reduces HIV plasma viral load²⁰ and also reduces quantities of HIV RNA detectable in potentially infectious body fluids, including semen,^{21,22} cervicovaginal secretions,^{23,24} and anorectal secretions.²⁵ Plasma HIV RNA viral load usually correlates with levels of HIV RNA detected in semen,²⁶⁻²⁹ cervicovaginal secretions,^{23,30,31} and anorectal secretions.^{28,32} Although use of effective ART with high adherence can suppress plasma and genital viral load, its use may not

^{§§} This recommendation supplements—and does not replace—federal recommendations to provide information about PrEP and nPEP to HIVuninfected persons at risk of HIV exposure.^{5,6}



^{††} PrEP is the daily, continuous use of a select regimen of antiretroviral medications for a period of time by an HIV-uninfected person to achieve levels of drug in the blood and anal and genital mucosa sufficient to reduce the risk of HIV acquisition.⁶

¹ nPEP is the use of selected antiretroviral medications by HIV-uninfected persons within 72 hours after isolated, nonoccupational exposures to body fluids potentially containing HIV, such as after unprotected sexual intercourse or condom breakage, in order to reduce the risk of HIV acquisition.⁵

eliminate *transmission risk*. Some persons with suppressed plasma viral loads may have detectable HIV in semen,^{21,22,26,33-36} in cervicovaginal secretions,^{23,30,37} and possibly in rectal secretions.^{28,32} Some *sexually transmitted diseases* (STDs) that cause genital inflammation may also increase shedding of HIV into semen^{34,38} and into cervicovaginal secretions,^{30,39,40} even in persons with low or undetectable plasma viral loads (see Section 9, STD Services). At least one case of HIV transmission from a patient with suppressed plasma viral load to a monogamous, uninfected sex partner has been reported.⁴¹

Observational studies of heterosexual couples⁴²⁻⁴⁶ have found that effective ART substantially reduces the risk of sexual transmission. A meta-analysis of these and other studies determined that ART decreased the risk of HIV transmission to uninfected heterosexual partners from 5.64 to 0.46 per 100 person-years, a reduction of 92%.¹ A subsequent RCT of 1,763 HIV-1 discordant couples enrolled mostly in Africa and Asia, 97% of whom were heterosexual, confirmed a 96% reduction in sexual HIV transmission associated with treating the HIV-infected partner (hazard ratio 0.04, 95% confidence interval 0.01–0.27, p<0.001).² In this study, infected partners with CD4 cell counts in the range of 350–550 cells/mm^3 were randomized to receive either ART immediately or when their CD4 cell counts declined to <250 cells/mm^3. This study concluded that sustained viral suppression in genital secretions resulting from sustained high adherence to ART explained this protective effect.

To date, no published RCT or cohort studies have demonstrated the influence of ART in preventing HIV transmission among MSM and persons who inject drugs (PWID). However, a priori biological plausibility and ecological analyses suggest that ART reduces HIV transmission from all persons with HIV, including MSM⁴⁷ and PWID.⁴⁸ An ongoing prospective observational study in 14 European countries is assessing sexual transmission among HIV-discordant couples in which the infected partners have plasma HIV RNA viral loads <200 copies/mL, the uninfected partners use neither PrEP nor nPEP, and the couples do not use condoms.⁴⁹ In preliminary analysis of data from 767 couples (282 MSM, 445 heterosexual) who contributed 894 couple-years of follow-up (CYFU) and engaged in an estimated 30,400 sex acts without condoms, no HIV transmissions were observed. Study enrollment and follow up continue to ensure the statistical power needed to refine the upper confidence limits associated with the risk of transmission; preliminary analysis yielded confidence limits from 4.0 infections per 100 CYFU for receptive anal sex with ejaculation in MSM couples to 1.5 infections per 100 CYFU for insertive anal sex in MSM couples and penile-vaginal sex in heterosexual couples. Mathematical models also indicate that ART could substantially reduce HIV transmission in MSM and other risk groups in the United States.⁵⁰⁻⁵³ This body of evidence suggests that ART is likely to reduce the risk of HIV transmission regardless of a person's age, race, ethnicity, sex, gender identity, sexual orientation, or HIV transmission risk category.17,47,48,54-57

Limited theoretical evidence suggests that perceptions about using ART for preventing HIV transmission may influence attitudes about sexual behaviors. A meta-analysis that included 25 studies found that persons with HIV were more likely to report that they might have *unprotected sex*^{***} if they agreed that taking ART or having an undetectable viral load protects against transmitting HIV or that the availability of ART reduced their anxiety about having unsafe sex.¹¹ Despite these findings, this study found that

^{***} Unprotected sex or unprotected sexual contact is sexual activity without using a physical barrier (i.e., penile sex without using a male condom; vaginal sex without using a male or female condom; oral-anal contact without using a dental dam or other barrier device; vaginaldigital contact without using a female condom, latex glove, or finger cot; or rectal-digital contact without using a latex glove or finger cot).



persons with undetectable viral loads were no more likely to engage in unprotected sex than persons with detectable viral loads.

A compelling body of evidence supports early initiation of ART at progressively higher CD4 cell counts to improve health outcomes, reduce mortality due to *AIDS* and other conditions, and prevent HIV transmission. Observational data on health outcomes after early treatment served as the basis for HHS and international recommendations to initiate ART regardless of CD4 cell count.^{3,9} An ongoing RCT is directly comparing the benefits and risks of starting newly recommended ART regimens at >350 cells/mm^3 versus >500 cells/mm^3,⁵⁸ including chronic diseases that are relatively common in persons with longstanding HIV infection but are not typically associated with immunosuppression. Two other factors support early ART initiation for health or prevention purposes: 1) contemporary initial ART regimens are more convenient, potent, and tolerable than earlier regimens;³ and 2) drug resistance occurs less frequently in persons who start ART early in the course of their infection,⁵⁹ partly because early initiation prolongs the period in which adherent persons can suppress their viral loads.

Comparisons of the lifetime costs of health care for persons starting ART with CD4 cell counts at 350 to 500 cells/mm^3 and persons starting ART with CD4 cell counts >500 cells/mm^3 have not yet been reported. However, studies and federal guidelines evaluating ART regimens used over the last two decades have shown that 1) starting ART soon after diagnosis is more cost-effective than delaying ART until CD4 cell counts have declined substantially (e.g., <350 cells per mm^3) and 2) early treatment reduces the costs of AIDS– and non-AIDS–related care even though it increases the lifetime cost of antiretroviral medications.^{3,60} Other sources describe the evidence supporting recommendations about the use of PrEP and nPEP.^{5,6}

Issues that Influence Implementation of the Recommendations

Implementation progress, challenges, and opportunities

Among all persons living with HIV in 2009, an estimated 82% had been diagnosed with HIV infection, 66% were linked to HIV medical care, 37% were retained in care, 33% were prescribed ART, and 25% had a suppressed viral load.⁶¹ However, among adults diagnosed with HIV who received ongoing HIV medical care between 2008 and 2010 (when HHS routinely recommended starting ART for persons with CD4 cell counts <350 cells/mm^3), an estimated 89% were prescribed ART, of whom 77% had suppressed viral load.^{61,62} However, among adults diagnosed with HIV who received ongoing HIV medical care as of the end of 2010 (when HHS routinely recommended starting ART for persons with CD4 cell counts <350 cells/mm^3), an estimated 90% reported taking ART, of whom 74% reported suppressed viral load at their last measurement.⁶³ Use of ART is expected to rise after 2012, the year HHS first recommended initiating ART, regardless of CD4 cell count, for both health and prevention benefits. Moreover, the newer ART regimens recommended by HHS are likely to be more acceptable than earlier regimens that were less effective, tolerable, and convenient.⁶⁴

Interest in using ART for prevention purposes is not well characterized. In one study, 50% of HIVinfected patients with CD4 cell counts >350 cells/mm^3 expressed interest in starting ART to decrease transmission risk.⁶⁵ Surveys of health care providers prescribing ART in Washington, DC, and the Bronx, NY found that 95% agreed or strongly agreed that ART can decrease HIV transmission and 75% would offer ART earlier to patients at high risk of transmitting HIV (defined as persons who have HIVuninfected partners or report sex without condoms with a partner of unknown HIV status).⁶⁶ People may delay initiating ART for health or prevention purposes for several reasons: denial that they are HIVinfected or that HIV is a serious medical condition; lack of understanding of the benefits of early treatment; lack of trusted relationships with health care providers; and lack of health insurance or access to federal and state medical assistance programs, such as Medicaid.^{61,67}

Access to affordable ART (and PrEP and nPEP for uninfected partners of persons with HIV) is a continuing challenge in the United States. Long-term use of ART is expensive because it requires multiple medications, most of which are not yet available in generic form. The annual, unsubsidized cost of ART regimens recommended by HHS as of 2014 exceeds \$10,000.³ Studies conducted before 2014 found that some persons declined or postponed ART because they were unaware of free or low cost ART sources, anticipated difficulty obtaining affordable ART, did not access subsidized ART through AIDS Drug Assistance Programs (ADAP), or were deterred by ADAP waiting lists.⁶⁸⁻⁷¹

As of 2014, many options can substantially reduce out-of-pocket costs of ART, including Medicaid and Medicare, state ADAP, private sector health insurance, health care exchange plans initiated under the Patient Protection and Affordable Care Act (ACA), and pharmaceutical company drug assistance programs.^{14,16,72,73} Increased enrollment in health plans with pharmacy benefits and near elimination of state ADAP waiting lists (as of April 2014) has improved access to subsidized ART.⁷⁴ Nevertheless, it has been estimated that under the ACA's health care exchange plans, coinsurance for ART may be substantial, with up to 55% of plans requiring enrollees to pay an average of 35% of their total ART cost.⁷³ In states that have not yet expanded the populations of low-income or disabled persons that are eligible for Medicaid, the Ryan White HIV/AIDS Program and ADAP will remain crucial sources of affordable HIV care and ART. In states that have expanded Medicaid, the Ryan White HIV/AIDS Program will continue to cover copays and deductibles for many persons with HIV. Disparities in access to ART are compounded by longstanding geographic, economic, social, racial, and ethnic disparities in the burden of HIV. This convergence of disparities reinforces ethical imperatives to increase access to HIV care and treatment.⁷⁵

Selecting appropriate ART regimens may be complex for persons who use other prescription, nonprescription, or recreational drugs, alcohol, or dietary supplements that may interact with ART or for women who are pregnant or attempting conception in whom fetal safety must be considered. Other federal guidance describes potential interactions between ART and other substances and preferred regimens during pregnancy and additional clinical evaluation needed in these situations.^{3,76} (Section 10, Reproductive Health Care, and Section 11, Pregnancy, address ART use in women who are attempting conception or pregnant, respectively.)

Public awareness of PrEP as an HIV prevention option is growing after the release of new guidance in 2014.^{6,77} Clinical providers and *partner services specialists*^{†††} can increase awareness of PrEP by encouraging persons with HIV to inform their HIV-uninfected partners about the availability of PrEP or by directly informing partners during couples counseling (see <u>Box 5-B</u> and the <u>Policy, Legal, and Ethical</u> Considerations topic in this section). Studies suggest that many persons with HIV, their health care

⁺⁺⁺ Partner services specialists include specially trained disease investigation specialists, public health investigators, or communicable disease investigators who work in health departments and staff of other agencies who are trained and authorized to provide partner services.



providers, and their uninfected partners are not familiar with the use of nPEP after isolated, inadvertent exposures after voluntary behaviors (e.g., condom failure) and involuntary behaviors (e.g., sexual assault).^{78,79} Two reviews of studies on nPEP use published from 2001–2008 found that less than half of U.S. health care providers working in emergency departments had ever offered nPEP to patients after sexual assault.^{80,81}

Some persons with HIV may consider sharing their ART medications with HIV-uninfected partners seeking PrEP or nPEP. This practice should be discouraged because 1) it may impair ART adherence; 2) medications used for ART may not be suitable for prophylaxis; 3) partners' perceived or reported HIV-negative status may be inaccurate, and 4) ART medications that are shared with partners seeking prophylaxis who are in fact HIV-infected may not provide optimal HIV treatment or may promote viral drug resistance.^{3,5,6,82,83}

Policy, legal, and ethical considerations

Use of ART for health or prevention benefits should be voluntary. The principal consideration in decisions about using ART is personal health, not reducing risk of HIV transmission. Clinical providers can help patients make informed choices about ART use by stressing that ART is the single most important intervention they can choose to maintain their health, prolong their lives, and reduce the risk of infecting others; noting potential harms, such as side effects; and reassuring patients who decline ART that they will not be denied medical or social services. This principle of autonomy also applies to HIV-uninfected persons offered PrEP or nPEP.

Clinical providers can caution their patients that sustained high adherence to ART substantially reduces the risk of transmission, but it may not eliminate the risk. Clinical providers can also discourage *risk compensation*, *‡‡‡* which may lead to deferral of condom use or of other safer sex or drug-injection behaviors (see the <u>Evidence</u> topic in this section). Patients who alert their partners to the limitations of ART may reduce partner distress and disputes if transmission should occur (see <u>Section 3, Context of Prevention</u>, for information on HIV *disclosure*). HIV-uninfected persons who use nPEP or PrEP also can benefit from knowing that these regimens may reduce, but may not eliminate, their risk of HIV acquisition.

Special populations

Several vulnerable or marginalized populations warrant specialized attention when offering, starting, and continuing ART. These populations include adolescents who are taking more responsibility for health decisions and leaving parental homes or foster care; persons entering or leaving correctional facilities; and immigrants who lack the documentation needed to receive HIV care through private insurance or medical assistance programs.

The presence of mental health or *substance use* disorders does not make a person ineligible for ART. If these conditions raise questions about a person's ability to effectively use ART, *referral* for appropriate mental health and substance abuse treatment is indicated.³ (Section 6, ART Adherence, addresses ART

^{***} Risk compensation is modifying sex or drug-injection behaviors in way that increases risk of HIV transmission or acquisition when other safeguards are introduced (e.g., when persons with HIV who believe that ART use reduces their infectiousness no longer use condoms to prevent HIV transmission).



for special populations. <u>Section 12, Other Medical and Social Services</u>, addresses specialty services that can facilitate initiation of HIV medical care and ART.)

Implementation Resources

Additional information and practical resources to support implementation of these recommendations can be found at <u>http://www.cdc.gov/hiv/guidelines/</u>. A list of wholesale costs of regimens that HHS recommends for persons starting ART is also available.³ <u>Section 6, ART Adherence</u>, includes a link for adherence assessment and support materials.

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Section 6. Antiretroviral Treatment Adherence

Background

Antiretroviral treatment (ART) adherence describes the extent to which a person takes ART according to the prescribed doses, dosing intervals, and other medication instructions. Sustained high adherence is essential to maximize the effectiveness of ART, which suppresses *viral load* and, in turn, preserves *CD4 cells counts*, prevents progression to *AIDS*, and prolongs lifespan. Inconsistent or low adherence can lead to *virologic failure** or the emergence of drug-resistant virus, both of which may limit future treatment options.²⁻⁷ Sustained high adherence is also critical for maximizing the benefits of ART in reducing the risk of sexual and perinatal HIV transmission.^{1-3,5-19}

Studies of early combination ART regimens found that adherence levels greater than 95% were needed to maximally suppress viral load.¹⁶ However, more recent studies indicate that viral suppression can be achieved with lower adherence levels, particularly when newer regimens are used.^{10,12,17} Because the level of adherence necessary for viral suppression may vary by regimen and adherence has been described in different ways in the scientific literature, there is no standard definition of *high adherence*.[†] The literature suggests that the levels of adherence needed to maximize treatment benefits may range from at least 80% to at least 95% of doses taken as prescribed.^{10,12,17} Given the uncertainty, persons with HIV should try to achieve and sustain the highest possible adherence to ART.¹⁷ To help persons with HIV reach their adherence goals, *clinical providers, nonclinical providers*, and selected health department staff can offer a variety of support strategies when needed.

This section addresses methods to assess adherence, factors that influence adherence and interventions that promote sustained high adherence. *Quality improvement*[‡] and program *monitoring and evaluation*[§] can determine if the interventions described in this section are implemented as intended, yield the expected outcomes, or warrant changes in delivery methods (see Section 13, Quality Improvement). Section 5, Antiretroviral Treatment, describes the benefits of ART use with sustained high adherence and factors other than adherence that influence treatment effectiveness, including concurrent medical conditions, drug-resistant virus, and the use of other drugs, alcohol, or dietary supplements that may alter ART absorption or metabolism. *Other federal guidance provides additional information about ART adherence, including clinical criteria for selecting initial and changing regimens that may influence adherence.*^{1,22} Section 4, Linkage to and Retention in HIV Medical Care, addresses issues affecting retention in HIV care, which is essential for sustained access to ART and adherence support.

⁸ Monitoring and evaluation is a process that involves the repeated, ongoing collection and review of information about program activities, characteristics, and outcomes in order to assess program implementation, coverage, acceptability, cost, and effectiveness.



^{*} The inability to achieve or maintain suppression of viral replication (to an HIV RNA level <200 copies/mL).¹

^{*} Studies published over the last decade have measured adherence using different methods, cut offs, and recall periods. Most studies

classified high adherence as a patient report of having taken at least 90% of medications as prescribed over the previous 7–30 days.^{20,21}
 Quality improvement is an approach to the continuous study and improvement of the processes of providing services that meet or exceed established professional standards and user expectations.

Recommendations

BOX 6. RECOMMENDATIONS—ANTIRETROVIRAL TREATMENT ADHERENCE

For nonclinical and clinical providers (including health department staff who provide individual-level services to persons with HIV), if allowed by professional authority and jurisdiction

- Participate in multidisciplinary teams with health educators, service linkage facilitators, community health workers,^a case managers, nurses, pharmacists, and physicians to assess and support adherence to antiretroviral treatment (ART)^{b,c} (i, ii, iii)
- Inform persons with HIV about the benefits of sustained high adherence, even if they are feeling well, and the
 risks of low adherence (e.g., illness, drug resistance, transmitting HIV to others)^{b,d} (i, ii)
- Provide adherence support tailored to each person's regimen and characteristics, according to provider role, authority, and setting^b (i, ii) (see <u>Box 6-A</u>)
- Provide or make referrals for services to address factors that may impair adherence (e.g., demographic, comorbidity, psychosocial, and structural issues)^b (i, ii) (see <u>Table 6-1</u>)
- Offer advice on how to obtain sustained coverage or subsidies for ART through private- or public-sector sources^b (i, iv, v, vi)

Specific to clinical providers (in addition to above recommendations)

- Before prescribing ART, assess patient readiness to start ART, sources of pharmacy coverage, and possible barriers to sustained high adherence (e.g., anticipated changes in health insurance, disruptive life events, mental illness) (i, ii)
- Offer highly effective ART regimens, preferably those that minimize pill burden, dosing frequency, and dietary restrictions (i, ii)
- Involve patient in decisions about treatment regimens (i, ii)
- Advise patients to take ART as prescribed; provide information about the regimen, and check for understanding in the following areas (i, ii):
 - Details of the regimen, including dosing method and schedule, dietary restrictions, and what to do when drinking alcohol or when missing doses
 - Consequences of missing doses, such as increased risk of HIV-related illness, developing drug resistance, and transmitting HIV
 - Potential side effects and what to do if side effects occur
 - Potential interactions with other prescription, nonprescription, and recreational drugs; alcohol; and dietary supplements that may impair ART effectiveness or cause toxicity that could impair adherence
 - The possibility of HIV transmission even when virus is not detectable in the blood because blood measurements may not reflect viral load in genital and anal fluids or may have increased since last measurement
- Routinely assess patient's questions, concerns, or challenges regarding ART use to identify potential problems before virologic failure^e occurs (i, ii)
- Remind patients to report current or planned use of prescription, nonprescription, or recreational drugs; alcohol; and dietary supplements because these may impair ART effectiveness or cause toxicity that could impair ART adherence (ii)
- Assess self-reported adherence at each visit using a nonjudgmental manner^f (i, ii)
- Assess and manage side effects at each visit (i, ii)
- Routinely use HIV viral load to monitor ART effectiveness that may be affected by adherence (i, ii)
- Consider assessing ART prescription refills or pill counts, if feasible, when needed to supplement routine assessment of self-reported adherence (e.g., when treatment response is not consistent with self-reported adherence) (i, ii)
- Do not directly administer ART to patients on a routine basis, except in settings where other medications are directly administered on a routine basis (e.g., young adolescents living with parents, prisons, residential substance use treatment centers, opioid replacement programs, mental health hospitals) (i)

BOX 6. RECOMMENDATIONS—ANTIRETROVIRAL TREATMENT ADHERENCE (cont)

For staff of health departments who provide population-level HIV prevention and care services

- Use HIV surveillance data to identify populations or individuals who have CD4 cell counts or viral load test
 results that indicate suboptimal treatment that may be related to low adherence and who may warrant being
 offered ART adherence support, if allowed by the jurisdiction (vii, viii)
- Engage health department disease investigation specialists or other community health workers, if allowed by the jurisdiction, in collaborating with health care providers to offer adherence support to their patients^{a,g}
- Support other population-level strategies to promote sustained high adherence (vii) (see <u>Box 6-B</u>)
- *Note.* In this report, *nonclinical providers* are defined as persons who work in community-based organizations or health departments operating outside of health care facilities and who provide HIV testing, health education, risk-reduction interventions, partner services, case management, or assistance with linkage or referral to medical and social services. These persons include HIV testing providers, peer and professional health educators, counselors, linkage facilitators, partner services specialists, case managers, and social workers. *Clinical providers* are defined as persons who work in health care facilities and who provide risk assessments, health education, counseling, screening, diagnosis, treatment, and other health-related services. These providers include physicians, registered nurses, advance practice nurses, physician assistants, dentists, mental health providers, pharmacists, health educators, case managers, social workers, and counselors. Some may be employees or contractors of health departments. Some of the recommendations specific to clinical providers apply only to clinical providers with authority for clinical evaluation and examinations, diagnosis, treatment, and prescribing.

Some of the federal guidelines cited in the Recommendation boxes may have been updated. For current federal recommendations, please refer to <u>http://www.cdc.gov/hiv/guidelines/personswithhiv.html</u>.

- ^a Linkage facilitators assist persons with HIV to access HIV medical care and other medical and social services through active methods (e.g., help making appointments, providing transportation to appointments).Community health workers might include community-based HIV prevention specialists contracted by health departments or employees of community-based HIV service organizations.
- The cited federal government guidance that supports this recommendation was intended for health care providers. Based on program experience and opinions of the Project Workgroup, the section writing group concluded that it would be beneficial and feasible for other types of providers to implement this recommendation.
- ^e In some jurisdictions, collaboration may involve communicating with HIV surveillance programs that monitor HIV viral load levels of reported HIV cases to identify persons with suboptimal treatment response that may be due to low adherence.
- ^d The source guidance only addresses the personal health benefits of high adherence, not the benefits of high adherence in reducing the risk of transmission to others.
- Virologic failure is the inability to achieve or maintain suppression of HIV replication to an HIV RNA level of <200 copies/mL.
- Some experts recommend asking patients to answer the question, "In the last 30 days, how good a job did you do at taking HIV medicines in the way you were supposed to?" using a multistep scale ranging from very poor to excellent.²³
- See the <u>Background</u> topic in this section for information supporting this statement.

Sources

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Box 6-A. Recommended adherence support strategies for nonclinical and clinical providers, if allowed by professional authority and jurisdiction

- Address misinformation, misconceptions, negative beliefs, or other concerns about ART regimen or adherence^a (i, ii)
- Acknowledge the challenges of maintaining high adherence over a lifetime and offer long-term adherence support, especially when health coverage, insurance, or other life circumstances change^a (i)
- Encourage disclosure of challenges to adherence in a nonjudgmental manner^a (i)
- Apply motivational interviewing techniques during routine adherence assessment^{a,b} (i, ii). These include
 - asking about methods persons have successfully used or could use to increase adherence
 - asking about recent challenges to adherence and how they could be overcome
- Offer advice, tools, and training tailored to individual strengths, challenges, and circumstances to support adherence^{a,b} (i, ii). Examples of advice include
 - linking dosing to daily events, such as meals or brushing teeth^a
 - using pill boxes, dose-reminder alarms, or diaries as reminders^a
 - carrying extra pills when away from home^a
 - actions to take if pill supply is depleted or nearly depleted^a
 - avoiding treatment interruptions when changing routines (e.g., travel, legal detention)^a
 - consulting HIV care providers before surgery or when experiencing a new health condition or a change in life circumstance that might impair ART use (e.g., change in prescription, nonprescription, and other drug use)^a
- Encourage persons to seek adherence support from family members, partners, or friends who are aware of their infection^{a,c} (i, ii)

The cited federal government guidance that supports this recommendation was intended for health care providers. Based on program experience and opinions of the Project Workgroup, the section writing group concluded that it would be beneficial and feasible for other types of providers to implement this recommendation.

- Information described in the Evidence topic of this section supports this recommendation statement.
- For information on how families can support adherence to ART among adolescents, see the Special Populations topic below.

Sources

- i. Panel on Antiretroviral Guidelines for Adults and Adolescents. *Guidelines for the use of antiretroviral agents in HIV-1–infected adults and adolescents*. 2014. <u>http://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-treatment-guidelines/0/</u>. Accessed July 7, 2014.
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Box 6-B. Examples of population-level strategies to improve adherence

- Develop protocols and data-sharing agreements with public- and private-sector entities to enable monitoring of the effectiveness of ART (e.g., longitudinal surveillance data on CD4 cell count or viral load test results that may provide indirect measures of adherence) in populations or individuals with HIV, if allowed by the jurisdiction
- Promote programs that help persons with HIV obtain continuous coverage for ART through public- or privatesector pharmacy benefit programs (e.g., Medicare, Medicaid, Veterans Affairs, private health insurance, government-sponsored insurance plans, AIDS Drug Assistance Program)
- Collaborate with public- and private-sector health systems and ART access programs to support retention in HIV care and sustained access to affordable ART when persons change their health care provider, source of health care coverage, or enter or are released from correctional facilities
- Make available summaries about antiretroviral medications (including their costs) that are covered by publicsector HIV clinical providers and drug formularies for clinical providers and persons with HIV
- Support training of clinical and nonclinical providers to increase awareness of the importance of sustained high adherence and sources of adherence support and affordable ART
- Support social marketing campaigns that promote sustained high adherence

How These Recommendations Differ from Previous Recommendations

The 2003 *Recommendations for Incorporating HIV Prevention into HIV Medical Care*²⁴ did not address adherence to ART as a means to suppress viral load or prevent HIV transmission. However, the recommendations in this section are consistent with the latest federal guidance for clinical providers regarding adherence assessment and support.^{1,22,25} They are also consistent with the latest federal guidance for health departments regarding collection and use of HIV surveillance data (as a measure of ART effectiveness, which may be affected by adherence) in populations or individuals, if allowed by their jurisdictions.²⁶⁻²⁸ These recommendations are also consistent with nearly all of the latest comparable recommendations about ART adherence of these nongovernmental organizations: the International Association of Physicians in AIDS Care Panel;²⁹ the HIV Medicine Association of the Infectious Diseases Society of America;³⁰ and the International Antiviral Society-USA Panel.^{31,32}

This report also makes new recommendations based on recent studies, programmatic experience, and/or expert opinion. These include recommendations for

- nonclinical providers (including community health workers employed by health departments or community-based organizations) to provide selected educational, counseling, and *referral*** services to support adherence, if allowed by their professional authority and jurisdiction (see <u>Box 6</u> and <u>Box 6-A</u>)
- nonclinical and clinical providers to apply motivational interviewing techniques to help persons taking ART identify strategies for maintaining or improving their adherence (see <u>Box 6-A</u>)

^{**} Referral is a process to help persons identify and access needed services by offering the service provider's address, phone number, directions, hours of operation, and other basic information.



health departments to engage health department disease investigation specialists or other community health workers in collaborating with health care providers to offer their patients adherence support, if allowed by the jurisdiction (see <u>Box 6</u>)

Methods

The section writing group based these recommendations on several sources of scientific information including federal guidance, published systematic reviews, and published primary studies.

- Previous recommendations of the U.S. Department of Health and Human Services (HHS), the Health Resources and Services Administration (HRSA), and the Centers for Disease Control and Prevention (CDC), all of which were based on a comprehensive review of a large body of scientific evidence, clinical experience, and expert opinion.^{1,22,25}
- Eighteen systematic reviews of studies about factors associated with ART adherence that were conducted in the United States and other countries and published from 2000–2013.^{8,20,33-48}
- Nineteen systematic reviews of studies that evaluated the efficacy of interventions to support adherence that were conducted in the United States and other countries and were published from 2000–2012.^{36,43,45,49-64} These reviews varied regarding the number of studies included, eligibility for inclusion (e.g., published versus unpublished literature, inclusion of randomized controlled trials [RCTs], one-group designs, or other designs), methods for assessing adherence, and methods for summarizing evidence. The reviews examined several types of adherence interventions; many combined education, adherence tools, and long-term support strategies.
- An electronically published systematic review, the PRS Compendium of Evidence-based HIV Behavioral Interventions (PRS Compendium) that is updated annually as new published studies that meet inclusion criteria are identified.⁶⁵ The 2014 compendium included 10 evidence-based behavioral interventions^{††} (EBIs) for improving adherence (described in 9 studies) that were determined to be efficacious based on PRS efficacy criteria (hereafter termed "adherence EBIs").⁶⁶⁻⁷⁴ Each study met pre-established criteria for rigorous evaluation design (i.e., used a comparison group), reported significant findings (i.e., statistically significant positive intervention effects on adherence or viral load), and was published in a peer-reviewed journal.⁷⁵
- Six cost-effectiveness analyses of adherence interventions in the United States.⁷⁶⁻⁸¹

Evidence Supporting the Recommendations

Methods to regularly assess adherence

Adherence can be measured using various methods, including self-reported medication use or pill counts, pill counts assessed by providers, electronic drug-monitoring data, pharmacy records, and drug levels in the blood. Each method has good correlation with one or more other measurement methods and with HIV viral load.^{14,15,21,82-84} There is no consensus on the most accurate, simple, and feasible method because each method has strengths and weaknesses.⁸² Self-reported adherence is commonly used in daily practice and is recommended for routine adherence assessment because it is inexpensive and easy to

^{††} Evidence-based interventions are individual-, group-, or population-level interventions that have been shown to promote safer behaviors or reduce HIV or STD transmission in research studies, program evaluations, or theory-based intervention experience.



implement.^{1,22} Most other methods are less practical in *clinical settings*^{‡‡} because of high cost, patient or provider burden, or require medical or pharmaceutical information systems that were not designed for routine adherence assessment. Although self-reported adherence tends to over-estimate adherence by up to 20%, certain response options and recall methods may improve accuracy.^{1,22,85} For example, some experts recommend asking patients to answer the question, "In the last 30 days, how good a job did you do at taking HIV medicines in the way you were supposed to?" using a multistep scale from very poor to excellent.²³ In addition, providers who use a positive, nonjudgmental manner with patients and acknowledge the challenges of adherence can encourage more accurate self-reporting.^{1,22} Current federal recommendations advise using pharmacy refill information and pill counts to supplement, but not replace, self-reported adherence measures only in clinical settings that can routinely collect this information and recognize biases when refill data are incomplete or patients discard pills before they are counted.^{1,22} Federal recommendations for clinical settings do not advise measuring antiretroviral drug concentrations in biologic specimens (which is costly and biased by short, drug half-lives) or recording data from electronic drug monitoring devices (which is often impractical).^{1,22}

Assessing factors that influence adherence

Achieving consistently high adherence over the span of chronic HIV infection is often challenging. Even persons who have maintained high adherence for long periods may have lapses in adherence due to medical or psychosocial issues or life events. While the most common reason for low adherence that patients cite is forgetting to take the medication,^{13,18,43,86-89} a complex set of personal, social, cultural, and structural factors can influence adherence.

<u>Table 6-1</u> summarizes the most common factors related to low adherence described in 18 published reviews on correlates and HHS guidelines on ART use.^{1,8,20,33-48} Low adherence was most often associated with patient factors—particularly alcohol or substance abuse and depression, anxiety, or other psychological conditions— and regimen factors, such as frequent or severe treatment side effects, high pill burden, and frequent dosing. Other common patient-level factors affecting adherence included negative attitudes or beliefs about HIV disease, fear of stigma, lack of social support, negative attitudes or beliefs about treatment, and lack of a daily routine. Several structural factors—such as homelessness or lack of insurance or financial assistance—were also associated with low adherence. The 3 reviews that focused on adolescents found that characteristics of parents or caregivers were associated with their adolescent's adherence; these included knowledge (e.g., education level, understanding about ART), perceptions (e.g., belief of treatment efficacy, self-efficacy), and well-being (e.g., stress).^{43,45,46}

^{‡‡} Clinical settings are health care facilities in which medical diagnostic, treatment, and disease prevention services are routinely provided.

Table 6-1. Factors associated with low adherence to ART in adults and adolescents

Factors

Patient-level factors

- Comorbidity and psychosocial factors
 - Current substance use, including alcohol^{8,34-36,38-41,43-45}
 - Mental and physical health problems, such as depression, anxiety, cognitive impairment, and poor vision^{8,33,35-40,43,45,90}
 - Low perceived quality of life or life satisfaction^{41,43}
 - Lack of social support^{33,36,39,40,44}
 - Negative attitudes and beliefs about HIV disease that may be associated with denial, nondisclosure, or fear of stigma^{36,41,43-45,47,91}
- Knowledge and competence regarding adherence
 - Low literacy level regarding health information and regimen-related instructions^{92,93}
 - Lack of knowledge or understanding about 1) treatment benefits, 2) the importance of sustained high adherence for health or viral suppression, or 3) regimen instructions^{8,41,45}
 - Negative attitudes and beliefs about treatment (e.g., mistrust, misconceptions, doubts about treatment effectiveness)^{8,36,41,43-45}
 - Low confidence in ability to follow regimen or limited self-management skills^{8,33,43}
- Chaotic lifestyle or lack of daily routine^{33,36,41,47}
- Lack of attendance at HIV care visits in which ART can be prescribed⁹⁴
- Younger age¹

Treatment regimen factors

- Regimen complexity (e.g., high pill burden, frequent or inconvenient dosing schedule, dietary restrictions, interactions with other drugs) and difficulty swallowing pills^{8,33,35,36,41-45}
- Frequency and severity of side effects^{8,33,35,36,41,43,44,47,48}
- Treatment fatigue (i.e., adherence wanes over time)¹

Patient-provider and other interpersonal factors

 Poor patient-provider relationship, such as limited provider adherence support, insufficient shared decision making, or changes in health care providers over time^{8,36,44}

Structural factors

- Inability to afford or obtain a continuous supply of ART due to lack of health insurance or enrollment in medical assistance programs^{35,36,39,41}
- Unstable housing, incarceration, and recent release from imprisonment^{35,36,38,40,41,43,45}

Strategies that increase adherence

The 19 systematic reviews that evaluated the impact of behavioral interventions on improving adherence included formal meta-analyses (n=6) and qualitative or semi-quantitative analyses (n=13). Many reviews concluded that adherence interventions resulted in statistically significant improvements in adherence (as measured by self-reported adherence, pill counts, or electronic medication monitoring devices), but that the magnitude of differences in adherence levels between intervention and comparison groups was moderate.^{49,54,56-58,60-64} Many reviews showed that persons who received adherence interventions also had reduced HIV viral loads, although effect sizes were weaker than those related to adherence

measures.^{49,53,54,56-58,60,62,63} Several reviews found that adherence increased during the intervention period but declined thereafter or that ongoing support was needed to sustain high adherence.^{49,54,56-58} Overall, the most effective interventions focused on educating and motivating patients, addressing concerns or negative beliefs about treatment, building patients' skills and providing tools for managing medications, and offering ongoing support.⁵⁶⁻⁵⁸ Several reviews suggested that to be effective, adherence interventions must use a multifaceted, long-term approach; engage members of multidisciplinary teams; and consider a variety of strategies tailored to the individual.⁵⁶⁻⁵⁹

Details on specific strategies that improved adherence when used alone or in combination with other strategies are summarized below.

Providers of adherence support

Several systematic reviews of intervention evaluations found that various types of providers who provide adherence support can improve adherence. A meta-analysis of 10 adherence interventions (7 of which specifically addressed ART) found that interventions in which nurses provided adherence counseling and other support significantly improved both short- and long-term adherence.⁶⁴ Another review found that engaging pharmacists to provide education, counseling, and training on adherence management tools was often associated with improved adherence and viral suppression.⁶⁰ In addition, interventions that used peer educators, community health workers, or *outreach* workers to educate patients about medication management and to provide repeated, long-term adherence support could improve adherence.⁵⁵

Simplified ART regimens

Several of the 18 systematic reviews that assessed factors associated with adherence found that greater pill burden and more frequent dosing were associated with lower adherence.^{8,33,35,36,41-45} One review described a meta-analysis of 11 RCTs that found that adherence to once-daily regimens was slightly better than adherence to twice-daily regimens in all patients (a difference of 2.9%) and in the subset of patients who had recently started treatment (a difference of 4.4%).⁴² In 6 of these studies, patients prescribed once-daily regimens had significantly higher adherence (a difference of 4.5%) and lower viral load levels (defined as <50 copies/ml, a difference of 5.7%) as compared with patients prescribed twice-daily regimens.⁴² All of these modest differences were statistically significant.

Management of side effects

Several of the 18 systematic reviews that assessed factors associated with adherence found that adverse side effects impair adherence.^{8,33,35,36,41,43,44,47,48} One meta-analysis found that patients reporting side effects were about 40% less likely to report high adherence than were patients reporting no adverse effects, although the magnitude of difference varied slightly by type of adverse effect.⁴⁸ None of the 19 systematic reviews of intervention evaluations reported the impact of strategies to manage side effects. However, 3 adherence EBIs in the *PRS Compendium* informed patients about ART side effects or provided tailored advice if patients reported that side effects as compared with many older regimens, side effects continue to impair adherence in some persons.

Adherence education and counseling

Three systematic reviews of intervention evaluations found that education and counseling that address cognitive and behavioral aspects of taking ART can improve adherence. These strategies included providing information about treatment; addressing negative beliefs about medication, lack of motivation to take medication, or unrealistic expectations about adherence; providing individually tailored approaches to build self-confidence and medication management skills; and encouraging seeking support for adherence from providers, fellow patients, friends, or family.⁵⁶⁻⁵⁸ A systematic review of 5 interventions that involved motivational interviewing found that 3 significantly improved adherence and 2 significantly reduced viral load.⁶³ In addition, 8 of the 10 adherence EBIs in the *PRS Compendium* focused primarily on educational or cognitive-behavioral approaches to improving adherence. Strategies included providing education about ART use and the health benefits of adherence and treatment goals, building adherence skills, and engaging support for adherence from previse.^{67-69,71-74}

Adherence tools

Two systematic reviews of intervention evaluations studies found that technology-based methods, such as mobile phones that generate auto alarms or text messages and other electronic reminder devices (e.g., pagers, alarms, and electronic pill boxes), do not improve adherence when used alone. However, they are effective when combined with other strategies, such as education and individually tailored counseling.^{59,61} A more recent systematic review examining 2 Kenyan trials found that weekly mobile text messages with adherence reminders significantly improved adherence and suppressed viral load.⁶² Of the 10 adherence EBIs in the *PRS Compendium*, 1 study sent daily pager messages that included reminders to take ART as the sole adherence support strategy.⁷² Persons who received messages were more likely to achieve undetectable viral load levels than were persons who did not receive messages.

Directly administered antiretroviral treatment or therapy^{§§} (DAART)

Two of the 19 systematic reviews of intervention evaluations compared DAART to self-administered treatment in various populations: HIV clinic patients, substance users (including those receiving and those deferring *substance use* treatment), *persons who inject drugs* (PWID), homeless persons, prisoners, and hospice patients. The reviews found limited evidence that DAART improved adherence or viral suppression.^{53,54} The first review found that DAART only significantly improved adherence or viral suppression in PWID and homeless persons.⁵³ The second review found that DAART improved adherence or viral adherence and viral suppression only during the intervention period but not thereafter.⁵⁴ Two of the 10 adherence EBIs in the *PRS Compendium* found that DAART for substance users resulted in significant reductions in viral load.^{66,70} One multifaceted intervention involved sending pager reminders to receive daytime doses (in a mobile van) and to take evening doses over a period of 6 months; it also included *case management*, social support, and medication management education to help transition *clients* after DAART ceased.⁶⁶ Persons who received this intervention were significantly more likely than persons who managed their own ART to achieve an undetectable viral load or a large reduction in viral load (70% vs 55%, p=0.017).⁶⁶ The other study provided DAART to clients of a methadone maintenance clinic who had started a new ART regimen.⁷⁰ Persons who received the intervention were more likely to have

^{§§} Directly administered antiretroviral treatment or therapy (DAART) is a form of drug administration in which a provider directly observes a person with HIV taking oral ART on a daily or nearly daily basis.



undetectable viral loads 6 months after starting DAART as compared with persons who managed their own ART (74% vs 41%, p<0.001). The studies raise questions about the general applicability of DAART, however, because the interventions were restricted to substance users, did not show a sustained effect after DAART ceased, and were fairly labor-intensive.

Multifaceted interventions with several components

Several adherence EBIs in the *PRS Compendium*⁷⁵ were found to improve adherence (n=7)^{67-69,71-74} or to reduce viral load (n=4).^{66,69,70,72} Seven evidence-based interventions were multifaceted and included several strategies for improving adherence, such as cognitive-behavioral approaches, social support, treatment delivery methods, and adherence tools.^{66-69,71,73,74} The interventions were directed to adults with varied characteristics and ART experience, including substance users, clinic patients, couples with discordant HIV status, persons starting ART, experienced users, persons switching regimens, and persons experiencing adherence problems. All interventions focused on populations comprising mainly racial/ethnic minorities, and most were implemented in clinics or directed to established clinic patients. The interventions also varied regarding delivery mode (individual, couples, group) and provider type (physician, nurse, peer counselor, outreach worker, other facilitators).

