

The surveillance case definition for acquired immunodeficiency syndrome (AIDS) developed by the Centers for Disease Control (CDC) in the U.S. Department of Health and Human Services (DHHS) is the primary public health surveillance tool for determining the scope of the AIDS epidemic. The CDC's case definition of AIDS in use as of April 1992 was developed in 1987. This complex case definition specifies 23 AIDS-defining conditions that are strongly associated with severe immune deficiency caused by the human immunodeficiency virus (HIV). In addition to being used for surveillance, the CDC's case definition of AIDS has been used as a clinical definition by physicians, in research protocols, in the allocation of Federal funds under the Ryan White Comprehensive Resources Emergency Act of 1990, and as a measure of disability in benefit programs administered by the Social Security Administration within the DHHS.

The CDC's existing case definition of AIDS has been criticized because some of the severe manifestations of HIV infection found in women and injection drug users are not encompassed by the current case definition, and therefore, the impact of the epidemic in these populations may be underestimated. This is of particular concern because a disproportionate number of HIV-infected women and injection drug users are African Americans or Hispanics.<sup>1,2</sup> In particular, several small studies and case reports have

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1 These groups are not mutually exclusive. The majority of HIV-infected women are injection drug users or the sexual partners of injection drug users.

2 Some estimates of the number of HIV-infected persons by race/ethnicity, sex, and exposure category are extrapolated from the reported number of AIDS cases in these groups; but other corroborating methods are also used (122).

found that gynecological conditions--cervical dysplasia, pelvic inflammatory disease, and recurrent vulvovaginal candidiasis--occur more commonly in HIV-infected women than in other women. There is also evidence that HIV-infected injection drug users are more likely to have pulmonary tuberculosis, endocarditis, sepsis, and bacterial pneumonias.

A controversy has also arisen over the use of the CDC surveillance case definition of AIDS as a disability definition by the Social Security Administration, a purpose that the case definition was not intended to serve. The concern was that some HIV-infected women and injection drug users were being denied disability benefits because their illnesses were not included in the AIDS case definition.

This OTA background paper is one in a series of papers on issues relating to HIV and AIDS that OTA has published since 1987, under a general authority from the OTA's Technology Assessment Board. This particular paper was requested by the Subcommittee on Human Resources and Intergovernmental Relations, House Committee on Government Operations.

OTA was asked to examine the CDC's 1987 surveillance definition of AIDS in light of the criticisms discussed above. In the fall of 1991, however, the CDC proposed to change its AIDS case definition and this paper focuses on *the* proposed definition. The remainder of this chapter provides a summary of the main findings of this report. Chapter 2 discusses the purpose of the CDC definition of AIDS and describes how the definition has changed over the course of the AIDS epidemic. It also examines the proposed change in the definition of AIDS, including the major criticisms of the proposed definition. Finally, it examines issues surrounding the implementation of the new

definition, including its impact on AIDS surveillance, the States, allocation of Federal resources, and individual privacy rights. Chapter 3 examines the controversy over the use of the CDC definition in Social Security disability determinations and recent changes in the Social Security disability process for HIV-infected persons.

#### SUMMARY OF THE FINDINGS

In November 1991, the CDC proposed to expand its AIDS case definition. Under the new definition, a person has AIDS if: 1) he or she has one of the 23 AIDS-defining conditions included in the 1987 definition of AIDS, or 2) he or she is HIV-positive and his or her CD4<sup>+</sup> lymphocyte count is below 200 cells per cubic millimeter (/mm<sup>3</sup>) of blood. The CDC plans to implement the new case definition in 1992, but has not set a specific date for implementation. According to the CDC, there are several objectives for these changes in the case definition of AIDS: to more accurately reflect the number of persons with severe HIV-related immunosuppression; to simplify the AIDS case reporting process, in part by making the AIDS case definition consistent with standards of medical care for HIV-infected persons; and to make possible laboratory-based reporting of AIDS cases, which will help State and local health departments to more efficiently identify persons who are likely to have AIDS.

