

The CDC AIDS Definition: Implications of the CD4⁺Lymphocyte Count

INTRODUCTION

The surveillance case definition of 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 (8). In all 50 States, the District of Columbia, Puerto Rico, and other territories, physicians and medical institutions are required to send information on new AIDS cases, including the names of persons with AIDS, to State or local health departments. The States then send information about each AIDS case to the CDC, absent the name of the individual, which is only retained by State or local health departments (34). The CDC uses this information to monitor trends in the number and distribution of AIDS cases and in the scope of severe morbidity due to infection with the AIDS virus, human immunodeficiency virus (HIV).

The CDC's case definition of AIDS in use as of April 1992 was developed in 1987 (208) (see app. B). This complex case definition specifies 23 AIDS-defining conditions, including *Pneumocystis carinii* pneumonia, Kaposi's sarcoma, esophageal candidiasis, toxoplasmosis of the brain, and HIV wasting syndrome. The AIDS-defining conditions are distinguishable from other HIV-associated illness because they are strongly associated with severe immunodeficiency, occur frequently in HIV-infected individuals and rarely in uninfected individuals, and cause serious illness or death. A person who has

any one of these AIDS-defining conditions and who meets other condition-specific criteria (e.g. , an age requirement, in some cases a requirement for a positive HIV test) is considered to have AIDS.

For some time now, the CDC's existing case definition of AIDS has been attacked by advocates and others (1,2,243). One of the criticisms has been that some of the severe manifestations of HIV infection in women and injection drug users are not encompassed by the current case definition. The critics claim that the 23 AIDS-defining conditions in the existing case definition are, for the most part, severe manifestations of HIV infection found most commonly in HIV-infected white men who have sex with men.¹As a consequence, critics charge, the CDC's current case definition of AIDS probably leads to undercounting of AIDS-related morbidity among the growing population of HIV-infected women and injection drug users. This is of particular concern because most HIV-infected women and injection drug users are African Americans or Hispanics (223) .^{2,3}

In November 1991, the CDC proposed to expand the surveillance case definition of AIDS to include as AIDS cases all HIV-positive persons with CD4⁺ lymphocyte counts below 200 cells per cubic millimeter (/mm³) of blood,

1 These critics allow, however, that these AIDS-defining conditions are not limited in occurrence to white men who have sex with men; the AIDS-defining conditions occur in all groups of HIV-infected persons with late-stage HIV infection. They argue that in addition to the AIDS-indicator conditions, a broader spectrum of illness occurs, and the pattern of both AIDS-defining conditions and these other illnesses varies among different groups.

2 These groups are not mutually exclusive. The majority of HIV-infected women are injection drug users or the sexual partners of injection drug users (223).

3 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).

regardless of whether they have any AIDS-defining conditions (219).⁴ The CDC believes this revised AIDS case definition will more accurately and completely measure the extent of severe immunosuppression in the HIV-infected population. Moreover, the CDC believes this proposed revision to the AIDS case definition will more adequately capture severe HIV-induced immunosuppression in women and injection drug users than would addition of more HIV-associated conditions to the definition.

This chapter provides a history of the CDC definition of AIDS and describes the ways in which the definition has been used. It also examines the arguments for and against the CDC's proposed revision of the AIDS definition, focusing on the impact of the revision on AIDS surveillance and clinical care. Finally, this chapter evaluates the impact of the change in the definition on Federal funding for AIDS care and services and the privacy implications of the change.

THE CASE DEFINITION OF AIDS: PURPOSE, HISTORY, AND PROPOSED CHANGES

In 1982, soon after the first cases of what is now known as AIDS were identified, the CDC developed a case definition to be used for AIDS surveillance (201). Based largely on illnesses noted in men who have sex with men,⁵ the AIDS case definition included reliably diagnosed "opportunistic" diseases that are at least moderately indicative of an underlying defect in cell-mediated immunity in the absence of known causes of immune defects. The

4 A low **CD4⁺** lymphocyte count in an HIV-infected person is a sign of severe HIV-related immunodeficiency.

5 Over 90 percent of the first 159 cases that were documented by 1982 were found in men who had sex with men (119),

case definition of AIDS was revised in 1985 with the discovery of HIV as the etiologic agent of AIDS (203). It was revised again in 1987, as clinicians gained experience with opportunistic diseases associated with the end stages of HIV infection (208). The 1987 expansion resulted in proportionately more HIV-infected injection drug users, women, and minorities being diagnosed with AIDS (156,211).⁶ As mentioned above, the 1987 definition, which is still in use, includes 23 AIDS-defining conditions; a person who has any of these 23 conditions and who meets other condition-specific criteria is considered to have AIDS.

The CDC's definition of AIDS has been used as a surveillance definition to monitor trends in the incidence and prevalence of AIDS over time, to characterize persons with end stage HIV disease, to identify risk factors and modes of transmission, and to predict the future course and impact of the AIDS epidemic (8). In addition to being used for surveillance, the CDC's case definition of AIDS has been used for other purposes. Specifically, it has been used as:

- a clinical definition by physicians,
- a definition for research, and
- a measure of disability in benefits and entitlement programs.

⁶ A large part of the rationale underlying the 1987 definition was recognition of the pattern of care and types of illnesses seen in the increasingly diverse population of persons with HIV-associated conditions, particularly injection drug users (15). The 1987 definition allowed practitioners to make diagnoses of some AIDS-defining conditions presumptively (i.e., on the basis of clinically observed signs and symptoms) rather than definitively (i.e., with confirmation of the diagnosis by a laboratory test). One rationale for including presumptive diagnoses of certain conditions was to accommodate the practices of overburdened public hospitals, where the pressures of providing care to large numbers of patients precluded consistent use of definitive diagnostic tests. It also accommodated situations where the urgency of the patient's critical condition requires presumptive diagnosis and empirical treatment.

In addition, AIDS surveillance data have been used to allocate Federal resources for HIV-related care and services among the States and metropolitan areas (40,58,185).

Some physicians have used the CDC's case definition of AIDS as a *clinical definition*. It is argued that, particularly for those physicians with relatively little experience treating patients with symptomatic HIV infection, the AIDS case definition directs the physician to consider the possibility of HIV infection in individuals with conditions included in the AIDS case definition (72). It is not known, however, to what extent the AIDS case definition guides clinical care (i.e., whether physicians who treat HIV-infected patients focus only on identifying those manifestations of HIV infection that are included in the AIDS case definition). It is also not known to what extent physicians suspect HIV infection in patients who display HIV-associated conditions that are not included in the AIDS case definition. For some other diseases, such as Lyme disease or toxic shock syndrome, clinicians use a broader definition in clinical practice than is used by the CDC for surveillance purposes (37).

The CDC's AIDS case definition has been used as a *research definition*. Some researchers have used CDC-defined AIDS as the outcome that is measured.⁷ In some instances, the use of this outcome is appropriate, such as when a researcher wishes to measure the occurrence of late-stage HIV infection (68). In other instances, the use of other outcomes is appropriate. In one analysis of data from the Multicenter AIDS Cohort Study (MACS), for example, the

⁷ Researchers can select outcome variables depending on the clinical parameters they are measuring (231).

endpoints included both clinical symptomatology and CD4⁺ lymphocyte counts (129) . These endpoints were more appropriate because the current AIDS case definition does not accommodate the immunological component of the disease.⁸

The AIDS case definition has been used by the Health Resources Services Administration (HRSA) of the DHHS in *allocating benefits and resources* under the Ryan White Comprehensive AIDS Resources Emergency Act of 1990 (Public Law 101-381). As discussed later in this paper, the distribution of Federal funds under three of the four titles of this act is tied to the number of reported AIDS cases in metropolitan areas and the States. Finally, the AIDS case definition has also been used by the Federal government in *determining eligibility for entitlement programs*. Perhaps, most notably, the AIDS case definition has been used in determining eligibility for Federal disability programs administered by the Social Security Administration (SSA) within the DHHS. Such programs include the Social Security Disability Insurance (DI) program and the Supplemental Security Income (SSI) program.

⁸ Certain research protocols exclude participants who do not have CDC-defined AIDS, and critics have argued that this practice may cause underrepresentation of women and injection drug users in research protocols (13). Furthermore, some have argued that much of HIV research has focused on AIDS itself-- opportunistic infections and cancers included in the **CDC's** current case definition, as well as on viral replication--and less emphasis has been placed on manifestations of HIV infection other than AIDS-defining conditions (100). It is important to note, however, that several factors other than the **CDC's** definition of AIDS may lead to the exclusion of injection drug users and women from research protocols (101,114). The failure to include these groups in clinical research protocols may be more related to lack of access to health care, and to the concerns of pharmaceutical manufacturers and researchers about liability with respect to women of reproductive age (116).

The Proposed AIDS Case Definition

In November of 1991, the CDC announced a proposal to expand its AIDS case definition (219) . HIV-infected persons diagnosed with any one of the 23 AIDS-defining conditions in the 1987 AIDS case definition will continue to be considered to have AIDS. In addition, the new definition will include all HIV-positive persons with CD4⁺ lymphocyte counts below 200 cells/mm³ (see app. B).⁹ CD4⁺ lymphocytes are the primary target cell for HIV, and CD4⁺ lymphocyte counts are a recognized marker of the progression of HIV-related immunosuppression. 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 this change in the case definition of AIDS. One objective is to make the AIDS case definition consistent with standards of medical care for HIV-infected persons (39,219). Monitoring CD4⁺ lymphocyte counts in HIV-infected patients has become a standard of clinical care,¹⁰ and the proposed expansion of the AIDS case definition is based on this recognized clinical standard.

9 The CDC's case definition of AIDS allows for the use of the CD4⁺ percent of lymphocytes when the CD4⁺ lymphocyte count cannot be obtained (219). HIV-infected persons with a CD4⁺ lymphocyte percent below 14 will meet the **proposed AIDS** case definition.

10 CD4⁺ lymphocyte counts are used to guide the initiation of **antiretroviral** therapy (224) and prophylaxis against *Pneumocystis carinii* pneumonia (210). **Antiretroviral** therapy is currently recommended for all persons with CD4⁺ lymphocyte counts below 500 cells/mm³ (224), and prophylaxis of *Pneumocystis carinii* pneumonia, the most common initial AIDS-defining condition, is recommended for all persons with CD4⁺ lymphocyte counts below 200 cells/mm³ (210).

Another objective of the new AIDS case definition is to simplify the AIDS reporting process (219). The CDC believes it will be both practical and simple for physicians to use CD4⁺ lymphocyte counts in AIDS case reporting because monitoring CD4⁺ lymphocyte counts in HIV-infected persons has become standard clinical care.¹¹

The new AIDS case definition may also make it easier for State and local health departments to identify persons who are likely to have AIDS but who have not been reported (56).¹² The proposed AIDS definition, by incorporating a laboratory marker of immune suppression into the definition, makes possible laboratory based reporting of AIDS cases. Once a laboratory identifies a patient with a CD4⁺ count below 200 cells/mm³, the laboratory can report the name of the person and the test result to the State or local health department. The health department can then prompt the physician who ordered the test to report the patient to the health department if the patient meets the criteria for an AIDS diagnosis.

Another objective of these changes in the AIDS case definition is to more accurately record the number of persons with severe HIV-related immunosuppression (219).¹³ Numerous conditions other than the 23 included in

11 A simplified AIDS case definition is particularly important as a greater proportion of AIDS patients is reported from outpatient clinics, which have had less experience with AIDS case reporting (219).

12 Currently in each State, health departments have identified unreported AIDS cases through reviews of hospital records, outpatient records, and death certificates. Each of these mechanisms to "capture" additional AIDS cases requires a substantial commitment of State health department staff time (56).

