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DEPARTMENT OF HEALTH & HUMAN SERVICES

Chief of Staff

Washington, D.C. 20201

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DATE:

TO:

Todd Summers

FAX#:

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FROM: Mary Beth Donahue
Chief of StaffPhone: 202/690-7431 Fax: 202/401-5783

COMMENTS:

Guidelines do not get published in
the Fed. Register notice. The 2-page
notice of availability is published,
guidelines must be obtained
from CDC as directed in the
FR notice

32 Pages [including this cover]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Draft Guidelines for HIV Case Surveillance, Including Monitoring HIV Infection and Acquired Immunodeficiency Syndrome (AIDS)

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services

ACTION: Notice and Request for Comments

SUMMARY: This notice announces the availability for public comment of a document entitled "Draft Guidelines for HIV Case Surveillance, Including Monitoring HIV Infection and Acquired Immunodeficiency Syndrome (AIDS)".

DATES: Comments must be submitted in writing on or before [insert date 30 days after date of publication in the *Federal Register*]. Comments should be submitted to the Technical Information and Communications Branch (Mailstop E-49), Division of HIV/AIDS Prevention, National Center for HIV, STD, and TB Prevention, Centers for Disease Control and Prevention, Atlanta, Georgia 30333; telephone: 404-639-2072; Fax: 404-639-2007.

FOR FURTHER INFORMATION CONTACT: Requests for copies of the draft HIV case surveillance guidelines should be submitted to the CDC National AIDS Clearinghouse, P.O. Box 6003, Rockville, Maryland 20849-6003; telephone (800) 458-5231; or copies can be obtained from the CDC website at http://www.cdc.gov/nchstp/hiv_aids/.

SUPPLEMENTARY INFORMATION: From 1995 to 1996, the incidence of both deaths and opportunistic infections (OIs) due to AIDS declined in the United States for the first time in the history of the epidemic (6 percent for OIs; 23 percent for deaths) as reported in the September 19, 1997, *Morbidity and Mortality Weekly Report (MMWR)* (Volume 46, pp. 861-867). These

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declines reflect recent advances in treatment of HIV infection and the provision of care and services that have slowed the progression of AIDS for HIV-infected persons on therapy and the success of HIV prevention and education efforts that have encouraged early diagnosis and have helped to reduce the number of Americans becoming infected with HIV.

In response to these changes in HIV treatment practices and new information needs of public health programs, CDC, the Council of State and Territorial Epidemiologists (CSTE), and most other public health and AIDS organizations have recommended that all States and Territories conduct HIV case surveillance in addition to AIDS surveillance. In this manner, the AIDS/HIV epidemic can be tracked more accurately, and appropriate information about HIV/AIDS can be made available to policymakers. As of July 1998, a total of 32 States were conducting HIV case surveillance using the same methods as surveillance for AIDS. Because some States (many with large numbers of AIDS cases) do not report HIV case numbers, interpretations of available HIV data are difficult. To gain more reliable information about the prevalence, incidence, and future directions of HIV infection and the impact on specific populations such as racial and ethnic minorities and women, CDC is proposing that the current surveillance system be expanded to include HIV case reporting for all States and is publishing guidelines that States can use to implement HIV surveillance.

Dated: _____

Jeffrey P. Koplan, M.D., M.P.H.

Director, Centers for Disease Control and Prevention

Recommended Surveillance Practices

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All State and local programs should collect a standard set of surveillance data for all cases that meet the reporting criteria for HIV infection and AIDS. The standard data set includes the (1) patient identifier, (2) earliest date of diagnosis for HIV infection, (3) earliest date of diagnosis of an AIDS-defining condition, (4) demographic information (date of birth, race/ethnicity, sex) and residence (city, State) at diagnosis of HIV and AIDS, (5) HIV risk exposure, (6) facility of diagnosis, and (7) date of death and state of residence at death. In addition to this information, the date of HIV diagnostic testing and the results of these tests should be collected for all infants with perinatal exposures to HIV. To address specific public health information needs, local surveillance programs may cross-match HIV and AIDS surveillance data with other public health data, such as for tuberculosis, and collect supplemental surveillance data on all or a representative sample of cases. CDC will provide technical assistance and standardized surveillance methods to assist in the collection of supplemental surveillance information. Surveillance information, without patient identifiers, should be encrypted and forwarded to CDC through the HIV/AIDS Reporting System, as is current practice.

Published evaluations of non-name based HIV surveillance in two States (41) together with results of meetings and consultations with States that have considered or used non-name identifiers have highlighted operational difficulties with these systems. Based on published evaluations, CDC has concluded that name-based HIV/AIDS surveillance systems are the most likely to meet the necessary performance standards (22, 57-61) as well as to serve the purposes for which surveillance data are required. Therefore, CDC advises that State and local surveillance programs use the same name-based approach for HIV surveillance as is currently used for AIDS surveillance nationwide. However, CDC recognizes that some States have adopted, and others may elect to adopt, non-name case identifiers for the public health reporting of HIV infection. CDC will provide technical assistance to all State and local areas to continue or establish HIV and AIDS surveillance systems and to evaluate their surveillance programs regardless of whether they use name or non-name based identifiers.
- HIV and AIDS surveillance should be used to identify rare or previously unrecognized modes of HIV transmission, unusual clinical or virologic manifestations, and other cases of public health importance. CDC will provide technical assistance to State and local health departments conducting such investigations and will revise public health recommendations based on the findings, as appropriate.
- HIV and AIDS case surveillance efforts should be directed toward the collection of data from all private and public sources of HIV-related testing and care services. Laboratory-initiated surveillance methods should be used to collect information for cases that meet the laboratory reporting criteria for HIV infection and AIDS. Statistics regarding persons who are tested anonymously should not be reported through the HIV/AIDS Reporting System. These test results are reported anonymously to the HIV Counseling and Testing database. HIV-infected persons who are initially tested anonymously are only eligible to be reported to HIV/AIDS surveillance after they have been diagnosed by a health care

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Draft Guidelines for HIV Case Surveillance, Including Monitoring
HIV Infection and Acquired Immunodeficiency Syndrome (AIDS)

AGENCY: Centers for Disease Control and Prevention (CDC), Department of
Health and Human Services (HHS).

ACTION: Notice and Request for Comments.

SUMMARY: This notice announces the availability for public comment of a
document entitled ``Draft Guidelines for HIV Case Surveillance,
Including Monitoring HIV Infection and Acquired Immunodeficiency
Syndrome (AIDS)''.

DATES: Comments must be submitted in writing on or before January 11,
1999. Comments should be submitted to the Technical Information and
Communications Branch, Mailstop E-49, Division of HIV/AIDS Prevention,
National Center for HIV, STD, and TB Prevention, Centers for Disease
Control and Prevention (CDC), Atlanta, Georgia 30333; Fax: 404-639-
2007; E-mail: hivmail@cdc.gov.

FOR FURTHER INFORMATION CONTACT: Requests for copies of the Draft HIV
Case Surveillance Guidelines should be submitted to the CDC National
Prevention Information Network, P.O. Box 6003, Rockville, Maryland
20849-6003; telephone (800) 458-5231; or copies can be obtained from
the CDC website at http://www.cdc.gov/nchstp/hiv_aids/dhap.htm.

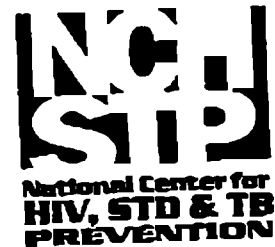
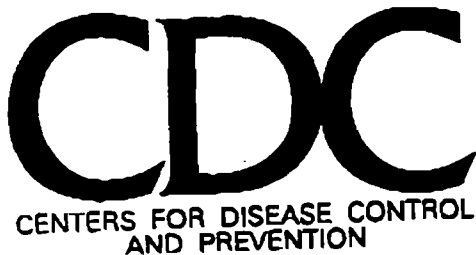
SUPPLEMENTARY INFORMATION: From 1995 to 1996, the incidence of both
deaths and opportunistic infections (OIs) due to AIDS declined in the
United States for the first time in the history of the epidemic (6
percent for OIs; 23 percent for deaths) as reported in the September
19, 1997, Morbidity and Mortality Weekly Report (MMWR) (Volume 46, pp.
861-867). These declines reflect recent advances in treatment of HIV
infection and the provision of care and services that have slowed the
progression of AIDS for HIV-infected persons on therapy and the success
of HIV prevention and education efforts that have encouraged early
diagnosis and have helped to reduce the number of Americans becoming
infected with HIV.

In response to these changes in HIV treatment practices and new
information needs of public health programs, CDC, the Council of State
and Territorial Epidemiologists (CSTE), and most other public health
and AIDS organizations have recommended that all States and territories
conduct HIV case surveillance in addition to AIDS surveillance. In this

manner, the AIDS/HIV epidemic can be tracked more accurately, and appropriate information about HIV/AIDS can be made available to policymakers. As of July 1998, a total of 32 States were conducting HIV case surveillance using the same methods as surveillance for AIDS. Because some States (many with large numbers of AIDS cases) do not report HIV case numbers, interpretations of available HIV data are difficult. To gain more reliable information about the prevalence, incidence, and future directions of HIV infection and the impact on specific populations such as racial and ethnic minorities and women, CDC is proposing that the current surveillance system be expanded to include HIV case reporting for all States and is publishing guidelines that States can use to implement HIV surveillance.

Dated: December 3, 1998.

Jeffrey P. Koplan,
Director, Centers for Disease Control and Prevention (CDC).
[FR Doc. **98-32617 Filed** 12-9-98; 8:45 am]
BILLING CODE 4163-18-P



CDC Draft Guidelines for Improved Data on U.S. HIV Epidemic New Systems Urgently Needed to Guide Prevention Efforts

The Centers for Disease Control and Prevention (CDC) has released draft guidelines calling on all States to track the course of the HIV epidemic as an extension of their AIDS surveillance programs. To address the urgent need for information to ensure effective targeting of prevention and care services while recognizing legitimate concerns about confidentiality and access to testing and care, CDC has called for all States and territories to conduct HIV surveillance in addition to their AIDS surveillance systems. The guidelines articulate performance standards that all States must meet within a reasonable time period. The decision on the surveillance system used to gather those data - either a name-based or an alternative "unique identifier" system - will be left up to the States. CDC is advising that, based on available evaluations of name-based HIV surveillance systems, name-based HIV surveillance systems are currently most likely to meet the necessary performance standards and provide the quality data necessary to direct community prevention and treatment programs.