Several critics of the CDC's current case definition of AIDS have argued that the definition should be expanded to include HIV-associated conditions that commonly occur in women and injection drug users because these conditions are associated with profound immunosuppression and poor prognosis. In addition, critics argue that, unless these conditions are included in the AIDS case definition, physicians may not consider the possibility of HIV infection

in patients presenting with these conditions, or physicians may fail to look for some of these HIV-associated conditions in patients that are known to be HIV infected. Other observers argue that physicians should have a much broader view of severe manifestations of HIV infection than is appropriate for inclusion in an AIDS case definition designed for surveillance purposes.

The CDC has opposed adding new HIV-related conditions to the AIDS case definition for several reasons. One is that doing so will add to the complexity of that definition, and this complexity will present an obstacle to reporting. The CDC has also opposed adding any infections and cancers to the AIDS case definition that do not appear to be specific for HIV infection or whose relationship to HIV infection is not adequately established. The current CDC AIDS case definition only includes opportunistic infections and cancers that rarely occur in persons whose immune systems are not compromised. The CDC believes that a profoundly depressed CD4<sup>+</sup> lymphocyte count in an HIV-positive patient is more specific for HIV-induced immunosuppression than are non-opportunistic infections and cancers. Finally, the CDC believes that the CD4<sup>+</sup> lymphocyte count cutoff is a more objective marker of HIV-induced immunosuppression than is the diagnosis of certain non-opportunistic illnesses, such as pelvic inflammatory disease. The CDC also argues that many of the concerns about the proposed definition would conceptually apply to alternative approaches to expanding the AIDS case definition, such as adding more diseases to the list of AIDS-defining conditions.

There is a considerable amount of variability in CD4<sup>+</sup> lymphocyte counts, although the amount of variability is within the range of other commonly used diagnostic tests. Moreover, the accuracy of CD4<sup>+</sup> tests is less important when interpreting population-based surveillance data than for clinical care of individual patients.

## The Impact of the New CDC Definition on AIDS Surveillance

In the long term, the increased efficiency of laboratory-based reporting of AIDS cases may enable some State and local health departments to save money in AIDS surveillance. Health departments, however, will need additional money to handle the initially larger AIDS case load, to establish new systems to more efficiently identify cases, and to provide CD4<sup>+</sup> lymphocyte testing to uninsured individuals who cannot afford it. According to the CDC, a typical CD4<sup>+</sup> lymphocyte test costs about \$50 plus personnel costs to perform, and the average charge to the patient is \$150.00 per test. The CDC's appropriations for 1993 do not provide additional funds for CD4<sup>+</sup> lymphocyte testing; however, the CDC will allow States to use money allocated for HIV testing and counseling to fund CD4<sup>+</sup> lymphocyte testing.

In the first years after implementation of the proposed case definition of AIDS, epidemiologists anticipate that the CDC will lose its ability to follow trends in the incidence<sup>3</sup> of AIDS. Once all prevalent<sup>4</sup> cases (i.e., those persons who currently have a CD4<sup>+</sup> lymphocyte count below 200 cells/mm<sup>3</sup> but who do not meet the 1987 AIDS case definition) are reported, the CDC will regain its ability to monitor the incidence of AIDS. The CDC, however, will have more difficulty using AIDS case reports to track changes in the incidence of each of the 23 AIDS-defining conditions included in the 1987 definition of

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3 Incidence is defined as the frequency of new occurrences of disease within a defined time interval.

4 Prevalence is the number of cases of disease present at a particular time and in relation to the size of the population. A prevalent case of a disease is a single case that exists at a particular time.

AIDS because many AIDS cases are likely to be reported on the basis of a positive HIV antibody test and a low CD4<sup>+</sup> lymphocyte count. The CDC may, however, be able to track these changes by having selected centers report on the incidence of AIDS-defining conditions as well as on the incidence of AIDS.

Although the proposed definition will increase the number of reported AIDS cases, the completeness of reporting will be difficult to assess, making interpretation of trends difficult. HIV-infected individuals with CD4<sup>+</sup> lymphocyte counts below 200 cells/mm<sup>3</sup> may not be counted as AIDS cases because they are either symptom free and do not seek health care, or they are symptomatic but they do not yet know they are infected with HIV. Availability of CD4<sup>+</sup> lymphocyte testing will also influence the accuracy of AIDS surveillance. Lack of access to CD4<sup>+</sup> lymphocyte testing would blunt the surge of new cases that would otherwise be anticipated under the proposed definition. In particular, poorer women and injection drug users, who generally have sporadic access to care, may have less access to CD4<sup>+</sup> lymphocyte testing. Populations of HIV-infected individuals with better access to CD4<sup>+</sup> lymphocyte testing will have proportionately greater increases in AIDS cases, and a distortion in the contribution of various risk groups to the pattern of the epidemic could result.