13 Epidemiologists' ability to track trends in HIV infection and AIDS may have been compromised by recent advances in therapy (60,142). There is evidence that AIDS-defining conditions have appeared later in the course of HIV infection because of the use of prophylaxis for *Pneumocystis carinii* pneumonia and **antiretroviral** therapy (234), and the appearance of AIDS-defining conditions have therefore become a less reliable measure of severe immune suppression in HIV-infected persons.

the CDC's 1987 case definition of AIDS are diagnosed in HIV-infected persons (15). These conditions, which are also diagnosed in persons with normal immune function, tend to increase in frequency and severity among persons who are immunosuppressed. Under the CDC's proposed definition of AIDS, persons who are severe HIV-related immunosuppressed, as determined by measurement of CD4⁺ lymphocyte counts, will be considered to have AIDS (219).

CDC's Decision Not to Increase the Number of AIDS-Defining Conditions

As mentioned earlier, the CDC's 1987 AIDS case definition currently in use has been criticized by individuals who claim that a significant proportion of HIV-infected persons have severe manifestations of HIV infection that are not included in the current AIDS case definition (1,2,243) . Excluded, in particular, critics argue, are some manifestations of HIV infection that occur in women and injection drug users. An increasing number of AIDS cases in the United States are occurring among women and injection drug users. The CDC reports that, through February of 1992, injection drug users accounted for 29 percent of all AIDS cases in the United States (223). Women accounted for 10.5 percent of AIDS cases reported through February 1992 (223). Approximately 50 percent of women with AIDS are injection drug users (223) . (See app. D.) Among men who have sex with men (excluding those who use injection drugs), the rate of increase in the number of AIDS cases began to decline in 1987; however, the rate of increase in the number of AIDS cases associated with injection drug use and heterosexual transmission has continued to rise. The rate of increase in the number of reported AIDS cases in women now exceeds that in men (124).

Many illnesses occur more frequently in HIV-infected persons compared to persons with normal immune function (15). At issue is whether all or some subset of conditions that are worse or more common in the presence of HIV

infection should be included in the AIDS case definition. Some observers have noted that several gynecological conditions--cervical dysplasia (23,52,74,81,96,103,104, 155,171,180,214,233) , pelvic inflammatory disease (75,148,155), and chronic and recurrent vulvovaginal candidiasis (26,27,82,140)--occur more commonly in HIV-infected women than in other women. Substantial evidence shows that HIV-infected women have an increased incidence of abnormal pap tests and cervical dysplasia (abnormal cells in the epitheliums of the cervix, thought to sometimes progress to cervical cancer) (52,104,133,151,233). There are also several cases where cervical cancer in HIV-infected women proceeded more rapidly than usual and where HIV-infected women were diagnosed with advanced disease (103). However, there are only 15 reported cases in the literature of cervical cancer in HIV-infected women (244).¹⁴ Given the long incubation time of cervical cancer and the short survival time after reaching a CD4⁺ lymphocyte count of 200 cells/mm³, it is not surprising that an epidemic of cervical cancer among HIV-infected women has not developed or been documented (232). At present, an association between HIV infection and invasive cervical cancer has not been established (37,134,214).

Several reports provide evidence that pelvic inflammatory disease in women immunosuppressed by HIV infection is more likely to be chronic, recurrent, and more severe than pelvic inflammatory disease in women with normal immune function (75,148). The studies that have been done involve limited numbers of patients, and the results may not be applicable to other populations (114).¹⁵

14 Also, there has been no increase in cervical cancer rates in States with the highest prevalence of HIV infection in women (135,214).

15 In addition, the diagnosis of pelvic inflammatory disease is often made imprecisely to explain pelvic pain or tenderness. This may lead to overdiagnosis of this condition (15).

There is some evidence that vaginal candidiasis (yeast infection of the vagina) is more common in HIV-infected women than in women without HIV infection (26,82,140). Although women not infected with HIV frequently contract vaginal candidiasis, studies suggest that the symptoms are often more severe in HIV-infected women. Vaginal candidiasis in an HIV-infected woman is not life-threatening, can occur in women with normal immune function or moderate degrees of immune dysfunction, and is usually well controlled with fungicides. In these respects, it differs from esophageal candidiasis, an AIDS-defining condition, which occurs in profoundly immunocompromised patients and is associated with a poor prognosis.

These conditions--cervical dysplasia, cervical cancer, pelvic inflammatory disease, and vaginal candidiasis--occur in women with normal immune function with and without HIV infection; hence, these conditions are not specific to HIV infection (114). By contrast, AIDS-defining conditions rarely occur among those who are not HIV-infected, except among persons who are severely immunocompromised for other reasons.

Several observers have noted that HIV-infected injection drug users, in addition to having AIDS-defining conditions, are more likely to have certain manifestations of HIV infection than men who have sex with men or those in other risk groups (159,160,174,209). In recent years, there has been an increase in the incidence of certain infections among injection drug users that has occurred coincident with the increased prevalence of HIV infection and AIDS (43,158,159,160,174, 209).¹⁶ These infections include pulmonary

16 Much of these data, however, were collected prior to implementation of the 1987 expanded AIDS case definition (176). In New York City, the Department of Health is investigating whether many of the injection drug users who failed to meet the pre-1987 AIDS case definition would be counted with the 1987 AIDS case definition (181).

tuberculosis (33,79,130,131,179,204, 206,207), endocarditis (inflammatory alterations of lining of the heart cavities) (117), sepsis (the presence in the blood of pathogenic micro-organisms or their toxins) (105), and bacterial pneumonias (177). It is argued that this increase in infections among injection drug users is a consequence of the HIV epidemical'

Pneumonia, sepsis, endocarditis, and pulmonary tuberculosis occur more commonly in HIV-infected injection drug users than in injection drug users who are not infected with HIV. Although one would expect these nonopportunistic illnesses to occur more frequently in immunosuppressed persons and follow a more severe course, these clinical conditions have a much less specific relationship to profound immunosuppression caused by HIV infection than do the 23 AIDS-defining clinical conditions listed in the CDC's 1987 case definition of AIDS. Pulmonary tuberculosis, bacterial pneumonias, sepsis, and endocarditis are frequently seen among injection drug users who are not infected with HIV (67,138,178,230,239) ; hence" it is difficult to evaluate the extent to which these conditions are related to infection with HIV.

Several critics of the CDC's current case definition of AIDS have argued that the case definition should be expanded to include HIV-associated conditions that frequently occur in HIV-infected women and injection drug users because they are associated with profound immunosuppression and poor prognosis (175). In addition, they argue that physicians may overlook these HIV-associated conditions in HIV-infected patients or fail to suspect HIV infection in high-risk patients who exhibit these HIV-associated conditions

17 Diseases such as bacterial pneumonia and sepsis are not conditions that occur exclusively in injection drug users, women, African Americans, and Hispanics. For example, Redd and colleagues documented an increase in **pneumococcal** septicemia in San Francisco, where the overwhelming majority of AIDS cases have occurred in men who have sex with men (137).

(243). (This latter argument has been made particularly with respect to gynecologic conditions, which are absent from the current AIDS case definition (72).) This argument assumes that physicians are informed by the CDC case definition. A number of observers, however, reject this assumption, arguing that physicians are educated from medical journals and other sources.¹⁸ No study has examined the extent to which physicians' diagnostic practices are influenced by the CDC's case definition of AIDS. If the problem lies in physician education, however, then the most direct solution may be changes in physician education rather than in the CDC's case definition.

Some observers argue that clinicians 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 (37,185). For a surveillance definition intended to monitor trends in the incidence and prevalence of disease, a limited definition encompassing only severe manifestations of end-stage HIV infection may be appropriate.¹⁹ In contrast, a clinician needs to identify and treat the broad spectrum of manifestations of HIV infection, and hence a broad clinical definition is more useful.

The CDC has opposed adding conditions to the AIDS case definition for several reasons (219). One is that doing so will add to the complexity of that definition. The 1987 case, definition currently in use has 23 AIDS-

18 At an OTA workshop, several physicians argued that they were educated by medical journals and other sources (194). This, however, was not a representative sample of clinicians because physicians at the workshop were AIDS experts.

19 One expert notes that the **CDC's** HIV classification system (See **app. E**), which is being revised in parallel with the AIDS case definition, acknowledges and accounts for many of the HIV-associated conditions seen in women and injection drug users, which, although not deemed AIDS-defining, nevertheless receive recognition as serious HIV-associated illnesses (161). Clinical staging and social **service** disability determinations could more appropriately be linked to the HIV classification system, and not to the AIDS case definition itself.

defining conditions, each with its own set of criteria. The CDC argues that the complexity of the definition presents an obstacle to reporting, especially since clinical care and reporting have moved from inpatient settings to ambulatory settings. The CDC points out that there is a broad spectrum of conditions that can occur with increased frequency and severity in HIV-infected persons, ranging from neurologic manifestations, dermatologic manifestations, infections, and other organ system conditions (15,134,135). The CDC and other experts argue that adding such conditions would increase the complexity of the case definition.

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 (217). The CDC believes that a depressed CD4⁺ lymphocyte count in an HIV-infected patient is more specific for HIV-induced immunosuppression than nonopportunistic infections and cancers (219). The CDC also believes that the CD4⁺ lymphocyte count cutoff is a more objective marker of HIV-induced immunosuppression than nonopportunistic illnesses.²⁰

20 The CDC argues that the CD4⁺ lymphocyte count is an objective marker of **immunosuppression**, whereas a clinician must use considerable subjective interpretation in determining whether clinical conditions such as recurrent vaginal candidiasis or pelvic inflammatory disease are present. Others have argued that, given the variability of the CD4⁺ lymphocyte count, its interpretation is also subjective.

ISSUES SURROUNDING THE IMPLEMENTATION OF THE PROPOSED REVISION OF THE CDC
DEFINITION OF AIDS

From an epidemiologic perspective, the CD4⁺ lymphocyte count may appear to be a better measure of severe HIV-induced immunosuppression than the presence of nonopportunistic infections or cancers. The accuracy of AIDS surveillance will largely depend, however, upon the accuracy and accessibility of the CD4⁺ testing. As is discussed below, there is substantial variability in CD4⁺ testing. This variability, however, may be of more concern in clinical care than in AIDS surveillance. Accessibility of CD4⁺ testing will depend upon the availability of test sites and the affordability of the test.

The new AIDS case definition is expected to increase the number of HIV-infected persons considered to have AIDS. This increase in the number of AIDS cases will affect allocations of Federal funds and will have implications for the privacy of the individuals with AIDS whose names will be reported to the State and local health departments. The following sections discuss these issues.

Accuracy of CD4⁺ Testing

There is a considerable amount of variability²¹ in CD4⁺ counts, although the amount of variability seen in flow cytometry is within the range of other commonly used diagnostic tests (e.g. , serum thyroxine measurements to diagnose thyroid abnormalities, serum cholesterol measurements to diagnose hypercholesterolemia, and creatine kinase measurements to diagnose heart

21 The variability of a test refers to the accuracy and reproducibility of a test (141).

attack) (76). However, because CD4⁺ counts require interpretation of results within a narrow range of values, variability must be more tightly controlled than with other tests where the diagnostic alternative covers a broad range of values (152).²²

The variability in CD4⁺ testing means that some HIV-infected individuals' CD4⁺ test results are likely to be higher than their "true" value, and therefore these immunocompromised individuals will not be counted as AIDS cases. Conversely, some relatively immunocompetent persons will be diagnosed with AIDS because their CD4⁺ test results are lower than the "true" value. The CDC states that the CD4⁺ lymphocyte count that should be used for a diagnosis of AIDS should be the one that the physician considers the most accurate (219). A physician who suspects that a CD4⁺ lymphocyte count is not accurate could validate the reading with a separate determination on a separate sample (78). The accuracy of CD4⁺ tests is far less important in interpreting population-based surveillance data than in clinical care of individual patients (17,162).²³ Confirmatory repeat testing, therefore, is not required under the new AIDS definition for the identification of cases of AIDS for surveillance.

22 One cannot compare the analytic variability of different tests without considering the clinical use of tests and associated diagnostic variability that can be tolerated. The amount of variability that can be tolerated for a clinical test, however, depends on the need to distinguish among diagnostic alternatives. If the diagnostic alternative covers a broad range of values (e.g., creatine **kinase**), the amount of analytic variability that can be tolerated is wide. However, if diagnostic alternatives require interpretation of results in a narrow range of values, such as with **CD4⁺** lymphocyte counts, analytic variability must be more tightly controlled (152).

