## EVIDENCE-STATEMENT: SEXUALLY TRANSMITTED INFECTIONS (Screening and Counseling)

# Human Immunodeficiency Virus (HIV) (Screening and Counseling)

	Clinical Preventive Service Recommendations
Special Notice	This special notice is included to alert readers about differences between Centers for Disease Control and Prevention (CDC) and U.S. Preventive Services Task Force (USPSTF) HIV screening recommendations for individuals who are not at increased risk for HIV infection.
	In 2006, the CDC issued new HIV testing guidance for healthcare settings that recommends screening all patients aged 13 to 64 years for HIV. In 2005, the USPSTF considered HIV screening and issued a "C"-rating, thereby making no recommendation for or against routinely screening adults and adolescents who are not considered to be at increased risk for HIV infection.
	The <i>Purchaser's Guide</i> recommendation reflects the broader CDC recommendation. The CDC recommendation is preferred because clinicians are not consistently able to distinguish between high- and no-risk testing candidates <sup>1-2</sup> and because spread often occurs between individuals who do not know that they are infected. <sup>3</sup>
U.S. Preventive Services Task Force Recommendation	The U.S. Preventive Services Task Force (USPSTF) recommends that clinicians screen all adolescents and adults with an increased risk of infection for human immunodeficiency virus (HIV). Increased risk is defined by the USPSTF as having one or more individual risk factor STIs or receiving healthcare in a high-prevalence or high-risk clinical setting. Please refer to the "Condition/Disease Risk Factors" section for additional information. <sup>4</sup>
	The USPSTF recommends that clinicians screen all pregnant women for HIV. <sup>4</sup>
Evidence Rating: A (Strongly Recommended/Good Evidence)	The USPSTF found good evidence that both standard and U.S. Food and Drug Administration (FDA)-approved rapid screening tests accurately detect HIV infection. The USPSTF also found good evidence that appropriately timed clinical intervention, particularly highly active antiretroviral therapy (HAART), lead to improved health outcomes for many of those screened, including reduced risk for clinical progression and reduced mortality. <sup>4</sup>
Evidence Rating: A (Strongly Recommended/Good Evidence)	The USPSTF found good evidence that both standard and FDA-approved rapid screening tests accurately detect HIV infection in pregnant women and fair evidence that the introduction of universal prenatal counseling and voluntary testing increases the proportion of HIV-infected women who are diagnosed and are treated before delivery. There is good evidence that recommended regimens of HAART are acceptable to pregnant women and lead to significantly reduced rates of mother-to-child transmission. <sup>4</sup>

CDC Recommendation	The Centers for Disease Control and Prevention (CDC) recommends that providers screen all patients aged 13 to 64 years for HIV unless prevalence of undiagnosed HIV infection among the provider's patient population has been documented to be less than 0.1%. <sup>5</sup> Subsequent HIV tests should be provided to all persons likely to be at high risk
	(i.e., sex partners of HIV infected persons, men who have sex with men, heterosexuals who themselves or whose sex partners have had a new sex partner or more than one sex partner since their most recent HIV test, injection drug users, and persons who exchange sex for money or drugs) all patients seeking treatment for an STI, and those who are initiating a new sexual relationship. <sup>5</sup>
	The Centers for Disease Control and Prevention (CDC) also recommends that clinicians screen all pregnant women for HIV. <sup>6</sup>
Evidence Rating:	CDC recommendations were developed with guidance from the scientific literature and expert technical opinion. Information was also drawn from a survey CDC conducted with HIV CTR practitioners. Internal CDC edits and public comments were obtained. <sup>5</sup>
Information Sources	<ul> <li>The recommendations and supporting information contained in this document came from several sources, including the:</li> <li>Centers for Disease Control and Prevention (CDC)</li> <li>Peer-reviewed research</li> <li>U.S. Preventive Services Task Force (USPSTF)</li> </ul>
	The background and supporting information contained in this document is a compilation of research findings. All information presented in this document should be attributed to its referenced source and should not be considered a reflection of other organizations cited in the text.
	Condition/Disease Specific Information
Epidemiology of Condition/Disease	Human immunodeficiency virus (HIV), the virus that causes acquired immune deficiency syndrome (AIDS), is a retrovirus that attacks helper T cells of the immune system. It causes immune deficiency because it reduces the number and functionality of CD4 lymphocytes. HIV is transmitted when the infected blood, semen, or vaginal secretions of an infected person comes into contact with the broken skin or mucous membranes of an uninfected person. Infected pregnant women can pass HIV to their babies during pregnancy or delivery, or when breastfeeding.
	HIV is known to affect between 1,039,000 and 1,185,000 persons in the United States; a quarter of those infected with the virus are unaware of their status. <sup>7</sup> There are approximately 40,000 new HIV infections diagnosed each year in the United States. <sup>8</sup> Untreated HIV infection eventually develops into AIDS and ultimately leads to death. <sup>9</sup> More than 500,000 people in the United States have died from AIDS; 18,000 in 2003 alone. <sup>8</sup>