The guidelines respond to recent treatment advances that have slowed the progression from HIV to AIDS for many individuals. Data on AIDS cases alone can no longer be reliably used to direct prevention efforts to communities currently at greatest risk. The new guidelines address the urgent need for information to ensure effective targeting of prevention services.

The draft guidelines represent the culmination of a lengthy effort by CDC with communities and public health partners nationwide to address emerging information needs and issues surrounding the effective implementation of HIV reporting. The proposed recommendations are designed to 1) provide accurate and reliable data for communities to effectively direct scarce resources for HIV prevention and treatment; 2) maintain strict confidentiality of HIV data, including controlled access and strong penalties for abuse; and 3) continue support for anonymous testing options so that systems do not deter individuals at risk from accessing HIV testing, treatment, and prevention services.

As of July 1, 1998, thirty-two states had implemented HIV surveillance using the same reporting system for both HIV and AIDS cases; three of these states conduct pediatric surveillance only. Additional states are now working to expand their AIDS surveillance systems to include HIV cases. The draft "Guidelines for National HIV Surveillance, Including Monitoring for HIV Infection and Acquired Immunodeficiency Syndrome" are designed to provide states recommendations on the best practices to ensure both quality and confidentiality of HIV data.

CDC Recommendations

Given the importance of HIV surveillance data for directing services and care to individuals with HIV infection, the draft CDC guidelines establish specified performance criteria to assure both the quality and confidentiality of that data. All states will be required to establish an HIV surveillance system that meets these quality and confidentiality criteria within a reasonable time period. The decision on the surveillance system used to gather those data – either a name-based or an alternative “unique identifier” system – will be left up to the states.

Based on available evaluations of name-based HIV surveillance systems, CDC believes that such systems are currently the most likely to meet the necessary performance standards and provide the quality data necessary to direct community prevention and treatment programs. However, CDC's draft policy does allow for flexibility for those states that decide to implement alternative systems. CDC will provide financial and technical assistance to states working to design HIV surveillance systems, including unique identifier-based and name-based systems.

During the next several years, CDC will assist states in implementing HIV surveillance systems, evaluating current performance levels, revising systems as necessary and reassessing performance. After this transition period, CDC will evaluate and award proposals for federal funding of state and local surveillance programs based on their capacity to meet the performance standards. At that time, CDC will work with states to adopt surveillance methods that will enable them to achieve the standards.

Criteria for Quality and Confidentiality

The draft guidance document outlines performance criteria to ensure the quality and confidentiality of HIV data. These criteria include strict confidentiality procedures and protections such as using a single registry, eliminating paper reports, using computer encryption techniques, setting up physical security and limited access to data, and penalties for abuse. Additionally, the guidelines set quality standards for data to ensure completeness (over 85% of diagnoses must be reported), timeliness (over 66% of diagnoses of reported within 6 months of diagnosis), no duplication (less than 5% of cases should be duplicate reports of a single case), and the ability to follow-up with providers on cases of public health importance (e.g., unusual modes of transmission or strains).

Efforts to Evaluate and Address Concerns About Name-Based HIV Reporting

CDC recognizes the concerns regarding name-based reporting of HIV infection and the greater sensitivity of HIV case data. CDC has worked for several years to evaluate and address these issues and has consulted with a diverse group of individuals and organizations from the scientific, public health, and AIDS advocacy communities in developing these proposed guidelines. Of course, CDC will continue to work with states to evaluate the impact of HIV case surveillance as implemented following these guidelines.

The draft guidelines present the results of these assessments in more detail, but several key steps have been taken, including:

Evaluation of Unique Identifier Systems

CDC has assessed the feasibility of using alternatives to name-based methods for HIV surveillance by reviewing a number of existing state systems that use a variety of numeric codes or "unique identifiers" (UI) rather than names.

Most recent evaluations looked at Social Security number-based systems. Several problems were found with these systems, including a high number of reports with incomplete codes (approximately 30-40%), low rates of completeness in reporting (approximately 25-50% complete), difficulty in conducting follow-up on specific cases, and the absence of behavioral risk data in this system. CDC also found difficulties in assessing the level of duplicate case reports or the ability to reliably link to other public health databases (e.g. death registries).

In UI-based systems, providers must maintain logs or other forms of documentation linking the UI to the name-based medical records. This process may pose additional confidentiality risks if physician-held surveillance registries are not protected by state confidentiality statutes or are located in non-secure areas.

Support for Anonymous Testing

While studies suggest that name-based HIV reporting does not serve as a major deterrent to testing, CDC continues to strongly support anonymous HIV testing and recommends that all states provide anonymous testing options. CDC studies indicate that the lack of anonymous testing serves as a deterrent to testing in some high-risk populations. Unless prohibited by law, CDC requires that states receiving prevention funds to make anonymous testing available. Maintaining anonymous test sites is important for prevention efforts and will not seriously inhibit efforts to track the epidemic. Most people are diagnosed with HIV infection in confidential care settings. Moreover, the time between HIV diagnosis and the point at which individuals enter the care system has become shorter, given new treatment advances. Maintaining an anonymous testing option may help ensure that more individuals learn their status, and if infected, seek early treatment and care. HIV home test kits now offer another anonymous testing option in the United States. And anonymous testing is available in publicly funded counseling and testing sites in all but eleven states. CDC strongly recommends that states not currently offering anonymous testing reevaluate their policies on this issue.

Strengthening Systems to Protect Confidentiality

Public health departments have maintained an exemplary record in protecting the confidentiality of HIV/AIDS data. Since 1981 there have been few reported breaches of confidentiality in state AIDS reporting systems.

Over the past few years, CDC has been working to evaluate additional measures at the state level that could improve confidentiality even further. CDC has recently reviewed state reporting programs and has developed enhanced standards to be used in developing local confidentiality plans. Local programs will be required to meet these performance standards and must ensure confidentiality as a condition of funding. One important security measure CDC is now making available to states is the option of using a double-keyed encryption program. With this system, names and other identifying information may only be accessed with both the key (password) held by the state and the key held by CDC.

To assess the strength of local confidentiality laws that protect HIV data, CDC requested that Georgetown/Johns Hopkins Public Health Law Project review local laws and regulations. All states and many localities have legal safeguards of confidentiality for government-held data, and these laws were found to provide greater protection than laws protecting health information held by private health care providers. Additionally, most states have specific statutory protections for public health data related to HIV. However, state legal protections vary widely.

CDC is therefore promoting efforts to enhance and standardize local confidentiality laws. CDC, in partnership with other public health agencies, the National Conference of state Legislatures, and the Georgetown/Johns Hopkins Public Health Law Project, is working to develop model legislative language to protect confidential, identifiable information held by state and local public health departments against unauthorized and inappropriate use, while still allowing the use of surveillance information to accomplish legitimate public health objectives.

Request for Public Comment

The draft Guidelines represent the combined efforts of CDC and numerous agencies and individuals nationwide. CDC is seeking public comment to ensure the final recommendations promote the best possible approaches to HIV surveillance, as a critical component of future HIV prevention efforts. After the public comment period, the comments will be carefully reviewed and considered. The Guidelines will be modified as needed before being published in the Morbidity and Mortality Weekly Report. For copies of the draft Guidelines and information on how to submit comments, call the CDC National Prevention Information Network at 1-800-458-5231 or send a written request to P.O. Box 6003, Rockville, MD 20849-6003.

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Office of HIV/AIDS Policy



Office of Public Health and Science
Office of the Secretary
200 Independence Avenue, S.W., Room 736-E
Washington, DC 20201

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From:

Deborah von Zinkernagel
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DRAFT

Guidelines for National HIV Case Surveillance, Including Monitoring for HIV Infection and Acquired Immunodeficiency Syndrome (AIDS)

The Centers for Disease Control and Prevention (CDC) recommends that all States and Territories conduct case surveillance for human immunodeficiency virus (HIV) infection as an extension of current acquired immunodeficiency syndrome (AIDS) surveillance activities. The expansion of national surveillance to include both HIV infection and AIDS cases is a necessary response to the impact of advances in antiretroviral therapy, the implementation of new HIV treatment guidelines, and the increased need for epidemiologic data concerning persons at all stages of HIV disease. Expanded surveillance will provide additional data on HIV-infected populations to enhance Federal, State, and local efforts to prevent HIV transmission, improve allocation of resources for treatment services, and assist in evaluating the impact of public health interventions. CDC will provide technical assistance to all State and Territorial health departments to continue or establish HIV and AIDS case surveillance systems and to evaluate the performance of their surveillance programs. This report includes revised case definitions for HIV infection in adults and children less than 18 months of age, recommended program practices, and performance and security standards for the conduct of HIV and AIDS surveillance by State and local health departments. The revised surveillance case definitions and associated recommendations become effective _____.

INTRODUCTION

AIDS surveillance has been the cornerstone of national efforts to monitor the spread of HIV infection in the United States and to target HIV prevention programs and health care services. Although AIDS is the end-stage of the natural history of HIV infection, in the past, monitoring AIDS-defining conditions provided population-based data that reflected changes in HIV incidence. However, recent advances in HIV treatment have slowed the progression of HIV disease for infected persons on treatment and contributed to a decline in AIDS incidence. These advances in treatment have diminished the ability of AIDS surveillance data to represent trends in HIV incidence or to represent the impact of the epidemic on the health care system. As a consequence, the capacity of national, State, and local public health agencies to monitor the HIV epidemic has been compromised (1-3). In response to these changes and following consultations with diverse constituencies, including representatives of public health, government, and community organizations, CDC and the Council of State and Territorial Epidemiologists (CSTE) have recommended that all States and Territories include surveillance for HIV infection as an extension of their AIDS surveillance activities (1,4). In this manner, the HIV/AIDS epidemic can be tracked more accurately and appropriate information about HIV/AIDS can be made available to policymakers.

