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average of 8-10 years, 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 (12-13). 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 an 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 (14-15). 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, 2). Revised HIV treatment guidelines recommend antiretroviral therapy for many HIV-infected persons in whom AIDS-defining conditions have not yet developed and public health programs should provide prevention services and referrals to medical care for all persons at early stages of HIV infection (16, 17).

In response to these changes in HIV treatment practices and the information needs of public health programs, CDC and CSTE have recommended that all states and territories implement HIV case surveillance as an extension of AIDS surveillance (1,4). HIV and AIDS surveillance programs are recommended to provide rates of newly diagnosed HIV infection, HIV prevalence, AIDS incidence, HIV-related mortality data, and the associated risk and demographic characteristics (4).

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Current Status of HIV Surveillance

As of January 1, 1998, 31 states had implemented HIV surveillance as an extension of AIDS case surveillance; 3 of these states conduct pediatric surveillance only (5) (map). These states use the same reporting system for both HIV and AIDS cases. The 28 states that conduct HIV surveillance for adults and adolescents report only about one third of total U.S. AIDS cases. In 1989, CDC initiated technical assistance for HIV surveillance to standardize state reporting practices and data collection methods (18). In 1993, CDC revised the HIV surveillance criteria for adolescents and adults; HIV surveillance criteria for children were revised in 1994 (9,19).

In contrast to AIDS surveillance and to other approaches such as clinic-based anonymous serologic surveys, HIV case surveillance provides community-based data to characterize persons newly diagnosed with HIV, particularly those with evidence of recent HIV infection such as adolescents and young adults (20-24). Of the 22,358 HIV infections reported from January 1996 through October 1997 in 26 states with HIV surveillance, 17% were in persons 13-24 years of age compared with only 4% of 28,185 persons reported with AIDS in the same areas. Compared with persons reported with AIDS, those reported with HIV infection in these areas were more likely to be women and from racial/ethnic minorities, reflecting more recent patterns of HIV transmission (24) (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% while the number of new HIV diagnoses among this population remained unchanged (Figure 2). Through October 1997, 139,492 persons were reported living with HIV in these 26 states; 140% more than the number of persons reported with AIDS (24).

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States have used HIV and AIDS surveillance data to better direct and evaluate HIV prevention and care services. For example, New Jersey included HIV surveillance data in economic models to evaluate proposed expansions to the AIDS Drug Distribution Program (ADDP) and through this data-driven process accurately estimated that new HIV therapies could be added to the formulary without a change in patient eligibility criteria (New Jersey, unpublished data). A review of HIV surveillance data by prevention planners in Bridgeton, New Jersey found that 39% of cases were 20-29 years and 43% were women. Based on the HIV surveillance data, this community started a targeted prevention program for younger women and youth (Douglas Morgan, personal communication). As additional examples, Minnesota has used HIV data to develop and target new programs for youth and Michigan has used the data to evaluate the geographic distribution of HIV prevention funds.

To evaluate efforts to prevent perinatal transmission of HIV, the 31 states with HIV and AIDS surveillance have been able to show most clearly the sharp decline in perinatally acquired HIV infection (22,23). Most of the 31 states with pediatric HIV surveillance report all perinatally exposed children and conduct public health follow-up to monitor the proportion of exposed children who become infected. The United States Public Health Service has issued guidelines to reduce the risk of perinatal HIV transmission (25, 26). States have used HIV surveillance data to monitor the implementation of these guidelines and have documented increases in the proportion of infected pregnant women who have been tested for HIV before delivery and that a high proportion of HIV-infected pregnant women accept zidovudine therapy (21-23). To evaluate perinatal prevention efforts nationwide, CSTE and the American Academy of Pediatrics have recommended that all states and territories conduct pediatric HIV surveillance

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that includes all perinatally-exposed infants (27).

HIV case surveillance has not been universally adopted in part because of public health and community concerns regarding name-based approaches to HIV surveillance. AIDS surveillance nationally and HIV surveillance in 31 states is conducted using the name-based methods for case ascertainment that are used by other public health information systems. A name-based approach is used to allow providers to report cases directly from their name-based medical records and to facilitate the elimination of duplicate case reports of the same person from surveillance registries. Local public health authorities also routinely use name-based records to link HIV and AIDS surveillance data with data from other public health systems (e.g., tuberculosis surveillance) and to follow-up with providers and collect HIV risk information and other data of public health importance. Through follow-up with providers, the AIDS surveillance system has been used to identify rare or unusual modes of HIV transmission, infection with rare strains of HIV, and to characterize persons diagnosed with preventable AIDS-related opportunistic illnesses (28-32).

Evaluations to Address Community Issues Regarding HIV Surveillance

In 1993, CDC held a meeting of public health and community consultants to discuss community issues regarding HIV surveillance. Community consultants were particularly concerned 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. To address these issues, CDC initiated projects to assess the effect of name-based HIV surveillance on persons' willingness to seek HIV testing, alternatives to name-based surveillance systems, and

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the security and confidentiality of state and local surveillance programs.

HIV surveillance and testing behavior

CDC supported the University of California at San Francisco and nine state health departments to survey high-risk persons about their perceptions and knowledge of HIV testing and HIV reporting practices; five of the nine states conducted name-based HIV surveillance (33,34). The survey, conducted in 1996, included 2,370 homosexual or bisexual men, injecting drug users, and heterosexual men and women seeking treatment for other sexually transmitted diseases. In this survey, only 15% of the respondents knew whether HIV infection was reportable to the health department in their state of residence. When asked about factors that may have delayed their seeking HIV testing, 18% of the high-risk persons surveyed included "reporting to the government" as one of the concerns that may have delayed their seeking HIV testing. However, only 2% of the respondents surveyed cited "reporting to the government" as the main reason they delayed seeking HIV testing.

CDC and six health departments reviewed data routinely collected from public-funded HIV counseling and testing sites to compare HIV testing patterns in the 12 months before and the 12 months after the implementation of HIV case surveillance (35). In these areas, the number of HIV tests increased in three states (16-63%), remained level in two states (-2%, 5%), and decreased in one state (-11%) (Figure 3). The state with a decline in HIV testing during the evaluation period had a decreasing trend in HIV tests before HIV surveillance was implemented.