Two of the 7 multifaceted EBIs were associated with significant decreases in viral load.^{66,69} One brief, clinic-based intervention consisted of brief (~3–5 minutes) counseling sessions by physicians at each HIV care visit along with clinic posters and patient education materials reinforcing ART adherence.⁶⁹ Patients who received this intervention were nearly 3 times more likely than patients who did not receive the intervention to report high adherence (\geq 95% of prescribed pills taken over the previous 7 days) (OR=2.9, p=0.001) and were less likely to have detectable viral load levels (>500 copies/mL) (OR=0.60, p=0.04).⁶⁹ In the other multifaceted intervention (described in the DAART topic above) persons who received DAART, pager reminders, case management, and other supportive services through a mobile van were more likely than persons who did not receive these services to achieve undetectable viral loads or large reductions in viral load 6 months after DAART started (70% vs 55%, p=0.017).⁶⁶

Cost-effectiveness of adherence interventions

Five cost-effectiveness studies published from 2000–2010 evaluated different adherence interventions, including individual counseling for gay, bisexual, or other men who have sex with men (MSM) provided by health professionals, home visits by nurses, and provision of DAART in the clinic or the home.⁷⁶⁻⁸⁰ The studies considered different comparison groups (i.e., persons taking placebos or persons receiving verbal reminders to take medications as prescribed), different populations (e.g., treatment naïve, specific CD4 cell count or viral load, demographic group), and different intervention providers (e.g., nurses, pharmacists). Two studies estimated intervention efficacy and cost from data collected during adherence trials,^{76,79} and 3 studies estimated cost data using data from other published reports.^{77,78,80} The studies found that adherence interventions cost from \$1,300 to \$90,000 per quality-adjusted life year gained (mean=\$43,970). In addition, modeling analysis estimating the cost effectiveness of adherence interventions (in which per-patient costs were based on 2 clinic-based interventions that appreciably improved adherence)^{76,95} found that providing adherence interventions to prevent HIV transmission was cost-saving compared with not providing interventions.⁸¹ It also concluded that the intervention cost per

new case of HIV averted was \sim \$339,000,⁸¹ slightly less costly than the lifetime cost of HIV treatment (>\$400,000).⁹⁶

Issues that Influence Implementation of the Recommendations Implementation progress, challenges, and opportunities

Studies over the last decade have shown that average rates of adherence (estimated at various times after ART initiation) range from 30% to $89\%^{5,6,11,13,14,16,18,86-88,97-103}$ and tend to decline over time.^{5,70,104-108} A recent meta-analysis estimated that, on average, only 59% (95% CI: 53%–65%) of persons with HIV in North America reported \geq 90% adherence to ART.²⁰ A 2011 evaluation of 128 HIV clinics funded by the Ryan White HIV/AIDS Program found that 15% of patients had a documented problem with adherence.¹⁰⁹ However, levels of adherence among persons with HIV may improve in the future for several reasons: 1) HHS now recommends use of ART for preventing HIV transmission; 2) newer medications require less frequent doses and cause fewer side effects; 3) access to pharmacy benefits from health insurance and expanded state Medicaid programs has increased under the Patient Protection and Affordable Care Act (ACA); 4) funding of the AIDS Drug Assistance Program and other programs that subsidize ART continues; and 5) cost of some ART medications will decline as patents expire.¹¹⁰⁻¹¹²

As more persons with HIV start ART for the dual purpose of treatment and preventing transmission, future studies can evaluate the impact of adherence support for persons who have high CD4 cell counts and feel well.¹ Two studies suggest that patients who start or use ART when they have high CD4 cell counts are less likely to have sustained high adherence than persons with low CD4 cell counts.^{113,114} Nevertheless, theoretical considerations suggest that when comparing the potential risk of low adherence in some persons starting ART at high CD4 levels to the potential benefit of decreasing the population viral load, large increases in the numbers of persons starting ART are likely to result in a net benefit in preventing HIV transmission.¹

Although many studies show the benefits of regular adherence assessment and support, many health care providers do not regularly assess adherence, address adherence barriers, or provide adherence support because of competing priorities or lack of experience.^{115,116} When time is limited, many providers prioritize support to patients who are starting or restarting ART, changing regimens, or reporting low adherence and adherence challenges. Use of multidisciplinary care teams, task sharing, and "medical homes" encouraged by the ACA can expand the range of providers who can support adherence.^{110,112} *Electronic medical records**** that can track viral load levels over time and generate reminders for health care providers when viral loads increase may prompt adherence assessment in some clinical settings.¹¹⁷

Anecdotal reports suggest that some persons with HIV may consider sharing their ART medications with other persons with HIV or with HIV-uninfected *partners* seeking antiretroviral medications for

^{***} An electronic medical record (EMR) is a patient record that is maintained using computer software. The record should include patient history, including diagnoses, treatments, prescribed medications, drug allergies, and self-reported problems; patient demographics; physician clinical notes; and laboratory and imaging results.



preexposure prophylaxis (PrEP)^{†††} and *nonoccupational postexposure prophylaxis*.^{‡‡‡} Providers should discourage sharing ART because it may impair adherence and pose other problems (see <u>Section 5</u>, <u>Antiretroviral Treatment</u>).^{1,118-121}

Policy, legal, and ethical considerations

Concerns about *confidentiality*, stigma, and social disapproval and nondisclosure of HIV infection status are associated with low adherence^{36,41,43-45,47,91} (see Section 3, Context of Prevention). Some persons may be reluctant to carry or display their ART in public or to seek adherence support from others if they fear legal consequences or deportation. A study of more than 1,800 persons with HIV in North America found that those living in areas where transmitting or exposing others to HIV was a crime reported lower adherence compared with persons living in other areas.¹²² Providers can assess adherence in a nonjudgmental manner, stress that adherence information is confidential, explain the relation between adherence and viral load, and help persons with HIV find practical adherence strategies. These strategies may encourage patients to honestly disclose their adherence levels, to admit adherence challenges, and to set realistic adherence goals. Several studies have also shown that persons who share decision making about ART adherence goals with their clinical providers have higher adherence.^{8,36,44} This approach respects the patient's autonomy while using clinical input about the levels of adherence needed to achieve treatment goals.

Other factors that influence adherence are described elsewhere: retention in *HIV medical care* (Section 4, Linkage to and Retention in HIV Medical Care); and sustained access to affordable ART (Section 5, Antiretroviral Treatment).

Special populations

Persons who have substance use problems, unstable housing, or other characteristics associated with low adherence can achieve high adherence when given adequate support.^{2,11,39,40,86,89,123-125} For example, providers who regularly monitor drug and alcohol use that signal life stressors may preempt lapses in adherence that lead to virologic failure.^{103,126}

Clinical providers who serve younger adolescents who rely on parents or caregivers to manage medicines can refer to adherence strategies for children recommended by HHS.¹²⁷ Providers serving older adolescents can honor confidentiality by asking which adults sponsor their health insurance, are aware of their HIV infection, and have the knowledge and attitudes about ART that enable them to provide adherence support.^{43,45,46,128}

ART adherence can be challenging for some older persons, particularly those taking many medications for other conditions or experiencing cognitive impairment.^{47,129,130} Several strategies may be helpful: avoiding prescribing drugs that may cause adverse interactions, managing drug interactions, and offering tools and training to organize medications. Patients who cannot read pill bottles or understand package

⁺⁺⁺⁺ The use of selected antiretroviral medications by HIV-uninfected persons within 72 hours after isolated, nonoccupational or occupational exposures to body fluids potentially containing HIV—such as after unprotected sexual intercourse, condom breakage, or needlesticks—in order to reduce the risk of HIV acquisition.



⁺⁺⁺ PrEP is the daily, continuous use of a select regimen of antiretroviral medications for a period of time by an HIV-uninfected person to achieve levels of drug in the blood and anal and genital mucosa sufficient to reduce the risk of HIV acquisition.¹¹⁸

inserts because of low literacy or language barriers may benefit from visual aids or simplified medication instructions in the appropriate language. <u>Section 12</u> describes assessment, linkage, and referral to other medical and social services for populations that face unique barriers to adherence.

Implementation Resources

Practical resources to support implementation of these recommendations, including a list of interventions shown to be efficacious in supporting adherence, can be found at

<u>http://www.cdc.gov/hiv/guidelines/implementationresources.html</u>. A list of wholesale costs of ART regimens recommended by HHS is also available.¹

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Section 7. Risk Screening and Risk-reduction Interventions Background

Risk screening is the collection of information to determine a person's risk of transmitting HIV to others. In this report, risk screening is defined as a brief *evaluation* of behavioral factors that may affect the risk of exposing others to HIV (e.g., *unprotected* sex* or sharing drug-injection equipment) and biomedical or biologic factors that influence HIV *viral load*, viral shedding, and infectiousness (e.g., *antiretroviral treatment [ART]* use, ART *adherence*, sexually transmitted disease [STD], and pregnancy). Risk screening[†] is used to identify behavioral or biomedical risk-reduction interventions suited to a specific individual.¹⁻⁴

Behavioral risk-reduction interventions include various services provided in clinical settings[‡] and *nonclinical settings[§]* that have been shown to promote safer behaviors and reduce the risk of exposing others to HIV. Many interventions address psychological, social, or structural factors that influence sexual, drug-injection, and reproductive behaviors. Some aim to provide information, build knowledge, and improve skills that lead to safer behaviors. Others increase motivation to adopt safer behaviors or modify social norms. Some interventions involve a structural component, such as increasing access to condoms. Behavioral risk-reduction interventions can be offered to individuals or groups through counseling, discussion, role plays, or exercises; through print media, such as brochures and posters; and through interactive media, such as computers, telephones, and mobile devices.⁵

This section addresses risk screening and behavioral risk-reduction interventions that can promote safer sexual and drug-injection behavior over a lifetime. *Quality improvement*** and program *monitoring and evaluation*^{††} methods can determine if the interventions described in this section are implemented as intended, yield the expected outcomes, or warrant changes in delivery methods (see Section 13, Quality Improvement). Because risk screening and risk-reduction interventions are central to HIV prevention with persons with HIV, other sections also describe behavioral and biomedical strategies to reduce the risk of HIV transmission: *linkage* to and retention in care (Section 4), antiretroviral treatment (Section 5), ART

^{††} Monitoring and evaluation is a process that involves the repeated, ongoing collection and review of information about program activities, characteristics, and outcomes in order to assess program implementation, coverage, acceptability, cost, and effectiveness.



^{*} Unprotected sex or unprotected sexual contact is sexual activity without using a physical barrier (i.e., penile sex without using a male condom; vaginal sex without using a male or female condom; oral-anal contact without using a dental dam or other barrier device; vaginaldigital contact without using a female condom, latex glove, or finger cot; or rectal-digital contact without using a latex glove or finger cot).

[†] Risk screening is the collection of information to determine a person's risk of transmitting HIV to others. In this report, risk screening is defined as a brief evaluation of behavioral factors that may affect the risk of exposing others to HIV (e.g., unprotected sex or sharing druginjection equipment) and biomedical factors that influence HIV viral load, viral shedding, and infectiousness (e.g., antiretroviral treatment [ART] use, ART adherence, sexually transmitted disease [STD], and pregnancy). Information gathered during this screening can be used to identify suitable behavioral or biomedical risk-reduction interventions.

Clinical settings are health care facilities in which medical diagnostic, treatment, and disease prevention services are routinely provided.

[§] Nonclinical settings are facilities that provide prevention, education, screening and interventions for risk behaviors, and referrals for medical and social services. Some nonclinical settings may also provide health promotion services and screening for HIV and some STD.

^{**} Quality improvement is an approach to the continuous study and improvement of the processes of providing services that meet or exceed established professional standards and user expectations.

adherence (Section 6), partner services^{$\ddagger \ddagger}$ (Section 8), STD services (Section 9), reproductive health care (Section 10), pregnancy services (Section 11), and services for other medical conditions and social factors that influence HIV transmission (Section 12).</sup>

Recommendations

BOX 7. RECOMMENDATIONS—RISK SCREENING AND RISK-REDUCTION INTERVENTIONS

For nonclinical and clinical providers (including health department staff who provide individual-level services to persons with HIV)

Organizational-level interventions

- Establish infrastructure to support routine risk screening and brief risk-reduction interventions (i) (see Box 7-A)
- Train staff to create a trusting, supportive, and nonjudgmental atmosphere that encourages persons with HIV to be honest, to voluntarily disclose sex and drug-use behaviors and health information, and to ask questions^a (ii)

Individual-level risk screening services

- Screen persons with HIV at initial and later encounters (at least yearly or more frequently as needed) for these
 risk factors: (i, ii, iii, iv, v, vi) (see <u>Box 7-B</u>)
 - Behavioral characteristics that affect their risk of exposing others to HIV (e.g., unprotected sex, sharing drug-injection equipment)^{b,c,d}
 - Biologic or biomedical characteristics that affect their level of infectiousness, (e.g., use of and adherence to antiretroviral treatment (ART), viral load level, sexually transmitted disease [STD] diagnoses, pregnancy)^{b,c,d,e,f,g,h}
 - Characteristics of partners that affect the partner's risk of acquiring HIV or STD, when information available (e.g., use of preexposure prophylaxis [PrEP]ⁱ or nonoccupational postexposure prophylaxis [nPEP]ⁱ)^{b,c,d,e,f,g,h}
- Offer positive reinforcement to persons who report safer behaviors and use of biomedical strategies that reduce their level of infectiousness to motivate their continued use (ii, iv, vii)

Partner services include an array of voluntary services for persons with HIV or STD and their sex and drug-injection partners that are intended to reduce HIV transmission: interviewing persons with HIV to obtain information to contact or locate their sex and drug-injection partners; notifying partners of possible HIV exposure; offering testing for HIV, sexually transmitted diseases, and other infections; providing condoms, prevention information, and counseling; and providing help in obtaining risk-reduction services, HIV medical care, and other medical and social services.



BOX 7. RECOMMENDATIONS—RISK SCREENING AND RISK-REDUCTION INTERVENTIONS (cont)

Individual-level risk-reduction services

- Use information collected during risk screening to identify risk-reduction messages and interventions that address the person's risk of exposing others to HIV, level of infectiousness, and partners' risks of acquiring HIV (i, ii, iii, iv, v, vi, vii, viii, ix, x)
- Offer risk-reduction information and interventions that are tailored to risks of the person with HIV (and of
 partners they refer) specifically:
 - Information about
 - behavioral interventions that can reduce the risk of exposing others to HIV (e.g., brief or intensive risk-reduction strategies that encourage safer sex and use of sterile drug-injection equipment, substance use treatment)^{d,I} (i, ii, iii, iv, vi, vii, viii) (see <u>Box 7-C</u>)
 - biomedical interventions that can reduce viral load or HIV shedding (e.g., HIV medical care, ART use,^e STD services,^f special reproductive and pregnancy services^{g,h}) (i, ii, iii, iv, vii, viii, ix, x) (see <u>Box</u> <u>7-C</u>)
 - strategies for uninfected partners to reduce their risk of acquiring HIV (e.g., partner notification,^c PrEP,ⁱ nPEP^j) (i, ii, iii, vii, viii) (see <u>Box 7-C</u>)
 - Correcting misconceptions regarding HIV transmission, acquisition, or prevention methods^k (i, ii, iii, v) (see <u>Box 7-C</u>)
 - Providing or making referrals for specialized behavioral counseling and psychosocial support to members of HIV-discordant couples,^m if available^a (ii)
 - Offering latex or polyurethane male and/or female condoms^a (ii, iii)
 - Providing or making referrals for new, sterile syringes through syringe services programsⁿ, pharmacists, physicians, or other legal methods to persons who lack consistent access to sterile drug-injection equipment (ii, iv, vi)

For staff of health departments and HIV planning groups who provide population-level HIV prevention and care services

- Support efforts to monitor HIV risk behaviors in community (see <u>Box 7-D</u>)
- Facilitate partnerships between clinical and nonclinical providers that provide services and programs to promote safer behaviors (xi) (see <u>Box 7-D</u>)
- Make available online directories of organizations that offer services to promote safer behaviors (xi) (see Box 7-D)
- Make available information about minors' access to and consent to risk-reduction services and devices (e.g., condoms) in the jurisdiction (xii)

Note. Persons with HIV may include members of HIV-discordant^m or HIV-concordant couples.

Note. In this report, *nonclinical providers* are defined as persons who work in community-based organizations or health departments operating outside of health care facilities and who provide HIV testing, health education, risk-reduction interventions, partner services, case management, or assistance with linkage or referral to medical and social services. These persons include HIV testing providers, peer and professional health educators, counselors, service linkage facilitators, partner services specialists, case managers, and social workers. *Clinical providers* are defined as persons who work in health care facilities and who provide risk assessments, health education, counseling, screening, diagnosis, treatment, and other health-related services. These providers include physicians, registered nurses, advance practice nurses, physician assistants, dentists, mental health providers, pharmacists, health educators, case managers, social workers, and counselors. Some may be employees or contractors of health departments. Some of the federal guidelines cited in the Recommendation boxes may have been updated. For current federal recommendations, please refer to http://www.cdc.gov/hiv/guidelines/personswithhiv.html.

BOX 7. RECOMMENDATIONS—RISK SCREENING AND RISK-REDUCTION INTERVENTIONS (cont)

- The cited source guidance that supports this recommendation was intended for health care providers. Based on opinions of the Project Workgroup, the section writing group concluded that it would be beneficial and feasible for other types of providers to implement this recommendation.
- See the Implementation Resources topic in this section for a link to examples of risk-screening tools.
- See <u>Section 8, Partner Services</u>.
- ^d See <u>Section 12, Other Medical and Social Services</u>.
- ² See <u>Section 5, Antiretroviral Treatment</u>.
- ^f See <u>Section 9, STD Services</u>, for recommendations on screening for STD with laboratory tests and treating persons diagnosed with STD.
- ^g See Section 10, Reproductive Health Care.
- ^h See <u>Section 11, Pregnancy</u>.
- PrEP is the daily, continuous use of a select regimen of antiretroviral medications for a period of time by an HIV-uninfected person to achieve levels of drug in the blood and anal and genital mucosa sufficient to reduce the risk of HIV acquisition.⁶ In July 2012, FDA approved one PrEP drug regimen for preventing sexual transmission. Although HHS recommendations in May 2014 advised use of this same regimen for persons who inject drugs, the product label only addresses use for preventing sexual transmission.

nPEP is the use of selected antiretroviral medications by HIV-uninfected persons within 72 hours after isolated, nonoccupational exposures to body fluids potentially containing HIV, such as after unprotected sexual intercourse or condom breakage, in order to reduce the risk of HIV acquisition.⁷ Use of antiretroviral medication for nPEP does not reflect labeling approved by FDA.

- Common misconceptions relate to perceptions of the relative, per-act risk of HIV transmission for various types of sexual contact; how behavioral, biologic, and viral factors influence transmission risk; whether ART use can reduce the risk of HIV transmission; and whether use of PrEP or nPEP with antiretroviral medications can reduce the risk of HIV acquisition by HIV-uninfected partners.
- Evidence-based interventions are individual-, group-, or population-level interventions that have been shown to promote safer behaviors or reduce HIV or STD transmission in research studies, program evaluations, or theory-based intervention experience. CDC has compiled and regularly updates a list of effective, evidence-based behavioral risk-reduction interventions that have been shown to be cost-effective for populations with similar HIV risk behaviors at http://www.cdc.gov/hiv/prevention/research/compendium/.
- ⁿ An HIV-discordant couple consists of one HIV-infected person and one HIV-uninfected person.
- Syringe services programs provide free, new, sterile syringes and needles in exchange for used syringes and needles to reduce transmission of bloodborne pathogens among people who inject drugs.

Sources

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Box 7-A. Examples of strategies to improve infrastructure for risk screening and riskreduction services

- Develop written procedures about staff members' responsibilities for providing risk screening and riskreduction interventions
- Provide staff training and tools that describe
 - methods to assess both behavioral and biologic risk information (e.g., condom use, viral load, concurrent STDs)^a
 - characteristics that influence risk screening and risk-reduction services, such as age, sexual orientation, health literacy, and cultural attitudes about health care
 - methods to offer risk-reduction interventions that emphasize healthy sexuality, avoiding substance abuse, and sustained high adherence to ART
 - state laws and regulations about confidentiality protections, HIV disclosure and possible consequences of exposing others to HIV, minors' access to risk-reduction services, and ways to access legal, sterile druginjection equipment
 - how to increase skills in serving persons with various ages, gender identities, sexual orientations, cultural backgrounds, education levels, and health literacy levels
- In settings that can monitor persons with HIV receiving risk-reduction services over time
 - establish monitoring systems that incorporate behavioral and medical information (e.g., viral load, recent STD diagnosis) to allow for more accurate risk assessment and more tailored risk-reduction interventions
 - provide reminders about periodic risk screening and track delivery of risk screening and risk-reduction interventions
- Establish agreements or contracts to link persons with HIV to risk-reduction interventions that are not provided onsite

See Section 6, ART Adherence, for more information on viral load and Section 9, STD Services, for more information on STD screening.

Box 7-B. Recommended topics to cover during risk screening

- Sexual behaviors
 - Sexual practices (e.g., vaginal, penile, anal, or oral sex; insertive vs. receptive sex, including recent condom use)
 - Sex partners (e.g., number, age, gender, HIV status, drug-use history, and recent STD diagnoses of partners; whether a partner is new or committed; where partners met; intimate partner violence)
 - Sexual activity that may expose others to blood (e.g., sexual abuse, sex during menses, or use of sexual aids, devices, or toys that cause anal or genital trauma, inflammation, or irritation)
 - Use of serosorting^a and seropositioning^b
- Alcohol and drug-use behaviors
 - Recent and ever use of substances for health or recreational purposes (e.g., alcohol, methamphetamine, ecstasy, ketamine, nitrites, marijuana, cocaine)
 - Use of these substances before, during, or after sexual activity
 - Sharing drug-injection equipment (e.g., needles, syringes, cotton, cooker, water)
 - Drug-injection partners (e.g., number of partners, partners' HIV infection status)
 - Use of new, sterile syringes and other drug-injection equipment, including sources of equipment
- Biomedical and biologic factors that may influence infectiousness or the risk of HIV transmission
 - Recent diagnosis of acute HIV infection^c based on HIV test results or clinical evaluation^d
 - Recent use of ART^e
 - Recent diagnosis of STD and STD treatment^f
 - Recent condom use
 - Contraceptive use^g
 - Current or planned pregnancy^h
 - Use of special conception methods^g
- Biomedical and biologic factors that may influence the risk of acquiring HIV by partners or the fetus or infant of a woman with HIV
 - Recent condom use
 - Recent diagnoses of STD^{f,i}
 - Current or planned pregnancy^{g,h,i}
 - Contraceptive use^g
 - Male circumcision
 - Inconsistent use of sterile drug-injection equipment
 - Use of PrEP or nPEP with antiretroviral medications^{e,i}

Box 7-B. Recommended topics to cover during risk screening (cont)

- ^a The practice of limiting unprotected sex (i.e., sexual activity without using a physical barrier) to partners believed to have the same HIV infection status (e.g., persons with HIV only have unprotected sex with persons believed to be HIV-infected).
- ^b The practice of modifying sexual activity based on beliefs about the partner's HIV infection status and the per-act risk of HIV transmission for a given type of contact (e.g., persons with HIV practice receptive fellatio [i.e., the practice of receiving a partner's penis in one's mouth] with HIV-uninfected partners because they believe this type of contact is less likely to transmit HIV than insertive fellatio [i.e., the practice of inserting one's penis into a partner's mouth], anal sex, or vaginal sex).
- ^c Acute HIV infection is the period between initial HIV infection and the expression of HIV antibodies that can be detected by HIV antibody tests. This period is characterized by high levels of HIV in the blood and a vigorous immune response.
- ⁴ A recent diagnosis may be based HIV test result indicative of acute infection (i.e., positive HIV antigen or nucleic acid amplification test or HIV antibody result indicative of recent seroconversion) and/or clinical evaluation of symptoms or signs of acute retroviral syndrome (e.g., fever, pharyngitis, rash, myalgia, arthralgia, diarrhea, headache, lymphadenopathy).
- ^e See <u>Section 5, Antiretroviral Treatment</u>, for recommendations on the use of ART to reduce the infectiousness of persons with HIV and to reduce the risk of their HIV-uninfected partners' acquiring HIV.
- ^f See <u>Section 9, STD Services</u>, for recommendations on STD screening and treatment to reduce the infectiousness of persons with HIV and the role of STD in facilitating HIV transmission.
- ^g See <u>Section 10, Reproductive Health Care</u>, for recommendations on family planning to prevent unintended pregnancy and special conception methods that reduce the risk of HIV transmission or acquisition.
- ^h See <u>Section 11, Pregnancy</u>, for recommendations on reducing the risk of sexual and perinatal transmission or acquiring HIV during pregnancy and the postpartum period.
- See <u>Section 8, Partner Services</u>, for recommendations on reducing the risk of acquiring HIV by HIV-uninfected partners, including STD screening and treatment, PrEP and nPEP, and reproductive and pregnancy services.

Box 7-C. Important topics when informing persons with HIV about how to prevent transmission of HIV to others

General topics

- How HIV is spread (e.g., exchange of body fluid) and not spread (e.g., handshake)
- How sustained high adherence to ART suppresses viral load and reduces the risk of transmitting HIV
- How preventing or treating symptomatic and asymptomatic STDs can improve health and decrease the risk of transmitting HIV
- How avoiding drugs and alcohol can improve health and may promote safer drug-use or sexual behaviors
- Benefits of support from family, friends, or partners to encourage safer behaviors
- Benefits and risks of selectively disclosing HIV infection to others (e.g., those at a heightened risk of HIV exposure, health care providers) and methods that minimize the risk of negative consequences of disclosure^a
- Benefits of knowing the HIV-infection status of sex and drug-injection partners
- How serosorting may result in HIV transmission if assumptions about partners' HIV status are incorrect or may
 result in acquiring STDs and, more rarely, new HIV strains from infected partners
- Characteristics of HIV-uninfected sex and drug-injection partners that increase their risk of HIV acquisition (e.g., sharing nonsterile drug-injection equipment, STDs)
- Availability of PrEP and nPEP for HIV-uninfected partners when clinically indicated to prevent HIV acquisition^{b,c}
- Availability of voluntary, confidential, and usually free health department services to notify sex or drug-injection partners of possible HIV exposure^d

Box 7-C. Important topics when informing persons with HIV about how to prevent transmission of HIV to others *(cont)*

Topics related to sexual transmission (or perinatal transmission if pregnant woman becomes HIV infected through sexual contact)^{e,f}

- Communicating with partners to foster healthy sexuality (e.g., noncoercive sexual contact, negotiating safer behaviors)
- Methods that HIV-discordant couples can use to reduce the risk of sexual HIV transmission, including the following:
 - Using latex and polyurethane male and female condoms: negotiating with partner to use; reminders to use; correct and consistent use
 - Using dental dams or other physical barriers while having oral-vaginal or oral-rectal sex
 - Using sexual positioning that lowers a partner's risk of acquiring HIV (order from lowest to highest risk: insertive fellatio, receptive fellatio, insertive penile-vaginal sex, receptive penile-vaginal sex, insertive anal sex, receptive anal sex)^g
 - Practicing mutual masturbation and digital penetration and using clean sex toys that do not cause anal or genital bleeding or trauma^h
 - Avoiding exposing partner to blood, semen, vaginal secretions, and other body fluids that are visibly contaminated with blood
 - Avoiding sexual intercourse with HIV-infected persons after invasive anal or genital procedures until healing is complete,ⁱ or when anal or genital bleeding, inflammation, or trauma may be present (e.g., if infected with STD or when using irritating sexual aids)^h
 - Using only water-based spermicides and lubricants that do not contain nonoxynol-9
 - Avoiding contact with body fluids of HIV-infected persons after invasive oral or dental procedures
 - Reducing the number of sex partners
- Risk of acquiring STDs in genital and nongenital sites if having genital, anal, or oral sexual contacte
- Presence of symptomatic or asymptomatic STD in persons with HIV^e
- Presence of symptomatic or asymptomatic STD in HIV-uninfected partners, which may increase their risk of acquiring HIV and may indicate a substantial risk for HIV that is a clinical indication for PrEP^c
- Methods to prevent unintended pregnancy^e
- Conception options that reduce the risk of HIV transmission^f
- Interventions to reduce the risk of perinatal transmission^f
- Evidence that male circumcision may reduce a man's risk of acquiring HIV from a female partner with HIV

Box 7-C. Important topics when informing persons with HIV about how to prevent transmission of HIV to others *(cont)*

Topics related to transmission resulting from substance use and sharing drug-injection equipment^k

- Health benefits of abstaining from or reducing substance use
- The relation between use of some recreational drugs and higher risk sexual practices (e.g., methamphetamines)
- Risk of transmitting HIV when sharing drug-injection equipment
- Benefits of completing substance use treatment (that may include relapse prevention and opioid substitution programs)
- Methods to reduce the risk of transmitting HIV if drug injection continues, including the following:
 - Reducing the number of drug-injection partners
 - Using new, sterile equipment from reliable sources (pharmacies, SSPs)
 - Using sterile needles, syringes, fluids, cookers, and cotton each time to prepare and inject drugs
 - Using sterile water (preferable) or fresh tap water when preparing drugs
 - Never sharing or reusing drug-injection or preparation equipment
 - Cleaning injection sites with alcohol swabs before injection
 - Disposing needles and syringes in safe places after each use

Note. Providers can address topics relevant to each person with HIV using print, audiovisual materials, or discussion over one or more encounters. The <u>Implementation Resources</u> topic in this section includes a link to print, audiovisual, and online risk-reduction interventions and materials that can be used in nonclinical and clinical settings.

^a See <u>Section 3, Context of Prevention</u>.

⁹ Preexposure prophylaxis (PrEP) is the daily, continuous use of a select regimen of antiretroviral medications for a period of time by an HIV-uninfected person to achieve levels of drug in the blood and anal and genital mucosa sufficient to reduce the risk of HIV acquisition.⁶ In July 2012, FDA approved one PrEP drug regimen for preventing sexual transmission. Although HHS recommendations in May 2014 advised use of this same regimen for persons who inject drugs, the product label only addresses use for preventing sexual transmission. nPEP is the use of selected antiretroviral medications by HIV-uninfected persons within 72 hours after isolated, nonoccupational exposures to body fluids potentially containing HIV, such as after unprotected sexual intercourse or condom breakage, in order to reduce the risk of HIV acquisition. Use of antiretroviral medication for nPEP does not reflect labeling approved by FDA.

- ^c See <u>Section 5, Antiretroviral Treatment</u>, for more information regarding the use of PrEP and nPEP.^{6,7}
- ^d See <u>Section 8, Partner Services</u>, for more information.
- ^e See <u>Section 10, Reproductive Health Care</u>, for more information on contraception and conception options.
- ^f See <u>Section 11, Pregnancy</u>, for more information on interventions to reduce the risk of perinatal HIV transmission.
- ^g Estimated risk of acquiring HIV from an HIV-infected partner (in order of lowest to highest risk): insertive fellatio, receptive fellatio, insertive vaginal sex, receptive anal sex, receptive anal sex.⁸⁹

^h Including penile piercing devices, constrictive penile rings, or other sex aids, devices, or toys that have touched the blood or genital secretions of HIV-infected persons (see the <u>Evidence</u> topic in this section for additional information).

Examples include tubal ligation; vasectomy; dilatation and curettage; and removal of vaginal, cervical, and penile warts, polyps, and precancerous lesions.

CDC has disseminated information from African trials showing that adult male circumcision may reduce a man's risk of acquiring HIV from an infected female partner.^{1,10}

More detailed CDC guidance on methods to reduce the risk of injection-related HIV transmission is found in other sources.¹¹

Box 7-D. Examples of population-level strategies for health departments to support risk screening and risk-reduction services

- Monitor prevalence of HIV risk behaviors in jurisdiction through behavioral surveillance or special projects
- Support programs that increase access to risk-reduction information, condoms, and legal, sterile syringes, if allowed in the jurisdiction
- Make available directories of:
 - risk-reduction services sites
 - condom distribution sites
 - legal sources of sterile syringes
 - substance abuse treatment programs
- Provide technical assistance to clinical and nonclinical providers about these topics:
 - how to access and strengthen risk-reduction services networks
 - financial and reimbursement issues
 - protecting confidentiality and data
 - security during the referral process

How These Recommendations Differ from Previous Recommendations

These recommendations are consistent with other current federal guidance that advises conducting routine, periodic risk screening; providing accurate information about HIV *transmission risk*; offering behavioral risk-reduction information; providing risk-reduction interventions tailored to an individual's risks onsite or through *referrals;*^{§§} encouraging safe and voluntary *disclosure* of HIV-positive status to *partners*; and informing partners about biomedical and behavioral methods to reduce their risk of acquiring HIV.^{1,6,7,12-17} These recommendations are also generally consistent with the latest guidance about these topics from several nongovernmental organizations.¹⁸⁻²³

However, these recommendations differ from the 2003 *Recommendations for Incorporating HIV Prevention into HIV Medical Care* by

- summarizing new evidence published since 2003 about behavioral and biologic risk screening and behavioral risk-reduction interventions
- advising regular screening for behavioral, biologic, and biomedical factors that may influence the risk of transmission of HIV or acquisition of HIV by uninfected partners
- advising the use of both behavioral and biomedical strategies to reduce the risk of HIV transmission when providing risk-reduction messages and interventions
- engaging *clinical* and *nonclinical providers* to provide risk-reduction services tailored to *HIVdiscordant couples* that might include behavioral counseling and psychosocial support
- advising providers of HIV risk-reduction services to encourage persons with HIV to start, continue, or reengage in *HIV medical care*

Referral is a process to help persons identify and access needed services by offering the service provider's address, phone number, directions, hours of operation, and other basic information.



- engaging clinical and nonclinical providers to inform persons with HIV about *biomedical interventions* (e.g., *preexposure prophylaxis* [PrEP]*** and *nonoccupational postexposure prophylaxis* [nPEP]^{†††}) for HIV-uninfected partners when clinically indicated to reduce their risk of HIV acquisition
- providing additional guidance on developing infrastructure to support risk screening and riskreduction interventions

Methods

The section writing group based these recommendations on

- a review of several current Centers for Disease Control and Prevention (CDC) and U.S.
 Department of Health and Human Services (HHS) guidelines about risk screening, risk reduction, and sexual practices that may influence HIV transmission^{1,6,7,12-15,24,25}
- published systematic reviews that included 2 meta-analyses^{26,27} and a qualitative systematic review about the effectiveness of risk-reduction interventions²⁸
- a systematic review of 48 behavioral risk-reduction interventions for persons with HIV that were conducted in the United States and published between 1988 and 2012.²⁹ (Section 2, Methods, describes how these interventions were identified through the CDC HIV/AIDS Prevention Research Synthesis Project's cumulative HIV/AIDS/STD prevention database.) Fourteen of the interventions met established criteria^{‡‡‡} for the CDC compendium of *evidence-based interventions*^{§§§} (EBIs).^{5,29} These criteria were related to a study design with a low risk of bias, rigor of implementation and analysis, and a statistically significant effect size on outcomes of reported unprotected sex or acquisition of bacterial STDs.⁵
- a narrative review of published literature in PubMed related to
 - types and effectiveness of interventions to reduce *risk behaviors*^{****} related to *substance use* in studies from the United States that were published between 2000 and 2012. Search terms included injection drug use and HIV risk; drug substitution; methamphetamine; and opioid substitution.
 - use of *syringe services programs* in studies from the United States and other countries that were published between 1997 and 2012. Search terms included sterile syringe access, syringe services programs, syringe exchange programs, needle exchange programs, and HIV.
 - influence of sexual practices on the risk of sexual transmission in studies from the United States that were published between 2000 and 2012. Search terms included HIV risk and sexual act; *serosorting*;†††† sex toys; lubricants; and spermicides.

^{††††} Serosorting is the practice of limiting unprotected sex to partners believed to have the same HIV-infection status (e.g., persons with HIV have unprotected sex only with persons believed to be HIV-infected).



^{***} PrEP is the daily, continuous use of a select regimen of antiretroviral medications for a period of time by an HIV-uninfected person to achieve levels of drug in the blood and anal and genital mucosa sufficient to reduce the risk of HIV acquisition.⁶

⁺⁺⁺⁺ nPEP is the use of selected antiretroviral medications by HIV-uninfected persons within 72 hours after isolated, nonoccupational exposures to body fluids potentially containing HIV, such as after unprotected sexual intercourse or condom breakage, in order to reduce the risk of HIV acquisition.⁷

^{‡‡‡‡} For the current number of evidence-based interventions and other updates, please refer to the CDC Compendium of Evidence-based Interventions and Best Practices for HIV Prevention (<u>http://www.cdc.gov/hiv/research/interventionresearch/compendium/</u>).

^{§§§} Evidence-based interventions are individual-, group-, or population-level interventions that have been shown to promote safer behaviors or reduce HIV or STD transmission in research studies, program evaluations, or theory-based intervention experience.

Risk behaviors are behaviors that can result in transmitting HIV to others or acquiring HIV through sexual contact, drug use, or during pregnancy (e.g., anal or vaginal intercourse without a barrier, sharing nonsterile drug-injection equipment).

- male circumcision and risk of HIV acquisition in studies from the United States and Africa that were published between 2000 and 2012. Search terms included male circumcision and HIV.
- a cost-effectiveness analysis of risk-reduction interventions for gay, bisexual, and other men who have sex with men (MSM); *persons who inject drugs* (PWID); and heterosexual persons with HIV in which per-client cost estimates and intervention effects were based on 5 effective interventions included in CDC compendium of EBIs^{5,30}

To describe the *prevalence* of sexual and drug-injection risk behaviors in persons with HIV in the United States, the writing group also conducted a narrative review of articles published in PubMed database between 2010 and March 2014 that were indexed with these terms: *HIV*, *risk behavior*, and *HIV transmission*.

Evidence Supporting the Recommendations

This topic summarizes evidence that supports recommendations on risk screening, several *behavioral interventions*, and one biomedical intervention (male circumcision). Other sections summarize the evidence that support recommendations about other biomedical interventions: <u>antiretroviral treatment</u> (Section 5), ART adherence (Section 6), partner services (Section 8), STD services (Section 9), reproductive health care (Section 10), pregnancy services (Section 11), and <u>services for other medical conditions and social factors that influence HIV transmission (Section 12).</u>

The role of risk screening for behavioral and biomedical factors that influence HIV transmission in guiding the content of risk-reduction interventions

Accurate information on behavioral and biologic risks of HIV transmission is needed to identify the most appropriate risk-reduction interventions. However, it can be difficult to accurately estimate a person's risk of HIV transmission because risk varies depending on the type and frequency of sexual and drug-injection behaviors, ART use and adherence, HIV viral load, concurrent STDs, pregnancy, partners' HIV status, and other factors over time. Moreover, the results of risk screening may be inaccurate due to³¹

- poor recall
- misunderstanding about risks associated with specific behaviors
- previous negative experience with disclosing risk behaviors
- fear of or experience with negative judgments, criticism, or stigmatization
- desire for social approval
- concerns about legal consequences of reporting risk behaviors
- doubts about *confidentiality* protections
- poor rapport with providers

Studies show that some persons who have been diagnosed with an acute bacterial STD—an objective marker of unprotected sexual activity—deny having unprotected sex.¹ However, providers who conduct risk screening using a nonjudgmental approach that stresses confidentiality may encourage trust and elicit more honest responses.^{32,33} Most clinical providers and some nonclinical providers can access biomedical

information, such as a recent STD diagnosis, that can help to validate the accuracy of reported risk behaviors.¹

Three controlled clinical studies²⁻⁴ found that information elicited during risk screening guided the content of motivational interviews and led to statistically significant reductions in the amount or frequency of unprotected anal or vaginal sex. By periodically screening for both behavioral and biologic factors that influence HIV transmission, providers can identify a wider range of risk-reduction options that are acceptable to persons with HIV and their partners.³⁴ For example, some persons with HIV may prefer lifelong ART use with high adherence rather than lifelong condom use. Other persons with HIV may urge partners to reduce their risk of exposure or biologic susceptibility to HIV by using condoms, taking PrEP, or seeking screening and treatment for STDs.

The role of behavioral risk-reduction interventions in promoting safer sexual behavior or reducing HIV or STD transmission

Characteristics of behavioral risk-reduction interventions associated with unprotected sex and STD acquisition in persons with HIV

Two 2006 meta-analyses evaluated a total of 18 different controlled trials of behavioral risk-reduction interventions conducted in the United States, Puerto Rico, and Canada after ART became available in 1996.^{26,27} The interventions involved single or multiple sessions in clinical or nonclinical settings.

Both meta-analyses concluded that behavioral risk-reduction interventions were effective in reducing the frequency or number of unprotected sex acts and/or the risk of acquisition of STDs by persons with HIV.^{26,27} Several intervention characteristics were significantly associated with a lower frequency of unprotected sex (i.e., 95% confidence intervals did not include 1.0). These characteristics included the following:

- based on cognitive behavioral theory²⁶ (OR=0.52)
- used motivational enhancement²⁷ (OR=0.32)
- offered skills building (e.g., correct use of male and female condoms, role play for negotiating condom use)²⁶ (OR=0.59)
- focused on HIV transmission behaviors in more than two-thirds of sessions²⁶ (OR=0.49)
- delivered to individuals with HIV²⁶ (OR=0.49)
- delivered by health care providers or professional counselors²⁶ (OR=0.52)
- delivered in settings where persons with HIV receive routine services or medical care and addressed mental health, medication *adherence*, and HIV risk behavior²⁶ (OR=0.41)
- involved ≥ 20 hours of total session time (OR=0.25) or a duration of >3 months²⁶ (OR=0.43)

Behavioral risk-reduction interventions in clinical or nonclinical settings

Several studies have shown that persons with HIV tend to report safer sexual activity after having received behavioral risk-reduction interventions in clinical or nonclinical settings. These studies include a demonstration project in public-sector HIV clinics³⁵ and 14 interventions that CDC classified as EBIs^{‡‡‡‡‡}

^{####} Fifteen EBIs have met the established criteria as of April 2016, but the current version of this guideline has not been updated to reflect that number.



(see the <u>Methods</u> topic in this section).^{5,29} These EBIs were conducted in clinical (n=8) or nonclinical (n=6) settings and involved single or multiple sessions of varied duration.^{5,29} Each intervention included at least one of the characteristics associated with intervention effectiveness listed above.

Brief prevention counseling messages during routine medical visits

Three interventions classified as EBIs found that adults who received brief prevention counseling messages from clinical providers (or from actors portraying physicians in a video) during all routine HIV medical visits were significantly less likely to report unprotected sex than adults who did not receive these repeated messages.^{2,3,36} These prevention messages were tailored to the patient's reported risk and/or focused on self-protection, partner protection, and HIV disclosure. All 3 interventions also included posters and/or patient brochures that reinforced the prevention messages provided by clinical providers.