This document provides revised case definitions for HIV infection in adults and children less than 18 months of age, recommended program practices, and performance and security standards for the conduct of HIV and AIDS surveillance by State and Territorial health departments. The HIV case definitions were developed in consultation with CSTE and include the current AIDS surveillance criteria as a component of the HIV infection case definition (5).

The recommended program practices and program performance and security standards are based on: (1) the established practices of AIDS and other public health surveillance systems; (2) reviews of State and local surveillance programs, confidentiality statutes, and security procedures; (3) studies of the performance of surveillance systems; (4) ongoing evaluations of determinants of test-seeking or test-avoidance in relation to State policies and practices on HIV testing and reporting; and (5) discussions at a consultation held by CDC and CSTE in May 1997. A draft of this document was made available for public comment in _____ 1998.

BACKGROUND

History of AIDS Surveillance

Since 1981, population-based AIDS surveillance (i.e., reporting of cases and their characteristics to public health authorities for analysis) has been used to track the progression of the HIV epidemic from the initial cases of opportunistic illnesses caused by a then unknown agent in a few large cities, to the reporting of 641,086 AIDS cases nationally through 1997 (6-9). The AIDS reporting criteria have been periodically revised to incorporate new understanding of HIV disease and changes in medical practice (10-13). In the absence of effective therapy for HIV, AIDS surveillance data have reliably detected changing patterns of HIV transmission and reflected the effect of HIV prevention programs on the incidence of HIV infection and related illnesses in specific populations (14-15). Because of these attributes, AIDS surveillance data have been used as a basis for the allocation of many Federal resources for HIV treatment and care services and as the epidemiologic basis for the planning of local HIV prevention services.

With the advent of more effective therapy that slows the progression of HIV disease, AIDS surveillance data no longer reliably reflect trends in HIV transmission and do not accurately represent the extent of the need for prevention and care services (16-17). In 1996, national AIDS incidence and AIDS deaths declined for the first time in the HIV epidemic (Figure 1). These declines have been primarily attributed to the early use of combination antiretroviral therapy to delay the progression to AIDS and death for persons with HIV infection (1-3). Revised HIV treatment guidelines recommend antiretroviral therapy for many HIV-infected persons in whom AIDS-defining conditions have not yet developed (18-19). In response to these changes in HIV treatment practices and the information needs of public health and other policymakers, CDC and CSTE have recommended that all States and Territories extend their AIDS case surveillance activities to also include HIV case surveillance (1, 4).

Current Status of HIV Surveillance

As of October 1, 1998, 32 States had implemented HIV case surveillance using the same reporting system for both HIV and AIDS cases; 3 of these States conduct pediatric surveillance only (6) (Figure 2). The 29 States that conduct integrated HIV and AIDS surveillance for adults, adolescents, and children report only about one-third of total U.S. AIDS cases.

In contrast to AIDS case surveillance, HIV case surveillance can provide data to better characterize populations newly diagnosed with HIV, particularly those with evidence of recent

HIV infection such as adolescents and young adults (20- to 24-year-olds) (20-21). Of the 52,690 HIV infections diagnosed from January 1994 through June 1997 in 25 States that conducted name-based HIV surveillance throughout this period, 14 percent were in persons aged 13 to 24 whereas of 20,215 persons diagnosed with AIDS in the same areas only 3 percent were in persons aged 13 to 24. Thus, AIDS case surveillance alone does not accurately reflect the extent of the HIV epidemic among adolescents and young adults. Compared with persons reported with AIDS, those reported with HIV infection in these 25 States were more likely to be women and from racial/ethnic minorities (22) (Table 1). HIV data also show patterns in rates of new diagnoses and HIV prevalence that are not affected by changes in treatment. For example, between June 1996 and June 1997, AIDS incidence among white men who had sex with other men (MSM) decreased more than 30 percent while the number of new HIV diagnoses among this population remained unchanged (Figure 3). In these States, as of December 1997, the number of persons (140,585) who were living with a diagnosis of HIV or AIDS was 139 percent greater than that represented by the number living with AIDS alone (6).

Most of the 32 States with name-based HIV case surveillance systems report all perinatally exposed children. These States have used HIV surveillance data to document a sharp decline in perinatally acquired HIV infection, an increase in the proportion of infected pregnant women who have been tested for HIV before delivery, and a high proportion of HIV-infected pregnant women who accept zidovudine therapy (23-28). These findings all have profound policy implications that would not have been as easily or quickly detected using only AIDS case surveillance. CSTE and the American Academy of Pediatrics have recommended that all States and Territories conduct pediatric HIV surveillance that includes all perinatally-exposed infants (29).

Persons may choose to be tested for HIV in the following ways: (1) anonymously--where identifying information including their name and other locating information is not linked to their HIV test result or included in the surveillance system report (e.g., anonymous testing sites), and (2) confidentially--where their HIV test result is linked to identifying information such as patient and provider names (e.g., medical clinics). In States that require HIV case reporting, providers in confidential medical or testing sites are required to report HIV-infected persons to public health authorities. Not all persons infected with HIV are tested, and of those that are, testing occurs at different stages of their infection. Therefore, HIV surveillance data provide a minimum estimate of the number of infected persons and are most representative of persons who have been diagnosed with HIV infection in medical clinics and other confidential diagnostic settings. The data represent the characteristics of persons who recognize their risk and seek confidential testing, who are offered HIV testing (e.g., pregnant women, clients at sexually transmitted disease clinics), who are required to be tested (e.g., blood donors, military recruits), and who are tested because they present with symptoms of HIV-related illnesses. CDC estimates that more than two-thirds of all infected persons in the United States have been diagnosed with HIV in such settings (30). HIV surveillance data do not represent untested persons or those who seek testing at anonymous test sites or with home collection kits; such persons cannot be reported through confidential HIV surveillance systems. However, the availability of these testing venues is highly important in promoting knowledge of HIV status among at-risk populations and provides an opportunity for counseling and referrals to appropriate medical diagnosis and care.

Despite some limitations, HIV and AIDS case surveillance would provide a clearer picture of the HIV epidemic than AIDS case surveillance alone. Therefore, CDC and CSTE continue to recommend that HIV case surveillance be implemented as part of a comprehensive strategy to monitor the epidemic that includes HIV incidence and prevalence surveys, HIV and AIDS case surveillance, monitoring HIV-related mortality, supplemental research and evaluation studies including behavioral surveillance, and statistical estimation of incidence and prevalence of infection and disease.

AIDS surveillance nationally and HIV surveillance in 32 States is conducted using the name-based methods for case ascertainment that are used by other public health information systems. A name-based approach allows providers to report cases directly from their name-based medical records, facilitates elimination of duplicate case reports, enables cross-matching of HIV and AIDS data with other name-based public health data (e.g., tuberculosis surveillance) and permits follow-up with providers to collect HIV risk information and other data of public health importance. Through follow-up with providers, the HIV/AIDS surveillance system has provided an effective means to identify rare or unusual modes of HIV transmission and infection with rare strains of HIV and to improve the prevention of HIV-related opportunistic illnesses (31-35).

Concerns Regarding HIV Surveillance

Since 1985, many States have implemented HIV case surveillance as part of their comprehensive surveillance programs. The implementation of the 1993 expanded AIDS surveillance case definition prompted discussions of the rationale and need for data representing HIV-infected persons who did not meet the AIDS-defining criteria. Because many States considered implementing HIV reporting, in 1993, CDC held a consultation with public health and community representatives to discuss issues and concerns regarding HIV surveillance. Community representatives' main concerns were that the security and confidentiality standards of surveillance programs may not be sufficient to prevent disclosures of information, and that many persons at risk for HIV infection may delay seeking HIV counseling and testing because of these confidentiality concerns. The consensus of the consultants was that there were few, if any, published studies of sufficient scientific quality to provide objective answers to these concerns. Therefore, the consultants identified several areas that required additional research and policy development before CDC and CSTE should consider recommending further expansion of HIV surveillance efforts. These areas included: (1) the impact of reporting policies on testing practices, including the decreased availability of anonymous testing in some States; (2) the role of surveillance data in linking reported persons to prevention and care programs; (3) the development of recommended uses and standards for the confidentiality of publicly held HIV and AIDS surveillance data; and (4) determining whether alternatives to reporting of patient names would reduce confidentiality risks while meeting the needs for surveillance data. In response to the consultants' recommendations, CDC initiated several research projects to:

(1) assess the effect of name-based HIV surveillance on persons' willingness to seek HIV testing and care; (2) evaluate the performance of non-name-based surveillance systems; and (3) review program practices and legal requirements for the security and confidentiality of State and local HIV/AIDS surveillance data. Findings from these projects and expert advice from participants at numerous technical meetings and consultations held during the intervening period have guided the formulation of the policies and practices recommended in this document. The interim findings from these projects are summarized in the following three sections:

HIV Surveillance and Testing Behavior

To determine the effect of changes in reporting policies on actual testing behaviors among persons seeking testing at publicly funded HIV counseling and testing sites, CDC and six State health departments reviewed data routinely collected from these sites to compare HIV testing patterns in the 12 months before and the 12 months after the implementation of HIV case surveillance (36). In these areas, the number of HIV tests increased in four States and decreased in two States; however, these declines were not statistically significant (Figure 4). Thus, these data do not suggest that in these States the policy of expanding HIV case surveillance adversely affected test-seeking behaviors overall, although some variability in testing trends was observed among racial/ethnic subgroups and HIV-risk exposure categories. CDC recognizes that careful attention to providing accurate public education, factual mass media messages, and special efforts to inform vulnerable populations will be important to ensure that adverse outcomes do not occur in States that implement HIV case surveillance based on these Guidelines.

In addition, CDC is supporting ongoing studies by researchers at the University of California at San Francisco (UCSF) and participating State health departments to continue to identify the most important determinants of test-seeking or test-avoidance among high-risk populations and to assess the impact of changes in HIV testing and reporting policies. Efforts to expand such studies to all States will assist them in more effectively monitoring the impact of changing medical interventions, epidemiology, and HIV case surveillance policies on test- and care-seeking behaviors.