HIV surveillance based on non-named unique identifiers

To assess the feasibility of using alternatives to name-based methods for HIV surveillance, CDC supported evaluations in two states that implemented an HIV case

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surveillance system based on a coded unique identifier (UI) rather than the name-based methods used by their AIDS surveillance systems (36). These states independently chose a UI based on data elements from the Social Security number and additional numbers representing demographic information. The evaluations conducted by these states indicated that their UI-based HIV surveillance systems were limited by the ability of providers to forward UI-based reports and by the proportion of persons with HIV infection reported without a Social Security number. These limitations affected the quality of HIV surveillance data by lowering the completeness of case reporting and by precluding the reliable removal of duplicate case reports from the surveillance systems. The UI-based HIV data could not be linked to other public health data such as tuberculosis surveillance and also did not include HIV risk information. HIV risk information is typically not available in laboratory records, a major source of HIV case reports, and may not be included in initial reports from other health care facilities. Public health follow-up with providers is often necessary to collect this information. For the follow-up of cases reported in a UI-based surveillance system, providers must maintain logs or other forms of documentation linking the UI to the name-based medical records. This process complicates efforts to collect reliable and complete HIV risk and other public health information and increases the number of lists of HIV-infected persons at risks in a breach of confidentiality.

Confidentiality of HIV surveillance data

In 1994, CDC and CSTE also sponsored a review of state confidentiality laws that protect HIV surveillance data (37). All states and many localities have legal safeguards of confidentiality of governmentally maintained health data, and these laws were found to provide greater protection than laws that protect the confidentiality of health information held by private

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health care providers in clinical records. State and local governments use a variety of legal protections of the health data collected by their agencies. Most states have specific statutory protections for the collection, use, and disclosure of data related to HIV and other sexually transmitted diseases. In 1998, CDC initiated a collaborative project to promote strong and uniform legal protections of confidentiality at the state and local level through the development of model confidentiality language for state and local legislation.

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 (38). CDC has previously issued technical guidance for security procedures and includes confidentiality and security safeguards as evaluation criteria for federal funding of state HIV/AIDS surveillance activities (39). The receipt of federal surveillance funding is dependent on the recipient's ability to ensure the physical security and confidentiality of case reports.

At the federal level, HIV/AIDS surveillance data are protected by (i) a limited right to informational privacy under the U.S. Constitution; (ii) federal statutes that protect the privacy of federal records, including the Privacy Act and exemptions to the Freedom of Information Act; and (iii) an assurance of confidentiality under Public Health law 308(d). Privacy is also ensured by the removal of names and the encryption of data transmitted to CDC, and by strict guidelines for the release of aggregate data.

HIV AND AIDS SURVEILLANCE GUIDELINES

HIV/AIDS Surveillance Case Definitions for Children and Adults

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CDC, in collaboration with CSTE, has established new HIV and AIDS case definitions that include revised surveillance criteria for HIV infection and that incorporate the surveillance criteria for AIDS (9,40) (Appendix). HIV and AIDS surveillance reports forwarded to CDC should be based on these surveillance criteria. The HIV and AIDS surveillance case definition for adults, adolescents, and children ≥ 18 months of age includes 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 by using recent data on the sensitivity and the specificity of HIV diagnostic tests, and in the recent clinical guidelines for *Pneumocystis carinii* pneumonia (PCP) prophylaxis for children (19,41-50). 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 will become effective the date of this publication.

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 (18,39).

Surveillance methods

- 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 (i) earliest date of diagnosis for HIV infection, (ii) earliest date of diagnosis

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of an AIDS-defining condition, (iii) demographic information (date of birth, race/ethnicity, sex) and residence (city, state) at diagnosis of HIV and AIDS, (iv) HIV risk exposure, (v) facility of diagnosis, and (vi) 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.

Depending on the availability of resources and local information needs, local surveillance programs may 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 for the enhanced planning and evaluation of prevention services and for referrals to health care services. Surveillance information, without patient identifiers, should be encrypted and forwarded to CDC through the HIV/AIDS Reporting System as is current practice.

- 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.
- The current AIDS surveillance infrastructure should be used for HIV case surveillance. 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

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the laboratory reporting criteria for HIV infection and AIDS. Reports from laboratories should be used by local programs to initiate the reporting process by health care providers and clinicians and to update records on previously reported cases. Statistics regarding persons who are tested anonymously should continue to be reported through the counseling and testing data collection system, but not through the HIV and AIDS case surveillance system. HIV-infected persons tested anonymously should be reported when they enter clinical care and have test results or clinical conditions that meet the HIV and AIDS reporting criteria.

- 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 meet the performance criteria typically used to evaluate public health information systems. HIV and AIDS surveillance systems should provide complete ($\geq 85\%$) and timely ($\geq 66\%$ of cases reported within 6 months of diagnosis) case reporting, with less than 5% duplicate case reporting; at least 85%, or a representative sample, of cases should have HIV risk information after epidemiologic follow-up is completed, and HIV and AIDS case data should be able to be linked with other data bases of public health importance such as tuberculosis and sexually transmitted disease surveillance systems. All HIV and AIDS surveillance systems should collect the recommended standard data in a reliable and valid manner, and to allow identification and follow-up of individual cases of public health importance. These designated performance criteria have been achieved

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by state and local AIDS surveillance programs evaluated by CDC (51-53). CDC recommends that state and local surveillance programs use the same name-based approach for HIV surveillance as is currently used for AIDS surveillance. Some states have adopted, and others may elect to adopt, non-name case identifiers for the public health reporting of HIV and AIDS. However, evaluations of HIV and AIDS surveillance systems suggest that name based surveillance systems are the most likely to meet the necessary performance criteria including the reliable collection of HIV risk data and other epidemiologic information. CDC will evaluate and award proposals for federal surveillance funding of state and local surveillance programs based on their capacity to meet these performance criteria.

- To assess the quality of HIV and AIDS case surveillance as specified in the performance criteria, states and local surveillance programs must conduct periodic evaluations that include the use of at least one appropriate population-based data source (e.g., Medicaid registries, outpatient clinic data) that is not used for routine case-finding. An evaluation must be conducted within 1 year after the implementation of HIV case surveillance. Programs should also review the extent to which surveillance data are being used for planning, targeting, and evaluating HIV prevention programs and services.
- 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 state and local public health agencies, academic institutions,

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providers and institutions that have reported cases, community-based organizations, HIV prevention community planning groups, and members of the general public. Local policies should preclude the release of data for statistical purposes that could directly or indirectly identify any persons reported with HIV or AIDS.

Security and confidentiality

The security and confidentiality policies and procedures of state and local surveillance programs should be consistent with CDC standards for surveillance programs. The required practices included in these standards must be met as a condition of federal HIV surveillance funding.

- CDC *requires* that state and local programs 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.
- CDC *requires* that data from the electronic HIV/AIDS Reporting system be protected by computer encryption before transfer. Laboratories and health care providers that forward electronic reports directly to the health department should also be asked to encrypt data before submission. 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 name-based HIV and AIDS surveillance records be protected by coded

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passwords to limit and control access, located in a physically secured area, and should be isolated from other components of the surveillance registry. For optimal security, name-based data should be maintained on a single electronic HIV and AIDS surveillance registry. In accordance with local laws, other files-- paper and electronic (except for a backup for the central system)-- that contain personal identifying information should be eliminated.