23 Others believe that confirmatory repeat testing is important from an **epidemiological** standpoint (77). Populations of individuals who receive **CD4⁺** testing frequently will on average qualify as AIDS cases more rapidly than populations of individuals who are tested less frequently. Confirmatory repeat testing makes it less likely an individual who is frequently tested will qualify as an AIDS case on the basis of one spuriously low **CD4⁺** count.

Accessibility of CD4⁺ Testing

States' capacity to perform CD4⁺ lymphocyte testing of HIV-positive patients is related both to the availability of flow cytometry capacity (equipment and personnel) and to the costs of CD4⁺ tests. Some critics have argued that the CDC's new AIDS case definition should not be implemented until adequate resources are available to accomplish the CD4⁺ testing that needs to be done (99).²⁴

Clinical flow cytometers cost approximately \$80,000 to \$100,000 each (123). Most small hospitals and clinics do not have a flow cytometer and therefore must send a patient's blood sample to a laboratory with flow cytometry equipment to obtain the CD4⁺ percent of lymphocytes. Nearly 1,000 laboratories in the United States have capabilities to perform CD4⁺ testing (229). According to a CDC survey, in most of these labs, flow cytometry capacity exists to perform additional tests. Although the number of flow cytometers may be sufficient for additional testing, new personnel will probably need to be trained to run the tests.²⁵

The extent to which flow cytometry can be performed at central facilities is limited because CD4⁺ lymphocyte percents are affected by the storage time and temperature of a blood sample. The CDC recommends running CD4⁺ lymphocyte percents within 24 hours after a blood sample is collected, and recommends rejecting samples that are over 48 hours old (109).

24 Many HIV-infected persons are either uninsured or are receiving Medicaid. See discussion in Chapter III of this report.

25 In a CDC survey of flow cytometry laboratories, most responded that it would take 6 to 24 weeks for flow **cytometer** operators to become proficient at performing CD4⁺ testing (229).

As of early 1992, only six State public health departments currently have an adequate number of flow cytometers to perform the CD4⁺ testing of HIV-positive patients that would be required under the CDC's new case definition of AIDS (9,28). In many States, however, private and university laboratories may have sufficient available flow cytometry capacity to handle most or all of a State's flow cytometry requirements, and State health departments with adequate funds could contract with these laboratories to perform CD4⁺ testing (152). According to the CDC, a typical CD4⁺ test costs about \$50, plus personnel costs, to perform, and the average charge to the patient is \$150 for a CD4⁺ test (108,152).

AIDS Surveillance Under the New Definition

In the long term, the increased efficiency of laboratory-based reporting of AIDS may enable some State and local public health departments to save money in prompting physicians to report AIDS cases (56).²⁶ Health departments, however, will continue to need money to collect risk factor information and other information on AIDS cases from physicians. Also, as the

26 Others anticipate that costs will increase over the long term. As one epidemiologist notes, "In New York City, I believe that exactly the opposite will occur. Patients with CD4⁺ counts of less than 200 who are reported by laboratories will need to be investigated to obtain the bulk of the AIDS case report information. With the extensive hospital contacts of our present **surveillance** system, this will not present a great problem for patients whose CD4⁺ tests were requested by hospitals. However, a CD4⁺ count of less than 200 in patients whose CD4⁺ tests are requested by private physicians will necessitate a large number of visits or telephone calls to literally hundreds of private physicians' offices that are not currently required" (70).

change takes place, public health departments may need additional money to handle the larger AIDS caseload, to establish new systems to more efficiently identify cases, and to provide CD4⁺ testing to uninsured individuals who cannot afford these tests (56).

The CDC has not clarified whether additional monies will be made available to manage the additional AIDS cases that are identified under its new case definition. In the past, the CDC has provided States, the District of Columbia, and U.S. territories with \$15 million for AIDS surveillance (15). Under cooperative agreements with the public health departments in the States, the District of Columbia, U.S. territories, and six metropolitan areas (New York, Houston, Los Angeles, Chicago, Philadelphia, and San Francisco), the CDC supports 65 HIV testing and counseling programs (220). The CDC has revised its agreement with the States to allow them to use some of the \$120 million provided under these agreements to fund CD4⁺ testing (56).

Some States will be placed in a dilemma over whether to provide additional funds to State public health departments for AIDS surveillance. On one hand, States will need to expend additional funds to identify a larger number of AIDS cases. In addition, although the expansion of the AIDS case definition will not increase the number of persons who need care, the surveillance system may identify more immunocompromised individuals who are in need of care. States may need additional funds to provide appropriate medical care for the immunocompromised individuals who are identified through CD4⁺ testing. On the other hand, those States that are better able to identify AIDS cases will get proportionately more Federal funds. The reason is that Federal funding is divided among States, in part, based on the number of AIDS cases identified. This point is discussed in more detail below.

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Concerns About the Accuracy of AIDS Surveillance Under the New Definition

In the first years after the CDC's case definition of AIDS is changed in 1992, there is likely to be a large increase in the reported number of new AIDS cases; this increase will reflect the identification and reporting of individuals who are diagnosed with AIDS on the basis of their CD4⁺ lymphocyte counts, but who would not have been considered AIDS cases under the 1987 definition. After the initial large increase, the reporting rate of new AIDS cases is likely to return to a rate nearer to the rate of previous years (most of the individuals who are identified as AIDS cases under the new definition on the basis of their CD4⁺ lymphocyte counts will eventually develop AIDS-defining conditions; with the development of such conditions, they would have been identified as AIDS cases under the 1987 definition) (32).²⁷

In the first years after implementation of the CDC's proposed case definition of AIDS, epidemiologists anticipate that the CDC will lose its ability to use AIDS case reports to follow trends in the incidence of AIDS (50).²⁸ The reporting of prevalent cases that meet the criteria for AIDS under the proposed case definition but do not meet the criteria for AIDS under the 1987 case definition will obscure changes in the incidence of AIDS. Once the prevalent cases are reported, however, the CDC will regain its ability to monitor the incidence of AIDS.

27 As HIV-infected persons are diagnosed with AIDS earlier in the course of infection, the number of persons living with AIDS will increase with implementation of the new definition.

28 The **CDC** could, however, create special studies to count cases meeting the 1987 definition as a subset of all reported cases. The **CDC** could also monitor trends in AIDS mortality as a substitute for AIDS incidence during the transition period.

Following the implementation of the proposed case definition of AIDS, it will be more difficult for epidemiologists to use AIDS case reports to track changes in the incidence of each of the 23 AIDS-defining conditions that are included in the 1987 definition of AIDS. The change in the definition will also make it difficult to compare AIDS surveillance data before and after the change is implemented. The CDC may possibly be able to monitor trends in the incidence of AIDS-defining conditions after the case definition is changed by having selected centers report on the incidence of AIDS-defining conditions as well as reporting new AIDS cases (182).²⁹

Not all of the HIV-infected persons with CD4⁺ lymphocyte counts below 200 cells/mm³ are likely to be counted as AIDS cases after the new case definition is put into effect. Severely immunocompromised individuals who are aware that they are HIV-infected and who receive CD4⁺ testing will be counted as AIDS cases. But other HIV-infected individuals with CD4⁺ counts below 200 cells/mm³ may not be counted because they are either symptom free and do not seek health care, or because they are symptomatic but their symptoms are not recognized as HIV-related.

Although the proposed definition will increase the number of reported AIDS cases, the completeness of reporting will be difficult to assess (47,50). The completeness of reporting under the proposed system will depend on diagnosis of HIV infection and regular monitoring of CD4⁺ lymphocyte counts. In contrast, completeness of reporting can more readily be assessed with the 1987 AIDS case definition. This is because almost all patients who develop an

²⁹ In fiscal year 1991, the CDC awarded funds to five areas to test simplified methods of AIDS surveillance. In anticipation of implementation of the revised definition of AIDS; the CDC is planning to shift the focus of this project to the type of evaluation described here (15).

AIDS-defining condition seek medical care. Once they enter the health care system, persons with AIDS-defining conditions may be diagnosed and reported as AIDS cases.³⁰

How many AIDS cases are identified after the new case definition is implemented will depend **to some** extent on the availability of CD4⁺ testing. Lack of access to CD4⁺ testing would blunt the surge of new cases that would otherwise be anticipated under the proposed definition. The size of the surge in case reports will also be related **to** the capacity of health departments **to** implement new surveillance procedures.

Differences **in access to** CD4⁺ testing may make interpretation of trends difficult (47). Populations of HIV-infected individuals with better access to CD4⁺ 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. Critics of the case definition of AIDS argue that" injection drug users and the poor are more likely to be diagnosed with AIDS based on the presence of AIDS-defining conditions rather than on the basis of low CD4⁺ counts (243). This is because persons of lower socioeconomic status and injection drug users have access to emergency rooms and hospitals when they are acutely ill, but they have much more limited access to outpatient care (10,25,62,164). Individuals with AIDS-defining conditions are likely to be diagnosed in an emergency room or when hospitalized. CD4⁺ testing, however, is unlikely to be performed in an emergency room because typically only the emergent problem is addressed. Although CD4⁺ counts may be obtained

30 Not all diagnosed AIDS cases are reported. This is particularly a problem when a private practice physician is responsible for reporting because the physician may be more responsive to the patient's wishes that his or her disease not be reported (83). Also, some HIV-infected persons, particularly injection drug users, seek care late in the course of an AIDS-defining condition and die before AIDS is diagnosed (175).

on a person who is hospitalized, CD4⁺ testing is not an indication for hospitalization. Surveillance methods, however, are available to detect and adjust for this reporting bias (15). Surveillance data may help to identify inequities in access to HIV diagnosis and treatment (e.g. , by comparing persons reported because they have a low CD4⁺ count to those reported because they have an AIDS-indicator illness). Furthermore, under the current AIDS definition or any other surveillance system, only those persons having some interaction with the health care system (either through the emergency room, clinic, or hospital) will be detected (15).

Several States have attempted to estimate the number of AIDS cases that will result from the change in the definition, and the estimates vary among jurisdictions. The variation in estimates may reflect differences in the data upon which the estimates were calculated, differences in the assumptions used in the calculations, or both.

The CDC estimates that there will be a 52 percent increase in the total number of living AIDS cases in the United States if the proposed expanded CDC AIDS case definition is used (218).³¹ For its estimate, the CDC relied on data from the Adult/Adolescent Spectrum of HIV Disease Project.³² The project includes nine centers in the United States: Los Angeles, Denver, Atlanta, New Orleans, Houston, Dallas, Detroit, San Antonio, and Seattle. The project

31 This estimate is based on the number of persons with CD4⁺ lymphocyte counts less than 200 **cells/mm³** and the number of prevalent AIDS cases in the Adult/Adolescent Spectrum of HIV Disease Project. If the number of incident cases is used (only those AIDS cases diagnosed in a 12-month interval) then the percent increase from the Adult/Adolescent Spectrum of HIV Disease Project would be approximately 75 percent (15).

32 The CDC's Adult/Adolescent Spectrum of HIV Disease Project analyzed data from 10,342 HIV-infected men and women in nine cities across the United States. The purpose of the project is to examine the spectrum of disease associated with HIV infection in men and women (15).

includes HIV-infected patients from public and private hospitals and ambulatory care clinics (16). One observer has noted that New York City and other northeastern cities with large numbers of HIV-infected injection drug users and other HIV-infected persons with poorer access to care are not included in these studies; thus conclusions from these studies may not be generalizable to these parts of the United States (175).