Data from surveys in selected States of high-risk persons about their perceptions and knowledge of HIV testing and HIV reporting practices found that few respondents had knowledge of the HIV reporting policy in their State (37-38). In these settings, respondents reported high levels of testing, with approximately three-fourths reporting that they have had an HIV test. The most commonly reported factors that contributed to delays in seeking testing or not getting tested were fear of being diagnosed as having HIV or belief that they were not likely to be HIV infected, factors reported by nearly half of respondents. Less than 20 percent responded that "reporting to the government" was a concern that may have delayed their seeking HIV testing; 2 percent of the respondents indicated that this was their main concern. Among different risk groups, the level of concern about name-based reporting of HIV infections to the government as a concern or as the main reason for delaying or avoiding HIV testing varied slightly. CDC will continue to assist States to evaluate the impact of policy changes on HIV testing patterns and HIV/AIDS surveillance data.

Surveys of persons reported with AIDS found that persons who recognized their HIV risk and sought testing at anonymous testing sites entered care at a significantly earlier stage of HIV disease than persons who were only tested in confidential testing settings including those who were first tested when they became ill (39). This study emphasizes the importance of anonymous testing options in promoting knowledge of HIV status and in accessing care in a timely way.

HIV Surveillance Based on Non-name Unique Identifiers

To assess the feasibility of using alternatives to name-based methods for HIV surveillance, several States implemented reporting of HIV cases or CD4 laboratory results using a variety of numeric codes. Other States considered or tried to conduct case surveillance without name-identifiers by using codes that were designed for non-surveillance purposes, e.g., codes that were intended for use in tracking patients in case management systems (40). CDC convened a meeting in May 1995 at which these States identified operational, technical, and scientific challenges in conducting surveillance using non-name codes. In addition, CDC supported research to evaluate the performance of a coded unique identifier (UI) in two States that implemented a non-name-based HIV case reporting system while maintaining name-based surveillance methods for AIDS (41). The evaluations conducted by these States from 1994 to 1996 indicated that social security number-based UI HIV surveillance systems were limited by the ability of providers to complete and forward UI-based reports, resulting in incomplete reporting. The evaluations were also unable to demonstrate that duplicate case reports could be reliably eliminated. For the follow-up of UI-based cases to collect risk and other epidemiologic data, providers maintained logs or other forms of documentation linking the UI to the name-based medical records. The willingness of health care providers to accept the additional disease reporting burden of constructing UI codes, maintaining logs, and adopting the level of security necessary to reduce the potential for a breach of confidentiality from such logs, are important considerations in assessing the utility and acceptability of UI HIV case surveillance systems. Of the two States that currently conduct HIV case surveillance using unique identifier codes, one has elected to continue to develop its UI HIV case surveillance system; the other has amended its regulations to begin name-based reporting of HIV infected persons.

Confidentiality of HIV Surveillance Data

In 1994, CDC and CSTE sponsored a review of State confidentiality laws that protect HIV surveillance data (42). All States and many localities have legal safeguards of confidentiality of government-held health data, and these laws were found to provide greater protection than laws protecting the confidentiality of health information held by private health care providers in clinical records. Most States have specific statutory protections for public health data related to HIV and other sexually transmitted diseases. However, State legal protections vary widely, and CDC is promoting efforts to enhance and standardize privacy protections for public health data, including HIV/AIDS surveillance data.

CDC has also reviewed State and local security policies and procedures. Since 1981, States have conducted AIDS surveillance, and few breaches of security have resulted in the

unauthorized release of data (43). Because HIV-infected persons are reported earlier in their disease course than persons with AIDS and many such persons are remaining AIDS-free for longer periods as a result of treatment advances, information about them may be maintained by public health surveillance databases for longer periods. This has caused increased concerns about confidentiality of surveillance data among public health and community groups. Therefore, CDC has issued technical guidance for security procedures that include enhanced confidentiality and security safeguards as evaluation criteria for Federal funding of State HIV/AIDS surveillance activities (44). The receipt of Federal surveillance funding is dependent on the recipient's ability to ensure the physical security and the confidentiality of case reports. At the Federal level, HIV/AIDS surveillance data are protected by several Federal statutes, and privacy is also ensured by the removal of names and the encryption of data transmitted to CDC. Based on the importance of maintaining the confidentiality of persons who are diagnosed as HIV-infected by public and private health care providers, CDC is recommending additional practices to enhance the security and confidentiality of HIV and AIDS surveillance data.

HIV AND AIDS SURVEILLANCE GUIDELINES

HIV/AIDS Surveillance Case Definitions for Children and Adults

CDC, in collaboration with CSTE, has established new HIV case definitions for adults and children less than 18 months of age that include revised surveillance criteria for HIV infection and incorporate the surveillance criteria for AIDS (10,12,13,45) (Appendix). HIV and AIDS surveillance reports forwarded to CDC should be based on these surveillance criteria. The HIV and AIDS surveillance case definitions for adults, adolescents, and children greater than or equal to 18 months of age include laboratory and clinical evidence specifically indicative of HIV infection and severe HIV disease (AIDS). The HIV surveillance case definition for children less than 18 months of age updates the definition in the 1994 revised classification system based on recent data on the sensitivity and the specificity of HIV diagnostic tests and clinical guidelines for *Pneumocystis carinii* pneumonia (PCP) prophylaxis for children (13, 46-58) and for the use of antiretroviral agents for pediatric HIV infection (59). This definition will apply to children less than 18 months of age, except for those who acquired HIV infection through modes of transmission other than perinatal transmission (e.g., blood/blood product recipients). The revised surveillance case definitions for adults and children less than 18 months of age will become effective _____.

HIV and AIDS Case Surveillance Practices

The following recommended practices update previous recommendations for State and local HIV reporting systems and are revisions to the *CDC Guidelines for HIV/AIDS Surveillance* released in April 1996 as a technical guide for State and local HIV and AIDS surveillance programs (20, 44).

Recommended Surveillance Practices

- All State and local programs should collect a standard set of surveillance data for all cases that meet the reporting criteria for HIV infection and AIDS. The standard data set includes the (1) patient identifier, (2) earliest date of diagnosis for HIV infection, (3) earliest date of diagnosis of an AIDS-defining condition, (4) demographic information (date of birth, race/ethnicity, sex) and residence (city, State) at diagnosis of HIV and AIDS, (5) HIV risk exposure, (6) facility of diagnosis, and (7) date of death and state of residence at death. In addition to this information, the date of HIV diagnostic testing and the results of these tests should be collected for all infants with perinatal exposures to HIV. To address specific public health information needs, local surveillance programs may cross-match HIV and AIDS surveillance data with other public health data, such as for tuberculosis, and collect supplemental surveillance data on all or a representative sample of cases. CDC will provide technical assistance and standardized surveillance methods to assist in the collection of supplemental surveillance information. Surveillance information, without patient identifiers, should be encrypted and forwarded to CDC through the HIV/AIDS Reporting System, as is current practice.
- Published evaluations of non-name based HIV surveillance in two States (41) together with results of meetings and consultations with States that have considered or used non-name identifiers have highlighted operational difficulties with these systems. Based on published evaluations, CDC has concluded that name-based HIV/AIDS surveillance systems are the most likely to meet the necessary performance standards (22, 60-66) as well as to serve the purposes for which surveillance data are required. Therefore, CDC advises that State and local surveillance programs use the same name-based approach for HIV surveillance as is currently used for AIDS surveillance nationwide. However, CDC recognizes that some States have adopted, and others may elect to adopt, non-name case identifiers for the public health reporting of HIV infection. CDC will provide technical assistance to all State and local areas to continue or establish HIV and AIDS surveillance systems and to evaluate their surveillance programs regardless of whether they use name or non-name based identifiers.
- HIV and AIDS surveillance should be used to identify rare or previously unrecognized modes of HIV transmission, unusual clinical or virologic manifestations, and other cases of public health importance. CDC will provide technical assistance to State and local health departments conducting such investigations and will revise public health recommendations based on the findings, as appropriate.
- HIV and AIDS case surveillance efforts should be directed toward the collection of data from all private and public sources of HIV-related testing and care services. Laboratory-initiated surveillance methods should be used to collect information for cases that meet the laboratory reporting criteria for HIV infection and AIDS. Statistics regarding persons who are tested anonymously should not be reported through the HIV/AIDS Reporting System. These test results are reported anonymously to the HIV Counseling and Testing database. HIV-infected persons who are initially tested anonymously are only eligible to be reported to HIV/AIDS surveillance after they have been diagnosed by a health care provider and have test results or clinical conditions that meet the HIV and AIDS reporting criteria.

- All State and local surveillance programs should regularly publish, in print or electronically, aggregated HIV and AIDS surveillance data in a format that facilitates the use of these data by Federal, State, and local public health agencies; HIV Prevention Community Planning groups; academic institutions; providers and institutions that have reported cases; community-based organizations; and the general public. The presentation of surveillance data should be consistent with established policies for data release that preclude the direct or indirect identification of a person with HIV or AIDS.
- All State and local surveillance programs should conduct regular, ongoing assessments of the performance of the surveillance system and redirect efforts and resources to ensure timely reporting of complete, representative, and accurate data. CDC will provide technical assistance and standardized evaluation methods to assist States in achieving the highest possible level of performance.

Performance Standards

- For the provision of accurate and timely data to monitor HIV and AIDS trends and to ensure a reliable measure of the number of persons in need of HIV-related prevention and care services, State and local HIV/AIDS surveillance systems must use reporting methods that provide complete (≥ 85 percent) and timely (≥ 66 percent of cases reported within 6 months of diagnosis) case reporting and unduplicated (≤ 5 percent duplicate case reports) surveillance data. At least 85 percent of cases, or a representative sample, should have HIV risk information after epidemiologic follow-up is completed. All HIV and AIDS surveillance systems should collect the recommended standard data in a reliable and valid manner, allow matching to other public health databases (for example, death registries) to benefit specific public health goals, and allow identification and follow-up of individual cases of public health importance.
- To assess the quality of HIV and AIDS case surveillance as specified in the performance standards, States and local surveillance programs must conduct periodic evaluations that include the use of at least one appropriate population-based data source (e.g., National Death Index) that is not used for routine case-finding. Program evaluations should also measure the potential impact of HIV surveillance on test-seeking patterns and behaviors and review the extent to which surveillance data are being used for planning, targeting, and evaluating HIV prevention programs and services. The goal of these performance evaluations is to enhance the quality and usefulness of surveillance data for public health action. During the next several years, CDC will assist States in transitioning from an AIDS-only surveillance program to an integrated HIV and AIDS surveillance system. CDC will assist States conducting HIV and AIDS surveillance to evaluate current performance levels, institute revised program operations and policies as necessary, and then reassess performance. CDC will evaluate and award proposals for Federal funding of State and local surveillance programs based on their capacity to meet these performance standards following this transition period. At that time, CDC will require that States adopt surveillance methods that will enable them to achieve the standards.