- 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 the access and use of surveillance data. Non-surveillance personnel should not have access to HIV and AIDS surveillance files.
- In accordance with local laws, data from HIV and AIDS surveillance records may be linked with data from other public health surveillance systems (e.g., TB) that have equivalent security and confidentiality protections and penalties for unauthorized disclosure as those for the HIV and AIDS surveillance data. Such linkages should share only the minimum amount of epidemiologic information necessary to accomplish a specific public health activity.

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- 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 analysis 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.
- State and local health departments should review their data retention policies. Local policies should provide the flexibility to remove cases that were reported in error, or that no longer meet the HIV reporting criteria. State and local programs may also consider removing the names from surveillance records that no longer serve a useful public health purpose (e.g., deceased persons) 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. Programs should demonstrate that the alternative methods of identifying these cases reliably identify duplicate case reports of the same individual.
- Breaches of confidential HIV/AIDS surveillance data are to be investigated thoroughly, sanctions imposed when appropriate, and reports of such incidents maintained. All breaches of confidentiality are to be reported to CDC immediately.

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- 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. Ideally, state and local confidentiality laws should include (i) the objectives of the collection of personal identifying information; (ii) the public health officials who have access to surveillance information and the justification for this access; (iii) the procedures including time frame for expunging personal identifiable information when no longer needed for the stated purpose; (iv) the safeguards against disclosing HIV and AIDS case surveillance data through subpoena or court order; and (v) the significant civil or criminal penalties for breaches of confidentiality. The confidentiality assurances should also follow the transmission of surveillance data, and penalties for violation of privacy and security should apply to all recipients of surveillance information. The use of personally identifiable information other than for legitimate public health purposes requires the person's informed consent.

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 law, 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 recommends that states prohibiting anonymous HIV testing reconsider this practice, given the overriding public health objective of encouraging knowledge of HIV serologic status.

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- All HIV testing services should continue to be voluntary and preceded by informed consent in accordance with local laws (54).
- All persons who are diagnosed with HIV infection should be referred to programs that provide HIV care, treatment, and comprehensive prevention case management services.
- The primary function of HIV and AIDS surveillance is the collection of accurate and timely epidemiologic data. State and local HIV and AIDS case surveillance programs are not required 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, HIV prevention programs may operate successfully without such linkages. CDC has previously recommended that interaction between clients and providers is the most effective approach to the timely delivery of prevention services and referrals. Areas that have elected to establish such linkages must require that recipients of surveillance information be subject to the same penalties for unauthorized disclosure as surveillance personnel. Prevention programs that use surveillance case data should evaluate the effectiveness of this public health approach, including acceptability to affected communities as reflected by the concurrence of community planning groups, and the program's policies and practices that protect against breaches of confidentiality. Data from individual HIV and AIDS case reports

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should not be shared with programs that do not have well defined public health objectives or with programs that cannot guarantee confidentiality.

COMMENTARY

HIV and AIDS Surveillance Case Definitions for HIV Infection And AIDS

The revised HIV and AIDS surveillance case definition integrates HIV and AIDS reporting criteria in a single case definition and incorporates new laboratory tests in the laboratory criteria for HIV case reporting. For adolescents and adults, the 1998 HIV and AIDS case definition includes viral detection tests that were not commercially available when the case definition was revised in 1993. The revised HIV case definition 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 the diagnosis for an individual patient. The laboratory criteria include the serologic HIV tests described in the clinical standards for HIV diagnosis (55). The other laboratory tests in the criteria (i.e., HIV culture, HIV nucleic acid assays) also provide results that if positive are highly indicative of HIV infection. These other tests may be used by clinicians to identify HIV infection in persons with recent risk exposures who have negative or indeterminate HIV serologic assay results. The HIV nucleic acid assays may also have an increasing role as a supplemental assay for the diagnosis of HIV infection (56).

The pediatric HIV reporting criteria include criteria for monitoring all children with perinatal risk exposures to HIV and reflect recent advances in diagnostic approaches that permit

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the diagnosis of HIV infection in the first months of life. With viral detection tests, HIV infection can be detected in nearly all infants 1 month of age or older. The timing of the HIV serologic and viral detection tests and the number of viral 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 (41-50).

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 AIDS-defining conditions. 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 immunosuppression and the opportunistic illnesses indicative of severe HIV disease. The development of AIDS-related opportunistic illnesses greatly increase mortality risks and almost all deaths among person with HIV infection are caused by AIDS-related opportunistic illnesses.(57)

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

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the implementation of the revised reporting criteria in 1993, the initiation of HIV surveillance by additional states will result in a sudden and large increase in HIV case reports (58). CDC has estimated that approximately 220,000 HIV-infected persons without AIDS-defining conditions have been tested confidentially and reside in states that do not currently conduct HIV case surveillance (59). According to this estimate, as many as 220,000 persons could be reported with HIV infection from these states in 1999. However, it is more likely that this increase will be spread over several years and that the annual increases will be more modest. Initially, most of these 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.

AIDS trends have declined nationally, and these declines are expected to continue. 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 estimate expected changes in AIDS trends. AIDS surveillance will continue to be important in evaluating access to care for different populations and 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 (60-62).

HIV and AIDS Surveillance Practices

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An integrated HIV and AIDS surveillance program promotes the greatest efficiency in surveillance practices. All areas of the country have AIDS surveillance programs, and these programs have established relationships with HIV laboratories and care providers. 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 data from laboratories and managed care organizations will increase the efficiency of local surveillance programs.

CDC has established performance criteria for HIV and AIDS surveillance 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 (51-53, 64). According to these evaluations, the completeness of HIV surveillance (79%-95%) and AIDS surveillance (85%-100%) is high; nearly one half of AIDS cases and three quarters of HIV cases are reported to the national HIV/AIDS reporting system within 3 months of diagnosis (5). In 1996, the duplication rate of HIV and AIDS cases reported from different states to the national surveillance data base, was less than 7% and 2%, respectively (5). 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 conducted to date of alternative case identifiers and the current infra-structure of state and local health departments, name-based methods for collecting

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and reporting public health data provide the most feasible means for ensuring timely, accurate, and complete HIV and AIDS case surveillance. Alternative methods are not currently available that perform at a level comparable to name-based surveillance systems. The CSTE, the Association of State and Territorial Health Officers, the National Alliance of State and Territorial AIDS Directors, and the CDC Advisory Committee for HIV and STD Prevention have all recommended name-based approaches to HIV case surveillance. States should continue the established practice of not including personal identifying information in the HIV and AIDS surveillance data forwarded to CDC.