Additionally, findings of an evaluation³⁵ of observational data from 13 clinics funded by the Health Resources and Services Administration (HRSA) were consistent with the 3 EBIs. Brief risk-reduction counseling sessions (lasting about 3–5 minutes) during all routine HIV care visits were associated with a significant reduction in the number of reported acts of unprotected vaginal and anal sex.³⁵

Intensive risk-reduction interventions during routine HIV care visits

Five randomized control trials classified as EBIs found that patients who participated in a series of several interactive prevention sessions, each lasting 40 to 120 minutes, had a significant reduction in the reported number of unprotected sex acts with partners at risk for acquiring HIV when compared with patients who received standard of care (e.g., basic HIV information) or non-HIV health promotion interventions (e.g., advice about nutrition or cancer prevention).³⁷⁻⁴² The interventions used various approaches:

- MSM with HIV serving as peer advocates offered MSM 4 individual counseling sessions and 2 follow-up sessions that focused on reducing unprotected sex with partners with negative or unknown infection status.⁴⁰
- Trained facilitators offered 2 individual and 5 group sessions that focused on ART, adherence to ART, and sexual decision making under various hypothetical conditions related to *substance use*, HIV status disclosure, treatment status, viral load, social relationships, and mood. The intervention was also associated with improved adherence to ART.³⁹
- Trained counselors offered individual, monthly sessions over 4 consecutive months. Sessions included motivational interviewing, CDs, and booklets that contained information about safer sex tailored to patients' risks, and 4 follow-up letters that reinforced the content of the preceding session.^{37,38}
- Trained female peer educators with HIV and professional health educators offered 4 group sessions to women with HIV. Sessions focused on gender pride, social support, healthy sexual relationships, and skills to negotiate safer sex.⁴¹
- Trained male and female facilitators offered 23 sessions (two sessions per week over 6 months) to groups of adolescents with HIV. Sessions focused on coping with an HIV diagnosis, HIV disclosure, participating in health care decisions, identifying factors that triggered risk behaviors, skills to negotiate safer sex, implementing daily routines to stay healthy, and reducing substance use and unprotected sex.⁴²

Intensive behavioral risk-reduction interventions in nonclinical settings

In 6 EBIs,⁵ peer educators or health educators led a series of interactive intervention sessions for individuals, small groups, or heterosexual HIV-discordant couples with varied demographic characteristics.^{29,43-50} Sessions focused on coping with an HIV diagnosis, building condom-use skills, negotiating safer sex behaviors, avoiding drug use that might increase the risk of HIV transmission, and other topics. Compared with groups who did not receive the interventions, participants of all 6 interventions were significantly less likely to report unprotected sex acts during the 3 to 12 months after sessions ended. The magnitude of reductions varied by intervention.²⁹

Condom distribution in clinical and nonclinical settings

A meta-analysis of 21 studies found that programs that increased the acceptability and accessibility of condoms in several sites used by persons with HIV and *persons at high risk for HIV*.⁵¹ These sites included: publicly-funded health care facilities (e.g., health clinics, mental health centers, substance abuse treatment centers), local businesses (e.g., hotels, bars, bathhouses, brothels), schools (e.g., outside classrooms and nurses' offices), and organized public events. The analysis of 20 studies reported significantly increased condom use among persons who access these sites (OR=1.81, 95% CI: 1.51, 2.17). An analysis of 5 studies found that condom distribution programs were associated with a reduced *incidence* of HIV and STD among persons who access these sites (OR=0.69, 95% CI: 0.53, 0.91).⁵¹

The cost-effectiveness of behavioral risk-reduction interventions

A recent cost-effectiveness analysis evaluated 5 individual- and group-level interventions shown to reduce unprotected sex in 3 hypothetical populations of persons with HIV (MSM, heterosexual persons, and PWID).³⁰ The evaluation found that providing these interventions to prevent HIV transmission was cost-saving compared with not providing the interventions and that the intervention cost per new case of HIV averted for a hypothetical population of MSM (~\$150,000)³⁰ was substantially lower than the lifetime cost of HIV treatment (>\$400,000).⁵² When these same estimates of intervention cost and intervention effectiveness were applied to hypothetical populations of heterosexual persons with HIV and PWID, these interventions were cost-effective in preventing HIV transmission (with a cost per quality-adjusted life year gained of ~\$550 for heterosexual persons and ~\$16,000 for PWID) compared with not providing the intervention cost per new case of HIV averted was slightly greater than the lifetime cost of HIV treatment for both populations.³⁰

The relation between sexual practices and risk of sexual transmission

Type of sexual activity

Seropositioning is the practice of modifying sexual activity based on beliefs about the partner's HIV infection status and the per-act risk of HIV transmission for a given type of contact. A recent study found the estimated relative risk of acquiring HIV varies by the type of sexual activity.⁸ The risk is highest for *receptive anal sex*, and decreases in the following order: *insertive anal sex*, *receptive vaginal sex*, *insertive fellatio*, *ssss* and *insertive fellatio*. ***** (The risk associated with

^{*****} The practice of inserting one's penis into a partner's mouth.



^{§§§§} The practice of receiving a partner's penis in one's mouth.

cunnilingus^{*†††††*} was not examined.) By extension, persons with HIV are most likely to transmit HIV to their uninfected partners when practicing insertive anal sex (person with HIV inserts his penis into partner's anus), followed in order by receptive anal sex (person with HIV receives partner's penis in his/her anus), insertive penile-vaginal sex (person with HIV inserts penis into partner's vagina), receptive penile-vaginal sex (person with HIV receives partner's vagina), receptive penile-vaginal sex (person with HIV receives partner's penis in her vagina), insertive fellatio (person with HIV receives oral stimulation of his penis by partner), and receptive fellatio (person with HIV orally stimulates penis of partner).⁸

Serosorting is the practice of having unprotected sex only with partners believed to have the same HIV infection status. Persons with HIV who have sex only with infected partners cannot transmit HIV to uninfected persons only if assumptions about partner infection status are correct. Serosorting among persons with HIV may rarely cause *HIV superinfection*,⁵³ the acquisition of another HIV strain that may reduce the effectiveness of HIV treatment if new, drug-resistant HIV strains are acquired.⁵⁴ Serosorting does not protect persons with HIV from acquiring hepatitis C virus infection or STDs, including STDs that may facilitate HIV transmission.^{1,13,55}

Practices that result in anal or genital trauma, inflammation, or bleeding

Some sex toys and products that contain nonoxynol-9 (lubricants and spermicides) may occasionally cause anal or genital trauma, bleeding, irritation, or inflammation that may increase the risk of HIV transmission, especially if these products are used frequently or for long duration.^{1,24,25,56-58}

Longstanding recommendations to inform women with HIV that unprotected sex during menses poses a potential risk of HIV transmission were based on evidence that menstrual fluid and female genital secretions may contain HIV.⁵⁹⁻⁶¹ The HIV viral load in menstrual fluids of women who have high adherence to effective ART is substantially lower than the viral load in menstrual fluids of women not taking ART.^{60,61} However, plasma viral load may not reflect the HIV viral load in female genital secretions and women with HIV can shed HIV even if their plasma viral load is undetectable.⁶² One nested case-control study of risk factors for prevalent HIV infection among uncircumcised Kenyan men, found that having sex with a partner during menses increased the odds of becoming HIV-infected about two-fold (OR 2.1, 95% CI: 1.1–3.7) after controlling for all other factors that were associated with prevalent HIV infection.⁶³ However, a longitudinal study of European HIV-discordant couples (in which either the man or woman was infected) who inconsistently used condoms did not report an association between sex during menses and HIV transmission.⁶⁴

Use of recreational drugs before or during sex

A 2012 systematic review of 61 studies among MSM with HIV found that those who used methamphetamine were more likely to engage in higher-risk sexual behaviors (e.g., having unprotected anal intercourse, group sex, sex with multiple partners, sex with casual partners, sex with PWID, sex with HIV-uninfected partners) than MSM with HIV who do not use this drug.⁶⁵ One U.S. study found that use of inhaled nitrites ("poppers") was associated with engaging in unprotected anal intercourse.⁶⁶ Several

^{******} Oral stimulation of the female genitals.

studies have shown that use of erectile dysfunction medications was associated with unprotected anal sex among MSM, including MSM with HIV.⁶⁷⁻⁷⁰

Male circumcision

Three well-designed clinical trials in African countries found that circumcision of HIV-uninfected men reduced their risk of acquiring HIV from women by 50% to 60%.⁷¹⁻⁷⁴ Observational studies in heterosexual, HIV-uninfected persons have found that male circumcision reduced a man's risk of acquiring STDs that facilitate HIV transmission or acquisition (e.g., syphilis, HSV-2) and reduced a female sex partner's risk of acquiring STDs that facilitate HIV transmission or acquisition (i.e., female genital ulceration, bacterial vaginosis, and trichomoniasis)⁷⁵⁻⁷⁸ (see Section 9, STD Services). A meta-analysis of the 7 well-designed studies conducted in African countries (1 randomized controlled trial [RCT] and 6 longitudinal analyses) found that female partners of circumcised men did not have a lower risk of acquiring HIV (RR 0.80, 95% CI 0.53–1.36).⁷⁹

Most HIV transmission in the United States occurs among MSM, most of whom practice both insertive and receptive anal sex.^{70,80,81} A recent Cochrane Review conducted pooled analyses of data from 20 observational studies of MSM that included more than 65,000 participants from low-, middle-, and high-income countries, most of whom were circumcised as infants.⁸² Pooled analyses of data from all MSM and the subset of MSM reporting receptive anal sex found that circumcision had no protective effect. The authors concluded that this evidence was insufficient to support a recommendation that adolescent or adult MSM undergo circumcision as an HIV prevention strategy.⁸²

The American Academy of Pediatrics (with endorsement by the American College of Obstetricians and Gynecologists [ACOG]), the American Academy of Family Physicians (AAFP), and the American Urological Association (AUA) stated that neonatal circumcision has potential health benefits, such as prevention of urinary tract infections, penile cancer, and some sexually transmitted infections, including HIV.⁸³⁻⁸⁶ Although the AAP, ACOG, and AAFP concluded that these health benefits were not sufficient to recommend routine neonatal circumcision for health reasons, they stated that the benefits of neonatal circumcision are sufficient to justify access to this procedure, including third-party payment, for families that choose it. The AAFP and AUA have cautioned that African studies showing that circumcision substantially reduces the risk of men acquiring HIV from women with HIV may not necessarily be extrapolated to men in the U.S. The AAFP list of recommended clinical indications for adult circumcision (penile abnormalities and diseases) does not include preventing HIV acquisition.⁸⁷ The AUA recommends presenting circumcision to men in the U.S. as one possible strategy to prevent HIV acquisition that should be used with other prevention methods such as safe sexual practices.^{86,87}

The role of risk-reduction interventions in promoting safer druginjection behaviors

Behavioral interventions

Studies are too few to determine if behavioral interventions can promote safer drug-injection behaviors (e.g., needle cleaning) in persons with HIV who continue to inject drugs.²⁶

However, several studies have shown that many PWID with HIV stop injecting drugs or inject less frequently after they obtain substance use treatment.⁸⁸⁻⁹⁰

Syringe services programs

Using nonfederal funds, many U.S. communities distribute sterile drug-injection equipment and/or information about the benefits of sterile syringes to PWID through *syringe services programs* (SSPs),‡‡‡‡‡ *outreach* workers, or vending machines.^{91,92} Several reviews of evidence from North America, including one systematic review conducted in the United States in 1997, found that SSPs lead to safer injecting behaviors and can be effective in reducing HIV transmission among PWID when part of comprehensive HIV prevention programs.⁹³⁻⁹⁸ The Institute of Medicine's evaluation of SSPs in the United States and other countries found that SSPs were associated with reductions in drug-use and injection-related risk behaviors (such as sharing injection equipment). However, it concluded that evidence of the effect of SSPs on HIV incidence was inconclusive.⁹³ A study from San Francisco that included about 100 PWID, including persons with HIV, found that many PWID relied on syringes from SSPs or pharmacies that sold sterile syringes, and that PWID were more likely to share injection equipment when access to these syringe sources was limited.⁹⁹

Legal access to syringes through physicians and pharmacists

Sterile syringes are sold in pharmacies in some states to reduce the risk of transmitting HIV and other bloodborne pathogens;^{§§§§§} some states require a physician's prescription to purchase syringes.^{100,101} A CDC report concluded that physician prescribing authority may not have a large-scale, population-level impact on HIV incidence, but this method offers PWID with HIV a safe means to obtain sterile syringes.¹⁰² A 2006 national physician survey found that fewer than 1% of participants reported prescribing syringes for PWID, including persons with HIV, but 60% reported a willingness to prescribe syringes for PWID.¹⁰⁰ Physicians with certain characteristics were more likely to report being willing to prescribe syringes: they served PWID, asked PWID about syringe sharing, believed that PWID share syringes because of lack of access to sterile syringes, knew that syringes were legally available in their community, and knew other physicians who prescribed syringes.¹⁰⁰ The effectiveness of physician prescribing authority as a strategy to promote safer injection behaviors and reduce HIV incidence has not been evaluated at a population level.

Oral opioid maintenance programs

A 2011 Cochrane systematic review assessed the influence of opioid substitution programs on injection and sexual behaviors. The review evaluated 38 studies, including many from the United States, involving more than 12,000 participants. The studies consistently found that oral methadone or buprenorphine maintenance treatment by opioid-dependent PWID was associated with statistically significant reductions (i.e., 95% confidence intervals did not include 1.0) in subgroups with these characteristics¹⁰³:

- used opioids (relative risk ranged from 0.37 to 0.81)
- used drug-injection equipment (relative risk ranged from 0.45 to 0.87)

information on funding opportunities.



^{\$\$\$\$\$\$} At the time of the review, these activities were not supported by federal funds. Check with your state health department for latest

- shared drug-injection equipment (relative risk ranged from 0.37 to 0.49)
- had multiple sex partners (relative risk = 0.37)
- exchanged sex for drugs or money (relative risk ranged from 0.62 to 0.65)

Issues that Influence Implementation of the Recommendations

Implementation progress, challenges, and opportunities

Abstinence from penetrative sexual intercourse is the most effective method to reduce the risk of sexual HIV transmission. However, many persons with HIV remain sexually active and use other methods to reduce their risk of HIV transmission after their diagnosis.¹⁰⁴⁻¹⁰⁶ An analysis of 2009 *surveillance* data found that among about 600,000 persons with HIV with unsuppressed viral load, 20% engaged in unprotected, *HIV-discordant risk behavior*, ****** resulting in an estimated transmission rate of 23.13%.¹⁰⁷⁻¹⁰⁹ A meta-analysis of 30 U.S. studies that included more than 18,000 MSM with HIV estimated that the prevalence of unprotected anal sex was considerably higher with partners with HIV (30%, 95% CI: 25%-36%) than with partners of unknown HIV infection status (16%, 95% CI: 13%–21%) or HIV-uninfected partners (13%, 95% CI: 10%-16%).⁸⁰

Abstinence from sharing drug-injection equipment with HIV-uninfected persons is the most effective method to reduce injection-related HIV transmission but many persons who are addicted to injected drugs continue to share injection equipment after their HIV diagnosis. In 2012, an estimated 3,456 reported cases of HIV were related to injection drug use, not including cases among MSM who injected drugs.¹¹⁰ Many cases occurred in areas where substance use treatment and legal sources of sterile syringes are available to PWID.

Baseline data from an ongoing RCT that enrolled 1,100 HIV-infected PWID found that 39.7% engaged in both sharing drug-injection equipment and unprotected sex.¹⁰⁹ In 2009, 25% of the estimated 165,900 PWID with HIV had unsuppressed viral load and reported unprotected sex with persons of different HIV infection status.¹⁰⁹ Of the 179 cases of perinatally infected infants diagnosed in 15 areas during 2005–2008, several were born to women who became infected after having sex or sharing drug-injection equipment late in pregnancy with a person with HIV.¹¹¹

Whenever possible, most persons with HIV should receive some risk-reduction counseling from their health care providers when they start HIV medical care. Nationally representative data indicate that only about 45% of persons receiving outpatient HIV medical care reported receiving *HIV prevention counseling*^{††††††} from a health care provider during the preceding year.¹¹² Evaluations of patients receiving HIV primary care through the Ryan White HIV/AIDS Program in 9 states found that 53% of all patients and 65% of PWID reported having discussed safer sex and HIV prevention methods with their providers during their last visit.^{113,114} Some clinical providers who provide HIV risk-reduction counseling at initial visits do not provide it at later visits. In one study, 60% of providers reported providing risk-reduction counseling to more than 90% of their newly diagnosed patients, but only 14% of providers reported such counseling to more than 90% of their returning patients.¹¹⁵ A study of patients with HIV in 15 Ryan

^{******} HIV prevention counseling is an interactive process between client or patient and counselor aimed at reducing sexual, drug-use, and reproductive behaviors that pose a risk of HIV transmission or acquisition.



^{******} HIV-discordant risk behavior is engaging in unprotected sex or sharing drug-injection equipment with a person with a different HIV infection status.

White-funded clinics in 12 states and Washington, DC, showed that providers reported counseling 69% of new patients but only 52% of returning patients.¹¹⁶

Lack of time and staff and competing priorities are common barriers to providing risk screening and riskreduction interventions in clinical settings, community-based organizations, and health departments.^{117,118} Intensive, multisession interventions are generally more effective in promoting safer behaviors among persons with HIV than brief interventions (see the <u>Evidence</u> topic in this section). However, intensive interventions are impractical without trained staff and dedicated space and they may appeal only to persons who will commit to attending several sessions. Some clinical providers may defer risk screening and risk-reduction interventions because they do not 1) have the needed skills or comfort, 2) believe that interventions will change behaviors, or 3) provide periodic STD screening that might identify patients with objective markers of unprotected sex.^{113,115,119-123}

A qualitative systematic review of 30 behavioral risk-reduction interventions found that several factors enabled provision of brief or intensive risk-reduction interventions in clinical settings²⁸:

- Securing buy-in from clinical providers before introducing the intervention
- Addressing provider attitudes and beliefs about risk reduction
- Overcoming resistance from providers who are uncomfortable with risk-reduction counseling
- Providing training in selected risk-reduction counseling techniques
- Anticipating changes in clinic flow due to the intervention
- Clarifying responsibilities of all members of the care team to provide or reinforce risk-reduction messages

At least three studies found that training and decision-support tools can enhance providers' comfort, skill, efficiency, and motivation to provide risk screening and risk-reduction interventions.^{120,122,124} Brief provider- or patient-administered risk-screening tools and computer-based and video-based risk-reduction interventions may be practical alternatives for both clinical and nonclinical providers when time is limited (see the <u>Implementation Resources</u> topic below).^{26,29} By offering accurate, self-collected STD screening tests that do not require provider time for specimen collection, providers can routinely use positive test results as markers of unprotected sex (see <u>Section 9, STD Services</u>).

Clear billing procedures, adequate reimbursement, and formal referral agreements with other providers of risk-reduction interventions also promote delivery of risk-reduction interventions.¹¹³ The Patient Protection and Affordable Care Act (ACA) enables clinical and nonclinical providers to bill risk screening and risk-reduction services.¹²⁵ Some health departments are exploring third-party reimbursement for risk-reduction services.^{126,127}

Policy, legal, and ethical considerations

Laws about HIV confidentiality protections, HIV disclosure, and duty to inform others about possible HIV exposure vary by jurisdiction. Providers who are aware of these laws are better equipped to fulfill their own obligations to notify persons of possible HIV exposure and to inform persons with HIV about their rights and responsibilities regarding HIV disclosure. (See <u>Section 3, Context of Prevention</u>, and <u>Section 8, Partner Services</u>, for details on the legal and ethical issues related to HIV exposure.)

In some jurisdictions, persons with HIV may hesitate to carry condoms or sterile drug-injection equipment in public settings if possessing these devices could result in charges of illegal sex work or drug use.^{128,129} Laws about the distribution and prescription authority for sterile drug-injection equipment vary by jurisdiction; some states do not authorize legal access to sterile equipment through medical care providers, pharmacists, or SSPs.¹³⁰ (See Section 12, Other Medical and Social Services, for details on referring persons with HIV to these services.)

Special populations

Some persons with HIV continue to practice behaviors that can transmit HIV despite risk-reduction interventions because of personal choice; substance abuse; mental illness; lack of access to new, sterile drug-injection equipment; reliance on sex work for financial survival; misconceptions that risk behaviors do not pose a risk of HIV transmission; and other factors (see Section 12, Other Medical and Social Services). These persons include adults and adolescents who are MSM, homeless, and incarcerated. Persons who continue risk behaviors or have a detectable viral load despite interventions may benefit from more intensive interventions and specialty services, such as substance use treatment (see Section 12, Other Medical and Social Services). Some persons with HIV require additional risk screening and risk-reduction services to reduce the risk of transmission during intervals when viral load is high (due to lapses in adherence to ART), when attempting conception through unprotected sex, or during pregnancy. (See Section 6, ART Adherence; Section 10, Reproductive Health Care; and Section 11, Pregnancy, for additional information.)

Implementation Resources

Resources to support implementation of these recommendations are available at <u>http://www.cdc.gov/hiv/guidelines/implementationresources.html</u>. These include risk-screening tools, training materials, and packaged information on *evidence-based* risk-reduction interventions.⁵

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Section 8. HIV Partner Services

Background

HIV partner services comprise an array of voluntary services intended to reduce HIV transmission. They are provided to 1) persons with HIV (described as *index patients**) who have been newly diagnosed in *clinical settings*[†] or *nonclinical settings*;[‡] represent a case of infection that is reported to health departments; or have been previously diagnosed and also pose a high risk of exposing others to HIV (e.g., a recently diagnosed STD that indicates *unprotected sex*[§] or may facilitate HIV transmission or sharing *drug-injection equipment***); and 2) their sex and drug-injection *partners*. The core components include interviewing persons with HIV to obtain information to contact or locate their sex and drug-injection partners; notifying partners of possible HIV exposure; offering testing for HIV, sexually transmitted disease (STD), and other infections; providing condoms, prevention information, and counseling; and providing help in obtaining risk-reduction services, *HIV medical care*, and other medical and social services.¹ This proactive approach can hasten the diagnosis of HIV and other infections; can prompt treatment before symptoms appear; and can reduce the transmission, burden, and costs of these communicable diseases in communities.

Reporting of cases of HIV, syphilis, gonorrhea, and chlamydial infection^{††} is required in all states, the District of Columbia, and U.S. territories.² In many jurisdictions, receipt of a laboratory or clinical case report of HIV or STD by a health department or its HIV or STD *surveillance* program will activate a health department's legal authority to provide partner services.¹ Cases of HIV identified at anonymous testing sites cannot be reported by name to health departments. Most health departments initiate HIV partner services after receiving reports of confirmed cases of HIV. However, some may initiate contact with "presumptive" index patients upon receiving reports of positive preliminary test results^{3,4} but defer notifying partners until additional testing of the index patient confirms HIV infection. Health departments can adopt this practice if they apply the 2014 Centers for Disease Control and Prevention (CDC) revised HIV surveillance case definition that allows routine reporting of positive preliminary HIV test results before confirmatory test results are available.⁵ CDC's revised surveillance case definition also recommends routine reporting of cases of acute infection diagnosed by HIV antigen or *nucleic acid amplification tests*.⁵ In states that adopt this case definition, health departments can rapidly identify acutely infected persons who are likely to be highly infectious and who warrant being offered expedited partner services. Some *clinical* and *nonclinical providers* contact health department *partner services*

^{*} A person with diagnosed HIV or STD and whose diagnosis prompts an investigation to identify other persons (known as partners) who may have become infected through sexual contact or exposure to blood or other body fluids of the index patient.

Clinical settings are health care facilities in which medical diagnostic, treatment, and disease prevention services are routinely provided.
 Nonclinical settings are facilities that provide prevention, education, screening and interventions for risk behaviors, and referrals for

medical and social services. Some nonclinical settings may also provide health promotion services and screening for HIV and some STD.
 Sexual activity without using a physical barrier (i.e., penile sex without using a male condom; vaginal sex without using a male or female condom; oral-anal contact without using a dental dam or other barrier device; vaginal-digital contact without using a female condom, latex glove, or finger cot; or rectal-digital contact without using a latex glove or finger cot).

^{**} Drug-injection equipment includes needles and syringes; drug preparation equipment, such as cookers, mixing containers, spoons, and filters; swabs; and water or some other liquid used for preparing a drug solution or for rinsing drug equipment.

^{††} Another document describes partner services that are prompted by the diagnosis of bacterial STD in index patients who are not infected with HIV.¹

specialists immediately after they identify persons with positive HIV tests—particularly persons with acute infection—rather than wait for receipt of a surveillance case report to activate partner services.^{1,3,4,6}

In the United States, most HIV partner services are provided by health department partner services specialists who are highly trained in providing voluntary, confidential partner services and can be engaged through routine case reporting, provider referral, and requests by persons with HIV.¹ Nevertheless, methods of delivering partner services may vary by jurisdiction. *Partner elicitation^{‡‡}* can be done by health department specialists, HIV testing providers, and other clinical or nonclinical providers who are trained and authorized to conduct partner elicitation.^{1,6} *Partner notification^{§§}* can be performed by health department specialists; physicians; nurse practitioners, and physician assistants who work under the authority of a physician; other clinical and nonclinical providers who are trained and authorized to provide partner notification; and index patients.¹ Some jurisdictions use hybrid methods in which 1) trained clinical providers or nonclinical HIV testing providers elicit partner information from index patients, but defer partner notification to health department specialists; 2) index patients give partner contact information to health department specialists, who in turn notify the partners; 3) index patients and health department specialists to notify partners within a specific time frame, and if this fails, the specialists attempt to notify partners.⁷⁻⁹

Health department partner services are voluntary and confidential and usually involve no cost to index patients or partners; specialists notify partners of possible HIV exposure without revealing the index patient's name or other potentially identifying information.¹ These specialists contact index patients and partners by phone, letter, email, or text message or in person at HIV testing sites, HIV clinical settings, STD clinics, homes, or other community settings where private communication is possible. In some health departments, specialists also use "screen names" or other information provided by index patients to contact partners who were found through Internet dating sites, "chat rooms," mobile device applications, or *social networking**** tools.^{1,3,10} Specialists may also help index patients use Internet^{†††} or social media sites to directly notify partners about possible HIV exposure.¹¹ In a national survey of 57 state or local health departments, two-thirds reported using Internet-based partner notification.⁹

Because partner services specialists routinely offer HIV testing to partners, they offer a form of targeted, community-based HIV screening for persons at high risk for HIV. Some partner services programs offer venue-based HIV testing in sites frequented by index patients or partners.¹ They also use *social network*^{*iiii*} or "cluster" approaches in which health department specialists encourage index patients or partners to recruit friends, family members, or others for HIV testing.¹ In some cases, specialists will actively link

^{***} A social network is a group of persons connected by social relationships, such as friends, family, sex and drug-injection partners, or persons who frequent the same physical or virtual venues.



^{‡‡} Partner elicitation is an early step of voluntary, confidential partner services in which a health department partner services specialist or other provider interviews or reinterviews a person with HIV or STD to collect names, descriptions, and locating and contact information of persons who are sex or drug-injection partners so the partners can be notified of possible HIV or STD exposure.

Partner notification is a step of voluntary, confidential partner services that involves locating and confidentially notifying sex and druginjection partners of persons infected with HIV or STD of possible exposure to HIV or STD.

^{***} Social networking is a strategy to recruit persons for HIV testing or prevention services in which high-risk individuals use their personal influence to recruit peers they believe are at high risk for HIV infection.

Recent information on Internet partner services can be found at <u>http://www.cdc.gov/std/program/ips/default.htm</u> (Introducing Technology into Partner Services toolkit for programs was published December 2015 and was not available at the time of initial publication of this report [December 2014]).

index patients or partners with HIV to HIV medical care.^{12,13} In addition, some health care providers provide HIV testing to partners who are referred by their patients with HIV.⁶

This section addresses partner services prompted by a diagnosis of HIV or the diagnosis of an STD in a person previously diagnosed with HIV. Other federal guidance describes partner services for HIVuninfected persons diagnosed with STDs.¹ *Quality improvement*^{§§§} and program *monitoring and evaluation*^{****} can determine if the services described in this section are implemented as intended, yield the expected outcomes, or warrant changes in delivery methods (see Section 13, Quality Improvement). Section 9, STD Services, provides more information about STD screening, treatment, and counseling of index patients and management of partners. Section 5, Antiretroviral Treatment, describes the use of *nonoccupational postexposure prophylaxis* (nPEP)^{‡‡‡‡} for HIV-uninfected partners with very recent HIV exposure, and *preexposure prophylaxis* (PrEP)^{‡‡‡‡} for HIV-uninfected partners at substantial risk for acquiring HIV infection.

Recommendations

BOX 8. RECOMMENDATIONS—HIV PARTNER SERVICES

For nonclinical and clinical providers (not including health department partner services specialists)

- Develop infrastructure, policies, and procedures that enable persons who warrant HIV partner services (index patients) to obtain services through the health department or other authorized providers (i) (see <u>Box 8-A</u>)
- Collaborate with health department staff to reinforce knowledge and skills about the following topics (i):
 - Methods to ensure that partner services are voluntary and confidential (see Box 8-B)
 - Elements of partner services (see <u>Box 8-B</u>)
 - Roles, responsibilities, and legal authority of nonclinical providers, clinical providers, and health department staff to provide partner services to index patients and inform their partners of possible HIV exposure
 - Laws, regulations, requirements, procedures, and guidelines in the jurisdiction (e.g., data confidentiality and security, index patient's and provider's duty to inform exposed partners, laws regarding prosecution for intentional HIV exposure)^a
- Identify index patients with HIV who warrant partner services and offer expedited interviews to those with the following characteristics (i, ii, iii, iv, v):
 - Acute HIV infection^b based on laboratory tests (e.g., positive result on HIV p24 antigen test, HIV nucleic acid amplification test, or HIV viral load test; or HIV antibody results indicative of recent seroconversion), or clinical evaluation (i.e., symptoms or signs of acute retroviral syndrome) that is associated with a high risk of HIV transmission
 - High HIV viral load that is associated with a high risk of HIV transmission
 - Newly reported or newly diagnosed HIV infection (based on preliminary and/or confirmatory HIV test results as allowed by the jurisdiction)

⁺⁺⁺⁺⁺ PrEP is the daily, continuous use of a specific regimen of antiretroviral medications for a period of time by an HIV-uninfected person to achieve levels of drug in the blood and anal and genital mucosa sufficient to reduce the risk of HIV acquisition.¹⁴



^{§§§} Quality improvement is an approach to the continuous study and improvement of the processes of providing services that meet or exceed established professional standards and user expectations.

^{****} Monitoring and evaluation is a process that involves the repeated, ongoing collection and review of information about program activities, characteristics, and outcomes in order to assess program implementation, coverage, acceptability, cost, and effectiveness.

^{††††} nPEP is the use of selected antiretroviral medications by HIV-uninfected persons within 72 hours after isolated, nonoccupational exposure to body fluids potentially containing HIV, such as after unprotected sexual intercourse or condom breakage, in order to reduce the risk of HIV acquisition.

BOX 8. RECOMMENDATIONS—HIV PARTNER SERVICES (cont)

- Newly diagnosed sexually transmitted diseases (STDs) that indicate recent unprotected sex (i.e., sexual activity without using a physical barrier) and facilitate HIV transmission—primary and secondary syphilis; gonorrhea and chlamydial infection (including rectal infection); herpes simplex virus type 2 (HSV-2); and trichomoniasis (in women)^c
- Increased risk of HIV transmission due to pregnancy^d
- Behaviors that pose a high risk of exposing others to HIV (e.g., multiple, anonymous partners; having unprotected sex with persons with negative or unknown HIV-infection status; sharing drug-injection equipment)^e
- A specific request for partner services
- Ask index patients if they have disclosed their HIV infection to all sex and drug-injection partners and if selfnotification would pose any risks (i, ii, v)
- Promptly refer index patients to health department partner services directly or through HIV case reporting according to the methods of the jurisdiction (i, ii, iii, iv, v, vi) (see <u>Box 8-B</u>)
- If the index patient declines referral for health department assistance, offer partner services as appropriate to the provider's legal authority and skills and the index patient's preferences (i, ii, iii, iv, v) (see <u>Box 8-B</u>)
- Offer services to partners who are referred by index patients as appropriate to provider's legal authority and skills (i, ii, v) (see <u>Box 8-B</u>)

For health department partner services specialists

- Provide partner services information, resources, advice, and assistance to HIV testing providers in nonclinical and clinical settings as allowed by professional authority and skills (i, vi) (see <u>Box 8-A</u>)
- Establish a partner services program with the following principles (i, vi, vii): (see <u>Box 8-A</u>)
 - Adheres to the laws, regulations, and standards of the jurisdiction and protects confidentiality
 - Promptly identifies index patients who warrant being offered partner services through HIV and STD case surveillance information, referring providers, or other methods allowed in the jurisdiction
 - Efficiently uses a well-trained workforce that demonstrates culturally appropriate interactions with community members
 - Expedites services to the highest risk index patients and partners
 - Considers innovative, evidence-based methods to notify partners (e.g., Internet, social media)
 - Monitors program effectiveness to guide guality improvement^{c,f}
 - Contact index patients and offer essential services (i, vi) (see <u>Box 8-B</u>)
- Notify partners and offer essential partner services (i, vi) (see <u>Box 8-B</u>)

Note. In this report, nonclinical providers are defined as persons who work in community-based organizations or health departments operating outside of health care facilities and who provide HIV testing, health education, risk-reduction interventions, partner services, case management, or assistance with linkage or referral to medical and social services. These persons include HIV testing providers, peer and professional health educators, counselors, service linkage facilitators, partner services specialists, case managers, and social workers. In this section, recommendations for health department partner services specialists are listed separately from recommendations for other nonclinical providers because state and local laws and regulations influence their roles and responsibilities. Clinical providers are defined as persons who work in health care facilities and who provide risk assessments, health education and counseling; disease screening, diagnosis, and treatment; and other health-related services. These providers include physicians, registered nurses, advance practice nurses, physician assistants, dentists, mental health providers, pharmacists, health educators, case managers, social workers, and counselors. Some may be employees or contractors of health departments. Most states authorize physicians to provide partner services as part of their duty to inform persons of possible exposure to HIV or STD. Some jurisdictions authorize other clinical providers to provide partner services because they work under the authority of a physician (e.g., nurse practitioners and physician assistants) or have been trained and authorized by health departments to provide partner services. Some of the federal guidelines cited in the Recommendation boxes may have been updated. For current federal recommendations, please refer to http://www.cdc.gov/hiv/guidelines/personswithhiv.html.



BOX 8. RECOMMENDATIONS—HIV PARTNER SERVICES (cont)

- ^a See Section 3, Context of Prevention, for more information on HIV disclosure.
- ^b Acute HIV infection is the period between initial HIV infection and the expression of HIV antibodies that can be detected by HIV antibody tests. This period is characterized by high levels of HIV in the blood and a vigorous immune response.
- ^c See <u>Section 9, STD Services</u>, for more information on STDs that may facilitate HIV transmission.
- See <u>Section 11, Pregnancy</u>, for more information on how pregnancy influences HIV transmission.
- ^e See <u>Section 7, Risk Screening and Risk Reduction</u>, for more information on risk behaviors.
- See Section 13, Quality Improvement, for more information.

Sources

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- v. HRSA. *Guide for HIV/AIDS Clinical Care—2014 Edition*. U.S. Department of Health and Human Services; 2014. http://hab.hrsa.gov/sites/default/files/hab/clinical-quality-management/2014guide.pdf. Accessed December 23, 2016.
- vi. HRSA. The Ryan White Care Act; Section 2631 [300ff-38]. Grants for Partner Notification Programs. October 30, 2009. <u>http://hab.hrsa.gov/livinghistory/issues/confidentiality_8.htm</u>. Accessed December 23, 2016.
- vii. CDC. Data security and confidentiality guidelines for HIV, viral hepatitis, sexually transmitted disease, and tuberculosis programs: standards to facilitate sharing and use of surveillance data for public health action. 2011. http://www.cdc.gov/nchhstp/programintegration/docs/PCSIDataSecurityGuidelines.pdf. Accessed March 15, 2013.

Box 8-A. Recommended strategies to establish infrastructure for HIV partner services

For nonclinical and clinical providers (not including health department partner services specialists)

- Establish clear policies and procedures that are consistent with laws and regulations in the jurisdiction and that relate to the following topics (i, ii, iii, iv, v, vi):
 - Strategies to notify the health department about index patients who warrant partner services, including those with acute HIV infection^a or other characteristics who should be offered expedited interviews (see <u>Box 8</u>)
 - Methods to protect and transfer confidential information about index patients and partners to health departments
 - Methods to help index patients notify partners
 - Methods to elicit partner information, notify partners, and provide testing and presumptive STD treatment to partners
 - Informing index patients and partners about the availability of preexposure prophylaxis (PrEP)^b and nonoccupational postexposure prophylaxis (nPEP)^c when clinically indicated for HIV-uninfected persons to reduce their risk of HIV acquisition^d
- Routinely provide verbal, print, or audiovisual materials to index patients that describe partner services' benefits, potential risks, procedures, and the availability of voluntary, confidential health department assistance (i, ii, iii)
- Periodically assess partner services to guide quality improvemente (i)

Box 8-A. Recommended strategies to establish infrastructure for HIV partner services (cont)

For health department partner services specialists

- Offer information, resources, advice, and assistance to nonclinical and clinical providers who provide HIV, STD, and viral hepatitis services, such as the following^f (i, ii, vi):
 - Provider and patient education materials that describe health department partner services and how they
 can be engaged
 - Decision-support tools or protocols that describe how to contact the health department regarding index patients who should be expedited for interviewing (e.g., those with acute HIV infection)
 - Staffing arrangements that expedite partner services at high-volume, high-prevalence HIV testing sites (e.g., assigning health department specialists to work onsite or on an on-call basis)
 - Information about state or local regulations regarding
 - legal interpretation of any provider responsibilities regarding the duty to inform partners of possible HIV exposure
 - reporting new cases of HIV or STD infection by health care providers and laboratories
- Provide or obtain ongoing training on effective partner services methods that are informed by local epidemiology, jurisdiction requirements, and CDC guidelines on the following topics (i):
 - Confidential, respectful, culturally sensitive communication
 - Assessing the risk of partner violence
 - Handling of complex or threatening situations in the field
 - Rights of minors
 - The effect of changes in health department staffing, HIV testing methods, and HIV surveillance case definitions on partner services priorities
 - Innovative, effective methods to reach index patients and partners (e.g., Internet and social media sites)
 - Methods to expedite HIV testing of partners (e.g., rapid, point-of-service tests)
- Establish and use systems to integrate or routinely match HIV and STD surveillance data to identify index patients who are coinfected with HIV and other STDs (i)
- Establish criteria to expedite offering interviews to index patients with the following characteristics (i, ii)
 - Acute HIV infection based on laboratory tests (e.g., positive result on HIV p24 antigen test, HIV nucleic acid amplification test, or HIV viral load test; or HIV antibody results indicative of recent seroconversion), or clinical evaluation (i.e., symptoms or signs of acute retroviral syndrome) that is associated with a high risk of HIV transmission
 - High HIV viral load that is associated with a high risk of HIV transmission
 - Newly reported or newly diagnosed HIV infection (based on preliminary and/or confirmatory HIV test results as allowed by the jurisdiction)
 - Newly diagnosed sexually transmitted diseases (STDs) that indicate recent unprotected sex (i.e., sexual activity without using a physical barrier) and facilitate HIV transmission—primary and secondary syphilis; gonorrhea and chlamydial infection (including rectal infection); herpes simplex virus type 2 (HSV-2); and trichomoniasis (in women)^g
 - Increased risk of HIV transmission due to pregnancy^h
 - Behaviors that pose a high risk of exposing others to HIV (e.g., multiple, anonymous partners; having unprotected sex with persons with negative or unknown HIV-infection status; sharing drug-injection equipment)ⁱ
 - A specific request for partner services

Box 8-A. Recommended strategies to establish infrastructure for HIV partner services (cont) Establish criteria for partners who warrant expedited notification with the following characteristics (i, ii): Likely to be infected with HIV or STD but unaware of their infection Had contact with index patients in the 3 months before their HIV diagnoses Warrant STD testing and presumptive STD treatment because the index patients are coinfected with STD Spouses, long-term partners, and other partners who had contact with index patient in the past 12 months Establish protocols regarding methods and preferred timeframes to expedite the following partner services (i): Communicating with index patients (preferably within 2–3 working days of identifying the index patient) and follow-up communication if the index patient did not provide partner information at the initial encounter (preferably within 2 weeks of the initial encounter) Notifying partners in person or by phone, letter, email, or other means (preferably within 2–3 working days of obtaining partner locating information) Providing index patients STD and viral hepatitis screening, reproductive health services, and relevant support services onsite or by linking to another provider (preferably within 2 weeks of initial encounter)^f Providing partners screening for HIV, STD, and viral hepatitis, evaluation for HIV prophylaxis, and other medical and social services onsite or by linking to another provider^f Periodically evaluate the partner services program to guide guality improvement^e (i) Another document describes additional recommendations on infrastructure.1 Note. Acute HIV infection is the period between initial HIV infection and the expression of HIV antibodies that can be detected by HIV antibody tests. This period is characterized by high levels of HIV in the blood and a vigorous immune response. PrEP is the daily, continuous use of a specific regimen of antiretroviral medications for a period of time by an HIV-uninfected person to achieve levels of drug in the blood and anal and genital mucosa sufficient to reduce the risk of HIV acquisition. In July 2012, FDA approved one PrEP regimen (tenofovir/emtricitabine) for preventing sexual transmission. Although HHS recommendations in May 2014 advised use of this same regimen for persons who inject drugs, the product label only addresses use for preventing sexual transmission. nPEP is the use of selected antiretroviral medications by HIV-uninfected persons within 72 hours after isolated, nonoccupational exposures to body fluids potentially containing HIV, such as after unprotected sexual intercourse or condom breakage, in order to reduce the risk of HIV acquisition. Use of antiretroviral medication for nPEP does not reflect labeling approved by FDA.

^d See <u>Section 5, Antiretroviral Treatment</u>, for more information about HIV prophylaxis for HIV-uninfected partners of persons with HIV.

^e See <u>Section 13, Quality Improvement</u>, for more information.

^f Viral hepatitis testing (and treatment of infected persons) has not been shown to influence HIV transmission but is included here because it is often offered in combination with HIV and STD testing for individual and public health benefits. This section does not address services for partners exposed to viral hepatitis by persons with HIV who are coinfected with viral hepatitis.

- ^g See <u>Section 9, STD Services</u>, for more information on STDs that may facilitate HIV transmission.
- ^h See <u>Section 11, Pregnancy</u>, for more information on how pregnancy influences HIV transmission.