Estimates of the increase in the number of AIDS cases that will result from the change in the definition vary among jurisdictions. The CDC estimates that the proposed expansion in the AIDS case definition will result in a 52 percent increase in the total number of living AIDS cases in the United States, with an increase in the proportion of AIDS cases reported among women and injection drug users. Other States estimate that the increase in the number of prevalent AIDS cases will be in the range from 36 to 135 percent.

## Federal Funding Allocations and the New Definition

The proposed change in the definition of AIDS will affect the distribution of funds under the Ryan White Comprehensive AIDS Resources Emergency Act of 1990 (henceforth referred to as the Ryan White Act). Title I of the Ryan White Act provides Federal money to metropolitan areas for ambulatory medical and support services for low-income individuals infected with HIV. In order to receive Title I funding, a metropolitan area must have at least 2,000 cases of AIDS documented with the CDC (or a per capita cumulative AIDS incidence rate of 0.0025). With an increase in the number of AIDS cases under the proposed definition, more cities will become eligible for funds distributed under Title I. Appropriations under Title I may therefore need to increase if the current level of funding for each metropolitan area is to be maintained. In addition, some deserving metropolitan areas may not receive Title I funds because they are not adequately prepared to identify AIDS cases under the new definition.

Title II authorizes the distribution of Federal funds to States and territories for health care and support services for poor HIV-infected individuals. The funds are distributed among States and territories based on the number of AIDS cases in each State (or territory) as a proportion of the number of AIDS cases reported in the entire United States. Although in theory the proposed change in the CDC's case definition of AIDS should not significantly influence the distribution of Title II funds among States (one would expect the number of AIDS cases in each State to increase by the same amount), in practice, the distribution of funds may not be proportional to the actual needs of each State if some States are much better able than others to identify AIDS cases. Approximately 50 percent of Title I funds are also

distributed by a similar formula and therefore metropolitan areas that are better able to identify AIDS cases may receive proportionately more Title I funds.

#### Privacy Issues and the New Definition of AIDS

The proposed change in the AIDS case definition raises privacy concerns because there will be an increased number of persons with AIDS reported by name to the State and local health departments. State and local health departments report information on AIDS cases, absent the individuals' names, to the CDC. Advocates are concerned that the States may not be adequately prepared for the increase in reported AIDS cases, and that inadvertent breaches of confidentiality are more likely to result. Although all States take measures to protect the confidentiality of the names of AIDS patients, and to date no unauthorized disclosure has taken place, the risk of unauthorized disclosure exists. In addition, most State laws authorize disclosure of an individual's HIV status to third parties who have, or may have been, exposed to the blood of HIV-infected persons (e.g., health care workers, emergency care providers, funeral directors, sexual assault victims, laboratory workers, and even schools). Advocates are concerned that States may expand the number of situations in which disclosure of an individual's HIV status is permissible in order to stem further transmission of the virus. With the expansion of the AIDS case definition, more HIV-infected persons will face this potential threat to confidentiality because more HIV-infected persons will be reported as AIDS cases to the State and local health departments.

On the other hand, any expansion of the CDC definition of AIDS would result in more names being reported to State health departments. In addition, as more States require name reporting of HIV-infection, more HIV-infected persons will have their names reported to the State and local health departments even before they develop AIDS.

With the change in the CDC definition of AIDS, laboratories that perform CD4<sup>+</sup> lymphocyte tests will become involved in AIDS case reporting, and thus there is an additional point at which confidentiality may be breached. Again, there is no evidence that laboratories cannot adequately maintain the confidentiality of CD4<sup>+</sup> lymphocyte test results; however, in planning to implement the new AIDS definition, State and local public health departments and clinical laboratories should reassess current laws and operational procedures that protect the confidentiality of CD4<sup>+</sup> lymphocyte test results.