Although no satisfactory UI currently known to CDC has sufficient performance characteristics to allow it to be recommended as a universal basis for HIV and AIDS surveillance, the adoption of a unique code system to identify patient records across all health care systems would increase the feasibility of this approach for public health surveillance. The Health Insurance Portability and Accountability Act mandates the universal use of a uniquely coded patient identifier system for medical records. A number of UIs have been proposed (65). The adoption of one of these proposed unique identifiers would likely result in a change in the traditional name-based record keeping of providers. If such identifiers were adopted, surveillance methods may need to be revised to reflect a change in health information practices.

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. Many state statutes that mandate the reporting and collection of public health data relating to communicable diseases and other

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reportable conditions typically specify measures to prevent unauthorized access to information and the criteria for the disclosure and use of the information. Although state confidentiality laws and regulations adequately protect privacy compared with the statutory protections of 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 for a variety of purposes. To help ensure uniform confidentiality protections, CDC, CSTE, ASTHO, the National Association 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 should be completed by the end of 1998.

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 surveillance alone. National HIV case surveillance will result in more persons being reported than are reported in AIDS surveillance, and such persons will be reported at an earlier stage of HIV infection. The revised security requirements are based on a CDC review of the security practices of most 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 is evaluating revisions to the current HIV/AIDS reporting system to

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preclude the need for multiple name-based surveillance registries at the state and local level.

Based on this evaluation, CDC will provide technical guidance and available resources to facilitate the use of this approach by project areas.

HIV Prevention and Care

Although HIV surveillance is an essential public health activity, HIV surveillance does not take precedence over the established and recommended prevention approaches that promote HIV counseling and testing services and knowledge of HIV infection status. Efforts to facilitate HIV counseling and testing are major components of prevention programs. CDC has published guidelines for targeting HIV counseling and testing services for several populations to whom HIV counseling and testing should be routinely offered (e.g., pregnant women and newborns, persons who have other sexually transmitted diseases, and persons seeking general medical care in areas of high HIV prevalence (17, 26,66-68). CDC also provides support for most public sources of HIV testing services and also sponsors community-based campaigns to encourage persons to seek HIV counseling and 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 and an increase in HIV-infected persons seeking testing services (69-71). In a CDC- sponsored survey of 2,370 high- risk persons, most persons (61%) correctly identified whether anonymous HIV testing services were available in their area and also reported an increased likelihood of seeking HIV testing in the future if anonymous HIV

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testing services were available (33). Anonymous HIV testing services are a required element of federally supported prevention programs unless prohibited by state law or regulation. Currently, 40 states, Puerto Rico, and the District of Columbia provide anonymous HIV testing services.

Because anonymous HIV test results are not captured by the surveillance system, anonymous HIV testing services will affect the completeness of reporting of persons diagnosed with HIV infection. To facilitate the interpretation of HIV surveillance data, 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 enter clinical care for their infection. These evaluations will be useful to determine the quality of HIV surveillance data as well as to determine the effectiveness of program efforts to refer persons into care services after any diagnosis of HIV infection. Persons whose HIV infection was diagnosed at either confidential or anonymous test sites should be promptly referred to facilities that provide confidential HIV care for a medical evaluation that includes CD4+ and viral load testing as well as appropriate antiretroviral therapy and antimicrobial prophylaxis if indicated.

The use of individual HIV surveillance case reports for public health programs such as partner notification is controversial. Communities may have particular concerns about programs based on HIV and AIDS surveillance reports that do not have well defined goals to benefit individual or public health and that use methods lacking stringent security and confidentiality procedures. 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 (72,73). States are required to develop

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standards and implement procedures for HIV prevention partner notification. States are also required to demonstrate a good faith effort to notify spouses of HIV-infected persons and to refer them for testing and prevention services. 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. CDC considers that the decision about linkage between surveillance systems and prevention and care management services should be made at the local level; if established such linkages should not compromise the quality or security of the surveillance system nor compromise the quality, confidentiality, and voluntary nature of HIV prevention services.

Although CDC is not directly responsible for the delivery of medical care for persons with HIV infection and AIDS-defining conditions, 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 Services Administration (HRSA) and the Ryan White CARE Act grantees. CDC has also undertaken a project to develop model contract language for Medicaid programs for people with HIV.

CONCLUSION

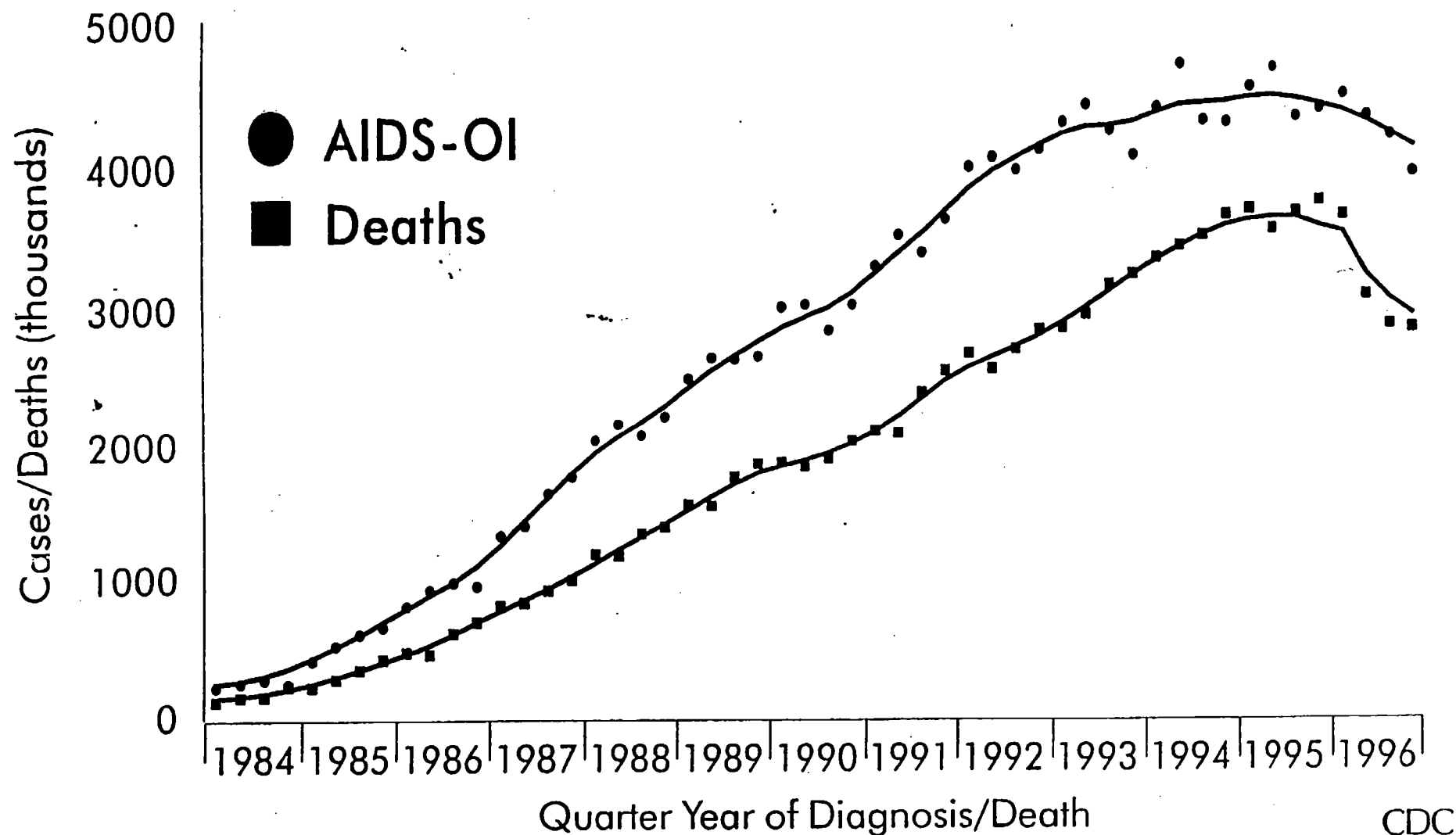
The HIV and AIDS surveillance network is the national system for monitoring HIV and AIDS trends in all communities throughout the United States. An expansion of this national surveillance network to include both HIV and AIDS surveillance in all areas of the country is a