Sources

- i. CDC. Recommendations for partner services programs for HIV infection, syphilis, gonorrhea, and chlamydial infection. *MMWR* 2008;57(RR-9). <u>http://stacks.cdc.gov/view/cdc/7074</u>. Accessed November 3, 2014.
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Box 8-B. Essential elements of HIV partner services

General principles (i, ii)

- Inform index patients and partners referred by index patients that partner services
 - have potential benefits and risks
 - are voluntary and confidential
 - can be provided in several ways, including through health department specialists
- Consider various methods to notify partners based on the preferences of index patients and their partners' characteristics (e.g., found through the Internet, risk of adverse reaction), including self-notification and assistance from health departments and providers
- Protect the confidentiality of the index patient and partners and the privacy of their health information^a
- Communicate in a nonjudgmental, culturally appropriate, and sensitive manner
- Monitor and adhere to changes in jurisdiction regulations that may affect partner services, especially these issues:
 - Any duty of index patients or providers to inform spouses or other persons of possible HIV exposure^a
 - Intimate partner violence, sexual assault, or child or elder abuse when index patients or partners report abuse or when abuse is suspected^a
 - Rights of minors^a

Services for index patients

- Offer voluntary, confidential partner notification assistance through health department partner services specialists and explain the notification process, the role of health department specialists, and confidentiality protections (i, iii, iv, v, vi)
- If the index patient accepts health department partner notification assistance, the health department specialist should take the following steps (i, iii):
 - Explain the rationale for notifying partners of possible HIV exposure (i.e., partners who had contact with the index patient in the 12 months before HIV diagnoses), with priority given to partners who had contact during the 3 months before HIV diagnosis or during the previous month if the index patient has acute HIV infection or high viral load
 - Ask the index patient which sex and drug-injection partners have already been notified of possible HIV exposure
 - Collect contact and other information, using CDC-recommended methods, about sex and drug-injection partners who have not been notified^b
 - Collect information about physical venues and Internet sites frequented by the index patient or members
 of his or her social network if using venue-based or social network HIV testing methods
 - Assess barriers and risks to partner notification for each named partner (e.g., physical or verbal abuse), offer advice and services to reduce this risk (e.g., describe measures to prevent partner violence), and defer notification if a risk is apparent
 - Notify the index patient's partners using CDC-recommended methods^b
 - Recognize that some index patients prefer to self-notify some partners but request assistance to notify other partners
- If the index patient declines referral to health department partner services by a nonclinical or nonclinical, the provider should take the following steps (i, iii, iv, vi):
 - Help the index patient develop a plan to notify partners directly or with provider assistance, as allowed by the jurisdiction
 - Offer assistance in testing partners for HIV, STDs, and viral hepatitis^{c,d,e}

Box 8-B. Essential elements of HIV partner services (cont)

- If the index patient seeks partner notification assistance from a nonclinical or clinical provider who is trained and authorized to provide partner services, the provider should take these steps (i, iii, iv):
 - Explain the rationale for notifying partners of possible HIV exposure (i.e., partners who had contact with the index patient in the 12 months before HIV diagnoses), with priority given to partners who had contact during the 3 months before HIV diagnosis or during the previous month if the index patient has acute HIV infection or high viral load
 - Ask the index patient which sex and drug-injection partners have already been notified of possible HIV exposure
 - Collect contact and other information, using CDC-recommended methods, about sex and drug-injection partners who have not been notified
 - Assess barriers and risks to partner notification for each named partner (e.g., physical or verbal abuse), offer advice and services to reduce this risk (e.g., describe measures to prevent partner violence), and defer notification if a risk is apparent
 - Notify the index patient's partners using CDC-recommended methods as appropriate to legal authority and skills^b
 - Recognize that some index patients prefer to self-notify some partners but request assistance to notify other partners
- If the index patient chooses to self-notify any partner without assistance, the provider should describe (i, iii, iv, vii):
 - Possible challenges of self-notification, such as partner violence, and discourage self-notification if a risk is apparent
 - Self-notification methods for known partners (e.g., in person) and anonymous partners (e.g., established Internet notification programs)
 - Methods to improve the effectiveness of self-notification (e.g., focus on partners over the previous 3 months or, if diagnosed with acute HIV infection or high viral load, focus on partners over the previous month; use a private, safe setting; anticipate and respond to negative partner reactions; seek provider assistance if questions arise)
 - Key messages for partners (e.g., how to obtain HIV, STD, and viral hepatitis testing and evaluation in facilities that link partners with positive tests to health care providers or to home HIV testing if the partners decline other testing options)^{c,d,e}
- If the index patient declines any partner services through the health department, provider or self-notification, re-offer partner services at the next encounter and/or notify the HIV care provider serving the index patient that partner services should be offered at the HIV care visit, when appropriate (i)
- Regardless of the partner notification method, the provider should promptly offer index patients the following prevention and care services onsite or through linkage, if not recently provided:
 - HIV medical care^c (i, iii, iv, vi, viii, ix)
 - STD and viral hepatitis testing, evaluation, treatment, vaccination, and counseling^{c,d,e} (i, iii, vi)
 - Risk-reduction services and devices (e.g., behavioral information, counseling, risk-reduction interventions, latex or polyurethane condoms)^{f,g} (i, iii, iv, vi, ix)
 - Information about the availability of PrEP and nPEP for HIV-uninfected partners when clinically indicated to reduce their risk of HIV acquisition^{h,i} (i, x, xi)
- Other medical or social services that influence HIV transmission (e.g., substance use treatment, mental health services)ⁱ (i, iii, iv, vi, ix)



Box 8-B. Essential elements of HIV partner services (cont)

Services for sex and drug-injection partners

- Notify the partner about possible HIV exposure (and STD exposure if the index patient is coinfected with STD) without disclosing the identity of the index patient, using CDC-recommended methods (i, vi, viii)
- Provide information about HIV, STD, and viral hepatitis infections (i, vi)
- Promptly offer the following services onsite or through linkage:
 - HIV testing if the partner is not known to be HIV-infected (followed by verification of test results)^k (i, iii, iv, ix)
 - HIV care, treatment, and partner services if a preliminary or confirmatory HIV test is positive^c (i, iii, vi)
 - Screening for STD and viral hepatitis if partner is asymptomatic, using tests recommended by CDC^{d,e} (i, iii)
 - Presumptive STD treatment (while awaiting results of STD testing or clinical evaluation) if the partner was
 exposed to STD^d (iii)
 - Testing and clinical evaluation for STD and viral hepatitis if partner has relevant symptoms^{d,e} (i, iii)
 - STD and viral hepatitis care and treatment if the partner is diagnosed with these conditions^{d,e} (i, iii, ix)
 - Risk-reduction services and devices (e.g., behavioral information, counseling, risk-reduction interventions, latex or polyurethane condoms)^{f.g} (i, iii)
 - Information about the availability of PrEP and nPEP for HIV-uninfected persons when clinically indicated to reduce the risk of HIV acquisitionⁱ and referrals to clinical providers who offer prophylaxis (x, xi)
 - Other medical and social services that influence HIV transmission (e.g., substance use treatment, mental health services)ⁱ (i, iii)
- Collect information about members of the partners' social network (including physical and virtual venues frequented), using CDC-recommended methods (i)

	Note.	Another document describes	additional recomme	ndations on how to	conduct partner services.1
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^a See <u>Section 3, Context of Prevention</u>.

- ^b See source i (below) for details on CDC recommended methods.
- ^c See <u>Section 4, Linkage to and Retention in Care</u>.
- ^d See <u>Section 9, STD Services</u>.

See Section 7, Risk Screening and Risk Reduction.

See Section 12, Other Medical and Social Services.

Viral hepatitis testing (and treatment of infected persons) has not been shown to influence HIV transmission but is included here because it is often offered in combination with HIV and STD testing for individual and public health benefits. This section does not address services for partners exposed to viral hepatitis by persons with HIV who are coinfected with viral hepatitis.

³ All these source guidance documents advise providing information and counseling about condom use; Health Resources and Services Administration (HRSA) guidance for persons attending publicly funded clinics specifies providing condoms.

^a The cited source guidance that supports this recommendation was intended for clinicians. Based on the opinions of the Project Workgroup, the section writing group concluded that it would be beneficial and feasible for other types of providers to implement this recommendation. See <u>Section 5</u>, <u>Antiretroviral Treatment</u>, for more information about PrEP and nPEP.

^k Partners who are unlikely to obtain prompt HIV testing in clinical settings should be linked to HIV testing at community-based organizations or home.

Box 8-B. Essential elements of HIV partner services (cont)

Sources

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How These Recommendations Differ from Previous Recommendations

The 2003 *Recommendations for Incorporating HIV Prevention into HIV Medical Care*¹⁵ (hereafter called the 2003 *Recommendations*) were based on CDC partner services guidelines published in 1998 and 2001.^{16,17} The updated recommendations in this section are consistent with 2008 CDC recommendations for partner services¹ and other current federal guidance about partner services.^{6,14,18-22} They are also consistent with the latest comparable guidance about notifying partners of patients with HIV from the International Antiviral Society-USA Panel.²³ They are also generally consistent with guidance about 1) social network, cluster, and Internet-based partner notification methods; 2) integrating and matching HIV and STD surveillance data to identify index patients eligible for partner services; and 3) *collaborations* among health departments, community-based organizations, and health care providers from the National Network of STD/HIV Prevention Training Centers,⁹ the National Coalition of STD Directors,¹⁰ and the National Alliance of State and Territorial AIDS Directors.²⁴

Compared with the 2003 Recommendations,¹⁵ these updated recommendations

- advise that health department specialists provide partner services whenever possible because of evidence that these specialists provide more efficient, effective, and cost-effective services than other providers
- stress building relationships between health departments and HIV testing, prevention, and health care providers (especially those serving a large number of persons with HIV) to expedite partner services to index patients who have been newly diagnosed with HIV or are at high risk of exposing others to HIV

- advise expediting interviews of index patients with laboratory or clinical evidence of *acute HIV* infection^{§§§§} who may be highly infectious
- stress actively helping index patients and partners with positive HIV tests to start or resume HIV medical care
- advise informing index patients about the availability of PrEP and nPEP for HIV-uninfected partners when clinically indicated to reduce their risk of HIV acquisition
- encourage health departments to consider using innovative methods to locate and notify partners (e.g., Internet)

Methods

The section writing group based most of these recommendations on the 2008 CDC recommendations for partner services that were based on a systematic literature review and expert opinion (that the writing group did not reexamine).^{1,25} Some recommendations were based on 1) other federal guidance about partner services and HIV case reporting published from January 2001 to May 2014^{6,14,18-22} and 2) scientific evidence from articles identified through a narrative review.

The writing group's narrative review included articles about partner services in the United States published in English from January 2007 through January 2014 retrieved from PubMed, Google Scholar, the Cochrane Database, and MEDLINE. They used these search terms in various combinations: *United States, HIV, sexually transmitted disease, chlamydial infection, gonorrhea, syphilis, reinfection, partner services, partner notification, disclosure, self-disclosure, nondisclosure, contact tracing, sexual networks, Internet partner notification, text notification, surveillance, self-referral, patient referral, partner referral, provider-assisted referral, contract referral, dual referral, index patient, patient-delivered partner treatment/therapy, disease intervention specialists, recurrence, partners and risk behavior, cost, and cost-effectiveness. The writing group found additional articles by manually searching references in articles identified by the database search. This narrative literature review yielded many recent articles, including a systematic review of partner notification, ²⁷ evidence-based guidance on partner services from an expert panel on community-based preventive services in the United States, ²⁸ and 2 studies of the cost-effectiveness of HIV partner services.*

Evidence Supporting the Recommendations

The literature review yielded new evidence about the relative effectiveness of health department partner services, the benefits of timely partner services, new methods to notify partners, and the cost-effectiveness of partner services.

Several studies confirmed earlier findings that health department partner services specialists contacted more partners with unrecognized HIV infection per index patient than other types of partner services providers.³¹⁻³⁴ Specialized training and field experience may enable health department specialists to elicit more accurate information about partners from index patients³⁵ and to identify more partners per index patient.³¹ In contrast, several studies indicate that many health care providers or HIV testing providers

Acute HIV infection is the period between initial HIV infection and the expression of HIV antibodies that can be detected by HIV antibody tests. This period is characterized by high levels of HIV in the blood and a vigorous immune response.



may not 1) understand health department partner services procedures; 2) routinely advise patients to notify their partners about possible HIV exposure; 3) routinely refer patients for health department assistance; or 4) have the skills or time to elicit, notify, or manage partners.^{31,36-38} Some providers do not inform persons newly diagnosed with HIV that case reporting required by health care providers and laboratories may activate health departments to offer partner services.¹

Several recent studies found that assigning health department specialists to work in clinics, hospitals, and private medical practices that provide a high-volume of HIV testing were more effective than traditional, offsite partner services.^{3,12,37,39,40} Assigning health department specialists to work in testing sites can also increase the proportion of index patients who receive partner services and shorten the interval between diagnosis and interview. This approach can also increase the proportion of partners who were located, were newly diagnosed with HIV infection, and obtained treatment.^{3,12,39,40}

Some health departments routinely use HIV surveillance data to identify persons with acute infection or routinely integrate or match HIV and STD surveillance systems to identify HIV-infected persons who have new STD diagnoses and warrant being offered expedited interviews.⁴¹⁻⁴⁵ Surveys of state and city health departments indicate that partner services programs that routinely access name-based HIV case reports and surveillance data can serve a higher proportion of index patients than health departments without such access.^{9,46}

Several studies found that partner services were more productive when they were offered to persons shortly after their HIV diagnoses or to persons diagnosed with acute HIV infection.^{34,47-49} A small study in San Francisco evaluated the effort to find 1 newly identified HIV-infected partner; health department partner services specialists had to interview only 8 HIV-infected index patients if their interviews occurred within 2 weeks after diagnosis, but had to interview 21 HIV-infected index patients if their interviews occurred more than 2 weeks after diagnosis (p=0.008).⁴⁸ A study in North Carolina compared interview outcomes of persons with acute HIV infection and persons with established infection: persons with acute infection named 2.5 times more partners (95% confidence interval: 2.1 to 3.0) and named 1.9 times more partners who were newly diagnosed with HIV infection (95% confidence interval: 1.1 to 3.5).³⁴ A study in 2 large cities evaluated partner notification services for 48 persons with acute HIV infection; 23 of the 72 named partners underwent HIV testing and 5 (21.7%) had positive test results.⁴⁹ A study in New York City found that after health department partner services specialists began to offer rapid, point-of-service HIV testing to partners, the proportion of partners who underwent testing rose from 52% to 76% (p<0.001) and the program identified more than twice the number of partners with newly diagnosed HIV infection than it had before rapid testing started.⁵⁰

At least 5 recent *evaluations* examined partner notification using electronic technologies. Three evaluations assessed ecards (using inSPOT software) sent by index patients to notify partners as a means to supplement traditional partner notification. Although most evaluations used indirect methods to estimate partners' receipt of ecards or to estimate follow-up HIV testing (because they did not know the identity of ecard recipients), these evaluations found that awareness and use of inSPOT was limited and resulted in few partners obtaining HIV testing.^{27,51,52} A few studies evaluated the acceptability of Internet-based partner notification. One found that gay, bisexual, or other men who have sex with men (MSM) were willing to receive or initiate emails about partner notification, regardless of their HIV infection status.⁵³ The investigators concluded that health departments considering Internet methods should use

culturally sensitive social marketing campaigns to increase awareness and acceptability of these methods. A study of MSM found that responders would be less likely to seek care and to notify partners if notified by anonymous ecards than if notified directly by their partner.⁵⁴

Studies in 2 states evaluated the cost and effectiveness of partner services programs that included counseling and rapid HIV testing.³⁰ When fixed program costs were excluded, the estimated cost per partner notified of a new HIV diagnosis was \$11,626 in Colorado and \$2,545 in Louisiana. A cost-effectiveness analysis assessed a set of partner services provided by health department specialists to 3 different hypothetical populations: MSM, *persons who inject drugs* (PWID), and heterosexuals. The services included HIV testing, referring HIV-infected partners to HIV care, and behavioral risk-reduction information.²⁹ These partner services were cost-saving compared with no intervention. Moreover, the intervention cost per new case of HIV averted in a partner (ranging from ~\$116,000 for MSM, ~\$263,000 for PWID, and ~\$349,000 for heterosexuals) was lower than the lifetime cost of HIV treatment (>\$400,000).⁵⁵

Other sections of this report cite evidence that supports recommendations about PrEP and nPEP (<u>Section</u> <u>5</u>, <u>Antiretroviral Treatment</u>) and STD screening and treatment (<u>Section 9</u>, <u>STD Services</u>).

Issues that Influence Implementation of the Recommendations

Implementation progress, challenges, and opportunities

A 2006 survey of more than 51 health departments in the United States found that 43% of persons with newly reported HIV infection received health department partner services; this was a significant increase from the proportion reported in a 2001 health department survey (32%).⁴⁶ According to a survey and interviews of staff of health departments from 51 states/territories and 6 large cities published in 2008,^{*****} health departments offered partner services to 47% to 79% of index patients with HIV.⁹ Health department partner services programs serving jurisdictions with low HIV morbidity and name-based HIV reporting were more likely than programs serving jurisdictions with high HIV morbidity without name-based reporting to report routinely use HIV surveillance to activate partner services, serve index patients diagnosed in private health systems, and notify a high proportion of partners. Many survey respondents reported that high caseloads in high-morbidity areas and unlinked or incompatible HIV surveillance and partner services information systems hindered partner services.

In general, persons diagnosed with HIV in public-sector clinics and HIV testing sites affiliated with health departments are more likely to receive health department partner services than persons diagnosed elsewhere.⁵⁶ These public-sector sites are more likely to routinely refer index patients to health department partner services specialists or to invite these specialists to work onsite. To increase use of partner services, some health departments have marketed their services to private-sector HIV testing providers or assigned partner services specialists to work in large HIV care practices.^{1,9,12,39,57} Since the passage of the Patient Protection and Affordable Care Act, some health departments are exploring third-party reimbursement to enhance program capacity.^{9,58}

^{*****} Most recent nationally reported data is available at http://www.cdc.gov/hiv/library/reports/evaluation.html.



Although partner services can benefit all persons with HIV, high caseloads or staffing shortages force most health departments to prioritize the order of interviewing index patients and partners.¹ Most health departments expedite interviewing of index patients who have newly reported and newly diagnosed HIV infection. The 2014 CDC revised HIV surveillance case definition recommends that laboratories and HIV testing providers report cases of acute HIV infection or preliminary positive HIV test results to expedite partner services.^{5,59} Some health departments also expedite interviewing of index patients with established HIV infection who have been recently diagnosed with STD (particularly infectious primary or secondary syphilis and rectal gonorrhea among MSM). Patients who are coinfected with HIV and STD are easier to identify if HIV surveillance and STD surveillance systems are integrated or routinely matched.^{3,42}

Policy, legal, and ethical considerations

Well-implemented partner services balance the interests of infected persons, their partners, and the community. Because partner services are voluntary and confidential, it is unethical to coerce, deceive, or withhold information from index patients when attempting to elicit partner information or notify partners. Index patients who feel pressured to provide partner information may not provide accurate partner information. Several studies show that most persons with HIV, their partners, and their health care providers accept partner services, including the involvement of health departments and Internet-based partner notification, and consider partner services a valuable service rather than an imposition.^{53,60-62} Developing standard referral procedures and interagency agreements that protect *confidentiality* may improve the acceptability of partner services and improve communication and collaboration between HIV testing providers and health departments^{1,9,10} (see the Implementation Resources topic below).

State and local laws and public health regulations generally protect the confidentiality of all HIV and STD information, including information obtained from or about index patients.¹ Persons who fear that partner notification might cause stigma; provoke physical or verbal abuse; harm relationships; or expose illegal activity may choose confidential partner notification (that does not reveal the identity of the index patient) over self-notification.⁶³⁻⁶⁶ Confidentiality is subject to practical limits when a person has a single, identifiable partner and when couples seek joint HIV testing and post-test counseling. Although there is growing interest in couple-based HIV testing and counseling after joint consent, some providers hesitate to offer this service because of concerns about violating HIV-related confidentiality protections.^{67,68}

Despite the longstanding practice of confidential health department partner services, some clinicians, HIV testing providers, and persons with HIV may be unaware of or doubt these confidentiality protections. Some individuals and communities do not favor health department access to personal health information for public health purposes because they distrust public health authorities or fear the information might be stigmatizing, provoke negative partner reactions, or have legal ramifications.^{1,62,69,70} Nevertheless, real or perceived breaches of confidentiality during provision of partner services appear to be rare. Several studies conducted from the late 1990s to 2011, most of which involved heterosexual partners, found that the risk of violence due to partner notification was low⁷¹⁻⁷⁴ and that partner notification itself did not increase rates of partnership dissolution.^{62,71,75}

Some jurisdictions have laws that require or allow public health officials or health care providers to notify partners who may have been exposed to HIV infection, even when index patients object.¹ Persons who misunderstand these laws may believe that all partner notification is mandatory or nonconfidential. To

minimize negative attitudes about partner services, providers can reassure index patients that partner services are strictly voluntary and confidential, are usually provided at no cost to index patients and partners, and are deferred if there is a risk of partner retribution.

<u>Section 3, Context of Prevention</u>, and <u>Section 9, STD Services</u>, provide further information on policy, legal, and ethical aspects of partner services.

Special populations

Some adolescents, undocumented immigrants, sexual assault survivors, prisoners, and other vulnerable or medically marginalized persons with HIV may resist health department partner services. Adolescents who do not know that these services are confidential, voluntary, and do not require parental consent in many states may appreciate careful explanations of consent and confidentiality procedures. Immigrants may believe that partner services conflict with their cultural norms or may prompt deportation or other legal action. Some immigrants may require partner services information in their own language.¹ Rapid, point-of-care HIV testing is useful when screening transient partners, such as migrant workers¹ (see Section 12, Other Medical and Social Services).

Implementation Resources

Additional information and resources to support implementation of these recommendations can be found at <u>http://www.cdc.gov/hiv/guidelines/</u>.

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Section 9. Sexually Transmitted Disease (STD) Preventive Services

Background

Sexually transmitted diseases (STDs), also known as sexually transmitted infections (STIs), are infections transmitted through penile, vaginal, oral, or anal sexual contact, regardless of the presence of symptoms or signs.¹ In this section, STD preventive services for persons with HIV are defined as the following: assessment of behavioral and biological factors that may increase the risk of transmitting HIV or STD; sexual risk-reduction interventions; screening asymptomatic persons for STD pathogens; clinical evaluation (including physical examination and *diagnostic testing** of persons with STD signs or symptoms); treatment; and *partner services*.[†]

STD preventive services are an essential component of HIV prevention because 1) the diagnosis of an STD is an objective biologic marker of *unprotected sexual activity* that may result in HIV transmission; 2) certain STDs may increase plasma HIV *viral load* and genital HIV shedding, which may increase the risk of sexual and perinatal HIV transmission; and 3) STD treatment may reduce STD-related morbidity and lower the risk of HIV transmission.¹

The vast majority of STD preventive services are provided in health care facilities. However, some *nonclinical settings*,[‡] such as intake units of correctional facilities and residential job-training sites, schools, and community-based organizations, offer risk assessments, risk-reduction interventions, screening, and subsequent *linkage*[§] to treatment and *partner services*.²

STD preventive services in nonclinical settings may be more convenient for populations who have limited or irregular access to health care. To be effective, nonclinical STD services must ensure prompt linkage of persons who have had STD symptoms, positive screening tests, or sexual contact with a *partner* treated for an STD to health care providers for examination and treatment and to health departments for voluntary, confidential partner services.² Self-collected specimens can be used to screen for some pathogens (i.e., chlamydial infection or gonorrhea using *nucleic acid amplification tests* [NAAT] tests) when requested by a physician or a *nonclinical provider* working under a physician's order. These specimens can be obtained at "express visits" in STD clinics, community-based organizations that offer HIV testing or risk-reduction services, or at home. Self-collected specimens collected in nonclinical

[§] Linkage to care is the process of helping persons with HIV to obtain HIV medical care and prevention or social services through active methods (e.g., appointment scheduling, reminders, transportation to appointments).



^{*} Testing that is initiated for a person with clinical signs or symptoms to obtain objective evidence of the presence or absence of diseases or infections.

[†] Partner services includes an array of voluntary services for persons with HIV or STD and their sex and drug-injection partners that are intended to reduce HIV transmission: interviewing persons with HIV to obtain information to contact or locate their sex and drug-injection partners; notifying partners of possible HIV exposure; offering testing for HIV, sexually transmitted diseases, and other infections; providing condoms, prevention information, and counseling; and providing help in obtaining risk-reduction services, HIV medical care, and other medical and social services.

[‡] Nonclinical settings are facilities that provide prevention, education, screening and interventions for risk behaviors, and referrals for medical and social services. Some nonclinical settings may also provide health promotion services and screening for HIV and some STD.

settings must be tested in laboratories that have validated procedures specified by the Clinical Laboratory Improvement Act (CLIA) for testing specimens obtained in nonclinical settings.³⁻⁵

Health departments are responsible for population-level STD prevention and control programs. These programs include STD case reporting and *surveillance*, outbreak detection and control, *prevention services* for persons with STD and their sex partners to stem onward transmission, assurance of STD preventive services in *clinical settings*, ** screening programs in nonclinical settings, antimicrobial drug resistance monitoring, provider and community education, and health promotion activities.

This section focuses on preventive services for 5 STDs that may increase the risk of transmitting HIV: syphilis, gonorrhea, chlamydial infection, and herpes simplex virus type 2 (HSV-2) in men and women and trichomoniasis in women.¹ This section does not provide comprehensive recommendations about STD preventive services for persons with HIV. Other guidance addresses 1) screening, treatment, vaccination, and other interventions for other sexually transmitted infections that are common among persons with HIV but have not been shown to increase the risk of onward HIV transmission (e.g., human papillomavirus, hepatitis A, B, and C) and 2) services for STDs that may increase the risk of HIV acquisition by HIV-uninfected persons (syphilis, gonorrhea, chlamydial infection, and HSV-2 in men and women; and trichomoniasis and bacterial vaginosis^{††} in women).¹

Quality improvement^{‡‡} and program *monitoring and evaluation*^{§§} can determine if the interventions described in this section are implemented as intended, yield the expected outcomes, or warrant changes in delivery methods (see Section 13, Quality Improvement). Section 7, Risk Screening and Risk Reduction, addresses sexual behavior, condom use, and screening for biologic risks for HIV transmission, such as STD symptoms; Section 8, Partner Services, addresses partner services for persons with HIV and their sex partners; and Section 3, Context of Prevention, addresses *confidentiality* and reporting of HIV and STD information and the duty to warn partners of possible HIV exposure.

^{§§} Monitoring and evaluation is a process that involves the repeated, ongoing collection and review of information about program activities, characteristics, and outcomes in order to assess program implementation, coverage, acceptability, cost, and effectiveness.



Clinical settings are health care facilities in which medical diagnostic, treatment, and disease prevention services are routinely provided.
 Although it remains uncertain if bacterial vaginosis results from acquisition of a sexually transmitted pathogen, this condition may increases

risk of HIV acquisition.⁶

^{‡‡} Quality improvement is an approach to the continuous study and improvement of the processes of providing services that meet or exceed established professional standards and user expectations.

Recommendations

BOX 9. RECOMMENDATIONS—SEXUALLY TRANSMITTED DISEASE (STD) PREVENTIVE SERVICES

For nonclinical and clinical providers (including health department staff who provide individual-level services to persons with HIV)

- At the initial HIV-related encounter and thereafter with a frequency appropriate to setting and risk assessment results, provide the following services:
 - Inform persons with HIV about:
 - methods to reduce the risk of HIV and STD transmission^a (i, ii, iii, iv, v)
 - STDs that can increase HIV viral load and may facilitate HIV transmission^a (i, iii, iv)
 - the benefits of screening for STDs (that are often asymptomatic) and STD treatment^a (i, iii, iv)
 - Assess these behavioral and biologic risk factors for HIV and STD transmission^o:
 - Sexual, alcohol, and drug-use behaviors that may lead to HIV or STD transmission^{a,b} (i, ii, iii, iv)
 - Recent sex partners who were treated for STD^{a,b} (i, iii, iv)
 - Past and recent STD diagnosis, screening, and symptoms^{a,b} (i, ii, iii, iv)
 - Concurrent STD infection by providing STD screening tests onsite (if allowed by professional authority) or linking to a health care facility that provides STD screening tests^{a,d,e,f} (i, iii, vi) (see <u>Box 9-A</u>)
 - Offer latex or polyurethane male and/or female condoms^g (i, ii, iii)
 - For persons with HIV who report sexual risk behaviors, provide the following services:
 - Provide or refer for brief or intensive behavioral risk-reduction interventions^b (i, ii, iii, v, vi)
 - Refer to voluntary health department HIV partner services or other trained partner services provider if
 persons are newly diagnosed with HIV or report new sex partners^h (i, ii, iii, iv, v)
- For persons with HIV who report symptoms suggestive of an STD or recent sex partners who were treated for syphilis, gonorrhea, chlamydial infection, or trichomoniasis, provide access to presumptive STD treatment according to the latest Centers for Disease Control and Prevention (CDC) STD Treatment Guidelines through
 - onsite clinical evaluation (including physical examination and diagnostic testing) followed by immediate presumptive treatment, if allowed by professional authority (i, iii, iv) or
 - immediate linkage to a health care facility that offers clinical evaluation and onsite presumptive STD treatment^{a,e} (i)
 - For persons with HIV who have positive STD screening tests, provide the following services:
 - Provide access to treatment according to the latest CDC STD Treatment Guidelines through onsite treatment or linkage within 24 hours to a health care facility that offers onsite STD treatment (including recommended injectable medications),^{a,e} as allowed by professional authority (i, iii, vi, vii)
 - Refer to voluntary health department HIV/STD partner services or other trained partner services provider^h (i, iii, iv)
 - Provide or refer to brief or intensive behavioral risk-reduction interventions^{a,b} (i, iii, vi)
 - Report cases of STD according to jurisdiction requirements and inform persons diagnosed with STD that case reporting may prompt health departments to offer voluntary, confidential partner services in some jurisdictionsⁱ (i, iii)

BOX 9. RECOMMENDATIONS—SEXUALLY TRANSMITTED DISEASE (STD) PREVENTIVE SERVICES (cont)

Specific to clinical providers (in addition to above recommendations)

- At initiation of HIV medical care, provide all persons with HIV the following services:
 - Detailed sexual history, including number and gender of sex partners; types of sexual practices; anatomic sites of sexual contact; condom use; previous STD screening, testing, diagnoses, and treatment; and recent sex partners who have had STD symptoms or treatment^b (i, iii)
 - Detailed history of alcohol and substance use^b (i, iii)
 - Detailed history of recent STD-related symptoms (e.g., urethral, vaginal, or anal discharge; dysuria; abnormal vaginal or rectal pain or bleeding; genital, perianal, or oropharyngeal exudate, sores or bumps; skin rash) (i, iii)
 - STD screening tests^{d,f} (i, iii) (see <u>Box 9-A</u>)
 - Physical examination for signs of STDs, including skin, oral, anal, genital, and gynecologic examinations for women and skin, oral, anal, and genital examinations for men (i, iii)
 - Diagnostic testing for STD if persons have STD signs or symptoms^f (i, iii)
 - For persons with HIV who report sexual or drug-injection risk behaviors, provide the following services:
 - Provide or refer to brief or intensive behavioral risk-reduction interventions^b (i, ii, iii, v, vi)
 - Refer to voluntary health department HIV partner services or other trained partner services provider if
 persons are newly diagnosed with HIV; have evidence of acute HIV infection or high HIV viral load; or
 report new sex partners^h (i, ii, iii, iv, v)
 - For persons with HIV who have a clinical evaluation indicative of STD or positive screening or diagnostic STD tests, or recent sex partners who have had STD symptoms or treatment for syphilis, gonorrhea, or chlamydial infection, provide the following services:
 - Provide oral or injectable STD treatment onsite, including presumptive treatmentⁱ (while awaiting STD test results) when indicated, according to the latest CDC STD Treatment Guidelines (i, iii, vi, vii)
 - Advise to return 3 months after treatment for gonorrhea, chlamydial infection, or trichomoniasis to
 obtain retesting for the relevant infection at the anatomic site of infection^k (i, iii) (see <u>Box 9-A</u>)
 - Advise persons diagnosed with syphilis to return for follow up serologic testing according to latest CDC recommendations^k (i) (see <u>Box 9-A</u>)
 - Provide or refer for brief or intensive behavioral risk-reduction interventions^b (i, iii, vi)
 - Refer to voluntary health department HIV/STD partner services or other trained partner services provider^h (i, iii, iv)
 - Report cases of STD according to jurisdiction requirements and inform persons diagnosed with STD that case reporting may prompt health departments to offer voluntary, confidential partner services in some jurisdictionsⁱ (i, iii)



BOX 9. RECOMMENDATIONS—SEXUALLY TRANSMITTED DISEASE (STD) PREVENTIVE SERVICES (cont)

At follow-up HIV care visits, provide all persons with HIV the following services:

- Review of sexual, alcohol, and substance use histories since last visit to determine if behavioral riskreduction interventions are warranted^b (i, iii)
- Review of STD symptoms since last visit and recent sex partners who have had STD symptoms or treatment to determine if STD testing, physical examination, or treatment is warranted (as described above at initiation of HIV care) (i, iii)
- STD screening at least annually or more often if indicated by sexual risk behaviors^{d,f} (i, iii) (see <u>Box 9-A</u>)
- Review of sex partners who were not notified of possible HIV or STD exposure to determine if offering HIV partner services is warranted^h (i, iii)
- For persons with a positive STD test; STD symptoms or signs; or recent sex partners who have had STD symptoms or treatment for syphilis, gonorrhea, chlamydial infection, or trichomoniasis or experiencing STD symptoms, provide the following services:
 - Provide oral or injectable treatment onsite according to the latest CDC STD Treatment Guidelines (including presumptive treatment (while awaiting STD test results) if indicated because of STD symptoms, or recent sex partners who have had STD symptoms or treatment)ⁱ (i, iii, vi, vii)
 - Advise to return 3 months after treatment for gonorrhea, chlamydial infection, or trichomoniasis to
 obtain retesting for the relevant infection at the anatomic site of infection^k (i, iii) (see <u>Box 9-A</u>)
 - Advise persons diagnosed with syphilis to return for follow up serologic testing according to latest CDC recommendations^k (i) (see <u>Box 9-A</u>)
 - Provide or refer to brief or intensive behavioral risk-reduction interventions^b (i, iii, vi)
 - Refer to voluntary HIV/STD partner services at health department or other trained partner services provider^h (i, iii, iv)
 - Report cases of STD according to jurisdiction requirements and inform persons diagnosed with STD that case reporting may prompt health departments to offer voluntary, confidential partner services in some jurisdictionsⁱ (i, iii)

For staff of health departments who provide population-level HIV prevention and care services

- Develop methods to integrate or routinely match HIV and STD surveillance case reports and use these surveillance data to routinely identify populations or individuals with HIV who have new STD infections and may warrant being offered HIV and STD preventive services, including voluntary partner services (iv, viii)
- Support efforts to promote STD and HIV prevention for persons with HIV in community (i, iv, viii) (see <u>Box 9-B</u>)

Note. In this report, *nonclinical providers* are defined as persons who work in community-based organizations or health departments operating outside of health care facilities and who provide HIV testing, health education, risk-reduction interventions, partner services, case management, or assistance with linkage or referral to medical and social services. These persons include HIV testing providers, peer and professional health educators, counselors, service linkage facilitators, partner services specialists, case managers, and social workers. *Clinical providers* are defined as persons who work in health care facilities and who provide risk assessments, health education, counseling, screening, diagnosis, treatment, and other health-related services. These providers include physicians, registered nurses, advance practice nurses, physician assistants, dentists, mental health providers, pharmacists, health educators, case managers, social workers, and counselors. Some may be employees or contractors of health departments. Some of the recommendations specific to clinical providers apply only to clinical providers with authority for clinical evaluation and examinations, diagnosis, treatment, and prescribing.

Some of the federal guidelines cited in the Recommendation boxes may have been updated. For current federal recommendations, please refer to <u>http://www.cdc.gov/hiv/guidelines/</u>.

BOX 9. **RECOMMENDATIONS—SEXUALLY TRANSMITTED DISEASE (STD) PREVENTIVE SERVICES** (cont)

- Some of the cited source guidance that supports this recommendation was intended for clinical providers and partner services specialists. Based on program experience in the United States, the section writing group concluded that it would be beneficial and feasible for some nonclinical HIV prevention providers to implement this recommendation.
- See Section 7, Risk Screening and Risk Reduction, for information on assessing behavioral and biologic factors that may influence risk of HIV transmission and risk-reduction interventions. Assessment of behavioral and biologic risks factors is recommended at initial and subsequent visits in clinical settings providing continuing care. In clinical or nonclinical settings that provide one-time or episodic STD services, assessment is recommended at initial encounter and when clients seek follow-up services; recalling clients specifically for risk assessment may not be feasible.
- In this section, the term "assess" means eliciting information about behavioral and biologic risk factors for HIV transmission, including history of STD and STD symptoms, and the term "screen" means testing for STD pathogens in persons without symptoms. In other sections, the term "screen" means a brief assessment of behavioral and biologic risk factors for HIV, including history of STD, and STD symptoms that differs from an intensive, individually tailored assessment of these factors; and the phrase "STD screening tests" means testing to assess the presence of infection.
- This section does not address screening persons with HIV for other conditions that have not been shown to facilitate HIV transmission to others, such as viral hepatitis and human papillomavirus infection.
- See Section 4, Linkage to and Retention in Care.
- Using the latest tests recommended by CDC.^{1,4}
- All source guidance advises providing information or counseling about condom use; guidance from the Health Resources and Services Administration advises providing condoms to patients in publicly funded clinics.
- See Section 8, Partner Services.
- According to the latest CDC STD Treatment Guidelines, ¹ immediate presumptive treatment (or immediate linkage to such treatment) is recommended for persons who report sexual contact with partners treated for syphilis, gonorrhea, chlamydial infection, or trichomoniasis or have STD syndromes in order to reduce the risk of onward STD transmission. STD syndromes are conditions that can be caused by sexually transmitted pathogens and that cause symptoms or abnormal findings (signs) on physical examination, such as genital ulcer disease, urethritis, cervicitis, pelvic inflammatory disease, epididymitis, and proctitis.
- Information in the Policy, Legal, and Ethical Considerations topic in this section supports this recommendation.
- The cited source guidance describes the rationale for retesting for syphilis, gonorrhea, chlamydial infection; the Evidence topic describes the rationale for retesting for trichomoniasis.

Sources

- i. CDC. Sexually transmitted diseases treatment guidelines, 2015. MMWR 2015;64(RR-3). http://www.cdc.gov/std/tg2015/. Accessed December 21, 2016.**
- CDC. Revised guidelines for HIV counseling, testing, and referral. MMWR 2001;50(RR-19). http://stacks.cdc.gov/view/cdc/7281. Accessed November 3, 2014.
- iii. HRSA. Guide for HIV/AIDS Clinical Care-2014 Edition. U.S. Department of Health and Human Services; 2014.
- http://hab.hrsa.gov/sites/default/files/hab/clinical-quality-management/2014guide.pdf. Accessed December 23, 2016. iv. CDC. Recommendations for partner services programs for HIV infection, syphilis, gonorrhea, and chlamydial infection. MMWR 2008;57(RR-9). http://stacks.cdc.gov/view/cdc/7074. Accessed November 3, 2014.
- v. CDC. Revised recommendations for HIV testing of adults, adolescents, and pregnant women in health-care settings. MMWR 2006;55(RR-14). http://stacks.cdc.gov/view/7316. Accessed November 3, 2014.
- vi. Panel on Opportunistic Infections in HIV-Infected Adults and Adolescents. Guidelines for the prevention and treatment of opportunistic infections in HIV-infected adults and adolescents: recommendations from the Centers for Disease Control and Prevention, the National Institutes of Health, and the HIV Medicine Association of the Infectious Diseases Society of America. 2013. http://aidsinfo.nih.gov/guidelines/html/4/adult-and-adolescent-oi-prevention-and-treatment-guidelines/0. Accessed April 27, 2014. (This document only addresses 2 of 3 STDs known to facilitate onward HIV transmission: syphilis and herpes simplex.)
- vii. CDC. Update to CDC's sexually transmitted diseases treatment guidelines, 2010: oral cephalosporins no longer a recommended treatment for gonococcal infections. MMWR 2012;61(31):590-594. http://stacks.cdc.gov/view/cdc/20852. Accessed November 3, 2014.
- Division of STD Prevention, CDC. Improving sexually transmitted disease programs through assessment, assurance, policy development, viii. and prevention strategies (STD AAPPS). http://www.cdc.gov/std/foa/aapps/default.htm. Updated March 5, 2014. Accessed March 6, 2014.

For the current version of Sexually Transmitted Diseases Treatment Guidelines and any updated resources and support materials, please visit http://www.cdc.gov/std/treatment/.

Box 9-A. Recommended STD screening for persons with HIV who are sexually active

For all males

- Provide the following tests at initial HIV care visit (or encounters in nonclinical settings that offer STD screening tests) and at least annually thereafter*:
 - Urogenital N. gonorrhoeae (using nucleic acid amplification tests [NAATs] on urine specimen)^{a,b} (i, ii, iii)
 - Urogenital C. trachomatis (using NAAT on urine specimen)^{a,b} (i, ii, iii)
 - Syphilis serology^c (i, iii, iv)

For gay, bisexual and other males who have sex with men (MSM), regardless of condom use

- Provide these additional screening tests at initial visit (or encounters in nonclinical settings that offer STD screening tests) and at least annually* thereafter^{a,d}
 - Rectal N. gonorrhoeae (using NAAT) if person reports receptive anal sex (i, ii, iii)
 - Rectal C. trachomatis (using NAAT) if person reports receptive anal sex (i, ii, iii)
 - Oropharyngeal N. gonorrhoeae (using NAAT) if person reports receptive oral sex (i, ii, iii)

* More frequent screening at anatomic sites of exposure (i.e., every 3–6 months) is indicated for MSM whose risk behaviors persist or have multiple or anonymous sex partners. (i, iii)

For males diagnosed with syphilis or treated for gonorrhea or chlamydial infection

- Retest persons diagnosed with syphilis using serologic tests recommended by CDC^c(i)
- Retest persons treated for gonorrhea or chlamydial infection for the relevant infection at the anatomic site of infection 3 months after treatment ^{a,b,d} (i, iii)

For all females

- Provide the following tests at initial visit (or encounters in nonclinical settings that offer STD screening tests) and at least annually thereafter:
 - Urogenital N. gonorrhoeae (using NAAT)^{a,b} (i, ii, iii)
 - Urogenital C. trachomatis (using NAAT)^{a,b} (i, ii, iii)
 - Syphilis serology^c (i, iii, iv)
 - Vaginal trichomoniasis test^{e,f} (i, iii)

For all pregnant females^f

- Provide the following tests at the first prenatal visit:
 - Urogenital *C. trachomatis* (using NAAT)^{a,b} (i, ii, iii)
 - Urogenital N. gonorrhoeae (using NAAT)^{a,b} (i, ii, iii)
 - Syphilis serology^c (i, iii, iv)
- Provide the following tests at the beginning of the third trimester for women at risk for STD⁹:
 - Urogenital *C. trachomatis* (preferably using NAAT)^{a,b} (i, ii, iii)
 - Urogenital N. gonorrhoeae (preferably using NAAT)^{a,b} (i, ii, iii)
 - Syphilis serology^c (i, iii, iv)

For females diagnosed with syphilis or treated for gonorrhea, chlamydial infection, or trichomoniasis

- Retest persons diagnosed with syphilis using serologic tests recommended by CDC^c (i)
- Retest persons treated for gonorrhea or chlamydial infection for relevant infection at the anatomic site of infection 3 months after treatment^{a,b,e,h} (i, iii)

Box 9-A. Recommended STD screening for persons with HIV who are sexually active (cont)

- *Note.* Source guidance that supports these recommendations also indicates that type-specific serologic testing for herpes simplex virus type 2 (HSV-2) infection can be considered in persons with HIV with unknown herpes infection status.^{1,7}
- *Note.* This section does not address screening for other conditions that may affect persons with HIV but have not been shown to facilitate HIV transmission to others, such as viral hepatitis, bacterial vaginosis, and human papillomavirus infection.
- *Note.* Most STD screening occurs in clinical settings. However, some nonclinical settings have the capacity to screen for gonorrhea and chlamydia (using self-collected urine, vaginal, rectal, and oropharyngeal specimens) or syphilis (using venous blood drawn by phlebotomy).
- ^a Using tests recommended by CDC for laboratory detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae*.⁴
- ^b For gonorrhea and chlamydia screening, optimal specimen types for NAATs are first-catch urine from men and vaginal swabs from women that are collected in clinical settings.⁴ In women with cervicitis, endocervical specimens and vaginal specimens yield comparable results when tested with NAATs. Commercially available NAATs for *C. trachomatis* and *N. gonorrheae* are not cleared by the U.S. Food and Drug Administration (FDA) for urine, vaginal, or rectal specimens collected outside clinical settings. However, some laboratories have established performance specifications for testing specimens collected outside clinical settings to meet requirements of the Clinical Laboratory Improvement Act for reporting test results for clinical management.^{14,8}
- ^c Using tests recommended by the most recent CDC STD Treatment Guidelines.¹
- ^d The FDA has not cleared commercially available NAATs to test rectal specimens for gonorrhea and chlamydial infection or oropharyngeal specimens for gonorrhea. However, some laboratories have established performance specifications for testing these types of specimens to meet requirements of the Clinical Laboratory Improvement Act for reporting test results for clinical management.^{14,8}
- ² NAATs are the most sensitive and specific tests to detect *Trichomonas vaginalis*.⁹
- ^f Pregnant women should be screened for vaginal trichomoniasis at the same frequency as nonpregnant women (i.e., at their initial HIV care visit and annually thereafter).
- ^g Characteristics of women at high risk are defined by the most recent CDC STD Treatment Guidelines.¹
- ^a The cited source guidance describes the rationale for retesting for gonorrhea and chlamydial infection; the <u>Evidence</u> topic describes the rationale for retesting for trichomoniasis.