Some advocates have suggested that special informed consent and counseling requirements should accompany CD4<sup>+</sup> lymphocyte testing, as is done for HIV antibody testing, but this counseling need not be of the same nature as the counseling that accompanies HIV tests. In addition, it has been suggested that anonymous CD4<sup>+</sup> lymphocyte testing should be made available so that people won't avoid seeking early medical treatment because of concerns about confidentiality. Nevertheless, people who know they are HIV positive have an incentive to seek medical treatment that may outweigh their fears about breach of confidentiality.

Social Security Disability Determinations and the CDC Definition of AIDS

The public debate over whether the CDC definition of AIDS adequately includes severe manifestations of HIV infection in injection drug users and women arose in large part because the Social Security Administration used the CDC definition of AIDS in evaluating disability under the Social Security Disability Insurance (DI) program and the Supplemental Security Income (SSI) program.

SSA regulations set forth a five-step process that is used by the SSA disability adjudicators to determine disability for SSI or DI. The first two steps are to determine (1) that the claimant is not working, and (2) that the claimant has a disabling condition that significantly limits the ability to work. The third step is to see if the claimant's condition is included in, or is equal in severity to, one of the medical conditions included in the SSA's "Listing of Impairments;" a list of medical impairments that the SSA has designated as so severe as to entitle that person to disability benefits. If the claimant's medical condition meets or equals, in terms of severity, one of the medical impairments from the "Listing of Impairments," the claimant is said to have met a Listing and is awarded disability. Claimants who do not have a listed impairment must demonstrate that they are unable to perform their previous job (step 4) or any other job in the national economy (step 5) (see app. G).

Since 1983, the SSA has treated AIDS, as defined by the CDC, as a Listing, and persons with CDC-defined AIDS were almost always awarded disability. Advocates claimed that SSA adjudicators denied disability benefits to other seriously ill HIV-infected claimants because their HIV-associated conditions were not included in the AIDS case definition. The

advocates argued that the SSA's disability adjudicators did not adequately evaluate the disabling effect of other HIV-associated conditions because they assumed that only persons with AIDS are disabled. The SSA strongly denied this was the case and the SSA's written instructions demonstrate their policies did not preclude other HIV-infected claimants from being awarded disability. In addition, their statistics show some HIV-infected persons who did not have AIDS were awarded disability. Nonetheless, a number of seriously ill HIV-infected claimants were denied disability and the reasons for these denials are not clear.

In December, 1991, the SSA published a ruling and proposed regulations that create a Listing for HIV infection (hereinafter "HIV Infection Listing"). This new criteria for evaluating disability in persons with HIV infection changes the focus of the debate. First, the SSA will no longer tie its disability determinations to the CDC's definition of AIDS, and therefore the expansion of the CDC's definition of AIDS will not enable more HIV-infected persons to obtain disability. Second, the new disability criteria include a number of HIV-associated conditions that advocates previously claimed the SSA did not adequately consider in its disability determinations for HIV-infected women and injection drug users.

The "HIV Infection Listing" incorporates all of the conditions included in the 1987 CDC definition of AIDS as well as other non-AIDS-defining diseases and symptoms, including pulmonary tuberculosis, endocarditis, bacterial pneumonia, bacterial or fungal sepsis, and vulvovaginal candidiasis. However, the "HIV Infection Listing" also requires that, in combination with many of these HIV-related conditions, the claimant demonstrate marked functional limitations in performing activities of daily living and/or work-related activities.

The functional limitation test for the "HIV Infection Listing" was derived from a functional limitation test used by the SSA in evaluating the severity of mental disorders, and it is unclear whether this functional limitation test is appropriate for evaluating the medical disabilities of HIV-infected persons. Moreover, a number of advocates have questioned the need to demonstrate marked functional limitations in two separate areas given that HIV-infected persons have already demonstrated that they have severe HIV-related medical conditions. Documenting functional limitations to the degree required under the new "HIV Infection Listing" may be especially difficult for poor claimants because they often do not have access to a regular physician who can document the existence of their functional limitations based upon their treatment history.

It is too early to evaluate what impact the new "HIV Infection Listing" will have on disability determinations, and the final regulations will not be issued until the SSA reviews the approximately 3000 comments it has received. The SSA does not expect the new Listing will result in an increase in the overall number of persons awarded disability, but does believe it will shorten the time between filing an application for benefits and the receipt of those benefits. The new "HIV Infection Listing" does, however, separate the debate over the proper disability definition for HIV-infected persons from the debate over the AIDS case definition, which is a surveillance definition.