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necessary response to new standards for HIV evaluation and care and will more accurately represent all persons infected with HIV. 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 dying with HIV and AIDS. The revised HIV surveillance case definitions and the establishment of performance criteria will promote uniform case ascertainment and will assure that the surveillance data are of sufficient quality for the planning and the allocation of resources for prevention and care programs. The successful implementation of HIV and AIDS surveillance will require that state and local areas further assure the security and confidentiality of surveillance data through enhancements to data systems and confidentiality policies, training and management of public health personnel, and by use of the community planning process to determine the appropriate use of surveillance data by prevention and care programs.

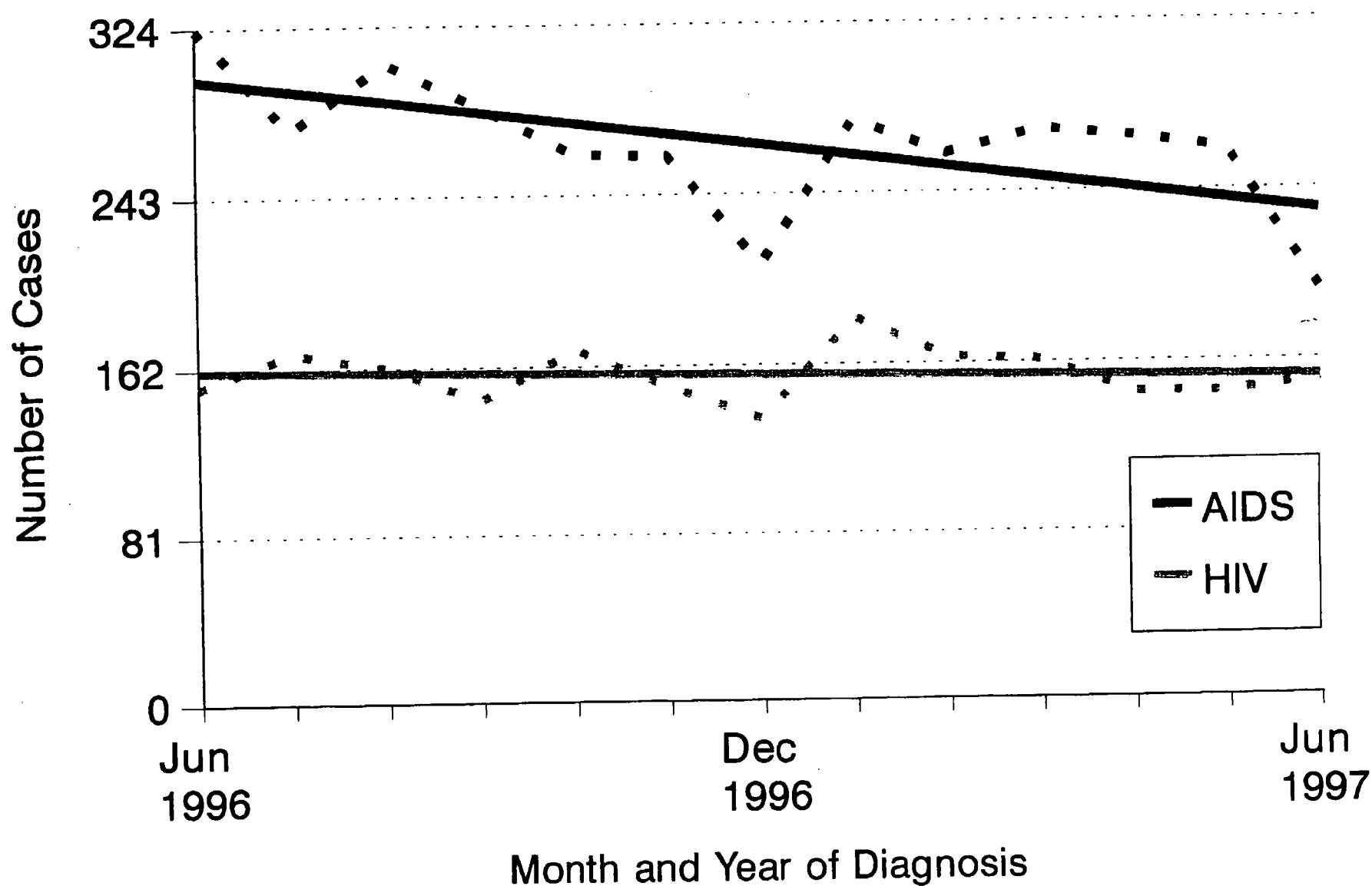
Estimated AIDS-OI Incidence and Estimated AIDS Deaths Among Men who have Sex with Men, U. S., 1984-1996