Sources

- i. CDC. Sexually transmitted diseases treatment guidelines, 2015. MMWR 2015;64(RR-3). http://www.cdc.gov/std/tg2015/. Accessed December 21, 2016.^{†††}
- ii. CDC. Recommendations for the laboratory-based detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae*—2014. *MMWR* 2014;63(RR-2):1–19. <u>http://stacks.edc.gov/view/cdc/25360.</u> Accessed November 3, 2014.
- iii. HRSA. Guide for HIV/AIDS Clinical Care—2014 Edition. U.S. Department of Health and Human Services; 2014. <u>http://hab.hrsa.gov/sites/default/files/hab/clinical-quality-management/2014guide.pdf</u>. Accessed December 23, 2016.
- iv. Panel on Opportunistic Infections in HIV-Infected Adults and Adolescents. Guidelines for the prevention and treatment of opportunistic infections in HIV-infected adults and adolescents: recommendations from the Centers for Disease Control and Prevention, the National Institutes of Health, and the HIV Medicine Association of the Infectious Diseases Society of America. 2013. <u>http://aidsinfo.nih.gov/guidelines/html/4/adult-and-adolescent-oi-prevention-and-treatment-guidelines/0.</u> Accessed April 27, 2014. (This document only addresses 2 of 3 STDs known to facilitate onward HIV transmission: syphilis and herpes simplex.)

ftt For the current version of Sexually Transmitted Diseases Treatment Guidelines and any updated resources and support materials, please visit http://www.cdc.gov/std/treatment/.

Box 9-B. Examples of health department strategies to promote STD preventive services that may prevent HIV transmission

- Educate providers and laboratories about the following:
 - The role of STD preventive services in HIV prevention
 - The latest CDC recommendations for STD screening and treatment
 - The benefits of screening MSM for gonorrhea and chlamydial infection in nongenital sites
 - N. gonorrhoeae antimicrobial drug resistance and the need for laboratory capacity for culture and antimicrobial susceptibility testing to evaluate treatment failures
 - Voluntary health department partner services
 - Case reporting and surveillance case definitions for STD
- Educate the community about
 - the local burden of STDs
 - characteristics of persons with HIV at greatest risk for STD infection and HIV-uninfected partners at risk for HIV (e.g., MSM diagnosed with STD, especially infectious syphilis and rectal gonorrhea or chlamydial infection; young men of color; transgender persons)
 - the role of STD preventive services in clinical and nonclinical settings for HIV prevention
- Increase access to routine behavioral risk-reduction services, STD screening services, and latex or polyurethane condoms in clinical and nonclinical settings
- Increase the capacity of laboratories to screen rectal and oropharyngeal specimens for *N. gonorrhoeae* and *C. trachomatis* using NAATs and to monitor gonococcal antimicrobial drug resistance trends using culture tests

How These Recommendations Differ from Previous Recommendations

These recommendations are consistent with current federal guidance about STD risk assessment, screening, and treatment, and HIV and STD partner services for persons with HIV published through April 2014.^{1,4,7,10-14} They are also consistent with most of the latest comparable recommendations about STD services for persons with HIV of the HIV Medicine Association of the Infectious Diseases Society of America¹⁵ and the International Antiviral Society-USA Panel.¹⁶

This report updates recommendations about assessing behavioral and biologic risks for HIV and STD and STD screening from the 2003 *Recommendations for Incorporating HIV Prevention into HIV Medical Care* in several ways.¹⁷ These updated recommendations advise the following:

- Screening for gonorrhea and chlamydial infection in genital and extra-genital sites using nucleic acid amplification tests (NAATs)
- Screening for women for trichomoniasis with more sensitive tests: NAAT or culture
- Informing persons with HIV that reporting of cases of HIV, infectious syphilis, gonorrhea, and chlamydial infection by laboratories and health care providers as required by state laws may prompt health departments to offer voluntary, confidential HIV partner services in some jurisdictions
- Retesting persons diagnosed with gonorrhea, chlamydial infection, or trichomoniasis 3 months after treatment
- Using the STD treatment regimens that have been most recently recommended by the Centers for Disease Control and Prevention (CDC) that include administration of two different antimicrobial drugs for gonorrhea, one of which requires injection^{1,14}

- Providing persons with HIV who have STD symptoms or report recent sexual contact with partners treated for syphilis, gonorrhea, chlamydial infection, or trichomoniasis with access to presumptive STD treatment (while awaiting STD test results) through onsite treatment at a health care facility or immediate linkage to a health care facility that offers clinical evaluation and onsite presumptive STD treatment
- Engaging *nonclinical providers* to
 - inform sexually active persons with HIV that some STDs may increase the risk of HIV transmission and that screening for these STDs at least annually is beneficial
 - offer recommended STD screening tests using venous blood specimens or provider-initiated self-collected specimens, if feasible in the nonclinical setting, or refer *clients* to clinical settings that offer STD screening
 - promptly link persons with HIV who report symptoms of STD or sexual contact with partners treated for syphilis, gonorrhea, chlamydial infection, or trichomoniasis to health care providers who can provide clinical evaluation (including physical examination and diagnostic testing) and *presumptive treatment*^{‡‡‡} with recommended injectable or oral antimicrobial drugs
- Engaging health departments to integrate or routinely match STD and HIV surveillance data to identify populations or individuals with HIV with STD coinfection who may warrant being offered HIV and STD preventive services, including voluntary HIV partner services

Methods

The section writing group compiled recommendations on STD services and STD laboratory testing for persons with HIV from CDC, the Health Resources and Services Administration (HRSA), and the U.S. Department of Health and Human Services (HHS) published through April 2014, and these recommendations will be revised periodically. All of this federal guidance was based on systematic reviews of evidence and, when evidence was sparse or absent, expert opinion.^{1,4,7,10-14} The group also reviewed recommendations about STD screening from the 2013 guidelines of the nongovernmental HIV Medical Association of the Infectious Diseases Society of America.¹⁵ In addition, the group reviewed the following sources on the role of STD screening and treatment in preventing HIV transmission that were published from January 2010 to March 2014: 2 published systematic reviews,^{18,19} 1 published narrative review,²⁰ recent CDC programmatic guidance to *state and local health departments*,²¹ and the 2015 CDC STD Treatment Guidelines.

Evidence Supporting the Recommendations

Certain STDs have been found to increase HIV-1 DNA or RNA in persons with HIV, which may increase the risk of HIV transmission.^{18,20} A meta-analysis conducted in 2007 found that persons with HIV who had been diagnosed with urethritis, cervicitis, gonorrhea, and chlamydial infection had a 2- to 3-fold increase in the frequency of HIV shedding in the genital tract.²² Trichomoniasis in women has been associated with increased vaginal HIV shedding²³ and increased risk of perinatal HIV transmission in pregnant women with symptomatic *T. vaginalis* infection.²⁴ Studies conducted outside the United States have shown statistically significant declines in the HIV concentration in semen of men who were treated

^{***} Presumptive treatment involves providing treatment for syphilis, gonorrhea, chlamydial infection or trichomoniasis before the results of STD testing or clinical evaluation are available. This treatment approach is recommended for persons who report symptoms suggestive of these STDs or recent sex partners who were treated for these STDs, or have clinical signs of these STDs.

for urethritis associated with *N. gonorrhoeae* or trichomonas and in the vaginal fluid of women who were treated for cervicitis associated with *N. gonorrhoeae*, *C. trachomatis*, and trichomonas.²⁵⁻²⁸ Because a high proportion of persons infected with these 3 STDs may lack symptoms or signs, periodic screening with sensitive laboratory tests is needed to detect infection.^{1,4} Men and women diagnosed with gonorrhea and chlamydial infection and women diagnosed with trichomoniasis can benefit from rescreening 3 months after treatment due to high rates of reinfection or persistent infection.^{1,14,29}

A meta-analysis of 11 studies conducted in 2010 showed that HSV-2 coinfection increased plasma HIV viral load by almost a quarter log (difference in mean VL 0.22 log10 copies/mL, 95% CI: 0.04–0.40).¹⁸ However, 2 randomized controlled trials conducted from 2004–2007 did not find that acyclovir treatment of persons coinfected with HIV and HSV-2 significantly reduced the risk of HIV transmission among *HIV-discordant couples*.³⁰

Reviews of trials and observational studies conducted in low-income countries have concluded that treatment of STDs detected through screening is associated with lower rates of HIV transmission in selected populations that have high STD burden; limited access to routine screening and prompt, effective treatment; and rising HIV *prevalence*.^{19,20} However, no controlled clinical trials of U.S. populations have evaluated the role of STD screening and treatment in preventing onward HIV transmission from persons with HIV. This section's recommendations about STD screening tests, screening frequency, and STD treatment are therefore based on biologic plausibility, epidemiologic risk factor studies, prospective studies of populations that differ epidemiologically from the United States, ecologic associations in the United States, and expert opinion.

Voluntary, confidential partner services can benefit many persons with HIV and STDs and their partners.¹⁰ Nevertheless, many providers do not explain the benefits of partner services, the role of trained health department specialists, or that reporting of cases of HIV or STD by laboratories and providers can activate voluntary, confidential health department partner services.¹⁰ Persons with HIV who are aware of the benefits of partner services may be more likely to accept these services. See <u>Section 8</u>, <u>Partner Services</u>, for additional evidence supporting recommendations about partner services.

Issues that Influence Implementation of the Recommendations

Implementation progress, challenges, and opportunities

STD screening is an underused prevention strategy despite the high *incidence* of STDs in some persons with HIV, particularly men who have sex with multiple male partners. A study of 8 large HIV clinics in 6 cities from 2006–2008 found that more than 65% of HIV-infected gay, bisexual, and other men who have sex with men (MSM) were annually screened for syphilis, but only 2.3% to 8.5% were annually screened for rectal chlamydial infection and rectal and oropharyngeal gonorrhea despite moderate to high positivity rates in specimens from asymptomatic patients (3.0% to 9.8%). Rates of annual urogenital chlamydial infection or gonorrhea screening were only modestly higher (13.8% to 18.3%).³¹ Several factors may contribute to low screening rates: reluctance to collect anal and genital specimens (in contrast to syphilis serology can use venous blood collected for *CD4 cell count* and HIV viral load testing³²); incomplete sexual behavior assessments that fail to identify the need for testing rectal and oropharyngeal



specimens; limited knowledge of NAAT tests for rectal and pharyngeal specimens (including how to access tests, seek insurance coverage, and apply billing codes); and competing clinical priorities.³¹

The performance of STD screening and diagnostic tests, like that of all clinical tests, may vary by test type, specimen collection and handling, prevalence of infection in a given population, and other factors; false positive and false negative results are rare.^{1,4} These recommendations advise use of sensitive, specific commercially available NAATs to detect gonorrhea in rectal and oropharyngeal specimens and chlamydial infection in rectal specimens, although use of these tests with rectal or oropharyngeal specimens is not cleared by the U.S. Food and Drug Administration (FDA). However, several state public health and national commercial laboratories have met all CLIA regulatory requirements for off-label procedures for testing rectal and oropharyngeal specimens and billing codes have been assigned.^{1,3,33}

STD treatment is generally safe and effective and rarely results in adverse reactions.¹ Emergence of antimicrobial-resistant pathogens may impair the effectiveness of some treatments over time. For example, in 2012 CDC recommended treating *N. gonorrhoeae* with two antimicrobial drugs (at least one requiring injection) that are more effective against antimicrobial-resistant strains.¹⁴ Poor *adherence* to STD treatment can impair effectiveness.¹ Persons with HIV can become reinfected with STD if any partners diagnosed with STD are not treated or they do not take their treatment as prescribed.¹ It is therefore important to offer partner services to persons with HIV who are diagnosed with STDs so that their partners can be notified and offered testing and presumptive treatment (see <u>Section 8, Partner Services</u>).

Some health departments integrate or routinely match HIV and STD surveillance data to identify persons with HIV who warrant being offered HIV and STD preventive services.²¹ Innovations in information technology and increased use of electronic medical information under the Affordable Care Act may expedite confidential, electronic reporting of surveillance data and support the assessment and assurance functions of public health programs.³⁴

Policy, legal, and ethical considerations

State laws generally protect the confidentiality of HIV and STD information reported to health department surveillance programs that may activate voluntary, confidential health department partner services. Nevertheless, some persons with HIV who are diagnosed with an STD may feel anxious about providers reporting cases to public health authorities or notifying sex partners because an STD diagnosis in a person with HIV is an objective marker of unprotected sexual activity that may result in HIV or STD transmission.¹⁰ In some jurisdictions, duty-to-inform regulations require or allow providers to inform sex and drug-infection partners of possible HIV or STD exposure, particularly if the person with HIV was aware of their infection before the activity or the activity was not consensual.^{10,35} Some persons with HIV worry that HIV or STD case reporting by laboratories or providers or *partner notification* might breach confidentiality or, in the case of minors, prompt unwanted parental notification (see Section 8, Partner Services). Health departments use methods similar to health care providers to rigorously protect personal health information and maintain the confidentiality of surveillance case reports that can activate voluntary, confidential health department partner services; however, they may release personal health information if subpoenaed or if required to enforce duty-to-inform statutes.³⁶ Providers who are aware of and adhere to laws and regulations about minors' rights to access and consent to confidential STD

preventive services are better equipped to serve and protect the *privacy* rights of minors.¹ See Section 3, Context of Prevention, and Section 8, Partner Services, for related information.

Special populations

Persons with HIV who continue to practice HIV *risk behaviors*, *§§§* particularly unprotected sex with multiple or anonymous partners, are highly likely to be exposed to STD and may benefit from screening every 3 to 6 months instead of annually (see Box 9-A). These persons may include some MSM and substance users as well as persons who are aware that their sex partners have multiple sex partners.¹

Implementation Resources

Additional information and practical resources to support implementation of these recommendations can be found at <u>http://www.cdc.gov/hiv/guidelines/</u>.

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Risk behaviors are behaviors that can result in transmitting HIV to others or acquiring HIV through sexual contact, drug use, or during pregnancy (e.g., anal or vaginal intercourse without a barrier, sharing nonsterile drug-injection equipment).



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Section 10. Reproductive Health Care for Women and Men

Background

Reproductive health care involves several services for adults and adolescents with HIV who are of reproductive age and wish to avoid unplanned pregnancies or reduce the risk of sexual HIV transmission.¹ These services are essential because most women and men with HIV in the United States acquired HIV through sexual exposure during their reproductive years and they remain sexually active after their diagnosis.²⁻⁷ Once aware of their infection, many persons with HIV engage in safer sex practices or use contraception to prevent unintended pregnancy, but some do not. Also, members of many *HIV-discordant couples* want to have children^{8,9} and therefore may benefit from conception methods that reduce the risk of sexual HIV transmission and perinatal transmission, if pregnancy occurs. Providing reproductive health services therefore supports the rights of persons with HIV to be sexually active, to prevent or attempt conception, and to have children.

This section addresses services for persons with HIV, HIV-concordant couples (in which both members are HIV-infected), or HIV-discordant couples (in which only one member is infected):

- Assessment of reproductive plans of women and men with HIV
- Assessment of pregnancy status of women with HIV
- *Reproductive health counseling** for persons with HIV and their *partners* regardless of their pregnancy intentions
- Information and services related to contraception
- Use of effective *antiretroviral treatment (ART)* before attempting to conceive
- Information and services related to conception methods that reduce the risk of sexual and perinatal HIV transmission
- Information on unique aspects of antiretroviral prophylaxis for HIV-uninfected members of discordant couples who are not consistently and correctly using condoms or are attempting conception

This section does not provide a comprehensive summary of all reproductive services for women and men with HIV, such as counseling or screening related to smoking, alcohol, substance use, and viral hepatitis.

Quality improvement[†] and program monitoring and evaluation[‡] methods can determine if the interventions described in this section are implemented as intended, yield the expected outcomes, or warrant changes in delivery methods (see Section 13, Quality Improvement). Section 11, Pregnancy,

[‡] Monitoring and evaluation is a process that involves the repeated, ongoing collection and review of information about program activities, characteristics, and outcomes in order to assess program implementation, coverage, acceptability, cost, and effectiveness.



^{*} Reproductive health counseling for persons with HIV includes information and counseling for HIV-infected women and HIV-infected men of reproductive age and their uninfected partners about preventing unintended pregnancy; pregnancy planning and spacing; the risks of HIV transmission when attempting conception; the risk of adverse maternal or fetal outcomes should transmission occur when attempting conception or during pregnancy; and methods to reduce these risks.

[†] Quality improvement is an approach to the continuous study and improvement of the processes of providing services that meet or exceed established professional standards and user expectations.

describes methods—including use of ART—to prevent sexual or perinatal transmission of HIV during recognized pregnancies of HIV-infected women or HIV-uninfected women who have partners with HIV. Other sections cover *linkage to HIV medical care*[§] (Section 4, Linkage to and Retention in Care), general aspects of ART use and use of antiretroviral prophylaxis by HIV-uninfected partners (Section 5, Antiretroviral Treatment), methods to reduce sexual transmission of HIV (Section 7, Risk Screening and Risk Reduction), and services for sex partners of persons with HIV (Section 8, Partner Services).

Recommendations

BOX 10. RECOMMENDATIONS—REPRODUCTIVE HEALTH CARE FOR WOMEN AND MEN

For nonclinical and clinical providers (including health department staff who provide individual-level services to persons with HIV)

- Assess pregnancy status of HIV-infected women and reproductive plans of women and men with HIV, with methods and frequency as appropriate to provider role and setting (e.g., self-reported pregnancy or referral for pregnancy testing)^a (i, ii, iii)
- Provide education, reproductive health counseling^b, and/or referral for contraceptive services as appropriate to provider role and setting^a, to women and men who wish to prevent or delay future pregnancy^a (i, ii, iii)
- Advise women and men with HIV (and HIV-uninfected partners referred by them) to use latex or polyurethane male or female condoms to reduce the risk of HIV transmission and unintended pregnancy even if using medical or surgical contraception^a (i, ii, iv)
- Inform persons with HIV about the role of antiretroviral treatment (ART) in reducing sexual HIV transmission and in preventing perinatal HIV transmission^a (i, ii, iii, iv) (see <u>Box 10-A</u>)
- Inform persons with HIV (and HIV-uninfected partners referred by them) about
 - the availability of preexposure prophylaxis (PrEP)^c for HIV-uninfected partners when clinically indicated to reduce the risk of HIV acquisition when attempting conception using penile-vaginal intercourse without a condom^a (i, v, vi)
 - the availability of nonoccupational postexposure prophylaxis (nPEP)^d for HIV-uninfected partners when clinically indicated on a one-time or infrequent basis to reduce the risk of HIV acquisition in the event of inadvertent sexual or parenteral HIV exposure within the past 72 hours (e.g., unprotected intercourse, condom breakage, shared drug-injection equipment)^a (i, vi, vii)
- Refer persons with HIV who wish to conceive to health care providers skilled in reproductive health counseling^b for persons with HIV^a (i, ii) (see <u>Box 10-A</u>)
- Offer periodic HIV testing to HIV-uninfected members of HIV-discordant couples, particularly those who are attempting conception or who report unprotected intercourse^a (i)
- Become familiar with state and local laws and regulations in the jurisdiction that affect access to contraceptive services, pregnancy termination, and other reproductive health services, including access for minors without parental consent^a (viii)

[§] Linkage to care is the process of helping persons with HIV to obtain HIV medical care and prevention or social services through active methods (e.g., appointment scheduling, reminders, transportation to appointments).



BOX 10. RECOMMENDATIONS—REPRODUCTIVE HEALTH CARE FOR WOMEN AND MEN (cont)

Specific to clinical providers (in addition to above recommendations)

- Assist persons with HIV who do not wish to conceive in making informed decisions about contraception that consider
 - the benefits of dual contraceptive methods (condoms plus other contraception) (i, iii, ix, x)
 - the high efficacy and safety profile of hormonal contraception and IUDs for women with HIV^e (i, iii, ix, x)
 - the benefits of using water-based spermicides and condom lubricants that do not contain nonoxynol-9 (xi, xii)
- Inform women with HIV who are considering medically attended pregnancy termination that available evidence indicates that HIV infection does not increase the risk of complications after the procedure^f
- Offer ART and adherence support according to U.S. Department of Health and Human Services (HHS) treatment guidelines to prevent sexual transmission of HIV and, should pregnancy occur, to prevent perinatal HIV transmission^g (i, iv, vi)
- Inform women with HIV who are using or considering using ART and hormonal contraception at the same time about possible drug interactions that might influence the efficacy of the ART or the hormonal contraception (ix, x)
- Provide (in consultation with HIV care experts) or make referral for^h (see <u>Box 10-A</u>)
 - additional preconception information and counseling for persons with HIV who are considering conception (preferably with their partner's participation) (i, ii, iv, vi)
 - information about conception methods for members of HIV-discordant couples that reduce the risk of sexual transmission of HIV or, should pregnancy occur, perinatal HIV transmission (i, iv, vi)
- Offer PrEP or nPEP to HIV-uninfected partners referred by persons with HIV when clinically indicated after considering factors specific to women who may be or intend to become pregnant^{c,d} (v, vii)

For staff of health departments who provide population-level HIV prevention and care services

- Make available online directories of health care providers and professional advice hotlines that offer reproductive health services to adults and adolescents with HIV (xiii)
- Provide information to clinical providers about state and local laws regarding minors' access to and consent for reproductive health servicesⁱ (xiv)
- Prioritize health department partner services for persons with HIV or partners who may be at risk for unintended pregnancy (e.g., adolescents)^j (xv)
- Support efforts and partnerships that increase access to reproductive health services for persons with HIV, including enrollment in private or public sector health plans and use of public sector clinics that serve uninsured persons (e.g., federally funded clinics) (xvi, xvii)
- Note. Section 11, Pregnancy, contains recommendations specific to women with recognized pregnancy and their partners.
- *Note.* In this report, *nonclinical providers* are defined as persons who work in community-based organizations or health departments operating outside of health care facilities and who provide HIV testing, health education, risk-reduction interventions, partner services, case management, or assistance with linkage or referral to medical and social services. These persons include HIV testing providers, peer and professional health educators, counselors, service linkage facilitators, partner services specialists, case managers, and social workers. *Clinical providers* are defined as persons who work in health care facilities and who provide risk assessment, health education, counseling, screening, diagnosis, treatment, and other health-related services. These providers, health educators, case managers, social workers, advance practice nurses, physician assistants, dentists, mental health providers, pharmacists, health educators, case managers, social workers, and counselors. Some may be employees or contractors of health departments. Some of the recommendations specific to clinical providers with authority for clinical evaluation and examinations, diagnosis, treatment, and prescribing. Some of the federal guidelines cited in the Recommendation boxes may have been updated. For current federal recommendations, please refer to http://www.cdc.gov/hiv/guidelines/personswithhiv.html.



BOX 10. RECOMMENDATIONS—REPRODUCTIVE HEALTH CARE FOR WOMEN AND MEN (cont)

The cited source guidance that supports this recommendation was intended for health care providers. Based on opinions of the Project Workgroup, the section writing group concluded that it would be beneficial and feasible for other types of providers to implement this recommendation.

Reproductive health counseling includes information and counseling for HIV-infected women and HIV-infected men of reproductive age and their partners about preventing unintended pregnancy; pregnancy planning and spacing; the risks of HIV transmission when attempting conception; the risk of adverse maternal or fetal outcomes should transmission occur when attempting conception or during pregnancy; and methods to reduce these risks.

PrEP is the daily, continuous use of a specific regimen of antiretroviral medications for a period of time by an HIV-uninfected person to achieve levels of drug in the blood and anal and genital mucosa sufficient to reduce the risk of HIV acquisition. In July 2012, FDA approved one PrEP drug regimen for preventing sexual transmission. Although HHS recommendations in May 2014 advised use of this same regimen for persons who inject drugs, the product label only addresses use for preventing sexual transmission. See <u>Section 5</u>, <u>Antiretroviral Treatment</u>, for more information regarding the use of PrEP.

nPEP is the use of selected antiretroviral medications by HIV-uninfected persons within 72 hours after isolated, nonoccupational exposures to body fluids potentially containing HIV, such as after unprotected sexual intercourse or condom breakage, in order to reduce the risk of HIV acquisition. Use of antiretroviral medication for nPEP does not reflect labeling approved by FDA. See <u>Section 5, Antiretroviral Treatment</u>, for more information regarding the use of nPEP.

The <u>Contraceptive Services</u> topic in this section describes special considerations for the use of hormonal contraception, intrauterine devices, and spermicides by women with HIV.

- Information in the <u>Contraceptive Services</u> topic in this section supports this recommendation.
- Also see Section 5, Antiretroviral Treatment; Section 6, ART Adherence; and Section 11, Pregnancy.
- These experts may include reproductive health care providers with HIV-related experience or the Clinician Consultation Center (1-888-448-8765 or http://nccc.ucsf.edu/clinician-consultation/perinatal-hiv-aids/).
- Information in the Policy, Legal, and Ethical Considerations topic in this section supports this recommendation statement.

See <u>Section 8, Partner Services</u>, for information about expediting services for persons with HIV and their partners.

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Box 10-A. Specific topics for counseling adults and adolescents with HIV who are considering conception

Information about rights, responsibilities, and decision-making

- Rights of persons with HIV to be sexually active, to prevent and attempt conception, and to have children
- Benefits of using contraception to prevent or delay pregnancy
- Importance of notifying partners about HIV infection status
- Benefits of engaging partners in decisions about reproduction
- Benefits of screening and treatment for STDs and other genital tract infections for couples before attempting conception
- Unique needs of HIV-exposed infants, including medical assessment, postexposure prophylaxis, avoidance of breastfeeding and premasticated food, and disclosure of the infant's status to all care providers

Information about benefits, risks, and how to reduce risks

- Sexual practices and interventions that reduce risk of sexual transmission when attempting conception^a
- Factors affecting the risk of HIV transmission or acquisition should pregnancy occur, including
 - the physiologic state of pregnancy, which may increase the risk of sexual HIV transmission and acquisition
 - the use of maternal ART during pregnancy and after delivery, which can reduce the risk of sexual and perinatal transmission of HIV
 - the use of postnatal infant prophylaxis^b with antiretroviral medications, which can reduce the infant's risk of acquiring HIV
 - delivery methods that reduce perinatal transmission risk
- Benefits of initiating ART before attempting conception to maximally suppress viral load
- Availability of PrEP for HIV-uninfected persons who are attempting conception using unprotected intercourse with an HIV-infected partner^o
- Availability of nPEP for HIV-uninfected persons to reduce the risk of HIV acquisition through unprotected intercourse within the past 72 hours with an HIV-infected partner^c
- Availability of special conception methods that lower, but do not eliminate, HIV transmission risk (compared with unprotected penile-vaginal intercourse), including
 - specifically timed, periovulatory unprotected intercoursed
 - intravaginal or intrauterine artificial insemination,^e in vitro fertilization, or intracytoplasmic sperm injection^f using semen of an HIV-uninfected donor or specially processed ("washed") sperm of an HIV-infected man^{g,h}

Note. Some topics may only be suited for providers with appropriate skills and training.

Box 10-A. Specific topics for counseling adults and adolescents with HIV who are considering conception

- ^a See Section 7, Risk Screening and Risk Reduction, for more information on strategies to reduce the risk of sexual transmission of HIV.
 ^b Postnatal infant prophylaxis is the use of selected antiretroviral medications for several weeks by newborns born to women with HIV to prevent HIV acquisition.
- ² See <u>Section 5, Antiretroviral Treatment</u>, for more information on ART, nPEP, and PrEP. HHS does not recommend repeated courses of nPEP¹⁰ (e.g., for discordant couples who rarely use condoms) as a long-term means to prevent HIV acquisition. Recent HHS guidance recommends consideration of PrEP as one of several options to protect HIV-uninfected partners in HIV-discordant couples from acquiring HIV infection when attempting to conceive.^{11,12}
- Timed, periovulatory intercourse is a conception method intended to reduce the risk of HIV transmission in HIV-discordant couples in which unprotected intercourse occurs only when infected partners have achieved maximal viral suppression, the woman is in the periovulatory period of her menstrual cycle, and condoms are used at all other times.
- ² Artificial insemination (intravaginal and intrauterine) is a conception method in which semen is collected and instilled into the uterus (by a physician) or into the upper vagina (by a physician, person with HIV, or partner).
- ^f Intracytoplasmic sperm injection is an in vitro fertilization procedure in which specially prepared ("washed") sperm of a man with HIV is injected directly into an egg retrieved from an ovarian follicle to achieve fertilization while minimizing the risk of HIV transmission to the female partner.
- ^g Sperm washing is a procedure that removes components (including seminal fluid that may contain HIV) other than sperm from a semen sample before it is used for artificial insemination. As of April 2013, the U.S. Food and Drug Administration has not reviewed sperm preparation procedures of HIV-infected men.
- ^h The <u>Evidence</u> topic in this section describes special conception methods to reduce the risk of HIV transmission that are recommended by HHS.

How These Recommendations Differ from Previous Recommendations

The recommendations in this section greatly expand on the only recommendation about reproductive health in the 2003 *Recommendations for Incorporating HIV Prevention into HIV Medical Care:* referring women with HIV for contraception and reproductive health services.¹³ These recommendations are consistent with current HIV-related federal guidelines about assessment of pregnancy status and reproductive health services,¹⁴ avoidance of *nonoxynol-9*–containing spermicides,¹⁵ behavioral methods to prevent HIV transmission, ART use to prevent sexual and perinatal HIV transmission,^{10-12,14,16-19} reproductive health counseling,^{11,14,18} and conception methods that reduce the risk of HIV transmission.^{11,14,17,20} The recommendations in this section are also consistent with the latest comparable recommendations of these nongovernmental organizations: the American College of Obstetricians and Gynecologists;²¹ the HIV Medicine Association of the Infectious Diseases Society of America;²² and the International Antiviral Society-USA Panel.^{23,24}

However, these updated recommendations provide new guidance for

- *nonclinical providers* to ask about pregnancy status and reproductive health plans and to refer *clients* to reproductive health counseling, contraceptive services, and other reproductive health care
- nonclinical and *clinical providers* to inform persons with HIV about
 - the benefits of ART for preventing HIV transmission in HIV-discordant couples who have *unprotected sex*** or are attempting conception

^{**} Sexual activity without using a physical barrier (i.e., penile sex without using a male condom; vaginal sex without using a male or female condom; oral-anal contact without using a dental dam or other barrier device; vaginal-digital contact without using a female condom, latex glove, or finger cot; or rectal-digital contact without using a latex glove or finger cot).



- the availability of *preexposure prophylaxis* (PrEP) and *nonoccupational postexposure prophylaxis* (nPEP) for HIV-uninfected partners when clinically indicated to reduce the risk of HIV acquisition
- health department staff to provide information to clinical providers about state laws regarding minors' access to and consent for reproductive health services

Methods

The section writing group based these recommendations on the latest guidance from the Centers for Disease Control and Prevention (CDC), the Health Resources and Services Administration (HRSA), and other federal agencies through May 2014. Those recommendations were based on a large body of scientific evidence and extensive experience of clinical experts.^{10-15,17,18,25} The writing group that compiled these recommendations did not reexamine the evidence supporting this federal guidance, but examined additional evidence from three other sources:

- Systematic reviews and meta-analyses from the CDC HIV/AIDS Prevention Research Synthesis (PRS) project's cumulative HIV/AIDS/STD prevention database identified using these search terms: *HIV infection* and *reproductive health*, *women*, *contraception*, *family planning*, *birth control*, and *reproductive health counseling* (see Section 2, Methods)
- Reviews of the publications referenced in the search results
- Narrative reviews of selected topics not addressed by federal guidelines listed above that were based on searches in PubMed, in OVID, and of scientific meeting abstracts published from 2000– 2013 using these terms: *HIV infection, family planning, reproductive health, nonoxynol-9, lubricants, sperm washing, artificial insemination, contraception, and birth control*

Evidence Supporting the Recommendations

This topic summarizes key evidence that supports the federal guidance on which the recommendations in this section are based or that was identified from the 3 additional sources described above.

Assessing pregnancy status, reproductive plans, and reproductive health service needs

Providers who routinely assess pregnancy status and the reproductive plans of persons with HIV are able to offer them reproductive health information, counseling, and services that enable them to make well-informed reproductive decisions that may reduce the risk of sexual and perinatal transmission of HIV.¹¹ This information and counseling also provides the opportunity to correct misperceptions about HIV *transmission risks* and options for contraception and conception.^{11,16} Federal guidance recommends including both members of the couple when possible to encourage shared decision making and cooperation.

Nonclinical providers can assess reproductive plans by asking about contraceptive use and current or planned pregnancies during *risk screening*,^{††} risk-reduction interventions, or making *referrals*^{‡‡} for other medical and social services (see Section 7, Risk Screening and Risk Reduction, and Section 12, Other Medical and Social Services). Clinical providers can assess reproductive plans and offer reproductive health counseling when providing HIV care, pregnancy testing, family planning, STD screening, cervical cancer screening, or other routine services. Providers who address assisted conception methods may benefit from consulting with the Clinician Consultation Center^{§§} or local reproductive health and HIV experts who can offer clinical experience and information about the latest technologies.

Use of antiretroviral medication for sexually active persons of reproductive age

Use of ART by persons with HIV

Current HHS recommendations and subject matter experts advise that health care providers offer ART to all persons with HIV to prevent sexual HIV transmission regardless of the use of condoms or other contraception.^{11,26} These recommendations also advise prescribing ART before persons with HIV attempt to conceive to provide time to maximally suppress *viral load*.^{11,14} The recommendations also state that women attempting conception should avoid starting agents with a potential increased risk of maternal complications should pregnancy occur (e.g., hepatotoxicity associated with initiation of nevirapine in women with *CD4 cell counts* of >250 cells/mm^3) or a potential increased risk of teratogenicity (e.g., efavirenz). However, women who present for prenatal care in the first trimester and are virologically suppressed while taking efavirenz can continue this medication.¹¹ In addition, HIV-infected members of HIV-discordant couples should not share their ART medication with uninfected partners who are seeking nPEP or PrEP. Sharing may impair *adherence* of the person with HIV, and regimens suitable for treating persons with HIV may not be suitable for HIV-uninfected partners (see <u>Section 5, Antiretroviral Treatment</u>).^{11,14}

Nonoccupational postexposure prophylaxis (nPEP) for HIV-uninfected partners of persons with HIV

An isolated, inadvertent episode of condom failure during intercourse within the past 72 hours with an HIV-infected partner may be an indication for nPEP.¹⁰ Current HHS recommendations state that isolated nPEP use is not contraindicated in women with suspected or confirmed pregnancy, but potentially teratogenic regimens should be avoided.¹⁰ However, these recommendations do not support repeated use of nPEP while an HIV-discordant couple is attempting conception through repeated acts of unprotected intercourse. Rather, HIV-discordant couples attempting to conceive should consider other conception

SS Clinician Consultation Center staff includes OB/GYNs, infectious disease specialists, internists, family practitioners, and clinical pharmacists at the University of California, San Francisco (1-888-448-8765 or <u>http://nccc.ucsf.edu/clinician-consultation/perinatal-hivaids/</u>).



Risk screening is a brief assessment of behavioral factors that may affect the risk of exposing others to HIV, such as inconsistent condom use or sharing drug-injection equipment, and biomedical factors that influence HIV transmission, such as viral load, antiretroviral treatment and adherence, sexually transmitted disease, and pregnancy. Risk screening is used to identify behavioral or biomedical risk-reduction interventions suited to a specific individual.

Referral is a process to help persons identify and access needed services by offering the service provider's address, phone number, directions, hours of operation, and other basic information.

methods that do not require unprotected intercourse (e.g., intrauterine insemination and *in vitro* fertilization) or the use of PrEP to prevent HIV acquisition (see <u>Section 5, Antiretroviral Treatment</u>).^{11,12}

Preexposure prophylaxis (PrEP) for HIV-uninfected partners of persons with HIV

The use of PrEP can reduce the risk of HIV acquisition by HIV-uninfected sex partners when attempting to conceive with a person with HIV.^{11,12} Current federal guidance recommends that providers address the use of PrEP with HIV-uninfected members of HIV-discordant couples who are attempting conception because of their risk of HIV acquisition (see Section 5, Antiretroviral Treatment). Current federal guidance and additional expert opinion also recommend that health care providers inform persons using PrEP that the effects of fetal exposure to PrEP are not yet fully assessed but that no harm has been reported to date.^{12,27}

Contraceptive services

Offering contraceptive services to sexually active persons with HIV who want to avoid, delay, or space pregnancies is essential, especially given the high proportion of women with HIV who report unintended pregnancies.²⁸ Current HHS recommendations and other evidence reviewed by the writing group indicate that contraceptive methods available in the United States are generally safe in women with HIV.^{17,18,29-33} Evidence-based*** criteria regarding medical eligibility for contraception for women with HIV are detailed in other documents.^{17,20} In brief, condoms, when used consistently and correctly, are effective 1) for contraception, 2) in preventing HIV transmission to HIV-uninfected partners, 3) in preventing HIV superinfection^{†††} of persons already infected with other HIV strains,^{21,34} and 4) in preventing other STDs. Current HHS recommendations conclude that concurrent use of barrier contraception, such as male or female condoms, and nonbarrier contraception, such as hormonal contraception and IUDs, is more effective in preventing pregnancy than using a single contraceptive method and reduces the risk of sexual transmission of HIV.^{11,14} Several methods are more than 99% effective in preventing pregnancy when used correctly with all acts of intercourse, but no contraceptive method, including male and female condoms, hormonal contraception, or IUDs, is 100% effective in preventing pregnancy.^{33,35} Many persons with HIV rely on ART to reduce the risk of transmitting HIV to others, especially when not routinely using condoms or when attempting conception using unprotected intercourse.

Hormonal contraception

Research studies identified through the systematic and narrative reviews and clinical experience (including postmarketing drug safety *surveillance*) indicate that hormonal contraception (including pills, injectables, rings, patches, implants, and *emergency postcoital contraception*^{‡‡‡}) is generally safe, effective, and suitable for HIV-infected women.^{30-32,36,37} Oral contraceptives are generally not contraindicated in HIV-infected women because they have not been shown to increase HIV progression or transmission, increase viral load, or reduce absolute CD4 cell count levels.^{17,29-31,38} However, a few oral contraceptives and some antiretroviral medications may interact with each other.^{14,16,39-43} For example,

^{‡‡‡} Emergency postcoital contraception is a type of oral hormonal contraception used within a few days after intercourse that is intended to prevent pregnancy by disrupting ovulation or fertilization.



^{***} Evidence-based interventions, strategies, guidelines, and recommendations are based on sound scientific research, testing, or program evaluation.

⁺⁺⁺⁺ HIV superinfection is the acquisition of another HIV strain that may reduce the effectiveness of HIV treatment if new, drug-resistant HIV strains are acquired.

women taking certain classes of antiretroviral medication (protease inhibitors or nonnucleoside reverse transcriptase inhibitors) may experience changes in levels of ethinyl estradiol and norethindrone found in some oral contraceptives. Decreased levels may reduce contraceptive effectiveness, while increased levels may increase adverse effects of oral contraception. HHS recommendations also note that some oral contraceptives may decrease levels of some antiretroviral medications and that potential pharmacokinetic interactions should guide ART and contraception choices.¹⁶ However, the recommendations state that concerns about possible drug interactions should not deter health care providers from recommending hormonal contraception to women taking ART. These recommendations highlight the benefits of informing women about 1) potential interactions between ART and hormonal contraception and 2) the use of hormonal contraception that may be used with condoms as a dual contraception strategy to avoid unintended pregnancy and perinatal HIV transmission.¹⁷

Little is known about how ART interacts with non-oral hormonal contraceptives.^{17,37,44} The fact that some non-oral contraceptives have lower systemic absorption than oral contraceptives, act locally, and in some cases do not depend on first-pass metabolism suggests that interactions with ART may be less likely than with oral contraceptives. Recent studies have raised questions about whether the use of depot medroxyprogesterone acetate, the injectable progesterone-only contraceptive agent available in the United States, may increase the risk of transmitting HIV to male sex partners or the risk of women acquiring HIV infection.^{37,45} Because the evidence remains inconclusive, CDC and the World Health Organization recently recommended that women with HIV who use this injectable contraceptive should ensure that male or female condoms are consistently used during intercourse.^{17,44}

Intrauterine devices (IUDs)

Two studies have shown that IUDs available in the United States (copper-releasing IUDs and levonorgestrel-releasing IUDs) are safe for HIV-infected women without *AIDS* who can regularly access providers to monitor for IUD-related complications, including possible infection.^{32,46} Clinical trials indicate these IUDs do not influence cervicovaginal shedding of HIV or increase risk of HIV transmission to sex partners.^{47,48} Current CDC recommendations state that IUD insertion and use are generally safe for women with HIV and that HIV-infected IUD users have no higher risk of IUD-related complications than HIV-uninfected IUD users. However, women with AIDS who are taking ART and not clinically well should generally not undergo IUD insertion, because the risk of pelvic infection outweighs the benefits of effective contraception.²⁰

Other contraceptive methods

HHS recommendations advise against use of spermicides and anal and genital lubricants containing nonoxynol-9 because when used frequently, long-term, or in high doses they can cause genital irritation and inflammation, which may increase the risk of HIV transmission.^{15,18,25}

HHS recommendations and studies identified through the narrative review indicate that voluntary tubal sterilization and vasectomy are safe, effective contraceptive methods for HIV-infected women and men, respectively.^{17,29,49}

Pregnancy termination

One study identified in the narrative review found that HIV-infected women do not have a higher *prevalence* of postabortion complications after medically attended surgical abortion than HIV-uninfected women; this finding supports the recommendation to inform HIV-infected women who are considering medically attended pregnancy termination that available evidence indicates that HIV infection does not increase the risk of complications after the procedure.⁵⁰ Women with HIV who undergo termination procedures should defer vaginal sexual contact until bleeding has ceased and healing is complete to lower the risk of HIV transmission to others.

Conception methods that reduce the risk of sexual and perinatal transmission in HIV-discordant couples

Current HHS guidelines recommend consideration of special conception options (preferably after expert consultation) that have been shown to reduce the risk of HIV transmission in HIV-discordant couples attempting conception.¹¹

- For couples who prefer natural conception after having received information and counseling about the risks of sexual transmission and perinatal transmission (should pregnancy occur) and assisted conception methods, these options include
 - *timed, periovulatory unprotected intercourse* after the partner with HIV has achieved maximal viral suppression through ART and the use of male or female condoms with all other acts of intercourse¹¹
 - the use of PrEP to further reduce the risk of HIV acquisition by the HIV-uninfected male or female partner during unprotected intercourse.¹²
- For couples in which the man is HIV-infected and can access assisted conception methods, these options include
 - preconception semen analysis to determine semen volume and any abnormal sperm characteristics that may influence conception decisions (because repeated semen exposure could result in HIV infection but not lead to conception or a viable fetus)¹¹
 - intrauterine artificial insemination,^{§§§} in vitro fertilization, or intracytoplasmic sperm injection,**** using semen or sperm from an HIV-uninfected donor, or if donor semen or sperm is an unacceptable option, sperm from the HIV-infected man that has undergone procedures^{††††} that remove seminal fluid that may contain HIV ("sperm washing")^{11,51-54}
- For couples who use natural or assisted conception methods that involve exposure to potentially HIV-infected semen or other genital secretions, periodic HIV testing of HIV-uninfected partners to identify early infection and to hasten linkage to HIV medical care is warranted.¹¹

The availability, insurance coverage, and affordability of these methods may vary by the individual's area of residence and health insurance status.