Recommended Security and Confidentiality Practices

- State and local programs should have a description of their security policies and procedures available for external review. CDC will require that State and local areas include their security policy in applications for Federal surveillance funds.
- For optimal security, data should be maintained on a single electronic HIV and AIDS surveillance registry. In accordance with local laws, other files such as paper and electronic (except for a backup for the central system) that contain personal identifying information should be eliminated. All States should continue the established practice of not including personal identifying information in the HIV and AIDS surveillance data forwarded to CDC.
- State and local health departments should review their data retention policies. Policies should provide the flexibility to remove cases that were reported in error. State and local programs should also consider removing the names from surveillance records that no longer serve a public health purpose and to identify these cases through other means such as the use of the alpha-numeric code scheme currently used in HIV and AIDS surveillance, date of birth, and other data routinely collected in case reports.
- State and local health departments should also review their confidentiality statutes to determine whether additional protections should be put in place before the implementation of HIV case surveillance. State and local confidentiality laws should include: (1) the objectives of the collection of personal identifying information; (2) the public health officials who have access to surveillance information and the justification for this access; (3) the procedures, including time frame, for expunging personal identifiable information when no longer needed for the stated purposes; (4) the safeguards against disclosing HIV and AIDS case surveillance data through subpoena or court order; and (5) the significant civil or criminal penalties for breaches of confidentiality. The confidentiality laws should protect surveillance data that are transmitted (in a secure and confidential manner consistent with CDC's HIV/AIDS surveillance program requirements) to other public health programs as part of evaluation studies or for follow up of cases of special public health importance. The penalties under law for violation of privacy and security should apply to all recipients of HIV and AIDS case surveillance information.

Security and Confidentiality Standards

The security and confidentiality policies and procedures of State and local surveillance programs should be consistent with CDC standards for surveillance programs. The following standards must be met as a condition of Federal HIV and AIDS surveillance funding:

- CDC *requires* that electronic HIV/AIDS surveillance data be protected by computer encryption during data transfer. Paper or unencrypted electronic case reports forwarded by providers should be used by surveillance staff to update the central surveillance registry and then should be destroyed.

- CDC *requires* that HIV and AIDS surveillance records be located in a physically secured area to limit and control access to surveillance records and that they be protected by coded passwords and computer encryption. To further enhance security and confidentiality of the data, States may elect to implement the use of a double-key encryption and decryption system, in which identifying information encrypted by the States using the first key can only be decrypted for access using the second key. CDC is developing this option to assist States to reassure HIV-infected persons that HIV and AIDS surveillance data will be held confidentially and will only be used for public health purposes. CDC will hold the second key under an Assurance of Confidentiality under Section 308(d) of the Public Health Service Act. Under this Assurance, the second CDC-held key would preclude States from accessing or releasing the HIV/AIDS surveillance data for non-public-health purposes.
- CDC *requires* that access to the HIV/AIDS surveillance registry be restricted to a minimum number of authorized surveillance staff who have been trained in confidentiality procedures and who are aware of penalties for unauthorized disclosure of surveillance information. The State Health Officer or other designated authorizing official should specify the persons who have access to confidential HIV/AIDS surveillance data and the duties to be conducted. Audit systems should be established to monitor access to and use of surveillance data.
- If State and local health departments develop data bases from the cross-matching of HIV/AIDS surveillance data with other surveillance data, HIV and AIDS surveillance records *must not* be used if the cross-matched data bases do not have equivalent security and confidentiality protections and penalties for unauthorized disclosure as those for the HIV and AIDS surveillance data. Such cross-matched data bases should use the minimum amount of surveillance data necessary to accomplish the specific public health activity.
- The use of HIV and AIDS surveillance data for research purposes *must* be approved by appropriate institutional review boards, and researchers should sign confidentiality statements. HIV and AIDS surveillance data made available for epidemiologic analyses must not include names or other identifying information. State and local data release policies should ensure that the release of data for statistical purposes does not result in the direct or indirect identification of persons reported with HIV and AIDS. If a breach of confidentiality occurs, State and local health departments should impose personnel sanctions and criminal penalties as appropriate.
- State and local health departments *must* investigate potential breaches of confidentiality, and impose personnel sanctions and criminal penalties as appropriate. All breaches of confidentiality are to be reported to CDC immediately. CDC will provide technical assistance to State and local health departments' investigations of such incidents, develop recommendations for improvements in local security measures, and provide oversight to monitor changes in program practices.

Relationship to HIV Prevention and Care Programs

- The implementation of HIV case surveillance should not interfere with HIV prevention programs, including those that offer anonymous HIV counseling and testing services. Unless prohibited by State law or regulation, CDC *requires* that States and local areas provide opportunities to receive anonymous HIV counseling and testing services as a condition of Federal funding for HIV prevention. CDC strongly recommends that States prohibiting anonymous HIV testing change this practice, given the overriding public health objective of encouraging knowledge of HIV serologic status.
- All HIV testing services should continue to be voluntary and preceded by informed consent in accordance with local laws (67).
- All persons who are diagnosed with HIV infection should be referred to programs that provide HIV care, treatment, and comprehensive prevention case management services. Provider-based referrals of patients to prevention and care services provide a timely, effective, and efficient means of ensuring that individuals who have been diagnosed with HIV receive needed services. The primary function of HIV and AIDS surveillance is the collection of accurate and timely epidemiologic data; therefore, State and local HIV and AIDS case surveillance programs are not directed by CDC to share individual case reports with prevention or care programs, including those that provide partner notification assistance, case management, and other services for individual clients. Although some areas have established direct linkages between surveillance and specific prevention programs, such linkages do not necessarily improve the provision of HIV prevention and care services. Areas that elect to establish such linkages must seek the concurrence of their prevention and care planning groups, require that recipients of surveillance information be subject to the same penalties for unauthorized disclosure as surveillance personnel, and evaluate the effectiveness of this public health approach.

COMMENTARY

The Surveillance Case Definition for HIV Infection and AIDS

The revised HIV case definitions for adults and children less than 18 months of age integrate HIV and AIDS reporting criteria in a single case definition and incorporate new laboratory tests in the laboratory criteria for HIV case reporting. For adolescents and adults, the 1999 HIV and AIDS case definition includes HIV nucleic acid (DNA or RNA) detection tests that were not commercially available when the case definition was revised in 1993. The revised case definition for HIV infection also permits the reporting of cases based on the result of any test licensed for the diagnosis of HIV infection in the United States. Although the reporting criteria generally reflect the recommendations for the diagnosis of HIV infection, the HIV reporting criteria are for public health surveillance and are not designed for making a diagnosis for an individual patient. The laboratory criteria include the serologic HIV tests described in the clinical standards for HIV diagnosis (68-69).

The pediatric HIV reporting criteria include criteria for monitoring all children with perinatal exposures to HIV and reflect recent advances in diagnostic approaches that permit the diagnosis of HIV infection in the first months of life. With HIV nucleic acid detection tests, HIV

infection can be detected in nearly all infants 1 month of age or older. The timing of the HIV serologic and HIV nucleic acid detection tests and the number of HIV nucleic acid detection tests in the definitive and presumptive criteria for HIV infection are based on the recommended practices for the diagnosis of infection in children less than 18 months of age and on evaluations of the performance of these tests for children in this age group (46-59).

The clinical criteria in the HIV and AIDS case definition are included to ensure the complete reporting of cases with documented evidence of HIV infection or conditions meeting the AIDS case definition. The AIDS-defining conditions are included as part of the integrated HIV and AIDS surveillance criteria. The presumptive and definitive AIDS-defining criteria have not been revised since 1993 and continue to include the laboratory markers of severe HIV-related immuno-suppression and the opportunistic illnesses indicative of severe HIV disease. The development of AIDS-related opportunistic illnesses greatly increases mortality risks. Almost all deaths among persons with HIV infection are caused by AIDS-related opportunistic illnesses (70).

Effect of National HIV Case Surveillance on Reporting Trends

The changes in the HIV reporting criteria will have little effect on reporting trends in States already conducting HIV case surveillance. The number of HIV cases reported nationally will increase primarily because of the implementation of HIV surveillance by the remaining States and local areas. Many of the States that will be implementing HIV case surveillance in the future have high AIDS incidence rates. Similar to the effect on AIDS surveillance trends after the implementation of the revised reporting criteria in 1993, the initiation of HIV surveillance by additional States may result in a sudden and large increase in HIV case reports (71). Based on CDC's estimates that approximately 220,000 HIV-infected persons without AIDS-defining conditions have been diagnosed with HIV in confidential testing settings and reside in States that do not currently conduct HIV case surveillance (30), it is possible that this many persons could be reported with HIV infection from these States in 1999. However, it is more likely that reporting of prevalent HIV infections will be spread over several years and that the annual increases will be more modest. Initially, most case reports will represent persons whose HIV infection was diagnosed before HIV surveillance was implemented. As the reporting of prevalent HIV cases is completed, the number of HIV case reports will decrease and case reports will increasingly represent persons with recent diagnosis of HIV infection.

To facilitate the interpretation of HIV surveillance data and given that CDC strongly promotes the continued availability of anonymous testing options, evaluations of HIV and AIDS surveillance systems will include assessments of the number of persons reported whose infection was initially diagnosed at an anonymous site and the time before these persons entered clinical care for their infection. These evaluations will be useful in determining the representativeness of HIV surveillance data, as well as the effectiveness of program efforts to refer persons into care services after the diagnosis of HIV infection in anonymous testing settings.