Kevin DeCock, 12/97 97-647 kdpacha1.cdr cwk

CDC

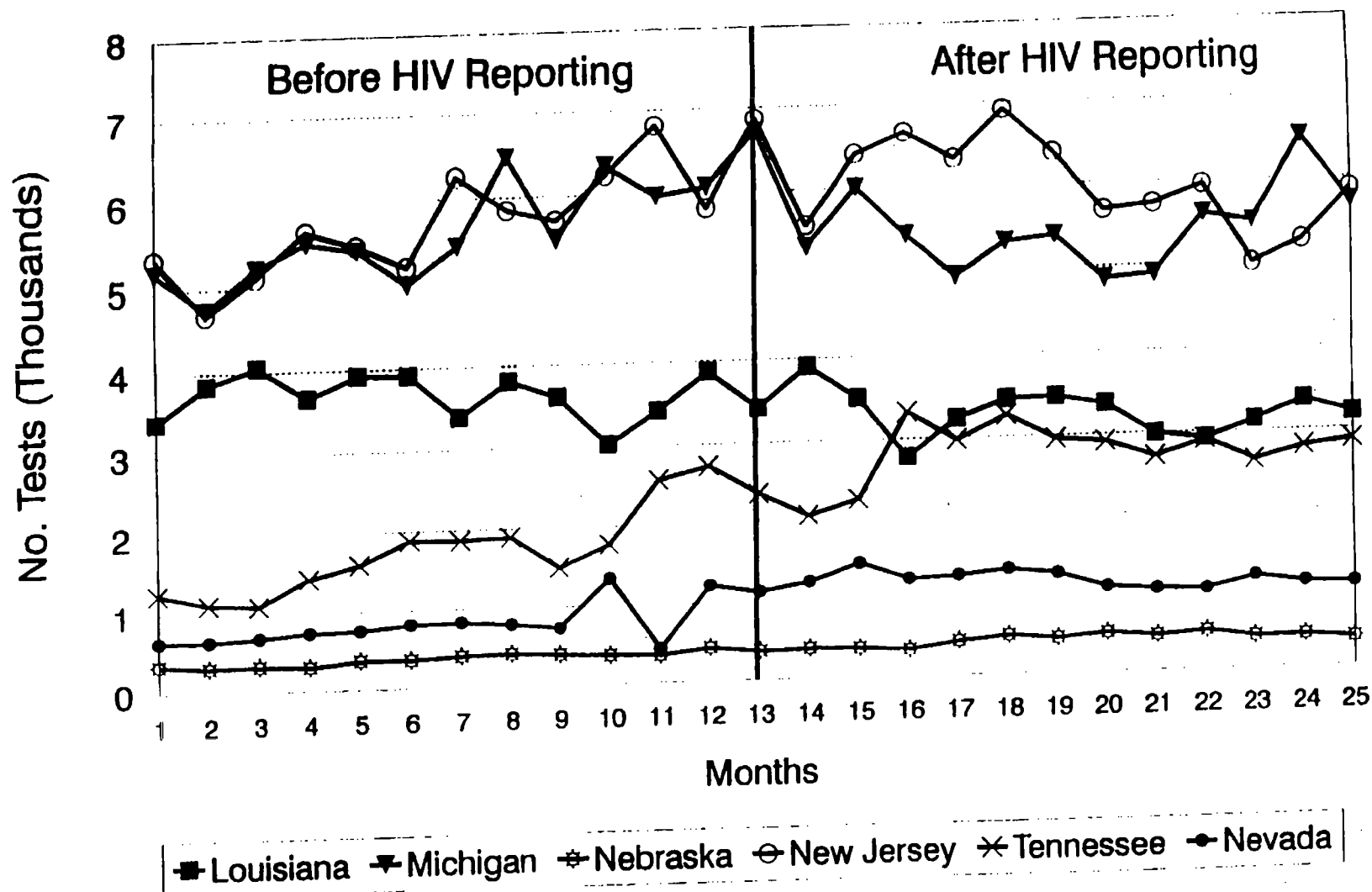
Number of HIV and AIDS Cases* Diagnosed Among White MSM in 25 HIV Reporting States, by Month, June 1996 to June 1997



*HIV and AIDS cases adjusted for reporting delays.

Number of HIV Tests Performed in Publicly-Funded HIV Counseling and Testing Sites 12 Months Before and After HIV Name Reporting Laws Were Implemented*

Figure 3



*Name Reporting Began: LA (Feb '93), MI (Apr '92), NE (Sep '95), NJ (Jan '92), TN (Jan '92), NV (Feb '92)

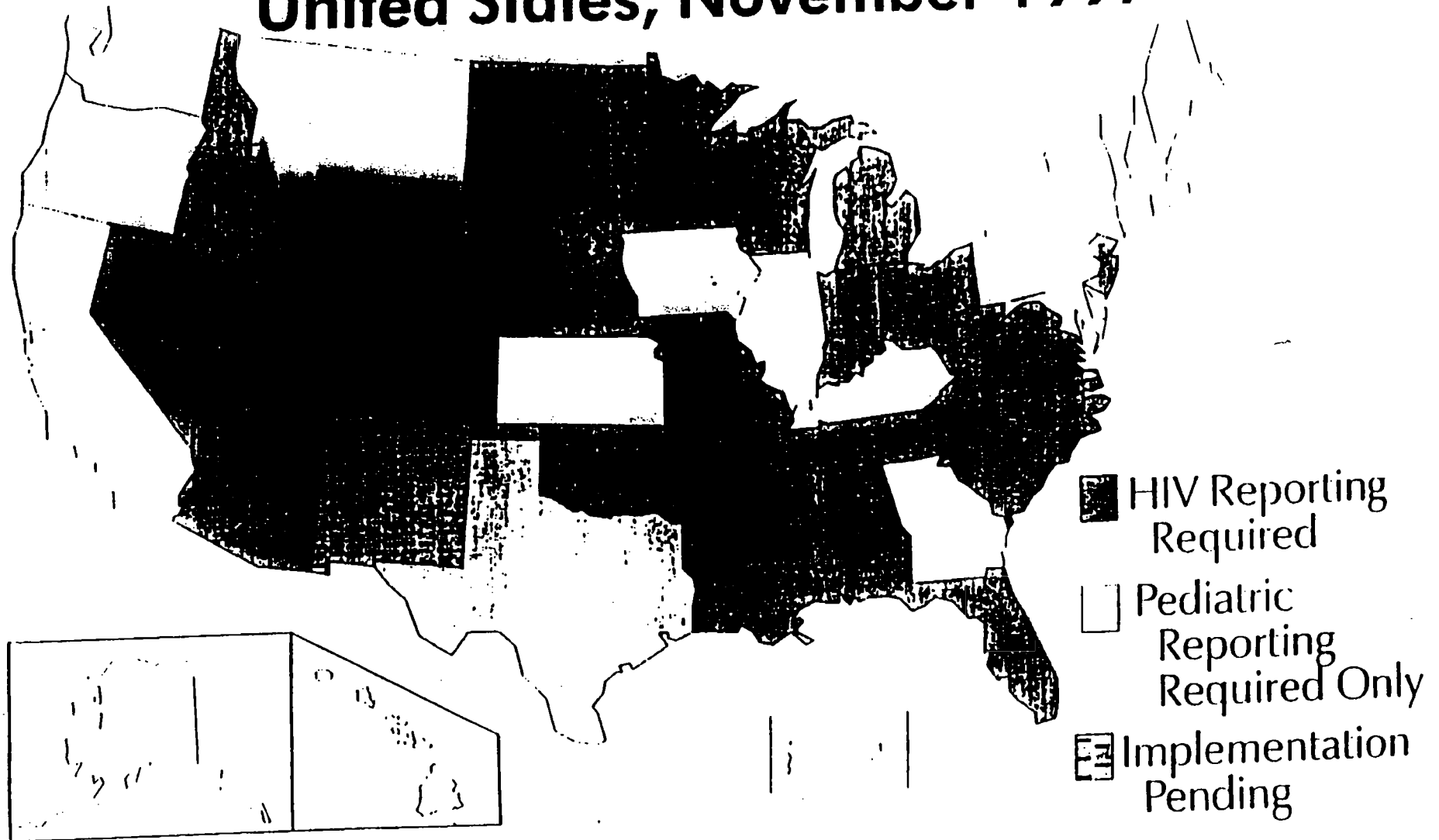
HIV and AIDS Among Persons in Care January 1996 through October 1997