^{****} As of April 2013, the U.S. Food and Drug Administration has not reviewed preparation procedures of semen from men with HIV.



Intrauterine artificial insemination is a conception method in which semen is collected and instilled into the uterus by a clinician.

^{****} Intracytoplasmic sperm injection is an *in vitro* fertilization procedure in which specially prepared ("washed") sperm of a man with HIV is injected directly into an egg retrieved from an ovarian follicle to achieve fertilization while minimizing the risk of HIV transmission to the female partner.

Issues that Influence Implementation of the Recommendations Implementation progress, challenges, and opportunities

Recent surveys indicate that 57% to 84% of all women with HIV report consistent condom use, depending on the HIV status of the sex partner.⁵⁵ However, less than 30% of women with HIV currently use condoms or other contraception; and use of ART does not influence prevalence of current contraceptive use.^{49,55,56} Also, about half of sexually active adolescents with HIV report engaging in unprotected sex after learning they are infected.⁵⁶ As with American women overall (in whom about half of pregnancies are unintended), unplanned pregnancies are common among women with HIV.^{28,57,58}

These findings underscore the benefits of expanding reproductive health care services to persons with HIV. Implementation of the Patient Protection and Affordable Care Act and continued support for federally funded family planning programs are expected to improve access to family planning and reproductive health services, including some assisted conception methods.^{59,60} However, access to health care providers with experience in reproductive health counseling, contraceptive methods, and assisted conception methods may continue to be limited for persons who do not have health insurance or who live in rural or other medically underserved areas.^{61,62} Primary care providers seeking information about reproductive considerations for persons with HIV can consult the Clinician Consultation Center (1-888-448-8765 or http://nccc.ucsf.edu/clinician-consultation/perinatal-hiv-aids/).⁶³

Policy, legal, and ethical considerations

Laws and regulations about consent, *confidentiality*, parental *disclosure*, and disease reporting for minors who seek family planning, pregnancy termination, or other sexual and reproductive health services vary by jurisdiction. Some states permit minors to receive a wide variety of sexual and reproductive health services without parental consent.⁶⁴ Providers who discuss sexuality, sexual behavior, and reproductive choices using a neutral, nonjudgmental style may elicit accurate information and foster autonomy in health decisions. Motivating persons with HIV to use sexual risk-reduction methods decreases the risk of exposing partners to HIV and the negative reactions, conflict, and legal disputes that may follow. See Section 3, Context of Prevention, and Section 8, Partner Services, for more information about legal and ethical issues related to HIV disclosure and notification of partners.

Special populations

Adolescents with HIV have high rates of unintended pregnancy. Navigating multiple health care providers is difficult, but these adolescents can benefit from linkage to HIV medical care providers who also provide reproductive health services.^{57,65} Expediting access to reproductive health services is also important for *transgender* persons, migrants, women at risk for sexual violence, sex workers, and others who may use contraception inconsistently or have trouble finding confidential or affordable health care.^{56,66} Integrating reproductive and HIV services within the same health care facility and cross-training HIV providers and reproductive health care providers may increase capacity for reproductive services and more comprehensive "medical homes" for persons with HIV.

Implementation Resources

More information on implementation, including training materials and decision-support tools, can be found at <u>http://www.cdc.gov/hiv/guidelines/</u>.

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Section 11. HIV Prevention Related to Pregnancy

Background

Specific prevention considerations are relevant for women who become infected with HIV during pregnancy or the postpartum period. Several interventions can reduce the risk of 1) sexual HIV transmission from pregnant women with HIV or to uninfected pregnant women and 2) perinatal transmission during pregnancy, labor, delivery, and the postpartum period, as well as during breastfeeding. *Unprotected sexual activity* may occur during pregnancy, especially when *partners* are no longer using condoms for contraception purposes.¹ Furthermore, the physiologic state of pregnancy may increase the risk of sexual HIV transmission both from HIV-infected pregnant women to uninfected male partners² and from HIV-infected male partners to uninfected pregnant women.² This increased risk may be due to changes in systemic or genital mucosal immunity, HIV shedding or virulence, HIV coreceptors, or other factors.² The initiation of prenatal care, here defined as health care for women with a recognized pregnancy, also provides opportunities for informing pregnancy. This care also enables offering HIV testing and retesting to sex partners of persons with HIV who are uninfected or have an unknown infection status.

This section addresses methods to reduce 1) HIV transmission from women with HIV and recognized pregnancies and 2) HIV acquisition by HIV-uninfected women with recognized pregnancies. *However, this section does not provide a comprehensive summary of all prevention and care services for pregnant women with HIV and their partners.*

*Quality improvement** and program *monitoring and evaluation*[†] methods can determine if the interventions described in this section are implemented as intended, yield the expected outcomes, or warrant changes in delivery methods (see Section 13, Quality Improvement). Other sections describe

- General aspects of antiretroviral treatment (ART) and prophylaxis by HIV-uninfected partners (Section 5, Antiretroviral Treatment);
- General aspects of adherence to ART (<u>Section 6, ART Adherence</u>)
- Contraception services and *reproductive health counseling^t* that can be provided in the postpartum period (<u>Section 10, Reproductive Health Care</u>)
- Behavioral risk-reduction interventions, including those for HIV-infected partners of pregnant women (Section 7, Risk Screening and Risk Reduction)
- Sexually transmitted disease (STD) services, including screening pregnant women for STD pathogens (Section 9, STD Services)

[‡] Information and counseling for HIV-infected women and HIV-infected men of reproductive age and their partners about preventing unintended pregnancy; pregnancy planning and spacing; the risks of HIV transmission when attempting conception; the risk of adverse maternal or fetal outcomes should transmission occur when attempting conception or during pregnancy; and methods to reduce these risks.



^{*} Quality improvement is an approach to the continuous study and improvement of the processes of providing services that meet or exceed established professional standards and user expectations.

[†] Monitoring and evaluation is a process that involves the repeated, ongoing collection and review of information about program activities, characteristics, and outcomes in order to assess program implementation, coverage, acceptability, cost, and effectiveness.

- Partner services,[§] including identification and notification of sex and *drug-injection partners* of HIV-infected women who are pregnant or of pregnant sex and drug-injection partners of persons with HIV (Section 8, Partner Services)
- Linkage to HIV care** of pregnant women with HIV (Section 4, Linkage to and Retention in Care)

Recommendations

BOX 11. RECOMMENDATIONS—HIV PREVENTION RELATED TO PREGNANCY

These recommendations apply to nonclinical and clinical providers (including health department staff) serving

- HIV-infected pregnant women (i, ii) (see <u>Box 11-A</u>, <u>Box 11-D</u>)
- HIV-infected women who have delivered live-born infants (ii) (see <u>Box 11-B</u>)
- HIV-uninfected pregnant women with HIV-infected partners (i) (see <u>Box 11-C</u>, <u>Box 11-D</u>)

Note. Section 10, Reproductive Health Care, includes recommendations for HIV-infected women who are not pregnant or have early, unrecognized pregnancies. Some of the recommendations specific to clinical providers can only be implemented by clinical providers with prescribing authority. Some of the federal guidelines cited in the Recommendation boxes may have been updated. For current federal recommendations, please refer to http://www.cdc.gov/hiv/guidelines/.

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Box 11-A. Recommended services for pregnant women with HIV

For nonclinical and clinical providers (including health department staff who provide individual-level services to persons with HIV)

- Promptly link women to HIV medical care, preferably to settings where providers have expertise in managing
 pregnancy in women with HIV^{a,b} (i, ii, iii, iv)
- Inform women (and their sex partners who are aware of the woman's infection status) about risks of perinatal and sexual HIV transmission^{a,c,d} (i, ii, iii, v) (see Box 11-D)
- Support adherence to antiretroviral treatment (ART) during the prenatal and postnatal periods for optimal maternal health and prevention of perinatal and sexual transmission^a (ii, v, vi)
- Inform women and HIV-uninfected partners they refer about
 - the availability of preexposure prophylaxis (PrEP)^e for HIV-uninfected partners when clinically indicated to reduce the risk of HIV acquisition during unprotected sexual intercourse^{a.c.f} (ii)
 - the availability of nonoccupational postexposure prophylaxis (nPEP)^g for HIV-uninfected partners to reduce the risk of HIV acquisition in the event of inadvertent sexual or parenteral HIV exposure within the past 72 hours (e.g., unprotected intercourse, condom breakage, shared drug-injection equipment)^{a,c,f} (vii)

^{**} Linkage to care is the process of helping persons with HIV to obtain HIV medical care and prevention or social services through active methods (e.g., appointment scheduling, reminders, transportation to appointments).



Partner services includes an array of voluntary services for persons with HIV or STD and their sex and drug-injection partners that are intended to reduce HIV transmission: interviewing persons with HIV to obtain information to contact or locate their sex and drug-injection partners; notifying partners of possible HIV exposure; offering testing for HIV, sexually transmitted diseases, and other infections; providing condoms, prevention information, and counseling; and providing help in obtaining risk-reduction services, HIV medical care, and other medical and social services.

Box 11-A. Recommended services for pregnant women with HIV (cont)

- Offer women support, information, and assistance to notify their sex and drug-injection partners about their HIV status^{a,c,h} (iii)
- Advise women to urge sex partners and drug-injection partners to get HIV testing and to use condoms to prevent HIV acquisition^{a,c} (ii, v)
- Offer latex or polyurethane male and/or female condoms^a (i)
- Inform women and their partners that breastfeeding by HIV-infected women is not recommended in the United States and that formula feeding is recommended for the infants of these women^a (i, ii)
- Provide education, counseling and/or referral for postpartum contraception services for women who wish to prevent or delay future pregnancy, as appropriate to the setting^a (ii, v)

Specific to clinical providers (in addition to above recommendations)

- Offer an ART regimen during the prenatal, intrapartum, and postpartum periods, regardless of maternal CD4 cell count, to prevent perinatal transmission and thereafter for the woman's health and to prevent HIV transmission to others, according to U.S. Department of Health and Human Services (HHS) recommendations (i, ii, v, vi) (see Box 11-D)
- Inform women about options for free or subsidized ART, such as AIDS Drug Assistance Program (ADAP) or pharmaceutical drug assistance programs to help address financial concerns that may deter ART use (i)
- Screen and treat women for STDs that may increase risk of HIV transmission during pregnancyⁱ (iii, v, vii)
- Do not use invasive prenatal and intrapartum procedures (e.g., amniocentesis, chorionic villous sampling, amniotomy, and transvaginal instrumentation) unless women have started an effective ART regimen and are, ideally, virally suppressed at the time of the procedure as these procedures may increase fetal exposure to maternal blood thereby increasing the risk of perinatal transmission (i, ii)
- Inform women of delivery options that can reduce the risk of perinatal transmission (ii)
- Discuss risks and benefits of cesarean delivery and recommend scheduled cesarean delivery at 38 weeks gestation for women with suboptimal viral suppression near the time of delivery (i.e., HIV RNA levels >1000 copies/mL) (i, ii)
- Notify infant health care providers of impending birth of HIV-exposed infants and any anticipated complications
 (ii)

For staff of health departments who provide population-level HIV prevention and care services

- Make available online directories of health care providers and professional advice hotlines that offer pregnancy services to women with HIV (iv)
- Provide information to clinical providers about state laws regarding consent for HIV testing during the perinatal period and minors' access to and consent for pregnancy servicesⁱ
- Prioritize health department partner services for pregnant women with HIV^k (iii)
- Support efforts and partnerships that increase access to pregnancy and perinatal services for persons with HIV, including enrollment in private insurance or medical assistance programs and use of public sector clinics (e.g., federally funded clinics) (ix, x, xi)
- *Note.* In this report, *nonclinical providers* are defined as persons who work in community-based organizations or health departments operating outside of health care facilities and who provide HIV testing, health education, risk-reduction interventions, partner services, case management, or assistance with linkage or referral to medical and social services. These persons include HIV testing providers, peer and professional health educators, counselors, service linkage facilitators, partner services specialists, case managers, and social workers. *Clinical providers* are defined as persons who work in health care facilities and who provide risk assessments, health education, counseling, disease screening, diagnosis, and treatment; and other health-related services. These providers, physicians, registered nurses, advance practice nurses, physician assistants, dentists, mental health providers, pharmacists, health educators, case managers, social workers, and counselors. Some may be employees or contractors of health departments. Some of the recommendations specific to clinical providers apply only to clinical providers with authority for clinical evaluation and examinations, diagnosis, treatment, and prescribing. Some of the federal guidelines cited in the Recommendation boxes may have been updated as of present. For current federal recommendations, please refer to http://www.cdc.gov/hiv/guidelines/personswithhiv.html.

Box 11-A. Recommended services for pregnant women with HIV (cont)

- The cited source guidance that supports this recommendation was intended for health care providers. Based on opinions of the Project Workgroup, the writing group for this section concluded that it would be beneficial and feasible for other types of providers to implement this recommendation.
- This includes women with preliminary or confirmed HIV positive test results.
- A woman with HIV must explicitly grant her provider permission to discuss her HIV infection status with her partners.
- See Section 5, Antiretroviral Treatment; Section 7, Risk Screening and Risk Reduction; and Section 8, Partner Services.
- ^e PrEP is the daily, continuous use of a select regimen of antiretroviral medications for a period of time by an HIV-uninfected person to achieve levels of drug in the blood and anal and genital mucosa sufficient to reduce the risk of HIV acquisition.³ In July 2012, FDA approved one PrEP drug regimen for preventing sexual transmission. Although HHS recommendations in May 2014 advised use of this same regimen for persons who inject drugs, the product label only addresses use for preventing sexual transmission.
- See Section 5, Antiretroviral Treatment, for information about notifying HIV-uninfected partners about PrEP and nPEP. The cited source guidance advises health care providers to inform HIV-uninfected persons about these interventions, but does not address the role of health care providers in informing HIV-infected persons about the use of PrEP or nPEP by their uninfected partners.
- ³ nPEP is the use of selected antiretroviral medications by HIV-uninfected persons within 72 hours after isolated, nonoccupational exposures to body fluids potentially containing HIV, such as after unprotected sexual intercourse or condom breakage, in order to reduce the risk of HIV acquisition.⁴ Use of antiretroviral medication for nPEP does not reflect labeling approved by FDA.
- See Section 3, Context of Prevention, and Section 8, Partner Services.
- See Section 9, STD Services.
- The <u>Policy, Legal, and Ethical Considerations</u> topic describes the benefits of awareness of testing laws. For a summary of state HIV testing regulations, see "Compendium of state HIV testing laws" (<u>http://nccc.ucsf.edu/clinical-resources/hiv-aids-resources/state-hiv-testing-laws/</u>).⁵ For a summary of minors' access to reproductive health services, see "An Overview of Minors' Consent Law" (<u>http://www.cuttwool.com.edu/clinical-resources/state-hiv-testing-laws/</u>).⁵ For a summary of minors' access to reproductive health services, see "An Overview of Minors' Consent Law"
- (http://www.guttmacher.org/statecenter/spibs/spib_OMCL.pdf).6
- See <u>Section 8, Partner Services</u>, for information about expediting services for persons with HIV and their partners.

Sources

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Box 11-B. Recommended postnatal services for women with HIV and their infants to reduce the risk of perinatal HIV transmission

For nonclinical and clinical providers (including health department staff who provide individual-level services to persons with HIV) serving postpartum women with HIV or their HIV-exposed infants

- Assist women to obtain regular HIV care and in adhering to their prescribed ART regimen to maximize their health^a (i, ii)
- Advise women with HIV not to breastfeed (even if taking ART) and provide information about how to obtain formula^a (i, ii)
- Advise women with HIV not to donate their breast milk to breast milk banks^a (iii)
- Advise caregivers with HIV not to prechew food for infants and children^a (ii, iv, v)
- Provide education, counseling, and/or referral for postpartum contraceptive services to women who wish to
 prevent or delay future pregnancy, as appropriate to the setting^a (ii)

Specific to clinical providers (in addition to above recommendations)

- Offer a 6-week, postnatal infant prophylaxis with antiretroviral medications according to HHS guidelines within 12 hours of birth to all HIV-exposed infants^b (ii)
- Provide infant caregivers information about the importance of adherence to postnatal infant prophylaxis and about services to support adherence^c (ii)
- Consider virologic testing^d of HIV-exposed infants within 24 hours at birth to monitor infant's infection status, especially when maternal virologic control during pregnancy was poor or if adequate follow-up of the infant may not be assured (i, ii)
- Assist parent or guardian in obtaining health care for the HIV-exposed newborn to monitor newborn's infection status (i, ii)
- Offer repeated virologic tests to the infant at ages 14 to 21 days, 1 to 2 months, and 4 to 6 months to assess the presence of HIV infection before 18 months of age (ii)
- Report cases of perinatally exposed or HIV-infected infants to health departments according to local requirements for HIV disclosure, confidentiality, and case reporting^e (vi)

For staff of health departments who provide population-level HIV prevention and care services

- Conduct surveillance for HIV-exposed infants (vi)
- If allowed in jurisdiction, use surveillance data for public health purposes (e.g., contacting health care providers who report cases of HIV-exposed infants) to ensure that (vii)
 - the infant's infection status is later ascertained and, if infected, ensure that the infant receives clinical care (including the offer of treatment) and the confirmed case is reported to the health department
 - the mother's HIV infection status is documented and the mother is offered help with starting HIV medical care^f

- ^d Such as nucleic acid amplification test for HIV RNA or DNA, according to HHS guidelines.⁷
- For state and territorial case reporting requirements, see guidance of CDC and the Council of State and Territorial Epidemiologists.^{8,9}
 Authorized uses of perinatal surveillance data vary by jurisdiction.⁹

^a The cited source guidance that supports this recommendation was intended for health care providers. Based on opinions of the Project Workgroup, the writing group for this section concluded that it would be beneficial and feasible for other types of providers to implement this recommendation.

^b Postnatal infant prophylaxis is the use of selected antiretroviral medications for several weeks by newborns born to women with HIV to prevent HIV acquisition. HHS guidelines describe specific regimens.⁷

^c The source guidance addresses initiation of postnatal infant prophylaxis and use of a 6-week regimen, but does not address infant adherence support.

Box 11-B. Recommended postnatal services for women with HIV and their infants to reduce the risk of perinatal HIV transmission *(cont)*

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Box 11-C. Recommended services for pregnant women who are HIV-uninfected or have unknown infection status and have sex or drug-injection partners with HIV

For nonclinical and clinical providers (including health department staff who provide individual-level services to persons with HIV) serving pregnant women or their HIV-infected partners

- Inform women and their partners about risks of sexual acquisition of HIV and, should infection occur, the risk of
 perinatal transmission, including transmission during breastfeeding^a (i, ii) (see <u>Box 11-D</u>)
- Encourage consistent, correct condom use throughout pregnancy and breastfeeding to prevent sexual and/or perinatal transmission^a (i, ii)
- Inform women that HIV testing is recommended for all pregnant women and provide information about the test (ii, iii).
- Conduct HIV testing using consent procedures consistent with state laws (e.g., inform women in states that allow opt-out testing that testing is done as part of the routine panel of prenatal tests unless they decline; obtain prior written consent if required by state law^b) (ii, iii)
- Address reasons for declining an HIV test (e.g., lack of perceived risk, fear of the disease, and concerns regarding partner violence, stigma, or discrimination) (ii, iii)
- Inform women about the symptoms of acute retroviral syndrome and the availability of tests for acute HIV infection if these symptoms occur or if a woman suspects recent HIV exposure^a (ii, iii)
- If serving HIV-infected partners of pregnant women, link partners who are not engaged in HIV medical care to health care providers who can recommend ART to reduce the risk of HIV transmission and support ART adherence^a (iv)
- Inform HIV-uninfected women who are considering starting or continuing use of PrEP during pregnancy or breastfeeding that pregnancy is not a contraindication for PrEP and provide information about known benefits and risks of PrEP to the woman and fetus to enable informed decision making^c (ii, v, vi)
- Inform women about the availability of nPEP to reduce the risk of HIV acquisition in the event of inadvertent sexual or parenteral HIV exposure within the past 72 hours (e.g., unprotected intercourse, condom breakage, shared drug-injection equipment)^c (v)
- Provide education, counseling, and/or referral for postpartum contraceptive services to women who wish to
 prevent or delay future pregnancy, as appropriate to the setting^{a,d} (vii, viii, ix)
- Offer latex or polyurethane male and/or female condoms (i)

Box 11-C. Recommended services for pregnant women who are HIV-uninfected or have unknown infection status and have sex or drug-injection partners with HIV *(cont)*

Specific to clinical providers (in addition to above recommendations)

- Include HIV testing early in pregnancy as part of routine prenatal screening panel; use opt-out approaches when allowed in the jurisdiction (ii, iii, vii)
- Conduct repeat testing during the third trimester (using a test that detects recent HIV infection^e) for women whose earlier HIV test was negative. When a woman reports a possible, recent HIV exposure that might result in a new infection that would not be detected by antibody test alone (i.e., during the window period^f) or has signs or symptoms of acute HIV infection, use both an HIV antibody test and a plasma RNA test to enable diagnosis of acute HIV infection (ii, iii)
- Screen and treat for STDs that may increase risk of HIV acquisition during pregnancy or thereafter⁹ (vii)
- For women who first present for pregnancy care during labor with unknown HIV status offer
 - expedited HIV testing (using opt-out testing strategy when allowed by the jurisdiction) and provide information about perinatal HIV transmission (ii, iii)
 - IV zidovudine immediately if preliminary test result is positive to prevent perinatal transmission (ii)
- For women who decline testing and whose HIV status remains unknown at delivery, take these steps (i, ii, iii):
 - provide expedited antibody testing of the newborn as soon as possible after birth using consent procedures consistent with state laws
 - inform the woman that identifying HIV antibodies in the newborn would indicate maternal HIV infection
- If the newborn HIV antibody test is positive, promptly inform the mother
 - that the newborn needs virologic testing and immediate initiation of postnatal prophylaxis (i, ii, iii)
 - that she may obtain these services (ii, iii):
 - voluntary HIV testing and HIV medical care during the postpartum period or later
 - other medical and social services that may guide future decisions about HIV testing or medical care for herself and her infant
- Offer PrEP during or after pregnancy when clinically indicated and manage women who are using PrEP during or after pregnancy according to HHS recommendations^c (ii, vi)
- Assess women with possible HIV exposure within the past 72 hours for indications for nPEP, and offer women with nPEP indications regimens that are suitable during pregnancy, based on HHS recommendations^c (v)

For staff of health departments who provide population-level HIV prevention and care services

- Make available online directories of health care providers and professional advice hotlines in jurisdictions that offer pregnancy services, including PrEP to HIV-uninfected, pregnant women at substantial risk of HIV infection^h (x)
- Make available information about state laws regarding consent for HIV testing during the perinatal period and minors' access to and consent for pregnancy servicesⁱ
- Prioritize health department partner services for HIV-uninfected pregnant women who have HIV-infected partners (iv)
- Support efforts and partnerships that increase access to pregnancy and perinatal services for persons with HIV and their partners, including enrollment in public or private-sector health plans and use of public sector clinics (e.g., federally funded clinics) (xi, xii, xiii)



Box 11-C. Recommended services for pregnant women who are HIV-uninfected or have unknown infection status and have sex or drug-injection partners with HIV *(cont)*

- ^a The cited source guidance that supports this recommendation was intended for health care providers. Based on opinions of the Project Workgroup, the writing group for this section concluded that it would be beneficial and feasible for other types of providers to implement this recommendation.
- ^b As of 2014, all but 2 states allow opt-out testing of pregnant women without prior written consent.
- ^c See <u>Section 5, Antiretroviral Treatment</u>, for more information regarding use of PrEP and nPEP.
- ^d See <u>Section 10, Reproductive Health Care</u>, for reproductive health services.
- ^e For additional information on FDA-approved tests to detect recent HIV infection, see "Complete list of donor screening assays for infectious agents and HIV diagnostic assays"
 (http://www.fda.gov/RiedericsPlacedVacamer/PlacedPlacedProducts/ApprovedProducts/LicencedProducts/PLAc/PlacedProducts/ApprovedProducts/LicencedProducts/Licen
- (http://www.fda.gov/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/LicensedProductsBLAs/BloodDonorScreening/InfectiousDisease/UCM080466).¹⁰
- ^f The window period is the interval between a person's infection with HIV and the production of HIV antibodies that can be detected by an HIV test.
- ^g See <u>Section 8, Partner Services</u>, for additional information about services for sex and drug-injection partners (including pregnant women) of persons with HIV and <u>Section 9, STD Services</u>, for information about STD that increase a woman's risk of acquiring HIV.
- ^h The source guidance does not address distributing information about PrEP providers or hotlines. For a summary of state HIV testing laws, see "Compendium of state HIV testing laws" (<u>http://nccc.ucsf.edu/clinical-resources/hiv-aids-resources/state-hiv-testing-laws/</u>),⁵ and for a summary of minors' access to reproductive health services, see "An overview of minors' consent law" (<u>http://www.guttmacher.org/statecenter/spibs/spib_OMCL.pdf</u>).⁶

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Box 11-D. Important messages regarding HIV prevention and pregnancy

For pregnant women with HIV who have HIV-uninfected partners

- Approximately 25% of HIV-infected women who are not treated with ART during pregnancy will transmit the virus to their infant during pregnancy, labor, or delivery, in nonbreastfeeding populations
- HIV can be transmitted through breast milk of a woman with HIV
- Use of ART by pregnant women with HIV is highly effective in protecting the infant from HIV infection and may improve the mother's health and prevent HIV transmission to their uninfected partners
- Other interventions that may further reduce the risk of transmission from HIV-infected women to their infant, including
 - nonemergent cesarean delivery at 38 weeks gestation that is initiated within 4 hours after the start of labor for women who do not have a suppressed viral load (<1000 copies/mL) at 34 to 36 weeks gestation
 - use of infant formula instead of breast milk from a woman with HIV to prevent HIV transmission through breast milk
 - not feeding infants food that has been prechewed by a person with HIV

For pregnant women who are HIV-uninfected or have unknown HIV status and have partners with HIV

- HIV testing is recommended for all pregnant women; repeated testing during pregnancy is indicated for sexually active women who are using PrEP or have HIV-infected partners who are not virally suppressed and do not consistently use condoms^b
- Women can decline HIV testing
- A person can be HIV infected and not know it
- HIV can be sexually transmitted throughout pregnancy, especially if condoms are not used correctly and consistently
- The physiologic state of pregnancy may increase the risk of sexual HIV transmission and acquisition
- Women who are exposed to HIV during pregnancy may benefit from
 - voluntary, confidential partner services provided by the health department^a
 - PrEP use^b
 - nPEP, if they have experienced a possible inadvertent HIV exposure within the past 72 hours^b
 - risk-reduction interventions^c

^a See <u>Section 8, Partner Services</u>.

^b See <u>Section 5, Antiretroviral Treatment</u>, for more information regarding use of PrEP and nPEP.

° See Section 7, Risk Screening and Risk Reduction.

How These Recommendations Differ from Previous Recommendations

These recommendations are consistent with current federal guidelines for HIV-infected pregnant women, HIV-exposed newborns, and HIV-uninfected pregnant women with HIV-infected partners.^{3,7,8,11-15} They are also consistent with the Centers for Disease Control and Prevention (CDC) recommendations that HIV-infected caregivers not prechew food for infants.¹⁶ These recommendations are also consistent with the latest comparable recommendations of these nongovernmental organizations: the American College of Obstetrics and Gynecology;¹⁷ the HIV Medicine Association of the Infectious Diseases Society of America;¹⁸ and the International Antiviral Society-USA Panel.^{19,20}

This section compiles existing federal recommendations, provides new evidence for their support, and makes one new recommendation for *nonclinical* and *clinical providers* to inform pregnant women with



HIV (and sex partners referred by them) about the availability of *preexposure prophylaxis* (PrEP) and *nonoccupational postexposure prophylaxis* (nPEP) for HIV-uninfected partners when clinically indicated to reduce their risk of HIV acquisition.

Methods

The section writing group compiled the most recent recommendations about HIV prevention related to pregnancy as of May 2014 from CDC, the Health Resources and Services Administration (HRSA), National Institutes of Health, and other federal agencies.^{7,8,11-14} Those recommendations were based on extensive clinical experience and a large body of scientific evidence that was not reexamined by the writing group. When existing guidelines contained no or limited evidence about a topic, the writing group examined evidence on the topic from three sources: 1) Systematic reviews and meta-analyses that were identified by searching the CDC HIV/AIDS Prevention Research Synthesis (PRS) project's cumulative HIV/AIDS/STD prevention database using the following terms: *HIV infection* and *pregnant women*, *newborn, infant feeding*, and *cesarean delivery* (see Section 2, Methods);²¹ 2) a narrative review of PubMed for articles indexed with the following terms: *HIV infection* and *prevention of mother-to-child transmission, pregnant women, newborn*, and *cesarean delivery*; and 3) relevant articles identified after manual review of the publications referenced in the search results.

Evidence Supporting the Recommendations

This section briefly summarizes evidence supporting these recommendations that has been described in other documents.^{7,8,11-14} See other sections for evidence related to STD services (Section 9, STD Services), *risk screening*^{††} and behavioral risk-reduction interventions (Section 7, Risk Screening and Risk Reduction), and *linkage to HIV medical care*^{‡‡} (Section 4, Linkage to and Retention in Care).

HIV testing for pregnant women and their partners

The start of prenatal care enables routine HIV testing of pregnant women and their partners. Use of an opt-out consent approach (whereby a woman is tested unless she specifically declines testing) that is consistent with state laws has been shown to yield higher testing acceptance. This approach also hastens HIV diagnosis and management and use of interventions to prevent sexual or perinatal transmission.¹¹ Because pregnancy can increase the risk of HIV transmission and acquisition² and new infection induces a rapid rise in *viral load*, repeated testing of pregnant women and their partners can identify persons at high risk of transmitting or acquiring HIV during pregnancy.¹¹ Testing of HIV-uninfected male partners of HIV-infected pregnant women and repeat testing of HIV-uninfected pregnant women during the third trimester are particularly important because of the increased risk of HIV transmission during pregnancy (both from man to woman, and from woman to man).^{2,7,11} Expedited HIV testing of women who have unknown HIV infection status when presenting in labor can quickly identify women with preliminary positive tests who warrant immediate interventions to prevent perinatal transmission.

Risk screening is a brief assessment of behavioral factors that may affect the risk of exposing others to HIV, such as inconsistent condom use or sharing drug-injection equipment, and biomedical factors that influence HIV transmission, such as viral load, antiretroviral treatment and adherence, sexually transmitted disease, and pregnancy. Risk screening is used to identify behavioral or biomedical risk-reduction interventions suited to a specific individual.

Linkage to care is the process of helping persons with HIV to obtain HIV medical care and prevention or social services through active methods (e.g., appointment scheduling, reminders, transportation to appointments).

HIV-uninfected pregnant women and their partners who are HIV infected or at high risk of HIV infection can benefit from knowing about symptoms of *acute retroviral syndrome* (e.g., fever, pharyngitis, rash, myalgia, arthralgia, diarrhea, and headache) and the increase in viral load during acute infection. This information may motivate them to seek testing for acute infection, to seek HIV medical care if infection is confirmed, and to make informed reproductive decisions.^{14,22}

HIV testing also offers opportunities to provide sexual risk-reduction information and interventions, as well as condoms.¹¹ Providing partner services to HIV-infected pregnant women or HIV-infected partners is important to prevent onward HIV transmission. Engaging voluntary, confidential health department partner services can be especially helpful for notifying multiple partners, estranged partners, or partners who do not attend prenatal care visits (see Section 7, Risk Screening and Risk Reduction, and Section 8, Partner Services).

Promptly referring HIV-infected pregnant women or uninfected pregnant women with HIV-infected partners for contraception services immediately after delivery can reduce the risk of future, unintended pregnancies (see <u>Section 10, Reproductive Health Care</u>). Prompt linkage of women who receive a preliminary or confirmed HIV diagnosis during pregnancy or the postpartum period can improve the health of both the woman and her infant and minimize *transmission risks* (see <u>Section 4, Linkage to and Retention in Care</u>).

Antiretroviral treatment and prophylaxis for pregnant women with HIV

The goal of ART during pregnancy is to maximally suppress viral load, restore or preserve immune function, improve quality of life, and prevent perinatal and sexual transmission. Maternal ART use that suppresses viral load to undetectable levels or to levels <50 copies/ml decreases the risk of HIV transmission from mother to infant from 25% to <1%.²³⁻²⁵ Regardless of their *CD4 cell count*, pregnant women who adhere to appropriate combination ART have a substantially lower risk of perinatal transmission than untreated women.^{7,26} Starting ART before conception provides more time to maximally suppress viral load before pregnancy and reduce the risk of perinatal transmission to the greatest degree (see Section 10, Reproductive Health Care). Choice of regimens may be affected by several factors, including the potential to maximize viral suppression, the risk of maternal and fetal toxicity, the need for dosing adjustments due to pharmacokinetic and physiologic changes during pregnancy, the presence of drug resistance, the degree of side effects, and patient preferences (see <u>Box 11-B</u>).

Invasive prenatal and intrapartum procedures

Invasive procedures in pregnant women with known or undiagnosed HIV infection can increase the risk of fetal HIV exposure. These procedures include amniocentesis, chorionic villous sampling, percutaneous umbilical blood sampling during the prenatal period, intrapartum amniotomy, placement of fetal scalp electrodes, episiotomy, and use of forceps or vacuum extraction delivery during labor.⁷ When these procedures are indicated, women who use effective antiretroviral treatment (ART) regimen before the procedure to maximally suppress viral load can reduce the risk of fetal exposure. If membranes rupture spontaneously before labor starts or early in labor, women in labor should be managed on an individual basis depending on how long since membranes ruptured, the plasma viral load, the current ART regimen, and the planned mode of delivery based on obstetrical indications. Data are limited regarding the

influence of cesarean delivery after rupture of membranes in decreasing the risk of perinatal HIV transmission.⁷

Cesarean delivery

The risk of perinatal transmission among women with suppressed viral load during labor who undergo a vaginal delivery is low, but increases as maternal viral load increases. Studies have shown that the risk of HIV transmission to the infant is less than 2% in women with varied levels of viral suppression who undergo cesarean delivery for obstetric indications after the start of labor and membrane rupture and in women who undergo vaginal delivery while taking prenatal ART.⁷ Assessing HIV viral load at approximately 34 to 36 weeks gestation can determine the extent of viral suppression and the safest mode of delivery.⁷ Because cesarean delivery reduces exposure to blood and vaginal secretions in the birth canal, current federal guidance recommends this procedure for women with viral load levels >1000 copies/mL at the time of delivery or for women who deliver 4 hours after membranes rupture.^{7,27,28} The presence of genital herpetic lesions during the intrapartum period (which may prompt some health care providers to offer cesarean delivery to reduce the risk of neonatal herpes^{§§}) also increases genital HIV shedding, which may increase risk of perinatal HIV transmission.^{29,30}

Interventions for newborns with known or suspected HIV exposure

Infant HIV testing and linkage to HIV care

HIV testing of the infants of women known to be infected during pregnancy is needed to determine if the infant is infected.⁷ Virologic tests (RNA or DNA *nucleic acid amplification tests* [NAAT]) are used to diagnose infant infection because infant HIV antibody tests during the first 18 months of life cannot distinguish passively acquired maternal antibody from antibody expressed due to infant infection. When maternal virologic control was poor during pregnancy or adequate follow-up of the infant is uncertain, some experts recommend *virologic testing* of the infant at birth using NAAT tests. Newborns with positive NAAT tests immediately after birth warrant being offered ART, whereas newborns with negative NAAT tests immediately after birth warrant being offered *postnatal infant prophylaxis**** with antiretroviral medications (see next topic).

Infants born to women whose HIV infection status is unknown at delivery can benefit from expedited antibody tests.⁷ A positive test identifies HIV-exposed infants who warrant being offered prophylaxis and later virologic testing to assess infant HIV infection. Positive infant antibody tests also identify infected mothers due to detection of maternal antibody. Notifying a mother that a positive infant antibody test indicates maternal infection may prompt her to seek HIV care for herself and follow up care for the infant.

Reporting of cases of HIV-exposed infants to health departments by health care providers or through hospital and birthing center *surveillance* programs may activate communication with health care providers who can engage care for the infant or mother⁸ (see Section 4, Linkage to and Retention in

^{***} Postnatal infant prophylaxis is the use of selected antiretroviral medications for several weeks by newborns born to women with HIV to prevent HIV acquisition.



^{§§} The American College of Obstetrics and Gynecology also recommends cesarean delivery for women with herpetic lesions or prodromal symptoms of genital herpes at the time of labor or after membrane rupture to reduce the risk of neonatal herpes.

<u>Care</u>). During follow-up visits for HIV-exposed or HIV-infected newborns and their parents or caregivers, providers can offer support for *adherence* to infant prophylaxis, ART, and maternal ART; reinforce the need to feed infants with formula instead of breast milk; and discuss postpartum contraception services.

Antiretroviral prophylaxis for newborns of women with HIV

All infants born to women with HIV warrant a postnatal regimen of prophylactic antiretroviral medications because this regimen can reduce their risk of HIV acquisition.⁷ Infant antiretroviral prophylaxis is most effective when started within 12 hours of birth and when adherence is high.⁷ Close clinical follow-up of these infants allows for sustained adherence support and HIV testing to confirm or exclude the infant's HIV diagnosis.³¹ Social workers, case managers, and home health personnel can help parents and caregivers support high adherence to infant prophylaxis. Detailed recommendations about treating HIV in infants are found in other documents.⁷

Infant feeding

Breastfeeding by women with HIV, even those taking effective ART, is not recommended in the United States because formula is a safe, affordable, available, and acceptable alternative.⁷ Breastfeeding increases risk of perinatal HIV transmission by 5%–20%.⁷ Some women face cultural or familial pressure to breastfeed and may need additional education and counseling to avoid breastfeeding.³² Because expressed breast milk may contain HIV and could expose recipients to HIV, it is not safe for women with HIV, regardless of their viral load or ART treatment status, to donate breast milk to human milk banks.³³

Infants may also acquire HIV by eating food that has been prechewed by a person with HIV. This may be due to obvious or inadvertent contamination of the food with blood from HIV-infected persons who have bleeding gums or other sources of oral bleeding or have had recent dental work.¹⁶

Interventions for HIV-uninfected pregnant women with partners with HIV

Methods that discordant couples can use to reduce the risk of HIV transmission during pregnancy are also described in other sections. <u>Section 7, Risk Screening and Risk Reduction</u>, and <u>Section 9, STD Services</u>, address *behavioral* and *biomedical interventions*, such as using condoms, sterile drug-injection equipment, and treatment for STDs that facilitate HIV transmission; and <u>Section 8</u>, Partner Services, describes screening HIV-uninfected partners for STDs that increase the risk of HIV acquisition.

Section 5, Antiretroviral Treatment, describes use of nPEP for persons who may have been inadvertently exposed to HIV within the past 72 hours. Isolated use of nPEP may be clinically indicated in HIV-uninfected pregnant women with HIV-infected partners who may have been recently exposed to HIV because of unprotected intercourse (including condom failure) or sharing drug injection equipment with a person with HIV. When prescribing nPEP regimens for pregnant women, providers should avoid antiretroviral medications that are known to cause maternal or fetal toxicity.

Federal guidance notes that pregnancy is not a contraindication for PrEP. Information on the safety of maternal PrEP use for the fetus and newborn is limited, but no harm has been reported to date.^{3,7} PrEP

may be clinically indicated for HIV-uninfected women with HIV-infected partners who are attempting conception or who are pregnant and have received counseling about the risks and benefits of PrEP use.^{3,7} Also, some HIV-uninfected women started taking PrEP before they became pregnant because of their substantial risk of acquiring HIV. Women who wish to sustain this protection during pregnancy may continue to use PrEP. Federal guidance recommends that health care providers prescribing PrEP for women during pregnancy notify other maternal or infant care providers about this PrEP use and submit reports about pregnant women using PrEP (with no identifying information about the pregnant women) to the Antiretroviral Use in Pregnancy Registry.³ Section 10 (Reproductive Health Care) describes use of PrEP in couples attempting conception. Section 7 (Risk Screening and Risk Reduction), Section 8 (Partner Services), and Section 5 (Antiretroviral Treatment) address use of PrEP in HIV-uninfected partners of pregnant women with HIV.

Issues that Influence Implementation of the Recommendations

Implementation progress, challenges, and opportunities

Over the last 3 decades, cases of perinatal transmission in the United States have declined due to many factors. These include widespread use of opt-out prenatal HIV testing of pregnant women, maternal ART, maternal and infant prophylaxis, scheduled cesarean delivery, avoidance of breastfeeding, and other maternal and infant interventions.³⁴ In 2012, an estimated 161 persons under the age of 13 years were diagnosed with perinatally acquired HIV infection in the United States.³⁵

An HIV diagnosis in a pregnant woman may be missed if prenatal HIV testing is not routine and is only directed to women classified as having high risk of HIV, or if repeat HIV testing is not offered to women who tested negative earlier in pregnancy. Women with HIV who are uninsured or who live in communities that are rural or have a low *prevalence* of HIV may have trouble finding or gaining access to affordable prenatal and postpartum care or health care providers skilled in managing pregnant women with HIV.³⁶ Implementation of the Patient Protection and Affordable Care Act and continued support for federally funded reproductive health programs may improve access to prenatal and postpartum care services.³⁷⁻³⁹ Providers who need information about reproductive issues for persons with HIV can consult the Clinicians Consultation Center (see the Implementation Resources topic below).⁴⁰ Community-based HIV testing programs for sex workers, drug users, and survivors of rape or intimate partner violence can also identify women at high risk of acquiring HIV infection before or during pregnancy.^{36,41,42} State and *local health departments* vary regarding their capacity to conduct active surveillance for cases of maternal HIV infection, HIV-exposed infants, and HIV-infected infants and to follow up with providers who reported these cases, particularly since some jurisdictions do not require reporting of HIV-exposed infants⁴³ (see Section 4, Linkage to and Retention in Care).

Policy, legal, and ethical considerations

State laws about HIV testing during pregnancy vary and are guided by principles of voluntary testing. Most states allow an opt-out approach. Others require written *informed consent*, special patient education, and medical record documentation before HIV testing. Regardless of the consent method, all states require that pregnant women should be aware when HIV testing is being performed, receive information about the test, and understand that they can decline testing without the risk of being denied medical care.⁵ Routine use of opt-out testing during prenatal care has increased the number of women who receive prenatal HIV testing and gain access to perinatal HIV prevention strategies.^{44,46} The number of adolescents using HIV testing services also increased in several states after they suspended parental consent requirements.^{47,48}

Nevertheless, cases of perinatal transmission continue to occur in the United States, primarily in women who are exposed to HIV or diagnosed with HIV infection after pregnancy is recognized or who decline services that prevent perinatal transmission. Some women may defer HIV testing or prenatal care if they believe that information about maternal HIV infection, sex work, or *substance use* may influence child custody decisions or provoke partner abuse.⁴⁹ When providers notify pregnant women who have declined prenatal HIV testing that their newborn's HIV positive test results indicate maternal infection, they should offer these women voluntary HIV prevention and care services but respect their right to decline them. These services include HIV testing, HIV medical care, and social services that may influence future decisions about HIV testing or infant care (e.g., counseling about how to avoid abuse by a partner who may become violent after learning of the infant's HIV infection status). Providers who are familiar with state laws about maternal and infant testing, case reporting, HIV *disclosure*, and protocols for confidential exchange of health information are in the best position to address these concerns while respecting patient autonomy about HIV testing. <u>Section 3, Context of Prevention, Section 8, Partner Services</u>, and <u>Section 9, STD Services</u>, address duty-to-inform laws that may prompt providers to notify pregnant sex partners of possible HIV or STD exposure.