South Carolina is one of two States that currently provides CD4⁺ tests to all individuals known by the State to be HIV-positive; extrapolating from data that have been collected there, one would anticipate that the number of living AIDS cases in South Carolina will increase by approximately 80 percent after the definition of AIDS is changed (88). Estimates of the increase in the number of living AIDS cases in San Francisco following the implementation of the new case definition of AIDS range from 92 percent to 135 percent (31,98,150,163). Estimates of the increase in the number of living AIDS cases in New York City range from 36 percent to 100 percent (70,181,182). The Los Angeles Department of Health Services anticipates an increase in number of living AIDS cases of approximately one-third (94,118).

As discussed earlier, some people have argued that HIV-infected women and injection drug users, many of whom are African American or Hispanic, are less likely than white men who have sex with men to be identified under the CDC's proposed case definition of AIDS. It is interesting to note that among participants in the CDC's Adult/Adolescent Spectrum of HIV Disease Project, people from different sexes, races, and risk groups were all about equally likely to have received CD4⁺ testing (218). These data have been used by the CDC to suggest that HIV-infected persons of different sexes, races, and risk groups who are aware of their HIV status and are able to receive clinical care are about equally likely to obtain CD4⁺ lymphocyte counts. These data do not,

however, reveal whether HIV-infected women and injection drug users are as likely to obtain clinical care as are members of other HIV-infected populations. These data do suggest, however, that once HIV-infected women and injection drug users enter clinical care, they receive CD4⁺ testing as frequently as HIV-infected individuals from other risk groups.

Data from the CDC's Adult/Adolescent Spectrum of HIV Disease Project indicate that women and injection drug users will make up a greater proportion of AIDS cases diagnosed under the proposed AIDS case definition than they do under the 1987 definition (218) . Whereas the total number of persons living with AIDS is expected to increase by 52 percent under the new AIDS case definition, the number of women living with AIDS is expected to increase by 61 percent. Data from the Adult/Adolescent Spectrum of HIV Disease Project also indicate that there will be a 55 percent increase in number of injection drug users living with AIDS under the new definition.

The CDC expects the proposed AIDS case definition to capture many of the profoundly immunosuppressed (with CD4⁺ counts less than to 200 cells/mm³) women and injection drug users who are suffering from HIV-associated conditions such as cervical dysplasia, pelvic inflammatory disease, chronic or recurrent vaginal candidiasis, pulmonary tuberculosis, sepsis, endocarditis, and nonopportunistic bacterial pneumonias. These conditions also occur, however, in HIV-infected persons who are relatively immunocompetent. The CDC argues that when these conditions occur in persons with lesser degrees of immunosuppression (i.e., whose CD4⁺ lymphocyte counts equal or exceed 200 cells/mm³), they are more likely to be merely coincidental to HIV infection (15). Therefore, the proposed AIDS case definition will capture those HIV-infected women and injection drug users whose symptoms are most likely to be related to HIV-induced immunosuppression.

Although some HIV-positive individuals with CD4⁺ lymphocyte counts below 200 cells/mm³ will not have any symptoms, the probability is high they will develop symptoms within 12 months (78). Data from the Multicenter AIDS Cohort Study (MACS) show that one-third of the individuals whose CD4⁺ lymphocyte counts fell below 200 cells/mm³ were asymptomatic (129).³³ Under the CDC's proposed AIDS case definition, asymptomatic individuals with CD4⁺ counts below 200 cells/mm³ will be diagnosed with AIDS, and some of these individuals may experience adverse psychological and social consequences (47,50). This is in contrast to previous definitions, which only included as cases persons who were diagnosed with AIDS-defining conditions.

The Impact on Federal Funding Allocations

In 1990, Congress passed the Ryan White Comprehensive AIDS Resources Emergency Act (Public Law 101-381) (henceforth referred to as the Ryan White Act). The Ryan White Act authorized payments of up to \$1.1 billion over a 2-year period for education about HIV infection and the prevention and treatment of HIV infection. Total Ryan White Act funding for 1991 and 1992 was approximately \$500 million, and the President's 1993 budget requests just over \$306 million in funding for the act (57).

33 The **MACS** primarily represents middle-class, white men who have sex with men. For the reasons discussed previously, the proportion of HIV-infected women and injection drug users who are **asymptomatic** with CD4⁺ counts less than 200 cells/mm³ is likely to be lower. Furthermore, persons in this study were "**asymptomatic**" if they did not have AIDS or one of a limited number of conditions often referred to as AIDS-related complex (which includes fatigue, fever, weight loss, persistent skin rash, oral hairy **leukoplakia**, herpes simplex, and oral thrush) (129). Hence, some persons characterized as **asymptomatic** may indeed be experiencing some HIV-related symptoms.

The Ryan White Act allocates funds under four separate titles, and for three of the titles, the numbers of reported AIDS cases are used in formulas for allocating funds among States and cities.³⁴ The change in the number of AIDS cases will only affect the allocation of funds under Titles I and II of the Ryan White Act, since Title III, Subpart 1, of the Ryan White Act is not currently funded. Moreover, the change will not affect funding allocations until 1994, because Ryan White funding is based upon the number of AIDS cases reported to the CDC as of March 31 in the year (or two years) prior to the fiscal year for funding.

The AIDS Housing Opportunity Act of 1990 (P.L. 101-625) also distributes funds based in part on the number of cases of CDC-defined AIDS. The act authorizes the U.S. Department of Housing and Urban Development (HUD) to distribute grants to cities and States for housing low-income persons infected with HIV. The grants are to be allocated among cities and States based on the number of AIDS cases; however, no funds have been distributed to date.

Title I Funding Allocations Under the Ryan White Act

Under Title I of the Ryan White Act, the Health Resources and Services Administration (HRSA) provides funds to metropolitan areas for ambulatory medical and support services for low-income individuals with HIV infection. In order to be eligible for Title I funding, a metropolitan area must have at least 2,000 cases of AIDS reported to the CDC by March 31 of the year prior to the year in which funding is appropriated, or a per capita cumulative AIDS incidence rate of 25 per 10,000 (0.0025) or greater (42 U.S.C. § 300ff-13).

³⁴ Title IV authorizes funds for research to explore the impact and cost-effectiveness of AIDS care. Funds are to be distributed on a grant basis. However, to date, no funds have been authorized under this title (57).

Half of Title I funds are divided among eligible metropolitan areas based on the ratio of the number of AIDS cases in each metropolitan area to the total number of AIDS cases in all eligible metropolitan areas. The other half of Title I funds are distributed to metropolitan areas that demonstrate to HRSA, among other things, that they have severe need for funds and they are able to use these funds immediately and in a cost-effective manner (42 U.S.C. § 300ff-13).

In 1992, 18 metropolitan areas shared \$121.8 million in Title I funds (196). In 1993, HRSA estimates that 24 metropolitan areas will qualify for Title I funds.³⁵ HRSA has estimated that by 1994 (the first year in which the new AIDS case definition will have an impact on the allocation of Ryan White Act funds), between 32 and 41 metropolitan areas may qualify for Title I funds (20). Because the new AIDS definition will include some people up to 2 years before their first serious opportunistic infection, the increase in the number of new AIDS cases that accompanies the change in the definition may not directly translate into a dramatic increase in health care needs. However, all HIV-infected persons with CD4⁺ counts of 200 cells/mm³ or less will need both antiretroviral therapy and pneumocystis prophylaxis. In addition, most of these persons with AIDS will require more comprehensive services within a year or less, which is approximately when the funding will actually be distributed to the cities. Because a larger number of metropolitan areas will be eligible for Title I funds under the proposed definition, the amount of money appropriated to Title I will need to substantially increase by 1994 to maintain the current level of funds that is provided to each metropolitan area.

35 This estimate is based on the predicted number of AIDS cases that will be reported to the CDC as of March 31, 1992, prior to the proposed change in the CDC AIDS case definition (57).

Fifty percent of the funds under Title I are distributed through a formula grant that provides each metropolitan area with a proportion of funds based on the ratio of the number of AIDS cases in the metropolitan area (and the per capita incidence of AIDS) to the total number of AIDS cases in all eligible metropolitan areas (and total per capita incidence of AIDS). Some cities may be less able than others to identify AIDS cases because, for example, they have a disproportionate number of HIV-infected persons with no access to ambulatory services, or because the local health department may not have adequate funds to carry out a comprehensive AIDS surveillance program (19). These cities may receive proportionately less Ryan White funds than other cities that are better prepared to document the number of AIDS cases.³⁶

Title II and Title III Funding Allocations Under the Ryan White Act

Title II of the Ryan White Act provides States and territories with Federal funds for health care and support services for poor HIV-infected individuals and their families (42 U.S.C. §§ 300ff-22 to 300ff-41). Each State and territory receives a proportion of these funds that is equivalent to the proportion of AIDS cases in the United States that were reported from that State or territory in the 2 years prior to the fiscal funding year. For example, if a State reported 10 percent of all AIDS cases in the Nation in those years, it would receive approximately 10 percent of the funds allocated under Title II, subject to adjustments and supplemental grants.

³⁶ Only 50 percent of Title I funds are distributed by a formula that uses the percentage of AIDS cases. The availability of supplemental grants may limit the impact on Title I funding of disproportionate resources among metropolitan areas for AIDS surveillance.

The Ryan White Act authorized \$275 million under Title II for 1991 and 1992, but Congress only appropriated \$87.8 million for Title II in 1991 and \$108 million in 1992 (57). Title II funds are divided over 57 States and territories, and in 1991 the majority of the funds was distributed as follows: New York and California (approximately \$13 million each); Florida (\$7 million); Puerto Rico (\$5 million); Texas and New Jersey (approximately \$4 million each); Georgia, Illinois and Pennsylvania (approximately \$2 million each); District of Columbia, Louisiana, Maryland, Massachusetts, Michigan, Missouri, North Carolina, Ohio and Washington (approximately \$1 million each); and Alabama, Colorado, Connecticut, Indiana, Mississippi, Oregon, South Carolina, and Tennessee (between \$500,000 and 800,000 each) (197). The President's proposed budget for 1993 would maintain Title II funding at \$108 million (57).

Because the amount of funds distributed under Title II of Ryan White is allocated on the basis of percentage of AIDS cases, a change in the definition of AIDS that increases the absolute numbers of AIDS cases will not affect the allocation of funds unless the change results in disproportionate increases in the numbers of cases identified in certain areas. A disproportionate increase could occur because: 1) some States have HIV name reporting and a few even have records of CD4⁺ counts on HIV-infected persons, and may be better able to target AIDS surveillance; 2) States with a large number of AIDS cases may not be able to carry out detailed case investigations required for reporting; 3) States may have a disproportionate number of HIV-infected persons who have limited access to ambulatory care and CD4⁺ testing; and 4) Some States may have a disproportionate number of HIV-infected persons who are profoundly immunosuppressed but who do not have one of the AID-defining conditions

included in the current case definition (19). In sum, States that have difficulty carrying out AIDS surveillance may receive less funds than deserved.

Title III of the Ryan White Act provides money for early intervention services, including HIV antibody testing and counseling, and other clinical and diagnostic services, such as CD4⁺ testing. Under Subpart I of Title III, CDC is authorized to distribute grants to each State, the District of Columbia, and Puerto Rico using a formula that is similar to the formula used under Title 11--i.e. , funds are distributed among States in proportion to the number of AIDS cases in each State in relation to the total number of AIDS cases in all States.

No money is currently being distributed under Subpart I of Title III because Title III requires a substantial expansion of CDC's counseling and testing activities and would therefore require a substantial increase in appropriations (63,195). As a result, the CDC's counseling and testing program continues to be carried out under the authority of Public Health Service Act, which does not mandate funding of clinical and diagnostic services (61). The CDC distributes funds for counseling and testing to the **States** and certain cities on the basis of need, but the CDC does not strictly adhere to a formula that is based on the number of AIDS cases in each State (61,220).

Title III, Subpart II, of the Ryan White Act, which is administered by HRSA, provides specific grants to public and nonprofit entities, such as migrant health centers and family planning centers, to be used for the same type of early intervention services specified for Subpart I. The funds are not distributed by a formula and therefore the change in the CDC definition of AIDS will not affect the allocation of funds under this title.