Table 1

	HIV (not AIDS) N=22,358 %	AIDS N=28,185 %
Female	30	21
Black, Non-Hispanic	55	50
White, Non-Hispanic	35	41
Hispanic	7	8
Age		
13-24	17	4
25-34	41	36
35-44	30	40
45+	12	20

* Reported from 26 states with HIV case surveillance

States with Confidential HIV Case Surveillance United States, November 1997



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Draft Surveillance Case Definition for HIV infection (including AIDS)

Appendix

This definition of HIV infection, which applies to any type of HIV (e.g., HIV-1, HIV-2), is intended for public health surveillance only. It is not presented as a guide to clinical diagnosis or for other uses (1,2).

- I. In adults, adolescents, or 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 (repeatedly reactive enzyme immunoassay) followed by a positive result on a confirmatory (sensitive and more specific) test for HIV antibody (Western blot or immunofluorescence antibody test)
- Positive result on any of the following HIV detection (non-antibody) tests:
 - HIV nucleic acid (RNA or DNA) detection (e.g., by PCR, nucleic acid sequence-based amplification, or branched DNA assay, including viral load determination)
 - p24 antigen test
 - Virus isolation (culture)

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Clinical Criteria (if the above criteria are not met)

- Diagnosis of HIV infection documented in a medical record by a physician
- Conditions included in the case definition for AIDS (3,4),

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

Laboratory Criteria

Definitive

- Positive results on two separate determinations (excluding cord blood) from one or more of the following HIV virologic tests:
 - Detection of HIV nucleic acid (RNA or DNA) (e.g., by DNA polymerase chain reaction [PCR], reverse transcriptase (RT) - PCR, RNA amplification, nucleic acid signal amplification
 - HIV virus isolation (culture)
 - HIV p24 antigen

Presumptive

- Positive results on only one (excluding cord blood) of the definitive HIV detection tests **AND** has NO subsequent negative detection* or HIV antibody tests;

Clinical Criteria

- Diagnosis of HIV infection documented in a medical record by a physician

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- Conditions included in the 1987 pediatric surveillance case definition for AIDS
(1, 2)

III. A child <18 months of age born to an HIV-infected mother will be categorized for surveillance as not infected with HIV according to the following criteria

Laboratory Criteria

Definitive

- Documented evidence of negative HIV-antibody test results (i.e., two or more negative EIA tests performed on separate specimens at or after 6 months of age)
- At least two negative HIV virologic test results (specifically, HIV culture or detection of DNA PCR *), both of which were drawn at ≥ 1 month of age and one of which was drawn at ≥ 4 months of age

AND

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

Presumptive

- One negative result from an EIA performed at ≥ 6 months of age
- OR**

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- One negative HIV virologic test result (specifically HIV culture or DNA PCR *) performed at ≥ 4 months of age
- OR**
- One positive HIV virologic test result with at least two later negative test results (i.e., specifically, culture or DNA PCR*), at least one of which is after 4 months of age; or negative EIA antibody test results, at least one of which is at ≥ 6 months of age

Clinical Criteria

- Determined by a physician to be uninfected 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 test results, if tests were 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 the absence of HIV infection (III).

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*A positive HIV RNA PCR in plasma can be used to define HIV infection. A negative HIV RNA assay will not be used to rule out HIV infection in an infant at this time. Similarly, standard and immune-complex dissociated p24 antigen tests are very specific for HIV infection. However, the sensitivity is less than other virologic tests and, therefore, will not be used to exclude HIV infection.

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1

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

CDC recommends that all states and territories conduct case surveillance for human immunodeficiency virus (HIV) infection as an extension of their acquired immunodeficiency syndrome (AIDS) surveillance activities. The expansion of national surveillance to include both HIV infection case surveillance and AIDS surveillance is a necessary response to the 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. This report includes revised case definitions for HIV infection in adults and children less than 18 months of age and recommended practices for the extension of AIDS case surveillance to incorporate reporting of non-AIDS defining HIV infection. The revised surveillance case definitions and the associated recommendations become effective the date of this publication.

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 services. Although AIDS is the end-stage of the natural history of HIV infection, monitoring AIDS-defining conditions provided population-based data that reflected the 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. The effect of these

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advances in treatment has diminished the capacity of national, state, and local public health agencies to monitor the HIV epidemic (1-3). In response to these changes, CDC and the Council of State and Territorial Epidemiologists (CSTE) have recommended that all states and territories conduct HIV case surveillance as an extension of AIDS surveillance activities (4).

This document provides the revised case definitions for HIV infection in adults and children less than 18 months of age and includes the current AIDS reporting criteria, performance guidelines for HIV and AIDS case surveillance systems, and recommended practices for state and local health departments to provide standardized and confidential HIV and AIDS surveillance data. The recommended practices are based on CDC evaluation studies, a review of state and local confidentiality statutes and security procedures, and a consultation held by CDC and CSTE in May 1997. A draft of this document was made available for public comment in March 1998.