	While antiretroviral therapies can slow the damage that HIV does to the body's immune system by decreasing the amount of virus is the body, HIV infection is not curable. An HIV-positive person will develop AIDS when CD4 lymphocyte levels have dropped so low as to allow opportunistic infections and/or cancers.
Condition/Disease Risk Factors	HIV infection is more common in certain segments of the U.S. population. There is some evidence that about half of all HIV infections are acquired by those under the age of 25. <sup>6</sup> Of newly diagnosed HIV infections in 2003, CDC estimates that 63% were among men who have sex with men (MSM), 50% were among blacks, 32% were among whites, and 16% were among Hispanics. <sup>10</sup>
	Individual risk factors include: • Men who have had sex with men (MSM) after 1975.
	• Men and women who have unprotected sex with multiple partners.
	• Past or present injection drug users.
	• Men and women who exchange sex for money or drugs or have sex partners who do.
	• Persons whose past or present sex partners were HIV-infected, bisexual, or injection drug users.
	• Persons being treated for sexually transmitted infections (STIs).
	• Persons with a history of blood transfusion between 1978 and 1985.
	Persons who request an HIV test despite reporting no individual risk factors may also be considered at increased risk. High-risk settings include STI clinics, correctional facilities, homeless shelters, tuberculosis clinics, clinics serving men who have sex with men, and adolescent health clinics with a high prevalence of STIs. High-prevalence settings are defined by the CDC as those known to have a 1% or greater prevalence of infection among the patient population being served.
	Value of Prevention
Economic Burden of Condition/Disease	The economic burden of HIV in the United States is substantial. The average <i>lifetime</i> cost per case (in year 2000 dollars) is estimated at \$199,800. <sup>11</sup> Accounting for the 15,000 new cases reported annually among 15 to 24-year- olds, the total direct cost of HIV in the United States was approximately \$3.0 billion in 2000. <sup>11</sup>
Workplace Burden of Condition/Disease	HIV/AIDS often affects people during their prime working years and HIV/AIDS-induced morbidity and mortality can result in significant economic losses to businesses. Considering only the changes in insurance premiums, disability payments, unemployment benefits, retirement and pension benefits, and lost productivity, a recent study found that, in 2002, an asymptomatic HIV- infected employee would cost an employer in the United States an estimated \$37,320 and a symptomatic HIV-infected employee would cost \$50,347 per person-year. <sup>12</sup>

Economic Benefit of Preventive Intervention	Earlier diagnosis of HIV infection is associated with less expensive treatment. For those with CD4 counts greater than 500, monthly expenditures for treatment total approximately \$500. This figure increases to \$2,300 per month for those with CD4 counts less than 50. Generally, the earlier HIV infection is detected, the higher the CD4 count. <sup>13</sup>
Estimated Cost of Preventive Intervention	In 2004, the private-sector cost of HIV screening averaged \$23; approximately 95% of all paid claims fell within the range of \$4 to \$75. <sup>14</sup> In 2004, the private-sector cost of HIV counseling averaged \$39 and approximately 95% of all paid claims fell within the range of \$0 to \$129. <sup>14</sup>
Estimated Cost of Treatment	The average annual cost of treating an HIV-infected patient is estimated to range between \$18,000 and \$20,000. <sup>15</sup>
Cost-Effectiveness and/or Cost-Benefit Analysis of Preventive Intervention	Researchers studied the costs associated with screening and treating HIV/AIDS in pregnant women and found that universal screening can be cost-saving in this population. For example, compared to no screening, a universal screening program targeting pregnant women would save an estimated \$3.69 million dollars and prevent 64.6 cases of pediatric HIV infection for every 100,000 pregnant women screened. <sup>16</sup>
	Preventive Intervention Information
Preventive Intervention: Purpose of Screening	Screening allows for the earlier diagnosis of HIV infection, which is associated with less expensive treatment, better health outcomes, and reduced risk of spread of infection to other persons.
Purpose of Counseling	Counseling services are required to educate screening candidates on 1) the benefits and risks of screening, 2) risk reduction strategies, and, for those who screen positive, 3) treatment options.
Benefits and Risks of Intervention	The benefit of screening and counseling includes early diagnosis of HIV infection, the potential for a longer life (due to earlier initiation of treatment), and the opportunity to prevent disease transmission. Counseling also allows prevention and risk-reduction messages to be conveyed. The benefits associated with screening pregnant women are also substantial. Screening allows for early detection and treatment and can prevent mother-to-child transmission. There is no evidence of an increase in fetal anomalies or other fetal harm associated with recommended antiretroviral regimens. <sup>4</sup>
	Risks associated with screening for HIV include false-positive test results and partner discord. Information about the effects of false-positive test results (e.g., anxiety, labeling) is predominately anecdotal. The standard method of diagnosing HIV infection (a repeatedly-reactive enzyme immunoassay followed by confirmation Western blot of immunoflourescent assay) has a 1 in 250,000 test chance of false-positive identification in a low prevalence setting. <sup>8</sup> Newer HIV detection technologies, specifically the rapid HIV tests, are similar to traditional tests with extremely low false-positive rates. False- and true-negative test results