AIDS Housing Opportunity Act of 1990

The AIDS Housing Opportunity Act of 1990 (P.L. 101-625) is designed to provide housing for low income persons with AIDS. Ninety percent of the funds are designated for: 1) metropolitan areas with populations in excess of 500,000 and which have over 1500 AIDS cases; and 2) States with more than 1,500 cases of AIDS outside of these metropolitan areas (42 U.S.C. § 12903(c)(1)). Metropolitan areas and States can be awarded grants only if they submit a housing strategy that is approved by HUD. Grants will be allocated among eligible metropolitan areas and States in proportion to the number of AIDS cases in each metropolitan area or State. The minimum grant to eligible areas will be \$200,000 (42 U.S.C. § 12903(c)(2)).

Currently, approximately 27 metropolitan areas and 12 States are eligible for grants based on the number of AIDS cases reported to the CDC through December 1991 (64,222). Because HUD has not yet promulgated regulations that will govern the grant application process, it is not known how many metropolitan areas and States will apply for grants. HUD recently announced it will publish regulations in June 1992, thereby allowing for disbursement of the \$50 million appropriated under this act by late summer of 1992 (5).

PRIVACY CONCERNS AND THE CHANGE IN THE DEFINITION OF AIDS

The proposed change in the CDC's case definition of AIDS has raised concerns about the confidentiality of CD4⁺ test results and the privacy of persons with AIDS. Because more HIV-infected persons will be diagnosed with AIDS under the proposed definition, an increased number of men and women will be reported by name as AIDS cases to State and local health departments. For persons with AIDS, name reporting raises serious privacy concerns. HIV infection has predominately affected men who have sex with men, injection drug users, and the sexual partners of members of these risk groups. Widespread societal condemnation of these risk behaviors, coupled with irrational fears of transmission (53,84,107), has led to discrimination against, and social ostracization of, persons with AIDS or HIV infection (4,120,193).

The States protect the confidentiality of information gathered through AIDS surveillance activities; however, the States also authorize disclosure of an individual's HIV status to third parties when necessary to stem the spread of the virus (45). Although these exceptions to the confidentiality of HIV-related information are limited, any unauthorized disclosure may be threatening to an HIV-infected individual. There are State and Federal laws that protect HIV-infected persons from discrimination, but these laws are effective only to the extent that they are enforced and they mainly redress wrongful discrimination only after it has occurred.

The incorporation of the CD4⁺ lymphocyte count into the CDC definition of AIDS will enable States to involve private and public clinical laboratories in AIDS case reporting. In addition, the debate over the change in the AIDS case definition has led to increased attention on the confidentiality of CD4⁺

lymphocyte test results. Although most State laws afford greater protections to the confidentiality of HIV antibody test results than other medical records, the States are split on whether this heightened confidentiality applies to other HIV-related information, such as the results of CD4⁺ lymphocyte tests. At issue is whether CD4⁺ lymphocyte test results should be afforded the same confidentiality protections as HIV antibody test results and whether the requirement for specific informed consent that applies to HIV antibody testing should also apply to CD4⁺ lymphocyte testing.

Name Reporting of AIDS and Confidentiality

The proposed change in the CDC's case definition of AIDS will increase the number of AIDS cases reported in each State and hence increase the number of names kept on the States' AIDS registries. It is important to note, however, that any expansion of the CDC definition, not just that which has been proposed, would result in more names being reported as AIDS cases to the State and local health departments. In addition, a number of States already require name reporting of all HIV-infected individuals to the State and local health departments (see app. H). In these States, the health departments are already responsible for protecting the confidentiality of all HIV-infected persons' names in their registries.

The CDC and the State and local health departments insist that name reporting of AIDS cases is essential to ensure the accuracy of surveillance. Some advocates for people with AIDS are concerned that States may not be adequately prepared to handle the surge of AIDS cases that will be reported upon implementation of the proposed definition, and they fear that breaches of confidentiality will be more likely to occur. They are also concerned about

the increase in the number of HIV-infected persons that are reported as AIDS cases to the States because they believe that States have become increasingly willing to allow the disclosure of a person's HIV status to third parties in order to stem further spread of infection with HIV. The following sections examine this debate.

AIDS Name Reporting

In all 50 States, the District of Columbia, Puerto Rico, and other territories, information on every confirmed AIDS case, including the name of the person with AIDS, is sent to the State or local health department. This AIDS case information, absent the person's name, is shared with the CDC for purposes of AIDS surveillance using a CDC form called the "Acquired Immunodeficiency Syndrome (AIDS) Adult Confidential Case Report" (see app. C) (34).³⁷

The CDC insists that name reporting of AIDS cases is necessary to identify and remove duplicate reports from multiple sites, to collect follow-up data as necessary, and to assess completeness of reporting (15).³⁸ Underreporting or overreporting may distort information about the pattern of the AIDS epidemic and bias interpretation of trends in the epidemic (186). For example, epidemiologists may make incorrect inferences about patterns of transmission, the relative contribution of various risk groups to the

37 Names of persons with AIDS are not reported to the **CDC**; rather each case is identified by a **Soundex** code.

38 In lieu of names being reported to State health departments, **Soundex** codes or other systems could be used. Without name reporting, however, duplicate reports cannot be eliminated because more than one person may have the same **Soundex** code (32).

epidemic, and the effects of treatment. With anonymous reporting, epidemiologists could not go back to the source for additional information,³⁹ perform survival analysis, or perform special studies on the data (32).

About one-half of the States require that the names of all persons infected with HIV be reported to the State or local health department (see app. H); however, information on the number of HIV-infected persons identified by the States is not yet being used by the CDC for surveillance purposes. Moreover, because most of these States permit persons to be tested anonymously for HIV (119), a substantial percentage of HIV-infected persons is not reported to State health departments. Nonetheless, in those States that require name reporting of persons with HIV infection, confidentiality is a concern to HIV-infected persons regardless of whether they have CDC-defined AIDS.

Confidentiality of HIV-Related Information

The States have a legal duty to protect the confidentiality of medical information that is collected in disease surveillance (238) and every State takes measures to protect the confidentiality of the names of persons in its AIDS case registry (45). In some States, laws governing the confidentiality of reports of sexually transmitted and communicable diseases apply to AIDS case reports.⁴⁰ A number of States also has confidentiality laws that specifically apply to AIDS and HIV-related information (45,97). According to

39 For example, approximately 10 percent of reported AIDS cases in New York do not list risk factors with the AIDS case report (32).

40 See, e.g., WYO. STAT. **§§** 35-4-130, 35-4-132 (1991); OR. REV. STAT. **§** 3701.24(C) (1989); N.D. CENT. CODE **§** 23-07-02.2 (Supp. 1991); NEV. REV. STAT. **§** 441A.220(Supp. 1989); MASS. GEN. LAWS ANN. ch. 111D, **§** 6 (West 1991, Supp.); DEL. CODE ANN. tit. 16, **§§** 3702, 3711 (1991).

one informed commentator, State and local health departments have an excellent record of protecting the confidentiality of reported cases (239). Indeed, OTA has found no reports of inadvertent disclosure of AIDS- or HIV-related information from State or local health departments.

Despite the fact that the States protect the confidentiality of HIV-related information, a number of States also authorize limited disclosure of a person's HIV status to third parties if necessary to protect them from being infected with HIV or to inform them that they may have been exposed to HIV. These disclosure laws are very controversial because they involve serious compromises of HIV-infected persons' privacy rights and yet in a number of instances the disclosure protects against seemingly small risks and the benefits of the disclosure are questionable (45).

Most State HIV and AIDS confidentiality statutes have a general statement that all protected information must be kept confidential and the statutes enumerate specific exceptions to that confidentiality. The types of persons to whom HIV test results and other HIV-related information can be disclosed often include the following: 1) another party pursuant to an authorized release by the person who was subject to an HIV antibody test, or whose medical records contain HIV-related information; 2) the public health department or Federal officials as required by law, or in order to protect public health; 3) the sexual and needle-sharing partners of an HIV-infected individual⁴¹; 4) for statistical purposes if the data is disclosed without identifiers; 5) third-party payers, as authorized; 6) facilities that use, process, or distribute human tissues and organs; 7) committees and other parties authorized to conduct oversight and quality reviews of health care

⁴¹ This type of disclosure usually requires the cooperation of the HIV-infected individual (183).

facilities; 8) health care workers who may have been exposed to HIV; 9) firefighters, emergency medical workers, and police who may have been exposed; 10) agencies involved in providing foster care services; and 11) schools. HIV-related information can also be disclosed in other situations as required by law (45,65). The laws and regulations that allow such disclosure vary from State to State.⁴²

Many State statutes also allow third parties to petition a court for permission to obtain information about whether a person is infected with HIV.⁴³ Some statutes, however, limit the court's authority to reveal HIV-related information to situations in which there is "clear and convincing evidence" of a "compelling need," or in cases in which the court determines that the public interest outweighs the potential harm due to the breach of the

42 See, e.g., **ARIZ. REV. STAT. ANN. § 366-664 (Supp. 1991)**; **COLO. REV. STAT. § 25-4-1404 (1991)**; **CONN. GEN. STAT. ANN. § 19a-503 (1990)**; **FLA. STAT. ANN. § 381.004 (West 1990, Supp.)**; **HAW. REV. STAT. § 325-101 (Supp. 1990)**; **ILL. ANN. STAT. ch. 111 1/2, para. 7309 (Smith-Hurd 1990, Supp.)**; **KAN. STAT. ANN. § 65-6002 (Supp. 1990)**; **ME. REV. STAT. ANN. tit. 6-7, § 19203-D (1991)**; **MICH. COMP. LAWS ANN. § 333.5131 (West 1991, Supp.)**; **N.D. CENT. CODE, §§ 23-07.1-02.1, 23-07.3-02 (Supp. 1991)**; **N.J. STAT. ANN. §§ 26C:5C-6 - 26:5C-14 (West 1991, Supp.)**; **N.Y. PUB. HEALTH LAW § 2782 (McKinney 1992, Supp.)**; 1989 **N.M. Laws** Chap. 227, House Bill 490; **OHIO REV. CODE ANN. § 3701.243 (Anderson 1990, Supp.)**; **OR. REV. STAT. § 443.045 (1989)**; **R.I. GEN. LAWS, § 23-6-17 (Supp. 1991)**; **VA. CODE ANN. § 32.1-36.1 (Supp. 1991)**; **WASH. REV. CODE ANN. § 70.24.105 (Supp. 1991)**.

43 See, e.g., **CONN. GEN. STAT. § 19a-583 (1990)**; **GA. CODE ANN. § 24-9-47(r) (Supp. 1991)**; **HAW. REV. STAT. § 325-101 (Supp. 1990)**; **ILL. ANN. STAT. ch. 111 1/2, para. 7309 (Smith-Hurd 1990, Supp.)**; **MICH. COMP. LAWS ANN. § 333.5131 (West 1991, Supp.)**; **N.J. STAT. ANN. § 26:5C-9 (West 1991, Supp.)**; **N.Y. PUB. HEALTH LAW § 2785 (McKinney 1992, Supp.)**; **OHIO REV. CODE ANN. § 3701.243 (Anderson 1990, Supp.)**; **PA. STAT. ANN. tit. 35, § 37608 (Purdon 1991, Supp.)**; **VA. CODE ANN. §§ 32.1-36.1 (Supp. 1985)**.

HIV-infected individual's privacy.⁴⁴ However, these standards do not guarantee that courts will make reasonable decisions based on objective evidence of risk (4).

Most State statutes give public health departments the discretion to disclose HIV-related information when necessary to protect public health (45). The U. S. Supreme Court has ruled that States have "broad latitude in experimenting with possible solutions to problems of vital local concern," even when the solution involves disclosure of confidential medical information that could "reflect unfavorably on the character of the patient" (238).⁴⁵ Therefore, this exception potentially allows for disclosure in a number of different situations.