AIDS trends have declined nationally; however, because the AIDS surveillance trends are affected by HIV incidence, as well as the effect of treatment on the progression of HIV disease, it is not possible to predict future AIDS trends. AIDS surveillance will continue to be important in evaluating access to care for different populations and in identifying changes in trends that might

signal a decrease in the effectiveness of treatment. The long-term benefits of antiretroviral therapy and antimicrobial prophylaxis for AIDS-related illnesses continue to be defined, and various factors such as access, adherence, treatment costs, and viral resistance will influence the utilization and effectiveness of these therapies and their effects on AIDS incidence and mortality trends (72-74).

HIV and AIDS Surveillance Practices

Laboratories will be an increasingly important source of information from which to initiate reporting. HIV infection is frequently diagnosed in the outpatient clinical setting, and laboratory-initiated reporting will be particularly useful in identifying outpatient sources of HIV testing (63). Although contact with individual providers is necessary to complete the reporting process, the routine collection of HIV and CD4 test data from laboratories and managed care organizations promotes simplicity and efficiency of case reporting to local surveillance programs.

Performance criteria for HIV and AIDS surveillance are necessary to ensure that surveillance data are of sufficient quality to target prevention and care resources and to detect emerging trends in the HIV epidemic. Evaluations of HIV and AIDS surveillance programs have shown that areas should be able to meet these performance criteria (6,22,60-66). According to these evaluations, the completeness of HIV surveillance (from 79 to more than 95 percent) and AIDS surveillance (from 85 to more than 100 percent) is high, and reporting is timely with nearly one-half of AIDS cases and three-quarters of HIV cases reported to the national HIV/AIDS reporting system within 3 months of diagnosis (6). In 1996, CDC estimated that the duplication rate of HIV and AIDS cases reported from different States to the national surveillance data base was less than 3 percent and 2 percent, respectively (6,22). The performance criteria also reflect the need for public health surveillance systems to serve as a basis for the identification and follow-up of cases of public health importance. Based on evaluation studies of non-name-based case identifiers and the current infrastructure of State and local health departments, name-based methods for collecting and reporting public health data provide the most feasible and reliable means for ensuring timely, accurate, and complete reporting of persons diagnosed with HIV and AIDS. Name-based reporting facilitates followup of perinatally exposed infants to determine their infection status and of persons reported with HIV to determine progression to AIDS and vital status. (22,28)

The Security and Confidentiality of HIV and AIDS Surveillance

The revision of the HIV reporting criteria provides an opportunity to review and strengthen State and local confidentiality laws and regulations. Although State HIV and AIDS surveillance confidentiality laws and regulations adequately protect privacy compared with the statutory protections of other health care data, State statutes differ in the degree of privacy protections afforded health information and the criteria for permissible disclosures of personal information. Most State statutes describe some permissible disclosures of public health information. To help ensure uniform confidentiality protections, CDC, CSTE, ASTHO, the National Conference of State Legislatures, and the Georgetown/Johns Hopkins Public Health

Law Project are conducting a model State privacy law project. This project is developing model legislative language to protect confidential, identifiable information held by State and local public health departments against unauthorized and inappropriate use while still allowing the use of surveillance information to accomplish legitimate public health objectives. This process is projected to be completed early in 1999, and States that plan to implement HIV case surveillance should consider adopting the model legislation.

Although HIV and AIDS surveillance systems have exemplary records of security and confidentiality, it is essential for all programs to identify ways to strengthen data protection because of the greater sensitivity of HIV case surveillance compared with that of AIDS case surveillance alone (75). The revised security requirements are based on a CDC review of the security practices of all State HIV and AIDS surveillance systems. The revised security standards will result in a reduction in the number of name-based surveillance registries and limitations on how these registries are used. CDC continues to conduct evaluations of methods to further enhance data security, including the use of coding and encryption of data collected in the HIV and AIDS reporting system. Based on these evaluations, CDC will provide technical guidance to facilitate the use of this approach by project areas.

HIV Prevention and Care

CDC has published guidelines concerning the provision and targeting of HIV counseling and testing services (19, 27, 76-78) and provides support for most public sources of HIV testing. The availability of anonymous HIV testing services may be particularly important for persons who delay seeking testing because of a concern that others may learn of their serologic status. Studies have shown that the availability of anonymous HIV testing is associated with increased numbers of persons seeking testing services (83,84). Anonymous HIV testing services are a required element of federally supported prevention programs unless prohibited by State law or regulation. Currently, 39 States, Puerto Rico, and the District of Columbia provide anonymous HIV testing services.

CDC advises that the decision about linkage between surveillance systems and prevention and care services, such as partner counseling and referral services (i.e., partner notification activities), be made at the local level. Voluntary partner notification services provide HIV counseling and testing to persons who may be unaware of HIV risk exposures, and these services are a required component of federally sponsored HIV prevention programs (77-78). All such prevention services are feasible and in well-managed programs have been highly effective without being directly linked to HIV or AIDS surveillance data. Translating surveillance data into prevention priorities and programs requires informed decision-making by public health and community partners through the HIV Prevention Community Planning process that should guide whether and how such linkages are achieved. Such linkages should neither compromise the quality and security of the surveillance system nor compromise the quality, confidentiality, and voluntary nature of HIV prevention services. The primary function of HIV and AIDS surveillance remains the provision of accurate epidemiologic data for public health information, planning, and evaluation.

Persons who have been diagnosed with HIV infection at either confidential or anonymous test sites should be promptly referred to facilities that provide confidential HIV care. Although not directly responsible for the delivery of medical care, CDC provides Federal direction for State and local programs that facilitate the referral of HIV-infected persons from counseling and testing centers and health education/risk-reduction programs to HIV care facilities. CDC has strengthened its technical assistance to HIV counseling and testing grantees to improve the referral system between HIV testing sites and care programs, in part by increasing coordination with the Health Resources and Services Administration and the Ryan White CARE Act grantees. To provide further guidance, CDC has also undertaken a project to develop model contract language for Medicaid programs that serve people with HIV.

CONCLUSION

The implementation of a national surveillance network to include both HIV and AIDS surveillance is a necessary response to epidemiologic trends and new standards for HIV care. Integrated HIV and AIDS surveillance programs will provide data to characterize persons newly diagnosed with HIV infection, including those with evidence of recent infection, persons with severe HIV disease (AIDS), and those succumbing to HIV and AIDS. The revised HIV surveillance case definitions and the establishment of performance criteria will promote uniform case ascertainment and will ensure that the surveillance data are of sufficient quality for effective planning and allocation of resources for prevention and care programs. The successful implementation of HIV and AIDS surveillance will require that State and local areas further ensure the security and confidentiality of surveillance data. This can be promoted through enhancements to data systems and confidentiality policies, training and management of public health personnel, and by use of the HIV Prevention Community Planning process to determine the appropriate use of surveillance data by prevention and care programs.

TABLE. Characteristics of persons aged ≥ 13 years with HIV, by disease status at initial diagnosis* — 25 states†, January 1994–June 1997

Characteristic	Disease status at initial HIV diagnosis				Total
	HIV		AIDS		
	No.§	(%¶)	No.§	(%¶)	
Sex					
Male	37,996	(72)	16,866	(83)	54,862
Female	14,689	(28)	3,348	(17)	18,037
Race/Ethnicity**					
White, non-Hispanic	17,929	(34)	9,171	(45)	27,100
Black, non-Hispanic	30,229	(57)	9,127	(45)	39,356
Hispanic	3,581	(7)	1,660	(8)	5,241
Other/Unknown	949	(2)	256	(1)	1,205
Risk/Exposure category					
Men having sex with men	17,098	(32)	8,866	(44)	25,964
Injecting-drug user	9,671	(18)	3,959	(20)	13,630
Men having sex with men/ Injecting-drug user	2,088	(4)	843	(4)	2,931
Heterosexual contact	9,279	(18)	2,428	(12)	11,707
Other/Unreported	14,552	(28)	4,116	(20)	18,668
Age group (yrs)					
13–24	7,200	(14)	653	(3)	7,853
25–29	9,384	(18)	2,239	(11)	11,623
30–34	11,916	(23)	4,503	(22)	16,419
35–39	10,030	(19)	4,608	(23)	14,638
≥40	14,159	(27)	8,210	(41)	22,369
Total††	52,690		20,215		72,905

*For persons who had not had an HIV diagnosis before being diagnosed with AIDS, their AIDS diagnosis date is considered their earliest HIV diagnosis date; for persons initially reported with HIV who subsequently had AIDS diagnosed and reported, they are presented by the earliest diagnosis date, which is their HIV diagnosis.

†Alabama, Arizona, Arkansas, Colorado, Idaho, Indiana, Louisiana, Michigan, Minnesota, Mississippi, Missouri, Nevada, New Jersey, North Carolina, North Dakota, Ohio, Oklahoma, South Carolina, South Dakota, Tennessee, Utah, Virginia, West Virginia, Wisconsin, and Wyoming.