A woman's decision to use antiretroviral medications during pregnancy is voluntary and must honor her autonomy. This decision may weigh considerations of fetal or newborn safety; pregnancy-related conditions, such as nausea; medication costs; and other factors. ART adherence may be especially challenging for pregnant women who face the many physical and psychological changes of pregnancy and newborn care. Providers can encourage pregnant women to stand and maintain high adherence to ART regimens that are safe during pregnancy by offering information about how to manage side effects and how to obtain affordable ART through insurance, the AIDS Drug Assistance Program (ADAP), or other drug assistance programs. Section 5, Antiretroviral Treatment, and Section 6, ART Adherence, describe other ART issues relevant to pregnant women.

Special populations

Some pregnant women and adolescents with HIV may practice sex work, be heavy alcohol and substance users, be incarcerated, experience mental illness or sexual violence, or lack regular health care.⁵⁰⁻⁵² Some may have limited knowledge about HIV transmission and the role of ART in preventing HIV transmission because of young age, cultural background, low health literacy, or other factors. These women may benefit from the support of multidisciplinary teams that can provide medical, psychosocial, and health navigation services, encourage ART adherence, offer emotional support, and make *referrals*^{†††} for substance abuse or mental health. Such teams may enlist obstetricians, maternal-fetal specialists, HIV clinical specialists, pediatricians, family practitioners, midwives, nurses, social workers, and peer educators.

^{***} Referral is a process to help persons identify and access needed services by offering the service provider's address, phone number, directions, hours of operation, and other basic information.



Implementation Resources

The Clinician Consultation Center provides telephone or online consultation from health care providers with expertise in managing pregnancies in women with HIV and preventing HIV transmission during labor and delivery and the postpartum period (1-888-448-8765 or <u>http://nccc.ucsf.edu/clinician-consultation/perinatal-hiv-aids/</u>). For resources to support implementation of these recommendations, including decision-support tools and a compendium of state HIV testing laws, see http://www.cdc.gov/hiv/guidelines/.

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Section 12. Services for Other Medical Conditions and Social Factors that Influence HIV Transmission

Background

A variety of special medical and social services can support persons with HIV who experience significant personal, social, and structural challenges, such as poverty, mental illness, *substance use*, and unstable housing. These specialty services can improve health outcomes and quality of life, reduce the risk of HIV transmission, and enable the use of HIV prevention and care services (see <u>Table 12-1</u>). Specialty services can hasten initiation of *antiretroviral treatment (ART)*; support retention in HIV care and *adherence* to ART; and encourage persons with HIV to engage in risk-reduction interventions, *partner services*, * sexually transmitted disease (STD) services, and reproductive health services that prevent HIV transmission¹⁻⁴. Some *clinical* and *nonclinical providers* have the resources and expertise to offer these services onsite. Other providers can link or refer persons with HIV to other providers or agencies and follow up to check if the services were accessed.

This section describes several medical and social issues that are common among persons with HIV and the special medical and social services that can address these issues.^{1,5-8} *Quality improvement*[†] and program *monitoring and evaluation*[‡] methods can determine if these services are implemented as intended, yield the expected outcomes, or warrant changes in delivery methods (see <u>Section 13, Quality Improvement</u>). <u>Section 3, Context of Prevention</u>, and the Special Populations topics of Sections 4 through 12 describe factors that influence the delivery of HIV prevention and care services for special populations. This section does not describe services for opportunistic infections or other medical conditions that do not influence HIV transmission; these are covered by other guidance.⁹

Recommendations

BOX 12. RECOMMENDATIONS—SERVICES FOR OTHER MEDICAL CONDITIONS AND SOCIAL FACTORS THAT INFLUENCE HIV TRANSMISSION

For nonclinical and clinical providers (including health department staff who provide individual-level services to persons with HIV)

- Establish an infrastructure for providing specialty services onsite or through referrals to other agencies or providers^a (i, ii, iii, iv, v, vi) (see <u>Box 12-A</u>)
- After helping persons with HIV to start or resume HIV medical care, offer or provide referrals to specialty services according to the person's unique needs (i, ii, iii, iv, v, vi) (see <u>Box 12-B</u>)

[‡] Monitoring and evaluation is a process that involves the repeated, ongoing collection and review of information about program activities, characteristics, and outcomes in order to assess program implementation, coverage, acceptability, cost, and effectiveness.



^{*} Partner services includes an array of voluntary services for persons with HIV or STD and their sex and drug-injection partners that are intended to reduce HIV transmission: interviewing persons with HIV to obtain information to contact or locate their sex and drug-injection partners; notifying partners of possible HIV exposure; offering testing for HIV, sexually transmitted diseases, and other infections; providing condoms, prevention information, and counseling; and providing help in obtaining risk-reduction services, HIV medical care, and other medical and social services.

[†] Quality improvement is an approach to the continuous study and improvement of the processes of providing services that meet or exceed established professional standards and user expectations.

BOX 12. RECOMMENDATIONS—SERVICES FOR OTHER MEDICAL CONDITIONS AND SOCIAL FACTORS THAT INFLUENCE HIV TRANSMISSION

For staff of health departments who provide population-level HIV prevention and care services

- Support the infrastructure to facilitate delivery of specialty services in the jurisdiction (i) (see <u>Box 12-A</u>)
- Provide information to nonclinical and clinical providers about protecting confidentiality and data security when referring persons with HIV to specialty services (vii) (see <u>Box 12-A</u>)
- Support programs and partnerships that increase access to and use of specialty services,^b including enrollment in health insurance, medical assistance programs, and social services (e.g., housing programs) (viii, ix) (see <u>Box 12-A</u>)

Note. In this report, *nonclinical providers* are defined as persons who work in community-based organizations or health departments operating outside of health care facilities and who provide HIV testing, health education, risk-reduction interventions, partner services, case management, or assistance with linkage or referral to medical and social services. These persons include HIV testing providers, peer and professional health educators, counselors, service linkage facilitators, partner services specialists, case managers, and social workers. *Clinical providers* are defined as persons who work in health care facilities and who provide risk assessments, health education, counseling, screening, diagnosis, treatment, and other health-related services. These providers include physicians, registered nurses, advance practice nurses, physician assistants, dentists, mental health providers, pharmacists, health educators, case managers, social workers, and counselors. Some may be employees or contractors of health departments. Some of the federal guidelines cited in the Recommendation boxes may have been updated. For current federal recommendations, please refer to http://www.cdc.gov/hiv/guidelines/personswithhiv.html.

^a Referral is a process to help persons identify and access needed services by offering the service provider's address, phone number, directions, hours of operation, and other basic information.

^b See Section 3, Table 3-2, for examples of federal and state programs that provide specialty services to persons with HIV.

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Box 12-A. Examples of strategies to improve infrastructure for specialty services for persons with HIV

For nonclinical and clinical providers^a (including health department staff who provide individual-level services to persons with HIV)

- Assess current infrastructure for providing specialty services directly or through referrals and identify gaps in service capacity
- Make available online directories of providers, agencies, telemedicine agencies, and professional advice hotlines that offer specialty services
- Develop and participate in provider networks that offer specialty services for persons with HIV, especially
 persons who are uninsured or underinsured or who live in underserved areas
- Develop written protocols, memoranda of understanding, contracts, or other agreements that define financial arrangements, staff and agency responsibilities for making referrals, and the tracking of referral completion and satisfaction
- Establish policies and procedures to safeguard the confidentiality of personal and health information exchanged during the referral process
- Train staff and any specialty service providers who are posted at clinical or nonclinical sites in the following topics:
 - Identifying specialty service providers who serve the community
 - Tailoring of services to personal characteristics (e.g., language, location, and insurance status)
 - Inter- and intra-agency referral procedures
 - Maintaining confidentiality of collected personal information
 - Advocating for persons who need specialty services
- Engage case managers, navigation assistants, or other staff to provide service coordination for persons with HIV who have complex needs
- Routinely provide print or audiovisual materials that describe specialty services provided onsite or through referrals
- Monitor the quality of referrals for specialty services to inform quality improvement strategies (e.g., proportion
 of referred persons who obtained specialty services, patient satisfaction, and barriers and facilitators to
 obtaining specialty services)

For staff of health departments and HIV planning groups who provide population-level HIV prevention and care services

- Identify gaps in available specialty services, recruit agencies and providers to fill these gaps, and support expansion of specialty services, if needed
- Make available online directories of agencies that provide specialty services to persons with HIV, including minors, rural residents, incarcerated persons, and immigrants
- Provide technical assistance to clinical and nonclinical providers about these topics:
 - How to access and strengthen specialty services and referral networks
 - Financial and reimbursement issues
 - Protecting confidentiality and data security during the referral process

Box 12-B. Examples of strategies to provide specialty services for persons with HIV

- Avoid stigmatizing, discriminating, or behaving judgmentally in relation to HIV infection, sexual orientation, gender identity, sex and drug-use behaviors, and medical or social characteristics
- Routinely assess persons with HIV—using tools and procedures suited to their language, gender, sexual orientation, and age—for special medical and social needs
- Identify highest priority specialty services, particularly those that influence HIV transmission risk or pose barriers to HIV medical care, ART use, and sustained high adherence to ART
- Identify the appropriate specialty provider (available onsite or through referral) and help the person with HIV contact the provider
- Provide persons with HIV the following information for each specialty service:
 - Informed consent procedures
 - Types of information shared with external agencies or providers
 - Measures to protect confidentiality
 - Cost, reimbursement, and other financial issues
 - Practical information, such as directions, transportation options, hours, and languages spoken
 - Document specialty services offered, accepted, and received by persons with HIV

Adapted from *HIV Screening and Access to Care*;¹⁰ *Recommendations for Case Management Collaboration and Coordination in Federally Funded HIV/AIDS Programs*;¹¹ and *Establishing Referral Networks for Comprehensive HIV Care in Low-resource Settings*.¹²

How These Recommendations Differ from Previous Recommendations

These recommendations are consistent with current guidance of the Centers for Disease Control and Prevention (CDC), the Health Resources and Services Administration (HRSA), and the Department of Health and Human Services.^{6,7,9,11,13-16} These recommendations are also generally consistent with the latest comparable guidance about specialty services for persons with HIV from these nongovernmental organizations: the Institute of Medicine, the World Health Organization, the HIV Medicine Association of the Infectious Diseases Society of America; and the International Antiviral Society-USA (IAS-USA) Panel.^{5,10,17,18}

Unlike the 2003 *Recommendations for Incorporating HIV Prevention into HIV Medical Care*, which did not stress active, early *linkage to HIV medical care*^{δ},² these updated recommendations advise providers to first offer specialty services that help persons with HIV to start or resume HIV medical care (e.g., providing transportation to the first visit), and then later provide specialty services that might reduce the risk of HIV transmission (e.g., substance use treatment).

Methods

The section writing group compiled these recommendations from several CDC, HRSA, and HHS guidance documents that were based on scientific evidence and expert opinion through May 2014.⁵⁻^{7,11,13,15,16} The writing group did not reexamine the evidence supporting these federal guidelines. The writing group conducted a narrative literature review about specialty services that are commonly needed or used by persons with HIV. The review involved searching PubMed for English-language articles

[§] Linkage to care is the process of helping persons with HIV to obtain HIV medical care and prevention or social services through active methods (e.g., appointment scheduling, reminders, transportation to appointments).



published from January 1, 2000 through October 1, 2010 that were indexed using terms related to HIV (*HIV*, *AIDS*, and *persons living with HIV/AIDS*) and terms related to specialty services (*substance abuse*, *mental health treatment*, *housing*, *transportation*, *case management*, and *ancillary services*). The writing group also identified additional articles published from October 2010 through June 2014 by reviewing the references of the publications identified through the PubMed search and articles suggested by reviewers (see Section 2, Methods, for details on reviewers).

Evidence Supporting the Recommendations

Poverty, unemployment, and lack of affordable health care

Surveillance data in geographic areas with the highest prevalence of HIV infection demonstrate that poverty, unemployment, and lack of job opportunities are common among persons with HIV.¹⁹⁻²¹ Nationally representative data indicate that nearly 44% of persons who received outpatient HIV medical care in 2010 reported household incomes at or below the federal poverty threshold.²² A study evaluating low-income, urban areas with high HIV prevalence found that the HIV prevalence of persons living below the federal poverty line was twice as high as that of persons living above the poverty line (2.4% prevalence vs. 1.2%, respectively).²³ Poverty and unemployment pose barriers to obtaining health insurance, HIV medical care, specialty services, and sustained access to costly ART. Poverty may also lead to unstable housing and lack of food that may force people to pay for basic necessities instead of ART medications.^{24,25} Compared with employed persons with HIV, unemployed persons with HIV report a lower quality of life and greater suffering from depression, suicidal thoughts, low self-esteem, and impaired memory.²⁶⁻²⁸ Steady employment is associated with higher adherence to ART and better health outcomes partly because it fosters regular schedules that serve as reminders to take ART and to keep HIV care appointments.^{27,29,30} Malnutrition related to poverty may exacerbate the immunosuppression associated with HIV; it may also impair ART tolerability, absorption, effectiveness, and adherence.^{25,31} Case management and *navigation assistance* have been shown to help persons with HIV obtain income assistance and health insurance¹¹ (see Table 12-1). Studies have also shown that many HIV service providers who recognize the psychological and structural benefits of employment refer persons with HIV to employment support services.^{26,28}

Unstable housing and homelessness

Persons who have unstable housing or are homeless have HIV/AIDS infection rates that are 3 to 9 times the rates of persons with stable housing.³² Unstable housing can cause psychological distress and lifestyles that lead to *risk behaviors*, ** such as having multiple sex *partners*, engaging in sex work, and abusing drugs or alcohol. One multicenter study published in 2008 found that homeless persons were 3 to 4 times more likely than persons with stable housing to use drugs or exchange sex for drugs or money and were significantly more likely to have elevated HIV *viral load* levels.³³ The lack of a consistent, secure place to store ART and lack of regular daily routines associated with stable housing can also impair adherence to ART. Residents of temporary housing who fear revealing their HIV infection status may hesitate to take ART in front of others or openly engage in HIV care and *prevention services*^{††, 34-36}

^{††} Prevention services include interventions, strategies, policies, and structures designed to reduce the transmission of HIV infection.



^{**} Risk behaviors are behaviors that can result in transmitting HIV to others or acquiring HIV through sexual contact, drug use, or during pregnancy (e.g., anal or vaginal intercourse without a barrier, sharing nonsterile drug-injection equipment).

Unstable housing may prompt some persons with HIV to have sex or inject drugs outdoors or in transient settings where condoms and sterile injection equipment are not available.^{33,37}

A variety of housing services have been developed specifically for adults and adolescents with HIV,^{33,38,39} and some have resulted in beneficial outcomes³³ (see <u>Table 12-1</u>). A study published in 2009 evaluated "supportive housing" for persons with HIV, a multifaceted strategy that provides stable housing, case management, risk-reduction counseling, ART adherence support, and psychosocial support. Provision of supportive housing to 678 homeless persons with HIV in San Francisco was associated with an 80% lower mortality rate over 5 years than persons who did not receive this intervention and was found to be cost-effective.³⁹ Studies published in 2008 and 2010 found that persons with HIV who received rental assistance were more likely than those who did not receive this aid to refrain from high-risk sexual behaviors and substance abuse and had better physical and mental health outcomes, including lower HIV viral load levels.^{33,40}

Substance use, including illicit drug injection

Alcohol and drug use are more common among persons with HIV; in 2012, about 7 percent of new HIV infections were among people who inject drugs.⁴¹ Substance use can promote HIV transmission through sharing nonsterile drug-injection equipment or through cognitive and emotional changes that cause disinhibition and poor judgment, which can result in high-risk sexual and drug-injection behaviors.⁴²⁻⁵⁴ The unstable, unstructured lifestyles and social isolation associated with substance abuse can also impair regular HIV care, high adherence to ART, and the ability to recruit family and friends to support safe behaviors and adherence to ART.⁴³⁻⁵⁵ Treatment for substance use and alcohol abuse, including oral substitution therapy for persons who inject opioids, can reduce drug and alcohol dependency and enable access to risk-reduction interventions that encourage safer sexual or drug-injection risk behaviors.⁵⁶⁻⁵⁹ Several studies have shown that persons receiving substance use treatment are more likely than those not receiving such treatment to start and remain in HIV medical care, to adopt safer behaviors, and to adhere to ART.^{1,44,60-63} (see Table 12-1).

Mental illness

Estimates of the prevalence of HIV infection among Americans with mental illness vary between 3% and 23%, with a mean of about 7%.⁶⁴ Depression and other mental illness are common among persons with HIV. A recent study of 1,061 persons receiving mental health services in 2 large U.S. cities found that their HIV prevalence was more than 4 times the prevalence of the cities' general populations.⁶⁵ A nationally representative, population-based study of 3,643 persons with HIV receiving outpatient HIV medical care found that 33% needed mental health counseling.⁶⁶ Psychosocial distress and mental illness may stem from the strain of coping with a difficult chronic disease, social isolation, limited social support, discrimination, abuse, or violence. Stigma and discrimination related to HIV, *sexual orientation* or *gender identity* (e.g., homophobia, *transphobia*),^{‡‡} poverty, race, substance use, and unstable housing may lead to psychological distress, depression, and other mental health problems that, in turn, can erode safe behaviors and cause immunosuppression.⁶⁷⁻⁷² Persons who anticipate being stigmatized when seeking HIV prevention and care services may also forego valuable services.^{68,69,73-75}

^{‡‡} Transphobia is an aversion to individuals who do not conform to the traditional or cultural norm of gender identity.

Mental illness can also hinder the use of safe sex and drug-using behaviors, the willingness or ability to use prevention and care services, and the use of and adherence to ART.⁷⁶⁻⁷⁸ Stress; depression; difficulty coping with a complex, potentially fatal chronic disease; and a lack of social support have also been associated with increases in viral load levels.⁷⁹⁻⁸³ Several studies have shown that receiving mental health services improves engagement and retention in HIV care and quality of life^{1.61,62,77,84} (see <u>Table 12-1</u>).

Legal detention and incarceration

In some jurisdictions, person with HIV who carry HIV prevention devices in public, such as condoms or sterile drug-injection equipment, may be vulnerable to prosecution for commercial sex work or drug use, respectively.^{85,86} HIV *incidence* is about 3 times higher in prisoners than in the general population.^{87,88} At the end of 2008, an estimated 1.5% of state and federal prisoners were infected with HIV.88 Adults and adolescents with HIV in jails, halfway houses, and parole programs may have unique HIV prevention and care needs.⁸⁹ Detainees with HIV may not disclose substance use, sex work, or other illegal activities that caused their infection because of concerns about prosecution, discrimination, or breach of confidentiality.⁹⁰ When persons with HIV move to or from correctional facilities, they may lose access to their usual source of HIV medical care and ART. Some prisons that provide substance abuse and mental health treatment and other specialty services onsite or through *referral^{§§}* cannot continue their services after an inmate is released. After release from detention, persons with HIV also face changes in housing, food supplies, employment, transportation, income, and health insurance. This forces many to focus on meeting basic needs of food and shelter and to delay seeking HIV medical care or specialty services.⁸⁹ For this reason, correctional facilities that provide reentry transition planning or case management can increase the proportion of persons with HIV who obtain HIV prevention and care services after their release^{89,91,92} (see <u>Table 12-1</u>).

Immigration

Many undocumented immigrants with HIV are ineligible for public- or private-sector HIV prevention, care, and specialty services, including services covered by health plans regulated by the Patient Protection and Affordable Care Act (ACA). Many low-income immigrants also lack health insurance or cannot afford to pay for services out of pocket.^{93,94} Some immigrants with HIV who are unaware of their infection may defer HIV testing and unknowingly transmit HIV to others. Those who are aware of their infection may delay HIV medical care or not disclose their infection to service providers if they fear arrest, deportation, or discrimination.⁹⁵ Recent immigrants may retain health care beliefs and practices from their country of origin and may hesitate to engage in mainstream medical care and use unfamiliar medications.⁹⁶ Immigrants who must rely on emergency departments, migrant health clinics, or other safety net providers often receive only sporadic care for acute conditions rather than continuous, long-term HIV medical care that is most effective.⁹³ Many communities have local providers, federally-funded clinics, and other medical assistance programs that provide medical and social services to immigrants (see <u>Table 12-1</u>). They are often staffed by professionals who have demonstrated cultural competence, language skills, and specialized legal and health navigation expertise.^{93,97-99}

Referral is a process to help persons identify and access needed services by offering the service provider's address, phone number, directions, hours of operation, and other basic information.

Cultural and linguistic background, gender identification, and sexual orientation

Persons with HIV who are racial or ethnic minorities or are not proficient in English may feel marginalized by their communities and may be unable to access HIV prevention and care information. They may also have trouble finding HIV service providers who speak their language or offer prevention and care services that reflect their cultural norms.^{93,96} *Evaluations* of health care systems in the United States suggest that providers who offer non-English language services and are trained in cultural competency are better equipped to serve culturally diverse persons with HIV.¹⁰⁰ The federal government has developed voluntary standards for language services, cultural competency training, and other means to improve access and quality of care.¹⁰¹ These standards also provide guidelines for federal, state, and national agencies that accredit health care organizations.¹⁰¹

HIV prevalence in the United States is very high among sexual minorities, particularly gay, bisexual and other men who have sex with men (MSM) and *transgender* women who practice high-risk sexual and drug-use behaviors.^{41,102} National surveys and focused studies have shown that many MSM and transgender women struggle to find health care providers who are experienced in serving sexual minorities. Many also anticipate stigma or discrimination when seeking health care.¹⁰³⁻¹⁰⁵ Some medical and social service organizations have issued guidance on professional competencies that foster more welcoming, effective services for sexual minorities.^{106,107} Specialized peer support, group counseling, legal services, and health navigation assistance can also help persons who feel medically marginalized, socially isolated, or vulnerable to stigma or discrimination (see <u>Table 12-1</u>).

Transportation and childcare barriers

Many persons with HIV lack transportation to HIV prevention and care services because their communities do not offer affordable public transportation or care services can only be accessed by car.^{22,61,100,108,109} A nationally representative, population-based HIV surveillance study of persons with HIV receiving outpatient HIV care through the end of 2010 found that 9% reported needing transportation assistance.²² Transportation is a challenge for both urban residents and rural residents who must travel great distances to obtain these services.^{22,108} Case management that includes arranging transportation assistance has been shown to hasten the initiation of HIV medical care, improve *retention in care*, and improve adherence to ART^{61,100,110,111} (see Table 12-1).

Lack of childcare can also impair engagement in HIV care. Studies in rural and urban Alabama have shown that HIV clinics that routinely assess childcare and transportation options, offer childcare and transportation assistance, and advocate for community programs for these services can help persons start HIV care.¹¹²⁻¹¹⁴ Several new *telemedicine services**** offer expert consultation, training, and professional skill-building to medical and social service providers serving persons with HIV in rural or urban areas.¹¹⁵

^{***} Telemedicine services involve the use of telecommunications technology to provide, enhance, or expedite health care services or to provide consultation, training, and mentoring to health care professionals.



Adolescence and legal minor status

Many adolescents and young adults with HIV experience age-related or legal circumstances that pose barriers to obtaining HIV prevention and care services. Some adolescents with HIV do not have established health care providers or do not know how to find HIV medical care. Several surveys demonstrate that adolescents may forgo health care if they believe information about rendered services (bills or explanations of benefits) can be disclosed without their consent to parents or guardians who sponsor their insurance.¹¹⁶⁻¹²¹ Even when minors have rights to confidential HIV services, their doubts about confidentiality protections may deter them from seeking services (see Section 3, Context of Prevention). For example, some minors who must provide family income records to confirm eligibility for Ryan White HIV/AIDS Program benefits or other HIV services may forego these services if their parents do not know their infection status.¹²² They may also defer contraception, other reproductive health services, and employment support that might influence the risk of HIV transmission. Some adolescents with HIV may fear, or have experienced, that disclosing their HIV infection to their parents prompts unwanted questions about sexual activity, sexual orientation, or substance use, or leads to accusations, abuse, or loss of parental financial support or housing. Youth with HIV who have not disclosed their diagnosis may find it difficult to adhere to ART if they must covertly take or store pills. Also, adolescents with perinatally acquired HIV often take more responsibility for managing their HIV care, ART supplies, and adherence than they did as children.¹²³

Providers can encourage youth to access HIV services by describing their rights to confidential health care (which may differ by state), parental *disclosure* requirements, and billing procedures. When confidentiality of billing information may be a problem, providers can refer adolescents to providers who do not charge for their services or do not bill parents. Some HIV prevention and care programs have created welcoming, "youth-friendly" environments that offer flexible service hours and age-appropriate education and skill-building about coping, communication, and adherence to ART.¹²⁴ Some of these orient adolescents who are transitioning from pediatric to adult health care providers about differences in patient support services.^{125,126} Other valuable services include patient navigation support by peer educators, case managers, and multidisciplinary teams that address the developmental, medical, legal, and educational needs of youth^{38,124,127,128} (see <u>Table 12-1</u>). With support from CDC, HRSA, and the National Institute of Child Health and Human Development, urban adolescent care centers, local health departments, and adolescent *outreach* experts are collaborating in a program that supports identification of youth with undiagnosed HIV and prompt linkage to providers of HIV medical care who practice in "youth-friendly" settings.¹²⁹ New guidance for adolescent health care providers who serve gay, bisexual, and transgender youth at risk of HIV is also available.¹⁰⁶

Advanced age

As persons with HIV in the United States live longer, the number of older persons with HIV is rapidly increasing. By 2020, an estimated one-half of all persons with HIV will be aged 50 years or older.¹³⁰ Many older persons with HIV have or will develop physical, mental health, or social needs related to chronic HIV infection and the normal aging process that may warrant special assessment, support, or services.^{131,132} For example, age-related changes in immune function may impair response to ART. Older patients with suppressed viral load consistently experience less robust *CD4 cell count* responses, possibly because CD4-cell–mediated immune reconstitution related to thymic function declines with age.¹³⁰

Cognitive decline, comorbid health conditions, social isolation, and "regimen fatigue" may also erode adherence to ART.¹³³ Aging may also change sexual practices. Persons who lose longstanding partners may seek new or casual sex partners. Persons may use sexual performance aids (e.g., penile rings) that may cause genital trauma or erectile dysfunction medications that have been associated with higher levels of *unprotected anal sex*^{†††}.¹³⁴⁻¹³⁷ Providers who routinely assess adherence to ART and risk behaviors of older persons with HIV can tailor services, risk-reduction messages, and HIV prevention and care services to any unique needs⁹ (see Section 7, Risk Screening and Risk Reduction, Section 6, ART Adherence, and Table 12-1). Guidance on achieving cultural competence when serving older MSM, lesbian, and transgender persons with HIV is available.¹⁰⁷

Table 12-1. Factors that can influence health, quality of life, risk of HIV transmission, and use of HIV prevention, medical, and social services among persons with HIV; and specialty services that address these factors

Factor(s)	Possible effect on health, quality of life, HIV transmission, and use of services	Examples of specialty services
Real or perceived alienation, discrimination, or stigma due to HIV infection, sexual orientation, sexual practices, drug use, race, ethnicity, age, gender, or other factors	 Factors may impair access to medical care, housing, or employment that can promote use of HIV prevention and care services cause physical and mental health problems, which can increase risk behaviors, substance use, or immunosuppression limit social support that can foster retention in HIV medical care, adherence to ART, transportation, housing, and use of other medical and social services that influence HIV transmission cause gay, lesbian, or transgender persons to defer HIV testing, prevention, or care services 	 Legal services Psychosocial services Mental health services Substance abuse treatment and counseling Supportive housing services

⁺⁺⁺ Unprotected anal sex is sexual activity without using a physical barrier (i.e., without using a male condom; oral-anal contact without using a dental dam or other barrier device; or rectal-digital contact without using a latex glove or finger cot).



 Table 12-1.
 Factors that can influence health, quality of life, risk of HIV transmission, and use of HIV prevention, medical, and social services among persons with HIV; and specialty services that address these factors (cont)

Factor(s)	Possible effect on health, quality of life, HIV transmission, and use of services	Examples of specialty services
Poverty, unemployment, food insecurity, and unstable housing	 Factors may lead to behaviors that can increase the risk of HIV transmission (e.g., exchanging sex for housing and money, sharing drug-injection equipment) hinder access to health insurance, medical care, ART, support for adherence to ART, risk-reduction interventions (e.g., condoms and sterile drug-injection equipment), and other medical and social services Malnutrition and inconsistent access to food may also weaken immune function and impair adherence to and absorption of ART, which may influence viral load and infectiousness Unstable housing or reliance on temporary shelter may also hinder the security and storage of ART and prevention devices (e.g., sterile drug-injection equipment and condoms) complicate adherence to ART 	 Public income assistance Job training and employment support Nutrition services, counseling, food stamps, food banks, and soup kitchens Housing services: rental assistance, community shelters, supportive housing Case management and navigation services to assist with enrollment in services
Inadequate health insurance or access to affordable health care services	 Factors may impair access to HIV medical care, ART, support for adherence to ART, risk-reduction interventions, condoms, sterile drug-injection equipment, and other medical and social services 	 Private health insurance and medical assistance programs Case management and navigation services to assist with enrollment and managing copayments and coinsurance
Limited education and health literacy	 Factors may impair understanding of the biologic or social basis for HIV transmission, prevention, and care impair understanding of educational materials about HIV prevention, care, and medications impair navigation of complex health systems and social service providers 	 Health literacy and peer education services Job training and employment support services Case management and navigation services to assist with understanding information about medical and social services

Factor(s)	Possible effect on health, quality of life, HIV transmission, and use of services	Examples of specialty services
Recreational substance and alcohol use and dependence, including drug injection	 Substance use may impair judgment, cause disinhibition, and increase sexual and drug-injection risk behaviors contribute to unstable and unstructured lifestyles, which can complicate regular HIV care and adherence to ART lead to social isolation, which can hinder recruiting of family and friends to support safe behaviors and adherence to ART cause mental illness and immunosuppression Sharing nonsterile drug-injection equipment may transmit HIV and other bloodborne infections 	 Substance abuse treatment and counseling, including opioid replacement programs Legal syringe services programs Legal physician and pharmacist syringe prescriptions or distribution Risk-reduction interventions for substance abusers and persons who inject drugs
Fear or risk of physical or verbal abuse, including domestic and intimate partner violence	 Factors may impair ability to negotiate safer sexual and drug-use behaviors impair ability to retain stable housing and financial resources that foster retention in HIV care and adherence to ART 	 Domestic violence/abuse counseling Mental health services that address abuse Legal services, including child protection Housing services: rental assistance, community shelters, supportive housing Job training and employment support
Commercial sex work, sexual coercion, and sexual assault	 Factors may result in inability to negotiate consistent condom use result in trauma that may result in bloodborne HIV exposure 	 Sexual assault services Mental health services Behavioral risk-reduction interventions Psychosocial support services (e.g., group or peer support) Condom provision Sex worker unions or advocacy organizations Legal services if charged with sex- related violence or offense

Factor(s)	Possible effect on health, quality of life, HIV transmission, and use of services	Examples of specialty services
Mental illness and psychological conditions, including depression, emotional distress, anxiety, and social isolation	 Factors may coexist with substance use impede willingness or ability to seek prevention services or use prevention strategies impair judgment and increase sexual and drug-injection risk behaviors that can expose others to HIV lead to unstable and unstructured lifestyles, which can hinder regular HIV care and adherence to ART lead to social isolation, which can hinder recruitment of family and friends to support safe behaviors and adherence to ART 	 Mental health services Substance abuse treatment and counseling Psychosocial support services (e.g., group or peer support) Specialized support for ART adherence (e.g., directly observed therapy) Risk-reduction interventions for substance users
Legal issues, including incarceration and laws criminalizing sex work, drug possession, and intentional HIV exposure	 Criminalization laws may deter possession or use of condoms and sterile syringes deter voluntary HIV disclosure and use of HIV care and other services that promote ART use and safe behaviors Incarceration may result in exposure to sexual violence lead to sharing of drug-injection equipment interrupt HIV care, ART use, substance use treatment, and other HIV-related services during incarceration or after release 	 Legal services Sex worker unions or advocacy organizations Mental health services Substance abuse treatment and counseling in correctional facilities and the community Case management and navigation services to assist with service linkage and coordination before and after detention
Immigration status	 Factor may deter HIV disclosure or prompt fear of arrest, detainment, or deportation that may deter or delay HIV services prohibit HIV care, ART use, and prevention services if person cannot provide documentation to confirm eligibility for services 	 Clinics and community-based organizations that serve immigrants Translation services Legal services

Factor(s)	Possible effect on health, quality of life, HIV transmission, and use of services	Examples of specialty services
Cultural and linguistic background, gender identification, and sexual orientation	 Factors may cause stigma or discrimination impair ability to find service providers who have common language skills, understand cultural norms about HIV prevention and care, or have experience in health care for gay, lesbian, and transgender persons hinder ability to access and understand HIV prevention information or to communicate with some service providers reduce willingness to consider unfamiliar HIV treatment or prevention strategies, including ART 	 Clinics and community-based organizations that serve relevant populations Translation services Psychosocial counseling and support services (e.g., group counseling, peer support) Legal services that address discrimination
Lack of transportation or childcare	 Factors may hinder access to regular HIV medical care that enables use of ART and reinforces safer behaviors caused missed appointments for HIV prevention and care services 	 Transportation assistance Public transit vouchers Onsite childcare Vouchers for childcare
Residence in rural or urban areas with limited medical and social services	 Factors may require traveling long distances to skilled service providers cause reliance on local providers who may not have experience in HIV prevention and care increase risk for confidentiality violations and may hinder HIV disclosure to supportive providers, partners, family, and friends 	 Transportation services Telemedicine services Case management and navigation assistance to assist with service linkage and coordination

Factor(s)	Possible effect on health, quality of life, HIV transmission, and use of services	Examples of specialty services
Adolescence and legal minor status	 Factors may hinder access to HIV services because of lack of awareness about ability to access services without parental consent and concern about confidentiality of medical records preclude having an established health care provider, having experience navigating HIV services, or having documents to confirm eligibility for HIV services (e.g., family income records needed for medical assistance programs) hinder access to age-appropriate specialty services (youth-friendly services) hinder HIV disclosure because of fear of parental abuse, loss of financial support or housing, or stigma about sexual or drug activity 	 Youth-friendly services Health literacy and peer education services Psychosocial counseling and support services (e.g., group counseling, peer support) Housing services for homeless youth Case management and navigation assistance to assist with care coordination
Advanced age	 Factor may lead to cognitive decline, comorbid health conditions, and social isolation that may impair adherence to ART loss of longstanding sex partners or sexual function that may lead to new or casual partners or renewed focus on HIV prevention use of sexual performance devices that may cause genital trauma use of erectile dysfunction medication that may increase the risk of HIV transmission 	 Mental health services Health literacy and peer education services Psychosocial counseling and support services (e.g., group counseling, peer support) Case management and navigation assistance to assist with care coordination

Note. For evidence supporting the factors listed in this table, see the <u>Evidence</u> topic in this section and <u>Section 7, Risk Screening and Risk</u> <u>Reduction</u>.

Issues that Influence Implementation of the Recommendations

Implementation progress, challenges, and opportunities

The capacity to provide specialty services to persons with HIV varies greatly by jurisdiction and is limited in many communities. For example, a study published in 2012 found substantial gaps in mental health services; substance use treatment; and support for food, housing, and transportation for persons with HIV. The study cautioned that this gap in infrastructure would increase if service capacity did not keep pace with the growing number of persons with HIV.¹¹⁰ Several factors impair the delivery of specialty services: lack of understanding that other medical and social issues influence HIV transmission; lack of established infrastructure, standard procedures, trained staff, and tracking methods; lack of time; and competing priorities.¹³⁸⁻¹⁴⁰ Case managers and coordinated case management systems for persons with HIV with complex navigation needs are scarce in many areas.^{11,66} Specialty services serving youth, rural residents, undocumented immigrants, and persons lacking health insurance are particularly overstretched.^{141,142}

Fortunately, implementation of the ACA promises to improve access to and use of specialty services by the growing number of persons with HIV who have enrolled in private insurance, Medicaid, or other medical assistance programs.¹⁴³⁻¹⁴⁵ The ACA will also enable health care providers working in Ryan White-funded clinics to bill Medicaid, other medical assistance programs, or private health insurance for specialty services related to HIV prevention and care.¹⁴⁶ Use of multidisciplinary teams, *collaboration*, and task-sharing can also facilitate access to specialty services^{8,10-12} (see <u>Boxes 12-A</u> and <u>12-B</u>). For example, clinical providers can engage mental health care, substance use treatment, or other special medical services that are provided onsite or through referral to other health care providers, while nonclinical providers can help persons with HIV find stable housing, transportation to medical visits, and condom supplies. Nonclinical HIV testing sites can assess specialty service needs as part of their routine *risk screening*^{‡‡‡} or post-test services for persons who test positive. Health care facilities that cannot hire onsite case managers may contract with community-based organizations that offer navigation assistance to persons with HIV.

Policy, legal, and ethical considerations

Referrals to specialty services usually require the exchange of confidential health information. Persons with HIV may be more willing to respond to a referral recommendation when providers seek explicit *informed consent* and describe measures to maintain confidentiality during the referral process, such as the *Health Insurance Portability and Accountability Act* and state or federal confidentiality standards specific to HIV¹⁴⁷ (see Section 3, Context of Prevention, for additional information on confidentiality).

Implementation Resources

Resources to support implementation of these recommendations are found at <u>http://www.cdc.gov/hiv/guidelines/implementationresources.html</u>. They include referral assessment tools, sample memoranda of agreement with referral agencies, and online directories of specialty service providers.

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Risk screening is a brief assessment of behavioral factors that may affect the risk of exposing others to HIV, such as inconsistent condom use or sharing drug-injection equipment, and biomedical factors that influence HIV transmission, such as viral load, antiretroviral treatment and adherence, sexually transmitted disease, and pregnancy. Risk screening is used to identify behavioral or biomedical risk-reduction interventions suited to a specific individual.



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Section 13. Quality Improvement and Program Monitoring and Evaluation

Background

Organizations that implement the interventions recommended in this report may choose to evaluate their acceptability, adoption, impact, and/or cost. Both *quality improvement* (QI) and program *monitoring and evaluation (M&E) methods* can be used to determine if interventions are implemented as intended, yield the expected outcomes, or warrant changes in delivery methods. This section describes best practices for QI and M&E that can be used to evaluate delivery of HIV care and *prevention services*^{*} in *clinical settings*[†] and *nonclinical settings*,[‡] including health departments.

QI relies on the routine, repeated use of demographic, administrative, and health data to improve clinical and public health systems, processes, and outcomes. QI has traditionally been the domain of health care administrators who are seeking better health outcomes, higher standards of care, more efficient operation, or greater patient satisfaction. Recently, health departments and nonclinical organizations have engaged in QI efforts.¹

QI is driven by 3 fundamental questions:

- "What change in health status or other outcomes do we want to achieve?"
- "What kinds of changes can we make that may result in an improvement?"
- "How will we know that a change led to an improvement (i.e., how is change measured)?"

QI usually involves small, incremental changes in practice and rapid feedback of results. It is often an iterative process of repeated cycles of change and feedback that can be integrated into practices and programs as a continuous, routine performance improvement strategy and can be led by internal staff (see <u>Table 13-1</u>). The process relies on collecting and analyzing "real-time" data that reflect current practice. In HIV medical settings, QI often focuses on guideline adherence; *evidence-based*[§] clinical decision making; or measures to increase efficiency, lower costs, strategically use staff and health information, or improve care *coordination* and patient flow. For example, staff in one HIV outpatient clinic compared 2 types of computer alerts in *electronic medical records (EMRs)*** used by physicians serving patients with high HIV *viral load* or suboptimal *retention in care*.² Use of "interactive alerts" that facilitated appointment scheduling and laboratory testing were associated with greater improvements in *CD4 cell counts* and follow-up visits than "static alerts" that only listed these patients.

^{**} An electronic medical record (EMR) is a patient record that is maintained using computer software. The record should include patient history, including diagnoses, treatments, prescribed medications, drug allergies, and self-reported problems; patient demographics; physician clinical notes; and laboratory and imaging results.



^{*} Prevention services include interventions, strategies, policies, and structures designed to reduce the transmission of HIV infection.

[†] Clinical settings are health care facilities in which medical diagnostic, treatment, and disease prevention services are routinely provided.

Nonclinical settings are facilities that provide prevention, education, screening and interventions for risk behaviors, and referrals for medical and social services. Some nonclinical settings may also provide health promotion services and screening for HIV and some STD.

[§] Evidence-based interventions, strategies, guidelines, and recommendations are based on sound scientific research, testing, or program evaluation.

Program monitoring involves the ongoing, repeated collection and review of information about the activities and operation of a program. Program *evaluation* involves periodic collection of information about program activities, characteristics, and outcomes in order to assess causal attribution, improve effectiveness, or identify lessons learned.³ M&E efforts usually focus on questions of program design, implementation, effectiveness, acceptability, coverage, and cost. They attempt to answer questions, such as the following:

- "What are we trying to accomplish?"
- "Are we doing it right?"
- "Are we implementing the program as planned and on a large enough scale?"
- "What assumptions or potential risks relate to this program?"
- "Are the interventions making a difference?"

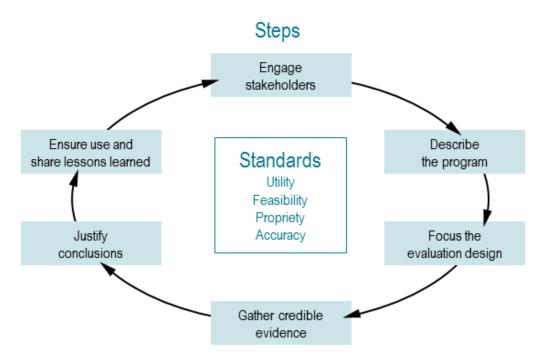
Because M&E can assess program coverage, impact, and costs, M&E is an essential accountability function of many health departments, *HIV planning groups*, and publicly funded community-based organizations. Recent federal M&E efforts have focused on monitoring *linkage*^{††} to (and retention in) *HIV medical care, antiretroviral treatment (ART)* use, and viral suppression, and the collected data and performance measurements are now used by several federal agencies (see <u>Table 13-2</u>). Some state health departments have analyzed population-level data about continuum of HIV care, such as the proportion of persons in the jurisdiction without laboratory reports indicating continued care and suppressed viral load. These analyses can identify populations that would benefit from being offered interventions to improve retention in care.⁴

The recommendations and examples of best practices for QI and M&E in this section were based on a review of federal and state recommendations for QI and M&E that are relevant to HIV clinical settings and nonclinical programs, national HIV *indicators* and performance measures, and opinions of experts on QI and M&E for HIV clinical care and community programs (see <u>Box 13-A</u> and <u>Figure 13-1</u>).⁵⁻¹² These practices can be applied to many interventions (see Sections 3–12) and used by government agencies, public and private payers, accreditation entities, health departments, community-based organizations, large health systems, and small clinical practices.