While some people may not object to current State laws that permit disclosure, there is the possibility that, in the future, State laws may be changed to allow for broader exceptions to the confidentiality of HIV-related information. In 1991, for example, the Illinois legislature passed a statute that requires the Illinois department of health to inform patients that they may have been exposed to HIV when they have been subject to an invasive

44 See, e.g., CONN. GEN. STAT. § 19a-583 (1990)(**compelling** need); GA. CODE ANN. § 24-9-47 (Supp. 1991) (clear and convincing evidence); ME. REV. STAT. ANN. tit. 6-7, § 19203-D (1991)(**good** cause); MICH. COMP. LAWS ANN. § 333.5131 (West 1991, Supp.) (**public** need outweighs potential injury); N.J. STAT. ANN. §§ 26C:5C-8, 26:5C-9 (West 1991, Supp.)(**good** cause); N.Y. PUB. HEALTH LAW § 2785 (McKinney 1992, Supp.)(**compelling** need; clear and imminent danger); OHIO REV. CODE ANN. § 3701.243 (Anderson 1990, Supp.)(**clear** and convincing evidence of compelling need) ; PA. STAT. ANN. tit. 35, § 7608 (Purdon 1991, Supp.)(**compelling** need).

45 In Whalen, the Court upheld a New York State law that required pharmacists to provide the New York Public Health Department with copies of all prescriptions of Schedule II drugs, including cocaine, opium, methadone, amphetamines, and methaqualone. These drugs are often used illegally and the New York legislature hoped to use the name reporting system to prevent the use of stolen or revised prescriptions, over-prescribing by physicians, repeated refills by pharmacists, and to prevent drug users from obtaining multiple prescriptions from different sources.

procedure in which an HIV-infected health care worker participated.⁴⁶

Conversely, health care workers who have performed invasive procedures on HIV-infected patients must be told that they may have been exposed to HIV (Ill. Ann. Stat. ch. 111 1/2, para. 7405.5 (Lexis 1991)). The health department is authorized to review medical records to determine who is at risk. The statute provides, however, that all records relating to these investigations shall be confidential. In addition, the health department must inform persons who are notified that they may have been exposed to HIV that the Illinois AIDS Confidentiality Act prohibits them from further disclosing this HIV-related information, and that willful and malicious disclosure is a Class A misdemeanor (Ill. Ann. Stat. ch. 111 1/2, para. 7405.5 (Lexis 1991)).

Despite these protections, and despite the fact that disclosure is only required if there is a risk of transmission, the statute is seen as setting a dangerous precedent by many advocates because it requires disclosure in circumstances where the risk of HIV transmission is considered very small (194). If aggressively implemented, the Illinois law could result in many patients being told that their physician, dentist, podiatrist, or nurse is infected with HIV, or it could result in medical workers being told that they've been put at risk of HIV infection by their patients. Even if the Illinois Department of Health does not reveal the name of the HIV-infected health care worker, the patient may be able to identify the health care worker or make assumptions about who put them at risk, and this will probably damage

46 The act states that it will use the **CDC's** list of invasive procedures. The **CDC** planned to develop a list of invasive procedures to be used to prevent HIV transmission from health care workers to patients. Strong opposition to the development of such a list, however, led the **CDC** to suspend its drafting of this list (3).

these health care workers' reputations and careers. (It is likely to be more difficult for health care workers to determine which of their patients may have exposed them to HIV if HIV-infected patients' names are not revealed.)

Protections Against Discrimination

If there are breaches in confidentiality, there are laws to protect a HIV-infected person from discrimination. The most important Federal law that protects HIV-infected persons from discrimination is the recently enacted Americans With Disabilities Act of 1990 (ADA)(P.L. 101-336), a comprehensive statute that prohibits many types of discrimination against persons with disabilities, including all persons infected with HIV.⁴⁷ In short, the ADA prohibits discrimination against the disabled by both public and private employers, discrimination by State and local governments, and discrimination by private entities that operate public accommodations and services. With respect to public accommodations, HIV-infected persons and other disabled persons must be afforded the opportunity for "full and equal enjoyment of goods, services, facilities, privileges, advantages, or accommodations" in any place of public accommodation- -e.g. , hotels, restaurants, theaters, auditoriums, laundromats, museums, parks, zoos, private schools, day care centers, professional offices of health care providers, and gymnasiums (42 u.s.c. § 12181(7), § 12182(a) (89). The ADA therefore insures that irrational fears will not prevent HIV-infected individuals from using public and private services and accommodations, including health care services (89).

⁴⁷ The statute itself does not explicitly state that HIV-infected individuals are disabled. In the legislative history of the act, however, Congress stated that persons infected with HIV would be considered disabled and therefore subject to the full protections of the act (125).

In addition to the protections provided by the ADA, virtually every State has laws that protect the disabled from various types of discrimination, and in at least 34 States, legal opinions or pronouncements of State Attorneys General have indicated that infection with HIV is a protected disability (65). Many of these State laws also prohibit housing discrimination, which is of particular concern to persons infected with HIV (66).⁴⁸

Ironically, HIV-infected persons and persons with AIDS are routinely discriminated against in obtaining health insurance. In every State, an insurance company may refuse to provide an individual insurance policy to a person who is HIV positive, and in many States, an insurance company can request an HIV test prior to issuing an individual policy or a small group policy (51,54,149). It is estimated that 20 percent of people with private insurance have individual policies (51).⁴⁹ The ADA does not prohibit insurance companies from discriminating among insureds on the basis of risk. (42 U.S.C. § 12201(c))(89).

The importance of the issue of discrimination against HIV-infected persons is demonstrated by the large amount of attention paid to this issue by legislatures and courts. Anti-discrimination laws, however, can provide redress only after the wrong has occurred and the damage is done. Even then, wrongs can be redressed only if persons who have been discriminated against

48 The Federal Fair Housing Amendments of 1988 also prohibit private owners and landlords from discriminating against persons with disabilities--including HIV-infected persons--in the sale or rental of housing (Public Law 100-430).

49 Even those persons who obtain insurance through their employer may not be safe from discrimination. Employers who self-insure their employees may be able to place a cap on medical benefits for treatment of AIDS. In a recent case, a record company lowered the maximum payable amount for AIDS-related claims from \$1 million to \$5000.00 shortly after it found out that one of its employees had AIDS. No limitations were placed on any other catastrophic medical coverage (110)

are willing and able to enforce their rights. Several factors may make HIV-infected persons less likely to sue. Perhaps most obviously, HIV-infected persons who are ill may not be able to endure the stresses of a lawsuit. Many HIV-infected persons who have suffered from discrimination may lack the financial resources to seek legal relief, and some may not even know that there are legal remedies available to them. In addition, HIV-infected persons who have been wrongfully discriminated against may not want to spend their remaining years fighting in court (236). Finally, anti-discrimination laws cannot prevent the more subtle forms of discrimination by colleagues and acquaintances that may have a substantial negative psychological impact on HIV-infected individuals. Therefore, for most persons infected with HIV, the best protection against wrongful discrimination is to limit disclosure of HIV-related information.

The Privacy Implications of Using a CD4⁺Lymphocyte Count

The use of the CD4⁺lymphocyte count in AIDS surveillance raises new issues about the involvement of public and private laboratories in case reporting. In addition, given the implications of a low CD4⁺lymphocyte count, there is a debate over the appropriate counseling that should accompany CD4⁺testing and over the confidentiality protections that should apply to CD4⁺test results.

Laboratory Reporting of AIDS

With the implementation of the proposed definition of AIDS, many States plan to require that laboratories report the names of all persons who have a CD4⁺lymphocyte count below 200 cells/mm³ to the State or local health

department. The State or local health department can then prompt physicians to report these patients as AIDS cases if they have a positive HIV test result or an AIDS-defining condition. (14,86,88,182). Advocates for HIV-infected persons believe that States, in an effort to ensure completeness of AIDS case reporting, may fail to enact laws and policies that adequately protect the confidentiality of these laboratory data.

These concerns, however, are theoretical, and there are reasons to conclude the laboratories will not be the weak link in the chain of confidentiality. First, laboratories are already responsible for protecting the confidentiality of all laboratory test results, including CD4⁺ test results, and there is no indication that they do not have adequate procedures in place to protect the results of CD4⁺ tests from wrongful disclosure. In addition, clinical laboratories are subject to State laws and regulations governing confidentiality of medical records, and these laws and regulations usually permit laboratories to disclose test results only to the State or local departments of health or to the physicians who ordered the test.

(38,102,242)(see e.g. ARIZ. REV. STAT. ANN. § 36-470 (Supp. 1990); CAL. [BUS. & PROF.] CODE § 1288 (West Supp. 1991); D.C. CODE ANN. § 32-1511 (Supp. 1991); N.J. STAT. ANN. § 45:9-42-34 (West 1990); OR. REV. STAT. s 438.310 (1989)).

If a laboratory employee breaches confidentiality, it is not unusual for him or her to be discharged (28,38). Laboratories are also governed by State HIV confidentiality laws and a number of these laws extend their protections to all information that may indicate that a person is infected with HIV or has

AIDS, including CD4⁺ lymphocyte counts.⁵⁰ In addition, CD4⁺ test results that are reported to the State or local health departments are subject to State laws regarding the confidentiality of reportable information for communicable or sexually transmitted diseases.⁵¹

One could argue that, although laws are necessary to protect the confidentiality of HIV-related information, they may not be sufficient; institutional procedures are probably more important in protecting against wrongful disclosures. Most laboratories have policies to protect against breaches of confidentiality (36,184). It may, however, be necessary to reevaluate security measures for CD4⁺ test results. The Association of State and Territorial Laboratory Directors has recommended that CD4⁺ test results be treated with the same degree of confidentiality as HIV antibody test results (38).

One way to ensure that the confidentiality of all HIV-related laboratory information is adequately protected is to require laboratories to codify security procedures in writing (184). Some State legislatures have enacted laws that require health care facilities to do this. In Maine, for example, health care providers with patient records that contain information about

50 GWU, IHPP, "Confidentiality/Laboratories, State Laws Regarding Confidentiality," (December 1991); ARIZ. REV. STAT. ANN. § 36-664 (Supp. 1990); COLO. REV. STAT. § 25-4-1404(3) (1991); CONN. GEN. STAT. ANN. § 19a-583 (West 1990); GA. CODE ANN. § 24-9-47 (Supp. 1991); HAW. REV. STAT. § 325-101 (Supp. 1990); KAN. STAT. ANN. § 56-6002(c) (Supp. 1990); MICH. COMP. LAWS ANN. § 333.5129 (Supp. 1991); N.J. STAT. ANN. § 26:5C-6 (West 1991, Supp.); N.Y. PUB. HEALTH LAW s 2782 (McKinney 1992, Supp.); OHIO REV. CODE ANN. § 3701.243 (Anderson 1990, Supp.); PA. STAT. ANN. tit. 35, ss 7603, 7607 (Purdon 1991, Supp.); WASH. REV. CODE ANN. § 70.24.105 (Supp. 1991)).

51 In order to ensure utmost confidentiality for CD4⁺ lymphocyte counts, however, the State **department** of health or Attorney General could issue an opinion that CD4⁺ test results are covered by the State's AIDS confidentiality statutes or fall within the confidentiality provisions of their communicable disease laws.

patients' HIV status must have a written policy regarding the confidentiality of patient information that is consistent with the Maine HIV confidentiality statute. These written policies must require, at a *minimum*, termination of employment for violations of the confidentiality policy (ME. REV. STAT. ANN. § 19203-D (West 1991)). A similar statute could apply to laboratories that handle HIV-related information.

A final issue that is raised by laboratory-based reporting of CD4⁺ lymphocyte counts is that some persons who are not infected with HIV will be reported to State health departments as suspected AIDS cases. This is because certain other viral infections, as well as some bacterial infections and hematological malignancies, may lower a person's CD4⁺ lymphocyte count (123). If laboratories report the names of all persons with CD4⁺ counts below 200 cells/mm³ to State health departments as suspected AIDS cases, a number of persons who are not infected with HIV may be reported.⁵²

A reporting requirement that would be more specific for HIV-induced immunosuppression would be to report only the names of persons whose CD4⁺ lymphocyte counts are below 200 cells/mm³, but whose counts of other T-lymphocyte subset are normal or elevated. HIV infection differs from most other medical conditions that depress T-lymphocyte counts because HIV selectively attacks the CD4⁺ subset of T-lymphocytes (106).