	may give false reassurance to those engaging in high-risk behavior, leading to its continuation. Finally, notification of a positive HIV test can cause emotional or psychological distress.
Initiation, Cessation, and Interval Screening	Although no studies have evaluated the optimal frequency of screening for HIV/AIDS, it is recommended that screening be conducted at the discretion of a clinician with frequency determined by an individual's risk factors and the characteristics of the region in which the clinician practices.
	All pregnant women should be screened as early as possible, ideally at the first prenatal care visit. <sup>17</sup> Pregnant women at high risk for infection or all women living in an area with high HIV prevalence among women of childbearing age should be re-tested during the third trimester. <sup>17</sup>
Counseling	Counseling should be provided before and after screening, as medically indicated.
Intervention Process Screening	The standard method of screening for HIV/AIDS uses an enzyme immunoassay on serum or plasma; if the enzyme immunoassay is repeatedly reactive, a confirmatory Western blot or immunoflourescent assay is then performed. Several HIV tests that provide results within 10 to 30 minutes are available. The Food and Drug Administration (FDA) has also approved a home collection kit, which uses a blood sample from a finger prick for testing purposes.
	<ul><li>There are three approved methods of screening for HIV, including:</li><li>Repeatedly-reactive enzyme immunoassay followed by confirmatory Western blot or immunoflourescent assay on serum or plasma.</li></ul>
	• Rapid HIV tests with result in 10-30 minutes; two point-of-care rapid tests are available (Uni-Gold Recombigen & Oraquick Advance) and one rapid test is intended for laboratory use.
	• A home collection kit (Home Access) that uses a dried blood spot.
Counseling	All patients should receive counseling and educational information on HIV and HIV screening before they are screened. Patients that have behaviors that place them at high risk for acquiring HIV infection (e.g., multiple sex partners, history of STIs, substance abuse, etc) should be referred to an HIV risk-reduction service (e.g., HIV centers with personnel trained in HIV counseling, drug treatment centers, etc). <sup>18</sup>
Treatment Information	Health benefits should include provisions for follow-up and treatment services.

## Strength of Evidence for the Clinical Preventive Service

The level of evidence supporting the recommendation in this section is described below.

### Evidence-Based Research:

U.S. Preventive Services Task Force (USPSTF) Strength of Evidence: A (Strongly Recommended/Good Evidence)

- The USPSTF found good evidence to support routine screening for HIV among all adolescents and adults with an increased risk of infection for human immunodeficiency virus (HIV).<sup>4</sup>
- The USPSTF found good evidence to support routine screening for HIV among all pregnant women.<sup>4</sup>

#### **Recommended Guidance:**

Centers for Disease Control and Prevention (CDC) Strength of Evidence: CDC recommendations were developed with guidance from the scientific literature and expert technical opinion. Information was also drawn from a survey CDC conducted with HIV CTR practitioners. Internal CDC edits and public comments were obtained.

- The CDC found good evidence to support routine screening for HIV among all pregnant women.<sup>5</sup>
- The CDC found good evidence to support the provision of HIV-related counseling, testing, and referral (CTR) to all patients on a routine basis to ensure that those clients that may benefit from the service have the opportunity to do so.<sup>5</sup>

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