^{††} Linkage to care is the process of helping persons with HIV to obtain HIV medical care and prevention or social services through active methods (e.g., appointment scheduling, reminders, transportation to appointments).







Adapted from Centers for Disease Control and Prevention.⁵

Recommendations

BOX 13. RECOMMENDATIONS—QUALITY IMPROVEMENT AND PROGRAM MONITORING AND EVALUATION

For nonclinical and clinical providers^a (including health department staff who provide individual-level services to persons with HIV)

 Engage in quality improvement (QI) activities that focus on improving the delivery and quality of HIV care and prevention services to persons with HIV^b (i, ii) (see <u>Box 13-A</u>)

For staff of health departments and HIV planning groups who provide population-level HIV prevention and care services

 Regularly monitor program implementation and periodically evaluate program outcomes according to best practices (i, iii, iv)

^a In this report, *nonclinical providers* are defined as persons who work in community-based organizations or health departments operating outside of health care facilities and who provide HIV testing, health education, risk-reduction interventions, partner services, case management, or assistance with linkage or referral to medical and social services. These persons include HIV testing providers, peer and professional health educators, counselors, service linkage facilitators, partner services specialists, case managers, and social workers. *Clinical providers* are defined as persons who work in health care facilities and who provide risk assessments, health education, counseling, screening, diagnosis, treatment, and other health-related services. These providers include physicians, registered nurses, advance practice nurses, physician assistants, dentists, mental health providers, pharmacists, health educators, case managers, social workers, and counselors. Some may be employees or contractors of health departments.

^b The cited source guidance that supports this recommendation was intended for health care providers. Based on opinions of the Project Workgroup and program experience, the section writing group concluded that it would be beneficial and feasible for other types of providers to implement this recommendation.

Note. Some of the federal guidelines cited in the Recommendation boxes may have been updated. For current federal recommendations, please refer to <u>http://www.cdc.gov/hiv/guidelines/personswithhiv.html</u>.

BOX 13. RECOMMENDATIONS—QUALITY IMPROVEMENT AND PROGRAM MONITORING AND EVALUATION (cont)

Sources

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Box 13-A. Examples of strategies to support quality improvement (QI) in HIV care and prevention services and programs

- Create QI infrastructure, including trained, dedicated staff who represent a variety of positions and perspectives
- Examine clinical and administrative data and solicit stakeholder input about the strengths, weaknesses, opportunities, and challenges of the service or program and priorities for improvement
- Develop a program improvement plan that describes the service or program purpose, defines QI goals and strategies, establishes accountability for the plan, and describes resources for QI activities
- Develop a "conceptual map" that depicts the relation between program inputs, outputs, and outcomes to pinpoint where to target improvement activities
- Design QI intervention cycles after reviewing past experience from literature, colleagues, technical assistance providers, and stakeholders
- Establish benchmarks, baseline measures, and performance goals based on national or local standards, clinical guidance, or accreditation standards
- Develop data collection methods that adhere to confidentiality and data security regulations
- Identify, test, refine, and use new or existing indicators to track service delivery, quality, satisfaction, and outcomes (see <u>Table 13-2</u>)
- Implement interventions by testing feasibility and evaluating results (e.g., "Plan-Do-Study-Act" approach) (see <u>Table 13-1</u>)
- Develop and execute a plan to interpret and communicate data after consulting with stakeholders
- Scale up successful, feasible interventions and identify lessons from interventions that did or did not result in desired change
- Repeat QI cycles to determine if interventions achieve desired outcomes

Source: Adapted from New York State Department of Health AIDS Institute.6,7

Table 13-1. Example of quality improvement (QI) activities to reduce the infectiousness of persons with HIV in an HIV medical clinic using the Plan-Do-Study-Act model

Step in QI Model	Activities to increase the proportion of patients who are virologically suppressed
Plan	 Planned the change and collected baseline data. Conducted medical record review that revealed only 10% of patients were virologically suppressed only 40% had a plan to support viral suppression in medical record only 20% had evidence that the plan was executed Set goals to increase the proportion of patients with a documented plan for viral suppression from 40% to 90% increase the proportion of patients with evidence of execution of the plan from 20% to 75%
Do	 Initiated system changes: Informed clinical providers and support staff about quality improvement plan Developed decision-support tools, including algorithm for antiretroviral treatment (ART) decision points, prompts in clinic database and visit forms, and patient reminder systems Introduced several small tests of change over 6 months; after each change, measured charting and execution of plans
Study	After 6 months, 100% of patients had a plan in their medical record and 71% had the plan executed.
Act	 Added fields for plan and execution of the plan to medical record system Added automatic prompts for clinician action when viral load changed

Source: Adapted from A Guide to Primary Care of People with HIV/AIDS;¹³ The Improvement Guide: A Practical Approach to Enhancing Organizational Performance;¹⁴ and Guide for HIV/AIDS Clinical Care.¹⁵

 Table 13-2.
 Selected common core indicators for monitoring HIV prevention, treatment, and care services for programs supported by the U.S. Department of Health and Human Services (HHS)

Measure	Numerator	Denominator
Linkage to HIV medical care	Number of persons who attended a routine HIV medical care visit within 3 months of HIV diagnosis	Number of persons with an HIV diagnosis in the 12-month measurement period
Retention in HIV medical care	Number of persons with an HIV diagnosis who had at least one HIV medical care visit in each 6-month period of the 24-month measurement period, with a minimum of 60 days between the first medical visit in the prior 6-month period and the last medical visit in the subsequent 6-month period	Number of persons with an HIV diagnosis with at least one HIV medical care visit in the first 6 months of the 24-month measurement period
Antiretroviral treatment (ART) among persons in HIV medical care	Number of persons with an HIV diagnosis who are prescribed ART in the 12-month measurement period	Number of persons with an HIV diagnosis who had at least one HIV medical care visit in the 12-month measurement period
Viral load suppression among persons in HIV medical care	Number of persons with an HIV diagnosis with a viral load <200 copies/mL at last test in the 12-month measurement period	Number of persons with an HIV diagnosis who had at least one HIV medical care visit in the 12-month measurement period
Housing status	Number of persons with an HIV diagnosis who were homeless or unstably housed in the 12-month measurement period	Number of persons with an HIV diagnosis receiving HIV services in the 12-month measurement period

Source: Adapted from Forsyth A, et al. Secretary Sebelius approves indicators for monitoring HHS-funded HIV services. http://blog.aids.gov/2012/08/secretary-sebelius-approves-indicators-for-monitoring-hhs-funded-hiv-services.html. August 3, 2012.¹⁶

Note. Many programs use additional, program-specific indicators.

Methods

The recommendations in this section were based on guidance from CDC and HRSA that were supported by scientific evidence, program experience, and expert opinion.^{5,10,17,18}

Issues that Influence Implementation of the Recommendations

Implementation progress, challenges, and opportunities

Many federal, state, and local programs routinely implement QI and program evaluation methods that address HIV prevention with persons with HIV.¹⁸⁻²⁰ Quality management programs that develop and encourage reporting of performance measures are more likely to motivate programs to participate in QI and M&E.²¹ For example, the Health Resources and Services Administration's HIV/AIDS Bureau engages in many quality initiatives for HIV services provided through the Ryan White HIV/AIDS Program that are guided by a set of clinical performance measures.²¹ This focus on QI and program evaluation has expanded the range of clinical and social services for persons with HIV, improved documentation and billing of rendered services, and introduced more versatile electronic medical information systems and novel uses of *surveillance* and administrative data.^{19,22,23}

QI and M&E are intended to improve service access, quality, cost, overall impact, and/or satisfaction for *clients* and other program stakeholders, but can sometimes disrupt service delivery priorities and require substantial resources. Developing or amending data collection processes and electronic information systems to collect or calculate performance data can be costly, complex, time-consuming, and require hiring of specialized staff.²¹ Burdensome data collection to meet internal demands or external accountability requirements can become an end in itself and is wasteful if it is not used to guide program improvement. If QI and M&E results are used to create incentives for improvement or change rather than to highlight failures, they are more likely to be acceptable to an organization's employees and leadership.

Policy, legal, and ethical considerations

Several organizations have issued guidance about policy, legal, and ethical factors that influence HIVrelated QI and M&E. This guidance addresses sharing health information, protecting patient *confidentiality*, using HIV-related surveillance and clinical data for QI and M&E, balancing data collection burdens with program benefit, maintaining integrity when evaluating publicly funded programs, and respecting staff and client time and *privacy*.²⁴⁻²⁸ Section 3, Context of Prevention, provides additional information on confidentiality issues.

Implementation Resources

Additional information on QI and M&E for HIV clinical and nonclinical settings can be found at <u>http://www.cdc.gov/hiv/guidelines/implementationresources.html</u>.

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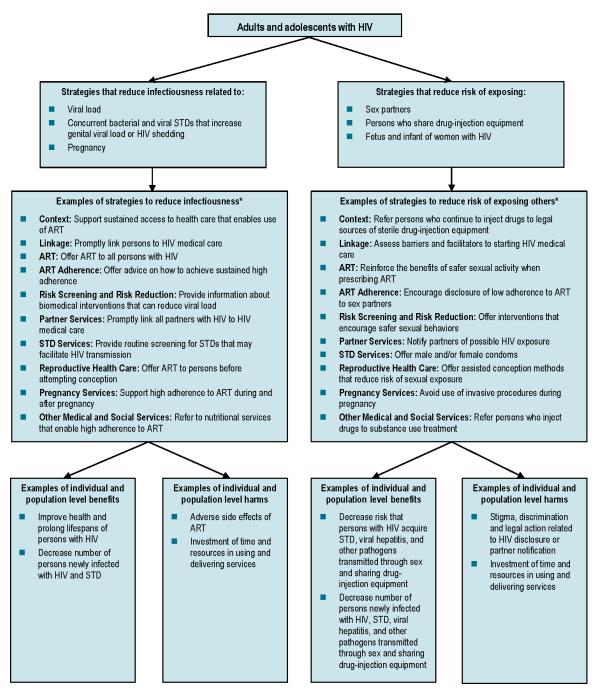
Appendices

Appendix A. Logic Model for HIV Prevention with Adults and Adolescents with HIV

Appendix B. Glossary

Appendix C. Organizations and Persons Contributing to this Report

Appendix A. Logic Model for HIV Prevention with Adults and Adolescents with HIV



Abbreviations: ART: Antiretroviral therapy; STD: Sexually transmitted diseases * One example was drawn from each of the sections 3-13

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Appendix B. Glossary

Acquired immunodeficiency syndrome (AIDS). A disease of the human immune system caused by infection with human immunodeficiency virus (HIV). It is characterized by a reduction in the numbers of CD-4 bearing helper T cells that may result in opportunistic infections and illnesses that may be potentially life-threatening.

Acute HIV infection. The period between initial HIV infection and the expression of HIV antibodies that can be detected by HIV antibody tests. This period is characterized by high levels of HIV in the blood and a vigorous immune response. Also referred to as primary HIV infection.

Acute retroviral syndrome. A symptomatic phase of acute HIV infection experienced by many, but not all, persons with HIV that is characterized by fever, lymphadenopathy, and other symptoms.

Adherence. The extent to which a person takes medication in the way it was prescribed by a health care provider. Adherence interventions focus on educating and motivating patients, building patients' skills, providing support and tools for medication management, and addressing barriers to adherence.

Antiretroviral treatment or therapy (ART). Medications used by persons with HIV to inhibit HIV replication in the body or, when used for preexposure prophylaxis or postexposure prophylaxis by HIV-uninfected persons, to prevent acquisition of HIV.

Artificial insemination (intravaginal and intrauterine). Conception methods in which semen is collected and instilled into the uterus (by a physician) or into the upper vagina (by a physician, person with HIV, or a partner). For HIV-discordant couples attempting to conceive, these methods pose a lower risk of HIV exposure because they avoid penile-vaginal intercourse.

Behavioral intervention. Specific activity (or set of related activities) intended to promote safe behaviors and reduce the risk of an individual spreading or becoming infected with the human immunodeficiency virus.

Behavioral risk-reduction interventions. Wide range of services intended to promote safe behaviors and reduce exposing others to HIV.

Biomedical intervention. The use of approaches designed to moderate biological and physiological factors to reduce the infectiousness of a person with HIV or to reduce a person's susceptibility to contracting HIV.

Case management. A service generally provided through an ongoing relationship with a client or patient that includes comprehensive assessment of medical and psychosocial support needs, development of a formal plan to address needs, provision of assistance and advocacy in accessing services, and monitoring of service delivery.

CD4 cell count. The number of CD4+ T-lymphocyte cells per millimeter cubed (mm³) of blood. CD4 cell count is a marker of the immune system's capacity to fight infection, CD4 cell count is used to assign stage of HIV disease, determine the risk of opportunistic illnesses, assess prognosis, and guide decisions about the need for treatment to prevent HIV-related diseases. **Client.** A person receiving prevention, testing, or social services from a health department or communitybased service providers, not including health facilities. This term is preferred over 'patient' in settings that provide healthy persons prevention and health maintenance services.

Clinical providers. Persons who work in health care facilities and who provide risk assessments, health education, counseling, screening, diagnosis, treatment, and other services to prevent, diagnose, treat, or manage health conditions. They include physicians, registered nurses, advance practice nurses, physician assistants, dentists, mental health providers, pharmacists, health educators, case managers, social workers, and counselors. Some may be employees or contractors of health departments.

Clinical setting. A health care facility in which medical diagnostic, treatment, and disease prevention services are routinely provided.

Collaboration. Working with another person, organization, or group for mutual benefit by exchanging information, sharing resources, or enhancing the other's capacity, often to achieve a common goal or purpose.

Colocating. The provision of more than one type of HIV service in the same physical space, such as providing substance use treatment in an HIV medical clinic or providing HIV partner services in an HIV testing facility.

Community-based HIV service organizations. Organizations that offer and deliver community-based HIV services, not including diagnostic and treatment services. Many collaborate with health departments to provide services to specific populations.

Confidentiality. Ensuring that information is accessible only to persons authorized to have access in order to maintain client and patient privacy.

Coordination. A process of creating more client-centered, streamlined, and nonduplicative systems that clarify communication methods, staff roles, use of health information, and reimbursement policies and procedures.

Culturally appropriate. Conforming to a culture's acceptable expressions and standards of behavior and thoughts. Interventions and educational materials are more likely to be culturally appropriate when representatives of the intended audience are involved in planning, development, and pilot testing.

Cunnilingus. Oral stimulation of the female genitals.

Diagnostic testing. Testing that is initiated for a person with clinical signs or symptoms to obtain objective evidence of the presence or absence of diseases or infections, including HIV and STDs.

Directly administered antiretroviral treatment or therapy (DAART). A method to promote ART adherence in which a clinical or nonclinical provider observes persons with HIV take all or most doses of prescribed ART. Also referred to as directly observed therapy (DOT).

Disclosure (of HIV infection status). A process in which a person with HIV reveals his or her HIV infection to others, or when an HIV prevention or care provider shares information about a person's HIV infection status with another HIV prevention or care provider.

Drug-injection partner. A person who has shared nonsterile or previously used needles, syringes, or other drug-injection equipment with another person.

Electronic medical record (EMR). A patient record that is maintained using computer software. The record should include patient history, including diagnoses, treatments, prescribed medications, drug allergies, and self-reported problems; patient demographics; physician clinical notes; and laboratory and imaging results.

Emergency postcoital contraception. A type of oral hormonal contraception used within a few days after intercourse that is intended to prevent pregnancy by disrupting ovulation or fertilization. It is most effective when taken as soon as possible after unprotected intercourse, but within 72 hours.

Enrollment. The process by which individuals are identified and invited to participant in HIV care and prevention services or interventions, such as HIV medical care or risk-reduction interventions.

Ethnicity. The cultural characteristics that connect a particular group or groups of people to each other, such as people of Hispanic/Latino origin.

Evaluation. A formal process to identify program strengths and areas for improvement.

Evidence-based. A characteristic of interventions, strategies, guidelines, and recommendations that are based on sound scientific research, testing, or program evaluation.

Evidence-based HIV behavioral intervention (EBI). Individual-, group-, or population-level interventions that have been shown to promote safer behaviors or reduce HIV or STD transmission in research studies, program evaluations, or theory-based intervention experience.

Gender identity. A person's private sense or personal experience of her/his own gender, or sense of being a man or a woman. Gender identity is not necessarily consistent with biological sex.

Health insurance marketplaces (previously known as "exchanges"). Competitive marketplaces created by the Patient Protection and Affordable Care Act (ACA) for individuals and small employers to directly compare available private health insurance options on the basis of price, quality, and other factors. The intent of marketplaces is to provide transparent, consumer education that enables persons to enroll in suitable, affordable health insurance.

The Health Insurance Portability and Accountability Act (HIPAA). HIPAA provides standards for protecting the privacy of individual-level, identifiable health information for certain electronic transactions initiated by health care providers, health plans, and health care clearinghouses. HIPAA is especially important for persons with HIV and other diseases that may result in stigma or discrimination.

HIV-discordant couple. An HIV-discordant couple consists of one HIV-infected person and one HIV-uninfected person.

HIV-discordant risk behavior. Engaging in unprotected sex or sharing drug-injection equipment with a person with a different HIV infection status.

HIV medical care. Medical services that address HIV infection and HIV-related diseases. These include evaluation of CD4 cell count and HIV viral load, prescribing antiretroviral treatment (ART), providing ART adherence support, prevention and treatment of HIV-related diseases, behavioral health education and interventions, and provision or referrals for other medical and social services, such as STD screening, partner services, reproductive and pregnancy services, substance use treatment, and mental health services.

HIV planning group. An official organization or committee that develops, advocates for, and implements a comprehensive plan for HIV prevention and care for a given jurisdiction.

HIV prevention counseling. An interactive process between client or patient and counselor aimed at reducing sexual, drug-use, and reproductive behaviors that pose a risk of HIV transmission or acquisition.

HIV superinfection. The acquisition of another HIV strain that may reduce the effectiveness of HIV treatment if new, drug-resistant HIV strains are acquired.

Human immunodeficiency virus (HIV). HIV is a retrovirus that causes immune deficiency and may eventually lead to AIDS, especially if appropriate treatment is not used.

Incidence. The number of new cases of a disease diagnosed in a defined population in a specified period, often a year.

Index patient. A person with diagnosed HIV or STD and whose diagnosis prompts an investigation to identify other persons (known as partners) who may have become infected through sexual contact or exposure to blood or other body fluids of the index patient

Indicator. A measure used to determine implementation over time of prevention or care services and the functions, processes, or outcomes of those services.

Informed consent. Communication between a person and a provider of prevention, testing, treatment or other health services, such as starting HIV treatment or referral to mental health services. It includes an oral or written summary of 1) the risks and benefits of the service, 2) documentation of services rendered and their outcomes, 3) the opportunity to ask questions, and 4) reassurance that declining a service will not result in denial of other clinical or nonclinical services.

Insertive anal sex. The practice of inserting one's penis into a partner's anus. Also known as insertive penile-anal sex.

Insertive fellatio. The practice of inserting one's penis into a partner's mouth. Also known as insertive penile-oral sex.

Insertive vaginal sex. The practice of inserting one's penis into a partner's vagina. Also known as insertive penile-vaginal sex.

Intracytoplasmic sperm injection. An *in vitro* fertilization procedure in which specially prepared ("washed") sperm of a man with HIV is injected directly into an egg retrieved from an ovarian follicle to achieve fertilization while minimizing the risk of HIV transmission to the female partner.

Linkage facilitator. Individual who assists persons with HIV to access HIV medical care and other medical and social services through active methods (e.g., help making appointments, providing transportation to appointments). May be called service linkage facilitator.

Linkage to care. The process of helping persons with HIV to obtain HIV medical care and prevention or social services through active methods (e.g., appointment scheduling, reminders, transportation to appointments). It is more active and immediate than referral and often includes navigation assistance and verification of rendered services.

Monitoring and evaluation (M&E). A process that involves the repeated, ongoing collection and review of information about program activities, characteristics, and outcomes in order to assess program implementation, coverage, acceptability, cost, and effectiveness.

Navigation assistance. The process of helping persons obtain timely and appropriate medical or social services given their preferences about providers, insurance status, scheduling issues, and other factors that may complicate access or utilization of services.

Newly reported HIV infection. A case of HIV infection that has been newly reported to a health department's surveillance registry.

Nonclinical providers. Persons who work in community-based organizations or health departments operating outside of health care facilities and who provide HIV testing, health education, risk-reduction interventions, partner services, case management, or assistance with linkage or referral to medical and social services. These persons include HIV testing providers, peer and professional health educators, counselors, service linkage facilitators, partner services specialists, case managers, and social workers.

Nonclinical setting. A setting that provides prevention, education, screening and interventions for risk behaviors, and referrals for medical and social services. Some nonclinical settings may also provide health promotion services and screening for HIV and some STD. Nonclinical settings do not routinely provide medical diagnostic and treatment services.

Nonoccupational postexposure prophylaxis (nPEP). The use of selected antiretroviral medications by HIV-uninfected persons within 72 hours after isolated, nonoccupational exposures to body fluids potentially containing HIV, such as after unprotected sexual intercourse or condom breakage, in order to reduce the risk of HIV acquisition.

Nonoxynol-9. An organic compound with spermicidal properties that is used in vaginal spermicides and anogenital lubricants.

Nucleic acid amplification test (NAAT). A type of sensitive laboratory test that detects genetic material of a pathogen, such as HIV or *Neisseria gonorrhoeae*.

Outreach. A systematic attempt to improve uptake of services by seeking persons who may benefit from services in community settings (e.g., parks, churches, bars).

Partner. A person with whom 1) a person with HIV (known as an index patient) has either had sex or shared drug-injection equipment at least once, or 2) a person with an STD has had sex at least once.

Partner elicitation. An early step of voluntary, confidential partner services in which a health department partner services specialist or other provider interviews or reinterviews a person with HIV or STD to collect names, descriptions, and locating and contact information of persons who are sex or drug-injection partners so the partners can be notified of possible HIV or STD exposure.

Partner notification. A step of voluntary, confidential partner services that involves locating and confidentially notifying sex and drug-injection partners of persons infected with HIV or STD of possible exposure to HIV or STD.

Partner services. An array of voluntary services for persons with HIV or STD and their sex and druginjection partners that are intended to reduce HIV transmission: interviewing persons with HIV to obtain information to contact or locate their sex and drug-injection partners; notifying partners of possible HIV exposure; offering testing for HIV, sexually transmitted diseases, and other infections; providing condoms, prevention information, and counseling; and providing help in obtaining risk-reduction services, HIV medical care, and other medical and social services.

Partner services specialists. Persons who provide partner services, including specially trained disease investigation specialists, public health investigators, or communicable disease investigators who work in health departments and staff of other agencies who are trained and authorized to provide these services.

Person at high risk of HIV infection. A person who has behaviors that place him/her at high risk of contracting HIV infection (e.g., having unprotected sex or sharing drug-injection equipment with a person known to be HIV-infected or with persons from communities with a high prevalence of HIV infection).

Persons who inject drugs (PWID). Persons who inject illicit drugs using equipment that may facilitate HIV transmission, such as nonsterile syringes, needles, cookers, or spoons.

Population-level intervention. An intervention intended to improve the risk conditions and behaviors in a population or community by focusing on the population or community as a whole, rather than on individuals or small groups. Examples include community mobilization, social marketing campaigns, community events, policy interventions, and housing programs meant to alter social norms, policies, or environmental characteristics.

Postnatal infant prophylaxis. The use of selected antiretroviral medications for several weeks by newborns born to women with HIV to prevent HIV acquisition.

Preexposure prophylaxis (PrEP). The daily, continuous use of a select regimen of antiretroviral medications for a period of time by an HIV-uninfected person to achieve levels of drug in the blood and anal and genital mucosa sufficient to reduce the risk of HIV acquisition.

Presumptive treatment. The provision of treatment for syphilis, gonorrhea, chlamydial infection or trichomoniasis before the results of STD testing or clinical evaluation are available. This treatment approach is recommended for persons who report symptoms suggestive of these STDs or recent sex partners who were treated for these STDs, or have clinical signs of these STDs.

Prevalence. The total number of cases of a disease in a given population at a particular point in time. HIV/AIDS prevalence refers to persons infected with HIV, regardless of time of infection or diagnosis date.

Prevention services (or program). Interventions, strategies, policies, and structures designed to reduce the transmission of HIV infection. Examples of HIV prevention services include risk-reduction information and interventions, condom distribution, use of antiretroviral therapy to reduce HIV viral load, and STD screening and treatment to control infections that can facilitate HIV transmission. A prevention program is an organized effort to implement one or more interventions.

Privacy. The right and power to control information about oneself.

Quality improvement. An approach to the continuous study and improvement of the processes of providing services that meet or exceed established professional standards and user expectations.

Receptive anal sex. The practice of receiving a partner's penis in one's anus. Also known as receptive penile-anal sex.

Receptive fellatio. The practice of receiving a partner's penis in one's mouth. Also known as receptive penile-oral sex.

Receptive vaginal sex. The practice of receiving a partner's penis in one's vagina. Also known as receptive penile-vaginal sex.

Reengagement. A process to help persons with HIV resume HIV medical care and attend scheduled HIV medical appointments after a lapse in care.

Referral. A process by which nonclinical or clinical providers assess a person's needs for prevention, care, and supportive services and help him or her identify and access services (e.g., providing directions and phone numbers of nearby facilities, providing information about how to enroll in health insurance). It is less intensive than active linkage assistance and may not include ongoing support or case management.

Reproductive health counseling. Information and counseling for HIV-infected women and HIV-infected men of reproductive age and their partners about preventing unintended pregnancy; pregnancy planning and spacing; the risks of HIV transmission when attempting conception; the risk of adverse maternal or fetal outcomes should transmission occur when attempting conception or during pregnancy; and methods to reduce these risks.

Retention in care. A process to help persons with HIV continue to attend scheduled HIV medical appointments after their initial HIV medical appointment.

Risk behaviors. Behaviors that can result in transmitting HIV to others or acquiring HIV (e.g., anal or vaginal intercourse without a barrier, sharing nonsterile drug-injection equipment).

Risk compensation. Modifying sex or drug-injection behaviors in way that increases risk of HIV transmission or acquisition when other safeguards are introduced (e.g., when persons with HIV who believe that ART use reduces their infectiousness no longer use condoms to prevent HIV transmission).

Risk screening. A brief assessment of behavioral factors that may affect the risk of exposing others to HIV, such as inconsistent condom use or sharing drug-injection equipment, and biomedical factors that influence HIV transmission, such as viral load, antiretroviral treatment and adherence, sexually transmitted disease, and pregnancy. Risk screening is used to identify behavioral or biomedical risk-reduction interventions suited to a specific individual.

Seropositioning. The practice of modifying sexual activity based on beliefs about the partner's HIV infection status and the per-act risk of HIV transmission for a given type of contact (e.g., persons with HIV practice receptive fellatio with HIV-uninfected partners because they believe this type of contact is less likely to transmit HIV than insertive fellatio, anal sex, or vaginal sex).

Serosorting. The practice of limiting unprotected sex to partners believed to have the same HIV infection status. For example, persons with HIV only have unprotected sex with persons believed to be HIV-infected.

Sexual orientation. A person's physical or emotional attraction to persons of the same and/or opposite gender, (e.g., heterosexual, bisexual, or homosexual).

Sexually transmitted diseases (STD). Diseases that are spread primarily through person-to-person sexual contact. Also referred to as sexually transmitted infections (STI).

Social network. A group of persons connected by social relationships, such as friends, family, sex and drug-injection partners, or persons who frequent the same physical or virtual venues.

Social networking. A strategy to recruit persons for HIV testing or prevention services in which highrisk individuals use their personal influence to recruit peers they believe are at high risk for HIV infection.

Sperm washing. A procedure that removes components (including seminal fluid that may contain HIV) other than sperm from a semen sample before it is used for artificial insemination.

State and local health departments. Governmental organizations in states, locales, territories, and tribes that provide planning, policy development, surveillance, partner services, and other services to promote the health of communities and control communicable and chronic diseases.

STD syndromes. Conditions caused by sexually transmitted pathogens that cause symptoms and/or abnormal findings on physical examination (signs). May include genital ulcer disease, urethritis, cervicitis, pelvic inflammatory disease, epididymitis, and proctitis.

Substance use or abuse. Recreational use of alcohol, legal or illicit drugs, and other substances that may impair judgment, influence HIV risk behaviors, hinder seeking of HIV prevention services, or cause other problems. In some cases, it is associated with dependence or addiction to the substance.

Surveillance. The ongoing and systematic collection, analysis, interpretation, and dissemination of data about occurrences of a disease or health condition.

Syringe services programs (SSPs). Programs that provide free, new, sterile syringes and needles in exchange for used syringes and needles to reduce transmission of bloodborne pathogens among people who inject drugs. May be called syringe exchange programs or needle exchange programs.

Telemedicine services. The use of telecommunications technology to provide, enhance, or expedite health care services or to provide consultation, training, and mentoring to health care professionals.

Timed, periovulatory intercourse. A conception method intended to reduce the risk of HIV transmission in HIV-discordant couples in which unprotected intercourse occurs only when infected partners have achieved maximal viral suppression, the woman is in the periovulatory period of her menstrual cycle, and condoms are used at all other times.

Transgender man. An individual whose assigned sex at birth is female but whose gender expression and/or gender identity is male.

Transgender woman. An individual whose assigned sex at birth is male but whose gender expression and/or gender identity is female.

Transmission risk. Factors identified as potential modes of HIV transmission (e.g., unprotected sexual contact, sharing drug-injection equipment).

Unprotected sex or unprotected sexual contact. Sexual activity without using a physical barrier (i.e., penile sex without using a male condom; vaginal sex without using a male or female condom; oral-anal contact without using a dental dam or other barrier device; vaginal-digital contact without using a female condom, latex glove, or finger cot; or rectal-digital contact without using a latex glove or finger cot).

Viral load. The HIV-1 viral load measurement indicates the number of copies of HIV-1 RNA per milliliter of plasma. It reflects the burden of infection and the magnitude of viral replication and is used to

assess the risk of disease progression, to monitor virologic response to ART, and to estimate the degree of infectiousness.

Virologic failure. The inability to achieve or maintain suppression of HIV replication to an HIV RNA level of <200 copies/mL.

Virologic testing. The process of using tests that detect HIV antigens or nucleic acids such as RNA or DNA

Window period. Interval between a person's infection with HIV and the production of HIV antibodies that can be detected by an HIV test.

Appendix C. Organizations and Persons Contributing to this Report

Project Workgroup

Project Leaders

Centers for Disease Control and Prevention (CDC), Atlanta, Georgia: Kathleen Irwin, MD, MPH; Peter Kilmarx, MD; Amrita Patel Tailor, MPH; Gema Dumitru, MD, MPH; Priya Jakhmola, MS, MBA; M. Chris Cagle, PhD; Jonathan Mermin, MD, MPH.

Health Resources and Services Administration (HRSA), Rockville, Maryland: Anna Huang, MD; Laura Cheever, MD, ScM.

National Institutes of Health (NIH), Bethesda, Maryland: Emily Erbelding, MD.

Members of Section Writing Groups

CDC, including staff of the Division of HIV/AIDS Prevention (DHAP), the Division of STD Prevention (DSTDP), the Division of Adolescent and School Health (DASH), and the Division of Reproductive Health (DRH): Elin B. Begley, MPH; Stuart Berman,* MD, ScM; Stephanie Bernard, PhD; Jeanne Bertolli, PhD, MPH; Gail Bolan, MD; Jeff Bosshart, MSW, MPH; John T. Brooks, MD; Meredith Carr,* JD; Nicole Crepaz, PhD; Kevin Delaney,* MPH; Ken Dominguez, MD, MPH; Sam Dooley, MD; Gema Dumitru, MD, MPH; Erica Dunbar,* MPH; Eileen Dunne, MD, MPH; Lytt I. Gardner, PhD; Pamela Morse Garland,* MS; Janet Heitgerd, PhD; Darrel Higa,* PhD; Matthew Hogben, PhD; Kathleen Irwin, MD, MPH; Priya Jakhmola, MS, MBA; Wayne Johnson,* MSPH, PhD; Patricia Jones, DrPH, MPH (now with the National Institutes of Health); Andrea Kelly, BA; Peter Kilmarx, MD; Linda J. Koenig, PhD, MS; Cindy Lyles, PhD; Gary Marks, PhD; Yoko Mizuno, PhD; Rebecca L. Morgan, MPH; Steve Nesheim, MD; Michelle Owen,* PhD; Tom Painter, PhD; David W. Purcell, JD, PhD; Susan Zik Shewmaker, MA, RN; Melanie Sovine, PhD; Dale Stratford,* PhD; Madeline Sutton, MD, MPH; Amrita Patel Tailor, MPH; Abigail Viall, MA; Paul Weidle,* Pharm D, MPH; Kimberly A. Workowski,* MD.

HRSA, including staff of the Office of the Administrator and the Bureaus of HIV/AIDS, Primary
Health Care, Health Workforce, and Maternal and Child Health: Songhai Barclift, MD;
Michelle Nichole Charlene Browne, MSW, CSW, MPA; Shaun Chapman, MS; John Fanning, JD;
Brian Feit, MPA; Mindy Golatt, MA, CPNP, MPH; Deborah Isenberg, MPH, CHES; Ericka Ligon, MPH;
Alice M. Litwinowicz, MA; Faye Malitz, MS; Sheila McCarthy, BSN, RN; Robert Mills, PhD;
Roberto A. Nolte, MD; Sid Petersen; Julie Ross, MPH; Helen M. Rovito, MS; Robert Settles,* LCSW;
Jason Stanford, MPA; Diana Travieso-Palow, MPH, MS, RN.

^{*} Participant did not provide a declaration of interest form. This applies to all names with asterisks in Appendix C.



Representatives of Nongovernmental Cosponsor Organizations

American Academy of HIV Medicine, Washington, District of Columbia: James M. Friedman, MHA; W. David Hardy, MD; Donna E. Sweet, MD.

Association of Nurses in AIDS Care, Akron, Ohio: Kimberly Carbaugh,* RN; Carole Treston,* RN, MPH (formerly of the AIDS Alliance for Children, Youth, and Families); Adele Webb, PhD, RN.

International Association of Providers of AIDS Care, Washington, District of Columbia: Joan P. Holloway, MA; Jose Zuniga, PhD, MPH.

National Association of People with AIDS, Silver Spring, Maryland: Vanessa I. Johnson,* JD; Frank J. Oldham,* BA. (*Note.* This organization disbanded during the late stages of development of these recommendations.)

National Minority AIDS Council, Woodbridge, Virginia: Kim M. Johnson, MD; Paul Kawata; Daniel Montoya.

Urban Coalition for HIV/AIDS Prevention Services, San Francisco, California: Marsha Martin, DSW; Israel Nieves-Rivera,* BS.

Contributors to April 2011 Consultation and/or Review of Draft Documents

CDC: Mary Angie Allen, MHS; Alexandra Anderson,* MPH; Pam Bachanas, PhD; Stephen W. Banspach,* PhD; Wanda D. Barfield,* MD, MPH, FAAP; Charles Basham III,* MBA, MHA; Linda Beer, PhD; Deanna Campbell, MPH; Vilma Carande-Kulis,* PhD; Janet Cleveland,* MS; Stephanie Creel,* MA; Kathryn M. Curtis,* PhD; Timothy Dondero,* MD; John Douglas,* MD; Frank Ebagua, BA; Sarah Ekerholm,* MPH; Laura Fehrs, MD; Lorrie Gavin,* PhD; Cindy Getty,* MPH; Kathleen Green, PhD; Timothy Green,* PhD; Nancy Habarta, MPH; Irene Hall,* PhD; James D. Heffelfinger,* MD, PhD; Denise Jamieson,* MD; Alessandria Killingsworth,* BA; Lisa W. Kimbrough, MS; Athena P. Kourtis, MD, PhD, MPH; Yzette Lanier,* MD, MPH; Amy Lansky,* PhD, MPH; Anne Fulton Laterra,* MPH; Mary Lou Lindegren,* MD; Khiya Marshall, PhD; David Massey;* Donna McCree, PhD, MPH, RPh; Laura McElroy, BA; Amy Medley, PhD, MPH; David Miller, BA; Kimberly D. Miller,* MPH; Yuko Mizuno, PhD; Peter Moore,* MPH; Ashley Murray;* Joseph Prejean, PhD; Sam Posner,* PhD; David W. Purcell, JD, PhD; Laurie Reid, MS, RN; Melinda Salmon,* MPH; Taraz Samandari,* MD, PhD; Stephanie Sansom, PhD; Alberto Santana, MS, BS; Shara Senior,* MPH; Phil R. Spradling, MD; Phyllis Stoll, MPH, CHES; Frank Strona,* MPH; Benedict I. Truman,* MD, MPH; Eduardo Valverde, MPH; Lee Warner,* PhD, MPH; John Weiser, MD, MPH; Samantha Williams,* PhD; Richard Wolitski,* PhD; Maria Zlotorzynska,* PhD.

HRSA: Rupali K. Doshi, MD; Glenn Clark,* MSW (formerly with the Maryland Department of Health and Mental Hygiene, Baltimore, Maryland); Susan E. Robilotto, DO.

NIH, from the Office of AIDS Research (OAR), National Institute of Allergy and Infectious Diseases (NIAID), National Institute of Mental Health (NIMH), National Institute of Drug Abuse (NIDA), National Institute of Child Health and Human Development (NICHD), Office of Science Policy (OSP), and Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI): Gina M. Brown, MD; Vanessa N. Elharrar, MD, MPH; Christopher Gordon, PhD; Cynthia I. Grossman, PhD; Richard A. Jenkins, PhD; Bill G. Kapogiannis, MD.

Center for Medicare and Medicaid Services, New York, New York: Nilsa Gutierrez,* MD, MPH.

Substance Abuse and Mental Health Services Administration, Rockville, Maryland: Kirk James,* MD; Gretchen Stiers,* MD.

U.S. Department of Health and Human Services, Washington, District of Columbia: Andrew Forsyth,* PhD.

U.S. Department of Veterans Affairs, Washington, District of Columbia: Maggie Czarnogorski, MD.

Other nongovernmental experts: David Acosta, BA, Philadelphia Department of Public Health, Philadelphia, Pennsylvania; Michelle M. Agnoli,* RN, MSN, ACRN, University of Illinois College of Medicine at Chicago, Chicago, Illinois; Michael W. Allerton, MS, Kaiser Permanente, Oakland, California; David Amarathithada,* MPH, HPA, Chicago Department of Public Health, Chicago, Illinois; Greg Bautista,* BA, Georgia Department of Community Health, Atlanta, Georgia; Lucy A. Bradley-Springer, PhD, RN, ACRN, Mountain-Plains AIDS Education and Training, Denver, Colorado; Natalie O. Cramer, MSSW, National Alliance of State and Territorial AIDS Directors, Washington, District of Columbia; Anitra P. Denson, MD, District of Columbia Department of Health, Washington, District of Columbia; Ivan Espinoza-Madrigal, Esq, The Center for HIV Law and Policy, New York, New York; C. Virginia Fields,* MSW, National Black Leadership Commission on AIDS, New York, New York; Bambi Gaddist, DrPH, South Carolina HIV/AIDS Council, Columbia, South Carolina; Dara L. Geckeler, MPH, San Francisco Department of Public Health AIDS Office, San Francisco, California; P. Justin Goforth, RN, Gay Men's Health and Wellness Clinic, Washington, District of Columbia; Claudia Gray, MS, Center for HIV Prevention, Baltimore, Maryland; Dena Gray,* BA, City of Houston Department of Health and Human Services, Houston, Texas; Keith R. Green, MSW, AIDS Foundation of Chicago, Chicago, Illinois; W. David Hardy, MD, Cedar-Sinai Medical Center, Los Angeles, California; C. Bradley Hare, MD, University of California-San Francisco, San Francisco, California; Kate Petersen Heyer, MPH, National Association of County and City Health Officials, Washington, District of Columbia; Michael Horberg, MD, MAS, Mid-Atlantic Permanente Medical Group, PC, Rockville, Maryland; Hutson W. Inniss,* BA, National Coalition for LGBT Health, Washington, District of Columbia (deceased); Roxanne Jamshidi, MD, MPH, Johns Hopkins Bayview Medical Center, Baltimore, Maryland; Ronald S. Johnson,* BS, AIDS United, Washington, District of Columbia; Angela Kapalko,* PA-C, American Academy of Physician Assistants, Philadelphia, Pennsylvania; Sharon Lee, MD, Southwest Boulevard Family Health Center, Kansas City, Kansas; Sharon Nachman, MD, Health Service Center, State University of New York, Stony Brook, New York; Jim Pickett, AIDS Foundation of Chicago, Chicago, Illinois; Lauren E. Poole,* NP, MSN, Positive Health Program, San Francisco, California; Anita Radix, MD, Callen-Lorde Community Health Center, New York, New York; Leo B. Rennie, MPA, American Psychological Association, Washington, District of



Columbia; Norma Rolfsen,* RN, FNP, MS, AACRN, Michael Reese Center, Chicago, Illinois; Beirne Roose-Snyder,* JD, Center for Health and Gender Equity, Washington, District of Columbia (formerly with Center for HIV Law and Policy, New York, New York); Jill M. Sabatine,* MSW, National Association of Social Workers, Providence, Rhode Island; Carl E. Schmid II, MBA, BA, The AIDS Institute, Washington, District of Columbia; Scott Schoettes, JD, Lambda Legal Defense and Education Fund; John W. Senterfitt, PhD, RN, MPH, Los Angeles County Department of Public Health, Los Angeles, California; Michael D. Siever,* PhD, San Francisco AIDS Foundation, San Francisco, California; Jane M. Simoni, PhD, University of Washington, Seattle, Washington; Neena Smith-Bankhead, MS, AID Atlanta, Inc., Atlanta, Georgia; Javid Syed,* MPH, Treatment Action Group, New York, New York; Tyler A. TerMeer,* MS, Ohio AIDS Coalition, Columbus, Ohio (formerly with the National Alliance of State and Territorial AIDS Directors, Washington, District of Columbia); Tim Vincent, MS, MFCC, University of California, San Francisco, California; Aimee Wilkin, MD, MPH, Wake Forest University School of Medicine, Winston-Salem, North Carolina; Ron Wilcox,* MD, Louisiana State University Health Sciences Center, New Orleans, Louisiana; Margaret Wolfe,* MPH, Puerto Rico Department of Health, San Juan, Puerto Rico; Barry Zingman, MD, Montefiore Medical Center, Bronx, New York.

External Peer Reviewers

A. Cornelius Baker, National Black Gay Men's Advocacy Coalition, Washington, District of Columbia; Carlos del Rio, MD, MPH, Emory University, Atlanta, Georgia; Seth C. Kalichman, PhD, University of Connecticut, Storrs, Connecticut; Jeanne M. Marrazzo, MD, MPH, University of Washington, Seattle, Washington; Mark W. Thrun, MD, Denver Public Health, Denver, Colorado; Rochelle Walensky, MD, MPH, Brigham and Women's and Massachusetts General Hospital, Boston, Massachusetts.

Editorial, Information Science, and Graphical Support

CDC: Michael Friend, ABJ; Mary Mullins, MLS; Robin Moseley, MAT; Kim Distel, MS, MLIS; Richard Noegel, BA; Marie S. Morgan, BA, ELS; Jarrad Hogg, BFA.

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