Increased Use of CD4⁺ Counts and Confidentiality

In addition to the confidentiality of CD4⁺ test results held by clinical laboratories, there is also concern about the confidentiality of CD4⁺ test results generally. Several advocates have argued that the laws that protect

52 The Maryland legislature is considering reporting all CD4⁺ lymphocyte counts below 500 cells/mm³ (22). This could result in a large amount of private medical information being unnecessarily reported to the health department.

the confidentiality of HIV-test results should be extended to protect the confidentiality of CD4⁺ test results. A number of State HIV confidentiality laws already protect all information that may indicate that a person is infected with HIV or has AIDS, and these laws should therefore apply to CD4⁺ test results.⁵³ These States have recognized that there is no distinction between the stigma attached to the disclosure of a positive HIV test and the stigma attached to the disclosure of any other information that may show that a person is infected with HIV. States whose HIV confidentiality statutes apply only to HIV antibody test results may need to consider broadening the scope of these statutes to also include CD4⁺ lymphocyte test results. It is important to note, however, that even in those States that do not have laws specifically aimed at protecting the confidentiality of CD4⁺ test results, these results are protected under State laws governing the privacy of medical records generally. Laws governing the confidentiality of medical records, however, may not provide as complete a protection of confidentiality as laws that specifically protect the confidentiality of HIV-related information.

(127,245)

53 In Georgia, for example, confidential AIDS information includes all information that discloses that a person: 1) has an AIDS diagnosis; 2) has been treated for AIDS; 3) has been determined to be infected with HIV; 4) has submitted to an HIV test; 5) has had a positive or negative result from an HIV test; 6) has sought or received counseling regarding AIDS; or 7) has been determined to be at risk for HIV infection (GA. CODE ANN. s 31-22-9.1 (Supp. 1991)); see also ARIZ. REV. STAT. ANN. §§ 36-661, 36-664 (Supp. 1991); COLO. REV. STAT. § 25-4-1402 (1991); CONN. GEN. STAT. s 19a-581 (1990); HAW. REV. STAT. § 325-101 (Supp. 1990); KAN. STAT. ANN. § 65-6002, (Supp. 1990) (protects information indicating that a person is suffering from AIDS); MICH. COMP. LAWS ANN. § 333.5131 (Supp. 1991) (protects records, reports, data, tests, etc., associated with a diagnosis of AIDS, HIV infection, or HIV-related illnesses); N.J. STAT. ANN. s 26C:5C-7 (West 1991, Supp.); N.Y. PUB. HEALTH LAW s 2780 (McKinney 1992, Supp.); N.D. CENT. CODE, § 23-07-02.2 (Supp. 1991) (protects records on HIV status, AIDS, HIV-related illness reported to States); OHIO REV. CODE ANN. § 3701.243 (Anderson 1990, Supp.); PA. CONS. STAT. ANN. § 7603 (Purdon 1991); WASH. REV. CODE ANN. § 70,24,105 (Supp. 1992) (protects any information relating to diagnosis or treatment of HIV infection) .

One argument against extending special confidentiality protections to all diagnostic tests that may be indicative of AIDS or HIV infection is that such protections may unduly complicate the practice of medicine. CD4⁺ lymphocyte counts are also used to monitor diseases other than HIV infection. The interference of these confidentiality laws with clinical practice should be limited, however, because most of these laws allow for free exchange of information among health care providers and their agents involved in treatment and care of HIV-infected persons.

Many State laws governing HIV testing also require special counseling and informed consent (65), and the question arises whether CD4⁺ testing should also be subject to these requirements. Counseling and informed consent for HIV antibody tests are required in order to: 1) educate the person about the HIV virus, the HIV antibody test, and risk behaviors that can lead to transmission of the virus; and 2) prepare person psychologically for the results of the HIV test (53).

It is standard medical practice to perform an HIV antibody test prior to a CD4⁺ test; thus most persons whose CD4⁺ lymphocyte counts are measured will have already received counseling about HIV infection. There may, however, be additional psychological implications of being told one has AIDS. It is not clear that this psychological impact warrants imposing mandatory pre- and post-test counseling and written consent requirements for CD4⁺ testing. Such requirements could greatly hinder the provision of medical services, especially in busy inner-city public clinics (182). As for any clinical test, physicians that order CD4⁺ lymphocyte counts should inform their patients about the purpose and implications of the test. It is not clear, however, whether physicians should have to obtain specific consent for CD4⁺ testing as they do for HIV testing (194).

Advocates for persons with HIV infection, however, are concerned that CD4⁺ lymphocyte counts will be used as a proxy for HIV antibody tests in order to avoid the cost and time involved in providing pre- and post-HIV test counseling. The extent to which CD4⁺ tests are used as a proxy for such HIV antibody tests is not known, although OTA has been told that it does occasionally happen in hospital settings (41). The potential use of CD4⁺ lymphocyte counts in this manner is present regardless of whether the CDC definition of AIDS is changed. Physicians who are in the position to order such tests are already aware of the connection between a low CD4⁺ lymphocyte count and HIV infection. Moreover, a low CD4⁺ lymphocyte count is not a very good proxy for HIV infection because other viral infections as well as certain bacterial infections and hematological malignancies may lower the CD4⁺ lymphocyte count (123).

Another debate is over whether HIV-infected persons should be able to have a CD4⁺ test performed anonymously. Unlike other clinical tests, HIV antibody tests are often provided anonymously. Anonymous HIV antibody tests are offered to encourage persons without symptoms to find out about their HIV status. There is an assumption that persons may avoid obtaining HIV tests if they fear that others may learn that they are infected or that they sought testing (53). In addition, as discussed earlier, a person known to be HIV positive may have a difficult time in obtaining individual health insurance. It has been suggested that anonymous CD4⁺ tests should be made available for similar reasons, especially since, under the proposed AIDS case definition, persons with CD4⁺ lymphocyte counts below 200 cells/mm³ may have their names reported to State health departments.

It is not clear, however, whether people who know that they are HIV positive will avoid CD4⁺ testing and medical treatment because of concerns about confidentiality. While the guarantee of anonymity may induce some

people to find out whether they are infected with HIV, once they know they are HIV positive, they have a greater incentive to seek health care, including CD4⁺ testing, and this may outweigh their concerns about confidentiality.

Anonymous testing gives HIV-infected persons more control over who has knowledge of their infection, which may be very important because HIV-infected persons have been subject to irrational discrimination. OTA has found one medical clinic, the NO/AIDS Task Force located in New Orleans, which recently started to offer anonymous CD4⁺ testing.⁵⁴ The clinic's medical director claims that many of the clients--which include men who have sex with men, a few African American and Hispanic male injection drug users, and a number of women who were tested for HIV at sexually transmitted disease and family planning clinics--place a high priority on confidentiality (90). The fact that the CD4⁺ test is free, however, may also have been an important reason that these clients sought testing at the clinic.

Anonymous CD4⁺ testing also presents several problems, the primary one being that, in the event that medical care is necessary, it is not possible to contact an individual who fails to return for their test results. Anonymous testing may therefore hinder programs designed to bring people into care and it may not be a cost-effective use of the limited resources for care of HIV-infected persons.

54 The clinic opened in August of 1991. The CD4⁺ tests are done by a State lab free of charge and by a private laboratory which charges \$40 per test (90).

SUMMARY

CD4⁺ Testing as a Surveillance Tool

The proposed incorporation of the CD4⁺ lymphocyte count in the CDC case definition of AIDS will have several advantages for surveillance. The CD4⁺ lymphocyte count provides a more objective guide to AIDS diagnosis⁵⁵; HIV-infected persons with CD4⁺ lymphocyte counts below 200 cells/mm³ will have AIDS. The CD4⁺ lymphocyte count also has the advantage of simplicity; HIV-positive patients may be diagnosed with AIDS on the basis of a single laboratory value. AIDS surveillance data will better reflect the extent of severe immune suppression due to HIV infection in the population.

The incorporation of CD4⁺ lymphocyte counts in the AIDS case definition may also increase the cooperation of physicians in AIDS case reporting, as regular CD4⁺ lymphocyte testing is already a part of the clinical management of HIV-infected patients. (The CD4⁺ lymphocyte count has been correlated with the appearance of opportunistic illnesses and is used by physicians to guide initiation of antiretroviral therapy and pneumocystis prophylaxis.) The cooperation of physicians in AIDS case reporting is also likely to be enhanced because use of a single test will simplify AIDS diagnosis and reporting. Finally, it seems likely that AIDS reporting will be facilitated through laboratory-based reporting of cases identified through CD4⁺ testing; hence, States may expend fewer resources in making sure that AIDS cases are reported.

⁵⁵ The CDC argues that a diagnosis based on a laboratory value is less prone to subjective interpretation than diagnoses based on the presence of clinical conditions (219). Given the variability inherent in CD4⁺ lymphocyte testing, however, diagnoses based on the CD4⁺ lymphocyte count will also involve some degree of subjective interpretation.

Despite its advantages, however, the CD4⁺ lymphocyte count is not a perfect AIDS surveillance tool. Individuals can only be diagnosed with AIDS through CD4⁺ lymphocyte counts if they have access to health care and if their physician knows or suspects HIV infection. Because many persons with AIDS under the proposed definition will be without symptoms, the completeness of reporting will be difficult to assess. Furthermore, population groups with less access to CD4⁺ testing will be underrepresented among identified cases of AIDS, and the interpretation of trends in the epidemic among major risk groups may therefore be subject to substantial bias. Those persons with less access to health care or who receive only discontinuous or emergency health care are unlikely to be diagnosed until they become ill with one of the AIDS-defining conditions. In particular, HIV-infected women and injection drug users, most of whom are African American or Hispanic, are on average poorer than members of other AIDS risk groups; members of these poorer groups may have less access to CD4⁺ lymphocyte testing and may be underrepresented in AIDS surveillance.⁵⁶

Differences in access to CD4⁺ lymphocyte counts could lead to a distortion of the trends in AIDS cases reported to the CDC. Once the proposed case definition of AIDS is implemented, the CDC should investigate instances where there appears to be substantial bias in AIDS case reporting that might be attributable to a lack of access to HIV testing and CD4⁺ testing and adjust for this bias when interpreting trends in the epidemic. The CDC, the National Institute of Allergy and Infectious Diseases, and other Federal agencies should continue to study the spectrum of disease associated with HIV infection, and improve our understanding in the differences in manifestations of HIV infection in injection drug users and women.

⁵⁶ The poor are more likely to use public clinics, however, and a greater proportion of AIDS cases are reported that are identified in public clinics than are identified in private clinics (186).

Once the new case definition of AIDS is implemented, epidemiologists will lose their ability to use AIDS case reports to track trends in specific AIDS-defining conditions. Special epidemiologic studies will be necessary to track these trends. Epidemiologists may also have substantial difficulty linking data collected under the new case definition of AIDS with data collected under the existing case definition.

The CDC 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. In particular, the CDC argues that any expansion of the surveillance definition will complicate the ability to monitor trends in AIDS and in specific AIDS-defining conditions.⁵⁷ Lack of access to care will hamper surveillance under any definition, not just one that includes CD4⁺ testing. The need for CD4⁺ testing is not changed by the proposed definition, because CD4⁺ counts are also used to guide clinical care of HIV-infected patients.

The AIDS Case Definition and Clinical Care

The CDC's proposed case definition of AIDS is not an ideal clinical definition, although the CDC did not intend it to be. There is mounting evidence that there is a broad spectrum of illnesses whose incidence or clinical course is affected by HIV-induced immune suppression. Although the proposed AIDS case definition captures a greater percentage of HIV-infected persons with profound immunosuppression, there are a number of serious HIV-

57 This effect was seen after the 1987 revision, which complicated trend analyses (211).

associated illnesses that are not among the 23 AIDS-defining conditions and which may occur in persons with CD4⁺ lymphocyte counts that exceed 200 cells/mm³. The HIV classification system, however, can be used by clinicians and includes a broad range of HIV-associated conditions.

