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Confronting the AIDS Epidemic: New Guidelines and Programs Offer Hope for Reduction of the Global HIV Burden

By Katherine Soreng, PhD

Answers for life.



Confronting the AIDS Epidemic: New Guidelines and Programs Offer Hope for Reduction of the Global HIV Burden

Recent data suggests increased HIV transmission in many countries, including regions in both Europe and the USA.^{1,2} This article discusses the importance of early identification of infected individuals to both reduce new transmission and promote earlier intervention with antiretroviral therapies. Revised guidelines from both the USA and European Union may dramatically increase screening for HIV infection. Sensitive testing technologies are central to this move toward more widespread screening, providing tools for early detection that support both optimal patient management and infection control.

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Infection with the Human Immunodeficiency Virus (HIV) leads to significant damage to the immune system and the clinical development of the Acquired Immune Deficiency Syndrome (AIDS). Without treatment, infection with opportunistic disease is almost certain. Common opportunistic diseases are listed in Figure 1. Death can occur from opportunistic infection or from co-infection, such as with hepatitis C. Although many factors can influence disease progression following HIV infection, the average new infection requires approximately 10 years to progress to the disease state clinically defined as AIDS. A diagnosis of AIDS indicates that substantial damage to the adaptive immune system has occurred, and the patient is at extreme risk for infection with opportunistic disease. Figure 2 lists the current clinical definitions of AIDS.

The stunning success of antiretrovirals and improved education on HIV risk factors has led many to believe that HIV infection could be on the wane. The recent

downward adjustment by the World Health Organization (WHO) of global estimates of HIV prevalence may have served to reinforce this perception. That optimistic picture was shaken with the release of data in October 2008 by the Centers for Disease Control and Prevention (CDC) showing that in the USA, the annual rate of new HIV infections was much higher than previously estimated.² The back calculation suggested a current annual infection rate of about 56,000 per year versus the previous estimate of 40,000 new HIV infections per year. However, study investigators suggested that the number of new infections likely represented the improved detection of early infection vs. a significant increase in overall rate. Men who have sex with men and black individuals remain disproportionately at risk in the USA. In the WHO European Region, the annual rate of HIV infection has almost doubled between 2000 and 2007, rising from 39 to 75 per million population.¹ IV drug abuse, heterosexual sex, and male-to-male sex all significantly contribute to the transmission of new infection.

These numbers emphasize the importance of identifying HIV-infected individuals and the need to develop effective prevention programs. While male-to-male sex remains a leading risk factor for HIV infection in men in the USA, heterosexual sex is a common route of transmission for women. In many countries with high prevalence of HIV, such as those in sub-Saharan Africa, heterosexual transmission is the most common route for both men and women.

In recent years, data has clearly demonstrated that many new HIV infections in the USA were transmitted by sexual partners unaware of their infection status.³ In addition, a troubling number of patients were being identified as HIV-positive within just one year of developing AIDS, often eliminating an important therapeutic window. Early knowledge of HIV infection allows initiation of highly-active antiretroviral therapy (HAART) that can dramatically improve life expectancy, particularly if begun prior to the onset of severe immunosuppression.^{4,5} Recognizing this,

1

Candidiasis (Thrush) is a fungal infection of the mouth, throat, or vagina.

Cytomegalovirus (CMV) is a viral infection that causes eye disease that can lead to blindness.

Herpes simplex viruses can cause oral herpes (cold sores) or genital herpes.

Mycobacterium avium complex (MAC or MAI) is a bacterial infection that can cause recurring fevers, general sick feelings, problems with digestion, and serious weight loss.

Pneumocystis pneumonia (PCP) is a fungal infection that can cause a fatal pneumonia.

Toxoplasmosis (Toxo) is a protozoal infection of the brain.

Tuberculosis (TB) is a bacterial infection that attacks the lungs, and can cause meningitis.

1 Common opportunistic infections seen with AIDS

2

Infected with HIV and: A CD4+ T-cell count below 200 cells/μl (or a CD4+ T-cell percentage of total lymphocytes of less than 14%)

Or

Infected with HIV and: Presenting with an AIDS-defining illness (see reference for full list of AIDS-defining disease)

2 Centers for Disease Control, USA, definition of AIDS



in 2006, the CDC revised the previous recommendations for HIV screening to move from screening only those considered “at risk” (such as males who have sex with males, IV drug abusers, and individuals who received blood or blood-derived products before the implementation of blood donation screening) to a general screening of anyone between the ages of 13 and 64 presenting in a healthcare setting.⁶ The need for comprehensive screening of all expectant mothers was also emphasized in the revised guidelines, underlining the fact that intervention can substantially reduce transmission from mother to child if the woman’s infection status is known. The previous CDC guidance requiring written (opt-in) permission for an HIV test was altered to

a verbal opt-out approach. In addition, the prior requirement for patient counseling for all confirmed positive results was removed. While many states in the USA are still operating under the previous guidelines, some have already updated their recommendations to reflect the new CDC guidelines. In 2009, the American College of Physicians (ACP) released similar screening guidelines, emphasizing general HIV screening for anyone 13 years and older as well as all pregnant women.