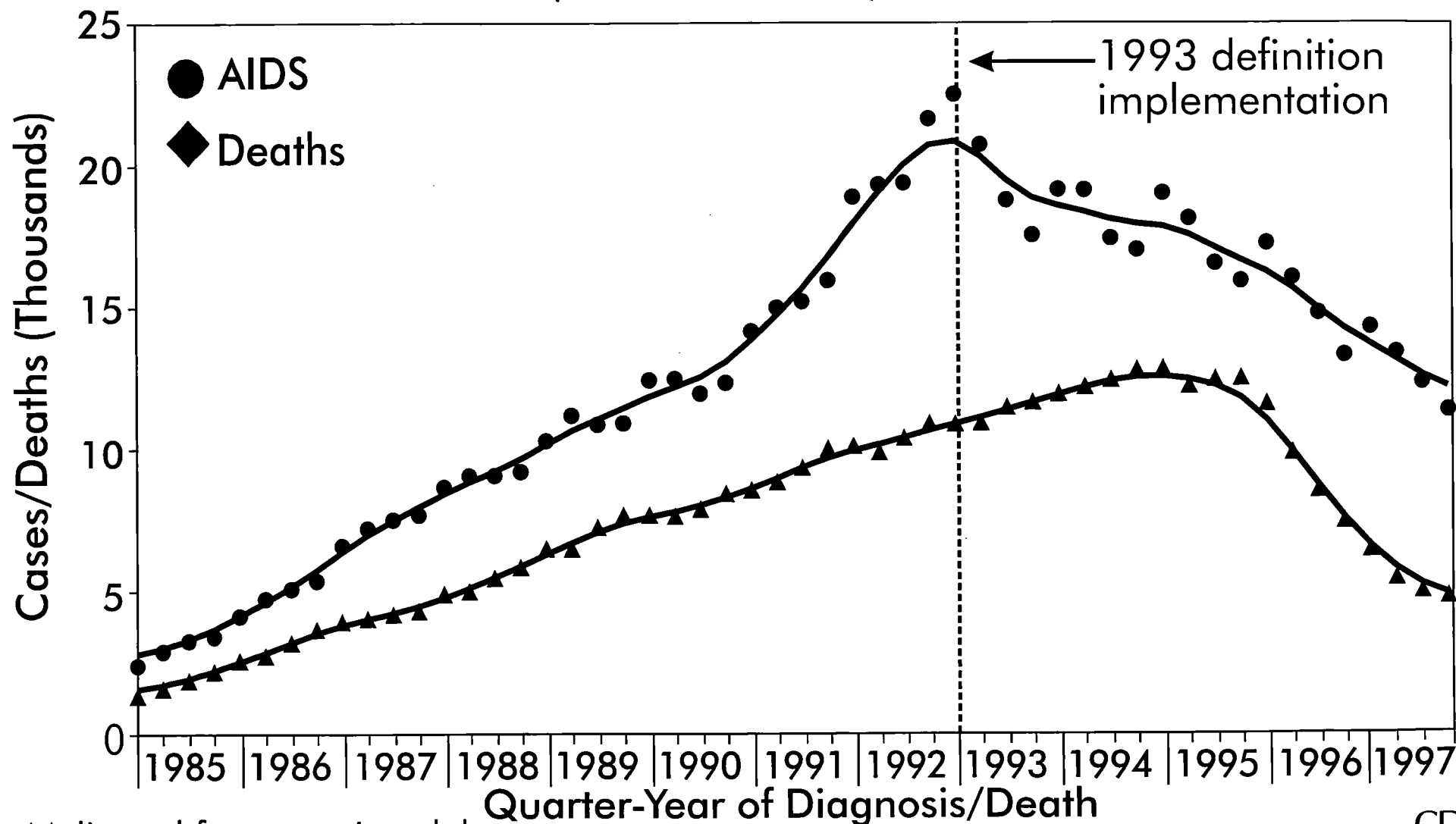
‡Numbers are estimates after adjustments for reporting delays. Point estimates are presented for reproducibility of the data.

¶Percentages may not total 100 because of rounding.

**Persons of races other than black and white were included under "other/unknown" because estimates were too small for meaningful analysis.

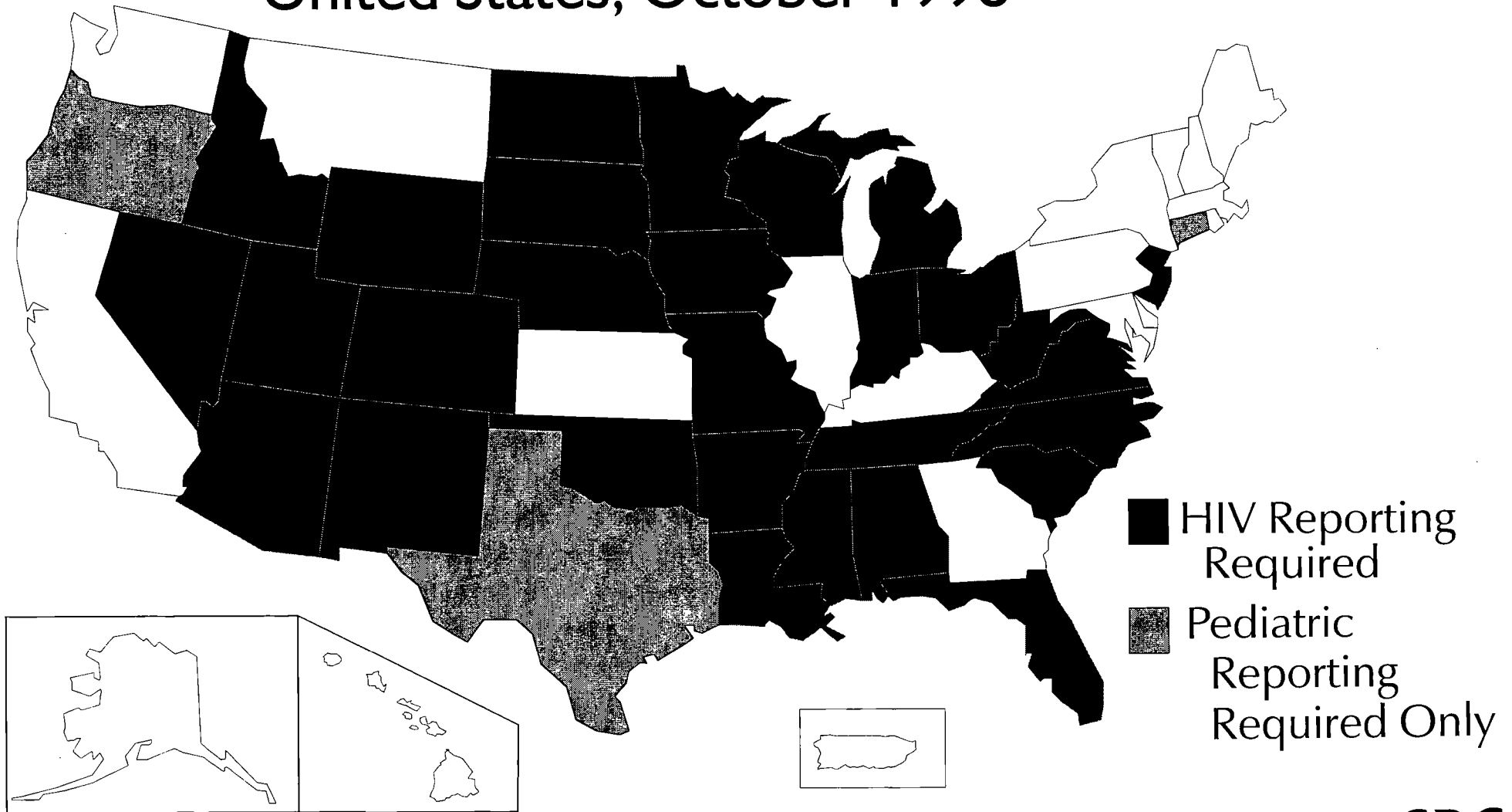
††Column totals include missing/other for some categories (e.g., missing sex). Persons infected through receipt of blood or blood products are included under other/unreported risk.

Figure 1. Estimated Incidence of AIDS and Deaths of Persons with AIDS*, 1985 - 1997, United States



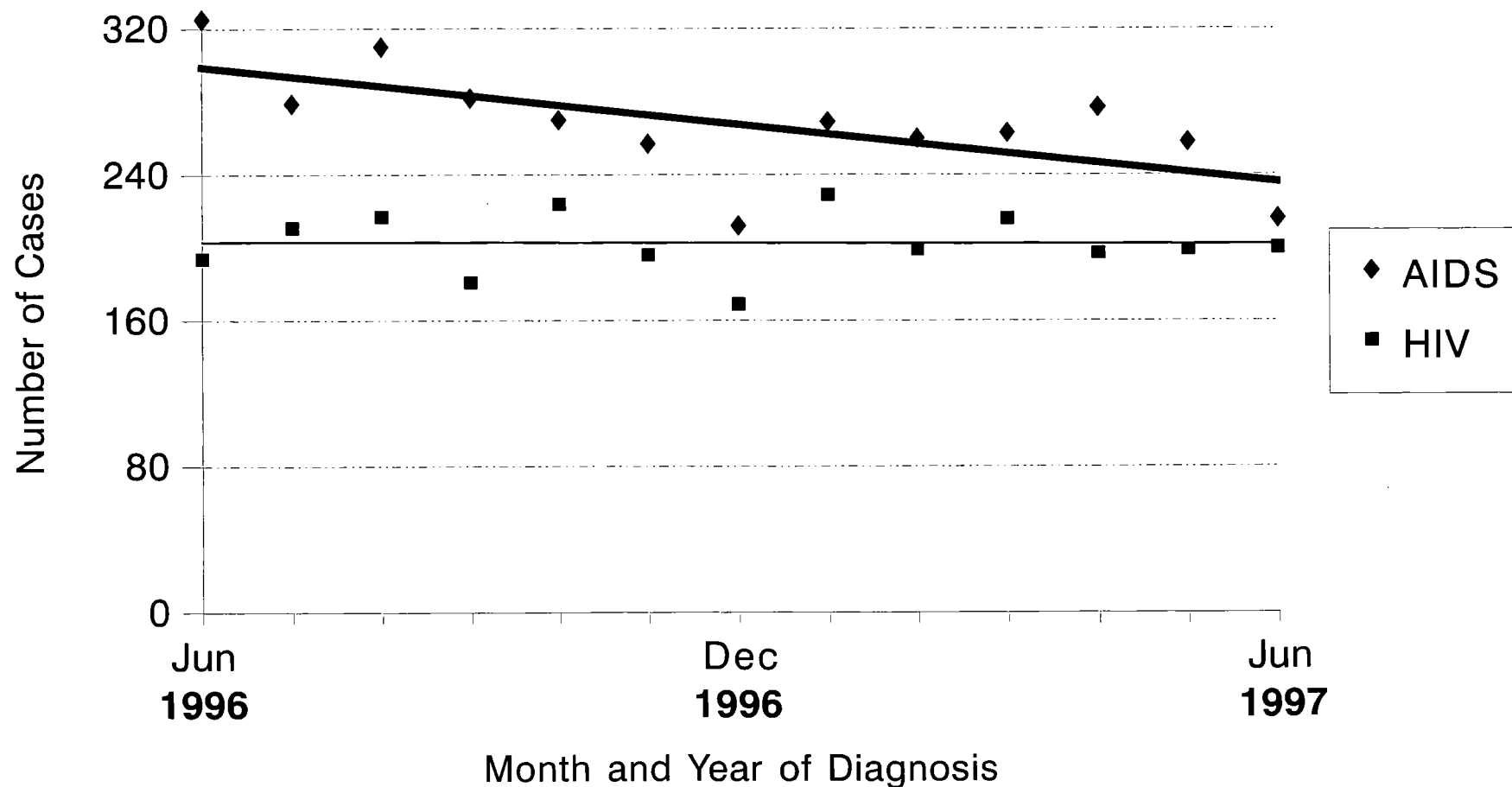
*Adjusted for reporting delays

Figure 2. States with Confidential* HIV Case Surveillance
United States, October 1998