Some experts have argued that we need two definitions of AIDS: a surveillance definition and a clinical definition. For epidemiologic purposes, it is useful to retain a definition that is highly specific for severe manifestations of HIV infection. A clinical definition may be less specific for HIV infection and more sensitive for symptoms that may be related to HIV infection. For example, one may look for manifestations of HIV infection in persons with pneumococcal pneumonia or *Hemophilus influenzae* pneumonia. These pneumonias are not specific for HIV infection, but more people with HIV-induced immune dysfunction will be captured (37). There are other diseases, such as Lyme disease and toxic shock syndrome, where the clinical definition is broader than the CDC, case definition (37). By maintaining these important distinctions between surveillance instruments and clinical classification schemes, the various goals -- i.e. , consistent

epidemiologic monitoring and surveillance, along with appropriate clinical and social service intervention for serious and disabling illnesses -- could be sened.⁵⁸

The new CDC definition of AIDS was developed primarily for surveillance needs. Therefore, clinicians should be made aware of the broad spectrum of HIV infection, including manifestations of HIV infection in women, injection drug users, African Americans, and Hispanics. There is growing evidence that there are a number of HIV-associated conditions in injection drug users and women that are not included in the AIDS case definition. Physicians' awareness of the relationship of HIV infection to some of these conditions, such as pulmonary tuberculosis and cervical dysplasia, is particularly important because early intervention may have an impact on outcome. These HIV-associated conditions are less- useful markers for AIDS surveillance because they are not specific for HIV infection. The CDC's case definition of AIDS was designed for surveillance, and should not be expected to substitute

58 One expert notes that the competing agendas may be satisfied by linking clinical staging and social **service** disability determinations to the HIV classification system, and not just to the AIDS case definition itself (161). The CDC HIV classification system, which will be revised in parallel with the AIDS case definition, does acknowledge and account for many of the HIV-associated conditions seen in women and injection drug users. (For a description of the current and revised HIV classification systems, see app. F.) Although these HIV-associated conditions seen in women and injection drug users are not deemed AIDS-defining, they nevertheless receive recognition in the HIV-classification system as serious HIV-associated illness. Others argue, however, that we need a single definition of AIDS as a common vocabulary (231). One expert believes that all three goals can be accommodated with one definition. He suggests revising the AIDS case reporting form to place those AIDS-defining conditions which virtually always occur at **less than 200 CD4⁺ cells/mm³** in a **sublist** placed after the shorter list of conditions that can occur at greater than or equal to 200 **CD4⁺ cells/mm³**. The majority of patients would be diagnosed with AIDS either on the basis of **CD4⁺** lymphocyte criteria or the short list of conditions that occur at higher counts, and physicians would only rarely have to refer to the longer list of AIDS-defining conditions that virtually always occur in persons with **CD4⁺** lymphocyte counts less than 200 **CD4⁺ cells/mm³**.

for proper physician education as to what screening tests should be done in HIV-infected persons. If the problem is in physician education, the most direct solution may be in physician education.

The CD4⁺ lymphocyte count is not an ideal clinical marker because it is highly variable and not well standardized. Although the high degree of variability is not important when one is measuring the extent of severe immunosuppression in a population, on an individual basis, an accurate assessment of the CD4⁺ lymphocyte count is important because it is used to guide therapy. Therefore, a physician should validate the CD4⁺ lymphocyte count by repeating the test if the initial count appears to be inaccurate, such as when a patient has a sudden large drop in CD4⁺ lymphocyte count.

On an individual basis, a number of HIV-positive individuals with CD4⁺ lymphocyte -counts below 200 cells/mm³ will not have any symptoms, although the probability that they will develop symptoms within a year is high. Data from the Multicenter AIDS Cohort Study (MACS) show that one-third of the individuals whose CD4⁺ lymphocyte counts fell below 200 cells/mm³ were asymptomatic (129).⁵⁹ Under the CDC's proposed AIDS case definition, asymptomatic HIV-positive individuals with CD4⁺ counts below 200 cells/mm³ will be diagnosed with AIDS, and some of these individuals are likely to experience adverse psychological consequences as a result of this diagnosis.

59 **MACS** participants are primarily middle-class, white men who have sex with men. For the reasons discussed previously, the proportion of HIV-infected women and injection drug users who are **asymptomatic** with CD4⁺ lymphocyte counts less than 200 **cells/mm³** is likely to be lower than that for HIV-infected white men who have sex with men. Furthermore, persons in this study were "symptomatic" if they did not have AIDS or one of a limited number of conditions often referred to as AIDS-related complex (which includes fatigue, fever, weight loss, persistent skin rash, oral hairy **leukoplakia**, herpes simplex, and oral thrush). Hence, some persons characterized as **asymptomatic** in this study may have been experiencing some HIV-related symptoms.

The Costs of Implementing the Proposed AIDS Case Definition

Each State will be responsible for implementing the CDC definition of AIDS. State health departments may need additional resources to implement the new definition, including money to establish flow cytometry facilities where necessary, to set up new systems to efficiently identify cases through laboratory-based reporting, and to handle the initial dramatic increase in caseloads. States may also need additional resources to provide adequate **access to CD4⁺ testing**. Outreach programs are needed to ensure that persons who in the past have had little access to medical care can enter into a care relationship and receive CD4⁺ testing.

States may invest in increasing the access of the medically underserved to CD4⁺ lymphocyte testing. One benefit of increased access **to CD4⁺ testing** is that more asymptomatic HIV-infected individuals with low CD4⁺ lymphocyte counts will be alerted to the need for medical treatment.⁶⁰ States may need additional funds to provide access to medical care for the profoundly immunosuppressed individuals who are identified through such surveillance.

Federal Funding Allocations and the New Definition of AIDS

The proposed CDC definition of AIDS may still be appropriate to use in allocating Ryan White funds because AIDS surveillance data, if accurate, will reflect the health care needs in each State. Some States, however, may be

⁶⁰ This does not necessarily mean that clinicians provide the same type of pre- and post-test counseling to persons obtaining a CD4⁺ lymphocyte count that is required for persons who are tested for HIV antibody. Clinicians should provide patients with an explanation of diagnostic and therapeutic implications of the CD4⁺ lymphocyte count.

less able than others to document AIDS cases because they may be unable to offer CD4⁺ testing to HIV-infected individuals who cannot this test. Physicians may also fail to cooperate with AIDS case reporting, or the State department of health may be overwhelmed by the number of AIDS cases that are reported and may be unable to carry out the detailed case investigations that are necessary.

Under the proposed AIDS case definition, a larger number of metropolitan areas will have the threshold number of cases necessary to qualify for Title I funds under the Ryan White Act. Appropriations for Title I will need to increase if the funding for each metropolitan area is to be maintained at current levels. In theory, the proposed change in the CDC's case definition of AIDS and the expected increase in the total number of AIDS cases should not significantly influence the distribution of funds among States and metropolitan areas under Titles I or II of the Ryan White Act, since they are distributed according to the proportion of AIDS cases, rather than absolute numbers of AIDS cases in each State. In practice, however, the distribution of funds may not be proportional to the actual needs of each State or metropolitan area if some States and cities are not as capable as others in implementing the new AIDS case definition.

The Office of Technology Assessment (OTA) has not determined whether the current Ryan White Act funding is meeting the States' needs. The President's Commission on AIDS, however, has repeatedly urged the President to recommend that the Ryan White Act be funded up to its full level (73,120). In addition, it is unfortunate that Title III, Subpart I, which authorized money for diagnostic tests for management of HIV infection, such as CD4⁺ lymphocyte counts, is not currently being funded.

As of April 1992, no money under the AIDS Housing Opportunity Act of 1990 had been distributed. Money will be distributed among eligible areas in proportion to the number of AIDS cases that are reported in each area. Therefore, allocations under this act may also be affected by the ability of the States and cities to document AIDS cases under the new definition.

Privacy Concerns and the New CDC Definition of AIDS

With the proposed expansion of the AIDS case definition, HIV-infected persons will be reported to the State and local health departments earlier in the course of their infections, and there consequently will be a greater number of names held in the AIDS registries of State and local health departments. Thus, there will be a greater number of HIV-infected individuals who will risk having their names disclosed to third parties whom the State decides need to know this information. On the other hand, in States that require name reporting of all HIV-infected persons, those individuals known by the State to be HIV-infected will have their names placed in an HIV registry regardless of whether the CDC definition of AIDS is expanded. In addition, any substantial expansion of the case definition would lead to large increases in case reports.

The States have an incentive to document as many of their AIDS cases as possible in order to obtain a larger share of Federal funds under the Ryan White Act. This goal should not overshadow the privacy concerns of the individuals whose names are being collected. States will have a responsibility to ensure that, in pursuing the goal of conducting comprehensive AIDS surveillance, the privacy rights of persons with AIDS are protected. In making plans to implement the new AIDS case definition, States

should reassess current laws and operational procedures that protect the names of HIV-infected persons. In particular, States should consider whether HIV confidentiality laws should be extended to protect the confidentiality of all information that may indicate that a person is infected with HIV, including the results of CD4⁺ lymphocyte counts.

State or local health departments may in the future expand the number of situations where the disclosure of the names of persons with AIDS is permitted in order to protect the public health. Some commentators see a disturbing trend toward expanding the instances where such disclosure is permitted. They believe the privacy rights of HIV-infected individuals are being unduly compromised in order to protect against small risks of transmission. Because more HIV-infected individuals will be reported to State and local health departments under the proposed AIDS case definition, more HIV-infected individuals will be subject to this potential disclosure risk. It is important to note, however, that any expansion of the CDC definition of AIDS, not just that which has been proposed, would result in more names of HIV-infected persons being reported to State and local health departments.

Under the proposed definition, States may enlist flow cytometry laboratories in identifying suspected AIDS cases. The enlistment of clinical laboratories in AIDS case reporting has highlighted concerns about the confidentiality of the results of CD4⁺ testing. A number of State HIV confidentiality laws also extend to other HIV-related information, including CD4⁺ lymphocyte counts. In addition, laboratories are subject to State laws governing the confidentiality of medical records generally. Laws protecting the confidentiality of HIV-related information may not be enough; laboratories should consider developing written policies to guard the confidentiality of CD4⁺ test results. It is important to note, however, that to date, flow

cytometry laboratories have protected the results of CD4⁺ tests and there is no indication that they will not continue to keep this information confidential.

States should evaluate the privacy implications of having flow cytometry laboratories send the names of all persons with depressed CD4⁺ lymphocyte counts to State or local health departments, because a number of diseases other than HIV infection can also depress CD4⁺ lymphocyte counts. In Maryland, the State legislature is considering a bill that requires that laboratories report the names of all persons with CD4⁺ lymphocyte counts below 500 cells/mm³ to the State health department. If this bill is enacted, laboratories would send the names of a large number of persons who are not HIV-infected to the Maryland Department of Health for investigation. If a State decides to implement laboratory reporting of CD4⁺ lymphocyte test results, a preferable alternative would be to have laboratories send to the **State** only the names of persons who have a depression of the CD4⁺ subset of T-lymphocytes and normal or elevated levels of other T-lymphocyte subsets. This is because the selective depression of the CD4⁺ subset of T-lymphocytes is a more specific indicator of HIV-induced immunosuppression.

There are strong arguments for treating CD4⁺ lymphocyte counts, along with other HIV-related information, with the same degree of confidentiality as HIV test results; however the arguments for requiring special informed consent or permitting anonymous testing are more compelling for HIV testing than they are for CD4⁺ testing. Persons who know they are HIV positive have additional incentives to obtain medical care and CD4⁺ tests, and therefore it may not be essential to offer anonymous testing to bring these HIV-infected persons into the health care system.