The 2008 European Guidelines on HIV suggest offering HIV testing to individuals aged 16 years and older presenting to a clinic for sexually transmitted infection regardless of signs, symptoms, or risk.

Screening recommendations in other countries vary. In 2007, the WHO published “Practical Guidelines for Intensifying HIV Prevention” that included a risk reduction strategy and assessment of prevalence and risk by country in the adoption of HIV prevention measures (including testing). Globally, HIV testing and treatment access are often a barrier to both HIV screening and optimal clinical intervention in many resource-limited countries.

New and more sensitive testing technologies are becoming available that allow earlier detection of HIV infection. Assays capable of recognizing IgM as well as IgG antibody to HIV can allow detection in as little as three weeks (based on seroconversion panels). Use of a combination test

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The REACH Program

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Africa contains some of the countries most burdened with high endemic rates of HIV. An estimated 22.5 million people in Africa are HIV-positive and 2 million new infections occur yearly. Programs are becoming available to help some of the hardest-hit countries both reduce transmission and improve management of HIV-infected individuals. One example is the REACH Program, where Siemens works with local partners to make critical molecular testing available to HIV-positive individuals living in areas with limited access to modern healthcare. Improved serology-based HIV screening and availability of molecular testing, particularly in remote areas endemic for HIV, are offering hope for increased prevention and better clinical outcomes in HIV-infected individuals.

For more information on the REACH Program please visit www.siemens.com/reach

that picks up the HIV p24 antigen (p24 is a protein that composes the HIV nucleocapsid) as well as antibody to HIV (an HIV Combo test) may provide a slight improvement in earlier detection when compared to existing, sensitive antibody-only immunoassays. It is important to remember that commercial immunoassays often contain design differences and can vary in sensitivity and specificity. Labs should be aware of both the strengths and limitations of the assay they are using. While the HIV Combo is becoming the standard screening technique recommended by the European Union, the USA currently has only FDA-approved HIV antibody screening assays. However, advances in the design characteristics of antibody screening technology, such as detection of both IgM and IgG and "two-pass" assays that improve sensitivity, are providing an increasingly robust and sensitive method for early detection of HIV antibody.

Point-of-care (POC) manual HIV tests can provide a rapid result compared with some bead or automated HIV immunoassays and have become widely available. POC testing is beneficial in some settings where an immediate result is desired (such as some STI clinics or field-based testing). For general HIV screening, both cost and time generally favor a move to automated immunoassays for the detection of HIV infection. Commercially accessible,

fully-automated HIV assays are available with high sensitivity and specificity. In addition, some assays offer the designed detection of HIV-1 Group M (and subtypes), HIV-1 Group O, and HIV-2 antibodies, providing an extraordinarily broad spectrum of detection to HIV infection. Not all assays offer designed detection of HIV-1 Group O, so labs should be aware as to whether their testing method relies on cross-reactivity or is constructed to specifically include detection of HIV-1 Group O virus as well as detection of Group M subtypes and HIV-2.

While only time will tell how many countries will ultimately move to either general screening for HIV or enhanced targeting of at-risk individuals, it is clear that early detection will support both optimal patient management and infection control. Most encouraging is the increasing availability of both serology testing and molecular testing in areas that previously had little access to these important testing modalities. Automated testing is a trend for many infectious disease states that includes not only HIV, but testing for other common infectious organisms, such as viral hepatitis, syphilis, and EBV. As labs move to face the increasing demand for ID testing, as well as deal with staffing challenges, automation and consolidation are likely to be key players.

Sources:

Figure 1: <http://www.aids.org/factSheets/500-Opportunistic-Infections.html#anchor51213>.

Figure 2: <http://www.cdc.gov/mmwr/preview/mmwrhtml/00018871.htm>.

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For more information
www.siemens.com/molecular

While only time will tell how many countries will ultimately move to either general screening for HIV or enhanced targeting of at-risk individuals, it is clear that early detection will support both optimal patient management and infection control.

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