* cases reported by patient name

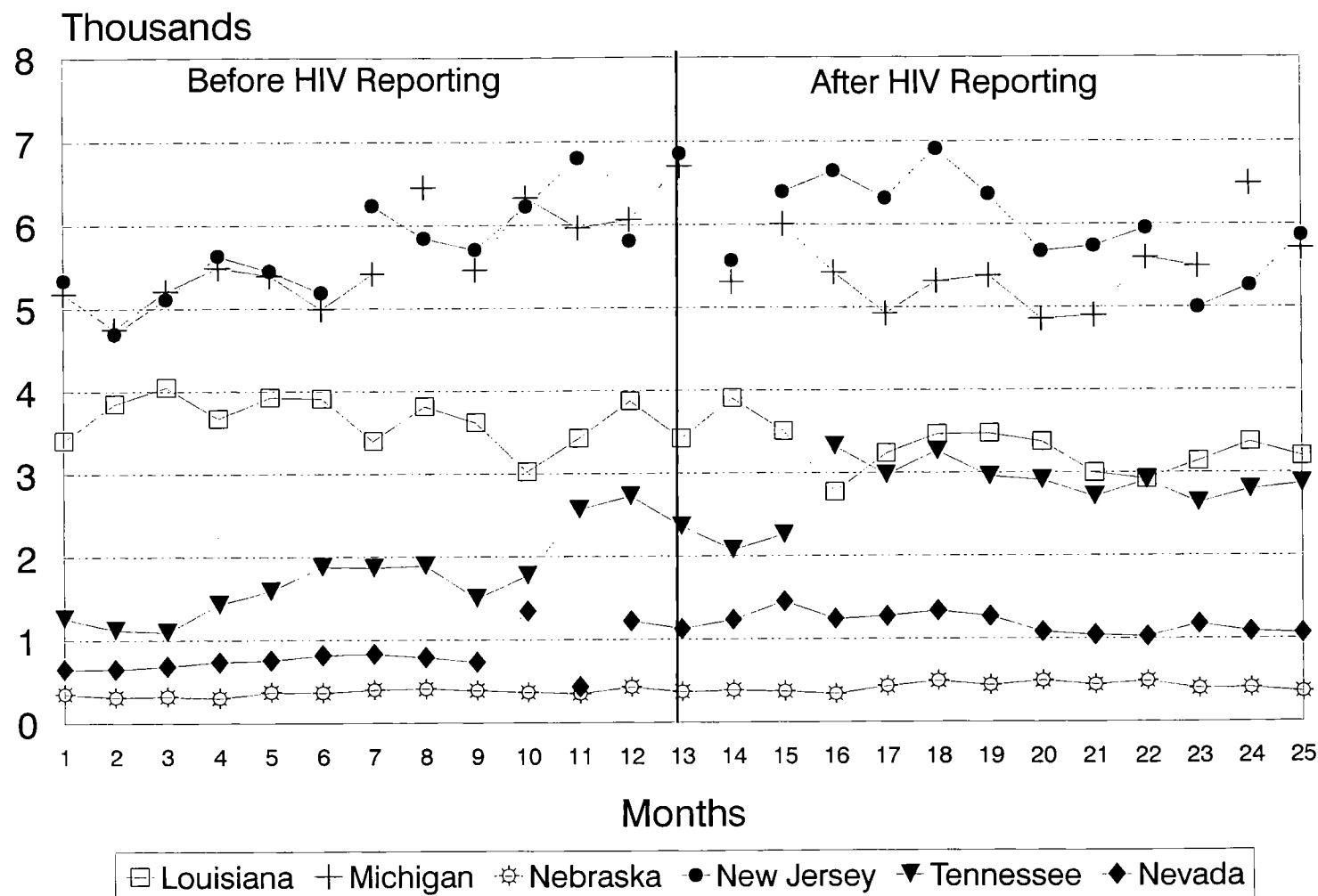
Figure 3. Number of HIV and AIDS Cases* Diagnosed Among White MSM in 26 HIV Reporting States, by Month, June 1996 to June 1997



*HIV and AIDS cases adjusted for reporting delays.

MSM= men who have sex with men.

Figure 4. Number of tests performed in publicly-funded HIV counseling and testing sites the year before and the year after HIV reporting laws were implemented, by month*



*Excludes sites performing <50 tests during 25 months surrounding HIV reporting; HIV reporting implementation - Louisiana (Feb 1993), Michigan (Apr 1992), Nebraska (Sep 1995), New Jersey (Jan 1992), Tennessee (Jan 1992). Nebraska (Sep 1995), Nevada (Feb 1992)

Appendix

Revised Surveillance Case Definition of HIV Infection (including AIDS)*

This revised definition of HIV infection, which applies to any type of HIV (e.g., HIV-1, HIV-2), is intended for public health surveillance only. The revised criteria for HIV infection update the definition of HIV infection implemented in 1993 (10); the revised HIV criteria apply to AIDS-defining conditions for adults (10) and children (12,13) which require laboratory evidence of HIV. This definition is **not** presented as a guide to clinical diagnosis or for other uses (10,12).

I. In adults, adolescents, children ≥ 18 months of age, a reportable case of HIV infection meets any of the following criteria:

Laboratory Criteria

- Positive result on a screening test for HIV antibody (e.g., repeatedly reactive enzyme immunoassay) followed by a positive result on a confirmatory (sensitive and more specific) test for HIV antibody (e.g., Western blot or immunofluorescence antibody test), OR,
- Positive result on any of the following HIV virologic (non-antibody) tests:
 - HIV nucleic acid (DNA or RNA) detection (e.g. DNA polymerase chain reaction (PCR), plasma HIV-1 RNA)#
 - HIV p24 antigen test, including neutralization assay
 - HIV isolation (viral culture)

OR

Clinical Criteria (if the above criteria are not met)

- Diagnosis of HIV infection, based on the laboratory criteria above, that is documented in a medical record by a physician, OR,
- Conditions that meet criteria included in the case definition for AIDS (10,12)

II. In a child < 18 months of age, a reportable case of HIV infection meets any of the following criteria:

Laboratory Criteria

Definitive

- Positive results on two separate specimens (excluding cord blood) using one or more of the following HIV virologic (non-antibody) tests:
 - HIV nucleic acid (DNA or RNA) detection
 - HIV p24 antigen test, including neutralization assay
 - HIV isolation (viral culture)

OR

Presumptive

A child who does not meet the criteria for definitive HIV infection but who has:

- Positive results on only one (excluding cord blood) of the above HIV virologic tests

AND has NO subsequent negative HIV virologic or negative HIV antibody tests,

OR

Clinical Criteria (if the above criteria are not met)

- Diagnosis of HIV infection, based on the laboratory criteria above, that is documented in a medical record by a physician, OR,
- Conditions that meet criteria included in the 1987 pediatric surveillance case definition for AIDS (12,13)

III. A child <18 months of age born to an HIV-infected mother will be categorized for surveillance purposes as not infected with HIV if the child does not meet the criteria for HIV infection but meets the following criteria:

Laboratory Criteria

Definitive

- At least two negative HIV antibody tests from separate specimens obtained at ≥ 6 months of age, OR,
- At least two negative HIV virologic tests** from separate specimens, both of which were performed at ≥ 1 month of age and one of which was performed at ≥ 4 months of age

AND

NO other laboratory or clinical evidence of HIV infection (i.e., has not had any positive virologic tests, if performed, and has not had an AIDS-defining condition)

OR

Presumptive

A child who does not meet the criteria for definitive “not infected” status but who has:

- One negative EIA HIV antibody test performed at ≥ 6 months of age and NO positive HIV virologic tests, if performed, OR,
- One negative HIV virologic test** performed at ≥ 4 months of age and NO positive HIV virologic tests, if performed, OR,
- One positive HIV virologic test with at least two subsequent negative virologic tests**, at least one of which is ≥ 4 months of age; or negative HIV antibody test results, at least one of which is at ≥ 6 months of age.

OR

Clinical Criteria

- Determined by a physician to be “not infected”, and a physician has noted the results of the preceding HIV diagnostic tests in the medical record
- AND**
- NO other laboratory or clinical evidence of HIV infection (i.e., has not had any positive virologic tests, if performed, and has not had an AIDS-defining condition)

IV. A child <18 months of age born to an HIV-infected mother will be categorized as having indeterminate HIV infection if the child does not meet the criteria for HIV infection (II) or the criteria for “not infected with HIV” (III).

*Draft revised surveillance criteria for HIV infection were approved and recommended by the membership of the Council of State and Territorial Epidemiologists (CSTE) at the 1998 annual

meeting (5). Draft versions of these criteria were previously reviewed by state HIV/AIDS surveillance staffs, CDC and CSTE laboratory experts; in addition the pediatric criteria were reviewed by an expert panel of consultants. [External Consultants: C. Hanson, M. Kaiser, S. Paul, G. Scott, P. Thomas. CDC staff: J. Bertolli, K. Dominguez, M. Kalish, M.L. Lindegren, M. Rogers, C. Schable, R.J. Simonds, J. Ward]

#In adults and adolescents, plasma viral RNA nucleic acid tests should **not** be used as HIV screening tests for the purpose of diagnosing HIV infection.

** HIV nucleic acid (DNA or RNA) detection tests are the virologic methods of choice to exclude infection in children <18 months of age. Although HIV culture can be used for this purpose, it is more complex and expensive to perform and is less well standardized than nucleic acid detection tests. The use of p24 antigen testing to exclude infection is not recommended because of its lack of sensitivity.

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