BACKGROUND

History of HIV and AIDS Surveillance

Since 1981, population-based AIDS surveillance 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 (5-8). The AIDS reporting criteria have been periodically revised to incorporate new understanding of HIV disease and changes in medical practice, allowing maximal ascertainment of persons with the severe immunosuppression, opportunistic infections, and cancers indicative of severe HIV disease (9-11). Although the time for the natural progression from HIV infection to AIDS is an

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average of 8-10 years, 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 (12-13). 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 an 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 (14-15). 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, 2). Revised HIV treatment guidelines recommend antiretroviral therapy for many HIV-infected persons in whom AIDS-defining conditions have not yet developed and public health programs should provide prevention services and referrals to medical care for all persons at early stages of HIV infection (16, 17).

In response to these changes in HIV treatment practices and the information needs of public health programs, CDC and CSTE have recommended that all states and territories implement HIV case surveillance as an extension of AIDS surveillance (1,4). HIV and AIDS surveillance programs are recommended to provide rates of newly diagnosed HIV infection, HIV prevalence, AIDS incidence, HIV-related mortality data, and the associated risk and demographic characteristics (4).

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Current Status of HIV Surveillance

As of January 1, 1998, 31 states had implemented HIV surveillance as an extension of AIDS case surveillance; 3 of these states conduct pediatric surveillance only (5) (map). These states use the same reporting system for both HIV and AIDS cases. The 28 states that conduct HIV surveillance for adults and adolescents report only about one third of total U.S. AIDS cases. In 1989, CDC initiated technical assistance for HIV surveillance to standardize state reporting practices and data collection methods (18). In 1993, CDC revised the HIV surveillance criteria for adolescents and adults; HIV surveillance criteria for children were revised in 1994 (9,19).

In contrast to AIDS surveillance and to other approaches such as clinic-based anonymous serologic surveys, HIV case surveillance provides community-based data to characterize persons newly diagnosed with HIV, particularly those with evidence of recent HIV infection such as adolescents and young adults (20-24). Of the 22,358 HIV infections reported from January 1996 through October 1997 in 26 states with HIV surveillance, 17% were in persons 13-24 years of age compared with only 4% of 28,185 persons reported with AIDS in the same areas. Compared with persons reported with AIDS, those reported with HIV infection in these areas were more likely to be women and from racial/ethnic minorities, reflecting more recent patterns of HIV transmission (24) (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% while the number of new HIV diagnoses among this population remained unchanged (Figure 2). Through October 1997, 139,492 persons were reported living with HIV in these 26 states; 140% more than the number of persons reported with AIDS (24).

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States have used HIV and AIDS surveillance data to better direct and evaluate HIV prevention and care services. For example, New Jersey included HIV surveillance data in economic models to evaluate proposed expansions to the AIDS Drug Distribution Program (ADDP) and through this data-driven process accurately estimated that new HIV therapies could be added to the formulary without a change in patient eligibility criteria (New Jersey, unpublished data). A review of HIV surveillance data by prevention planners in Bridgeton, New Jersey found that 39% of cases were 20-29 years and 43% were women. Based on the HIV surveillance data, this community started a targeted prevention program for younger women and youth (Douglas Morgan, personal communication). As additional examples, Minnesota has used HIV data to develop and target new programs for youth and Michigan has used the data to evaluate the geographic distribution of HIV prevention funds.

To evaluate efforts to prevent perinatal transmission of HIV, the 31 states with HIV and AIDS surveillance have been able to show most clearly the sharp decline in perinatally acquired HIV infection (22,23). Most of the 31 states with pediatric HIV surveillance report all perinatally exposed children and conduct public health follow-up to monitor the proportion of exposed children who become infected. The United States Public Health Service has issued guidelines to reduce the risk of perinatal HIV transmission (25, 26). States have used HIV surveillance data to monitor the implementation of these guidelines and have documented increases in the proportion of infected pregnant women who have been tested for HIV before delivery and that a high proportion of HIV-infected pregnant women accept zidovudine therapy (21-23). To evaluate perinatal prevention efforts nationwide, CSTE and the American Academy of Pediatrics have recommended that all states and territories conduct pediatric HIV surveillance

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that includes all perinatally-exposed infants (27).

HIV case surveillance has not been universally adopted in part because of public health and community concerns regarding name-based approaches to HIV surveillance. AIDS surveillance nationally and HIV surveillance in 31 states is conducted using the name-based methods for case ascertainment that are used by other public health information systems. A name-based approach is used to allow providers to report cases directly from their name-based medical records and to facilitate the elimination of duplicate case reports of the same person from surveillance registries. Local public health authorities also routinely use name-based records to link HIV and AIDS surveillance data with data from other public health systems (e.g., tuberculosis surveillance) and to follow-up with providers and collect HIV risk information and other data of public health importance. Through follow-up with providers, the AIDS surveillance system has been used to identify rare or unusual modes of HIV transmission, infection with rare strains of HIV, and to characterize persons diagnosed with preventable AIDS-related opportunistic illnesses (28-32).

Evaluations to Address Community Issues Regarding HIV Surveillance

In 1993, CDC held a meeting of public health and community consultants to discuss community issues regarding HIV surveillance. Community consultants were particularly concerned 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. To address these issues, CDC initiated projects to assess the effect of name-based HIV surveillance on persons' willingness to seek HIV testing, alternatives to name-based surveillance systems, and

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the security and confidentiality of state and local surveillance programs.

HIV surveillance and testing behavior

CDC supported the University of California at San Francisco and nine state health departments to survey high-risk persons about their perceptions and knowledge of HIV testing and HIV reporting practices; five of the nine states conducted name-based HIV surveillance (33,34). The survey, conducted in 1996, included 2,370 homosexual or bisexual men, injecting drug users, and heterosexual men and women seeking treatment for other sexually transmitted diseases. In this survey, only 15% of the respondents knew whether HIV infection was reportable to the health department in their state of residence. When asked about factors that may have delayed their seeking HIV testing, 18% of the high-risk persons surveyed included "reporting to the government" as one of the concerns that may have delayed their seeking HIV testing. However, only 2% of the respondents surveyed cited "reporting to the government" as the main reason they delayed seeking HIV testing.

CDC and six health departments reviewed data routinely collected from public-funded HIV counseling and testing sites to compare HIV testing patterns in the 12 months before and the 12 months after the implementation of HIV case surveillance (35). In these areas, the number of HIV tests increased in three states (16-63%), remained level in two states (-2%, 5%), and decreased in one state (-11%) (Figure 3). The state with a decline in HIV testing during the evaluation period had a decreasing trend in HIV tests before HIV surveillance was implemented.

HIV surveillance based on non-named unique identifiers

To assess the feasibility of using alternatives to name-based methods for HIV surveillance, CDC supported evaluations in two states that implemented an HIV case

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surveillance system based on a coded unique identifier (UI) rather than the name-based methods used by their AIDS surveillance systems (36). These states independently chose a UI based on data elements from the Social Security number and additional numbers representing demographic information. The evaluations conducted by these states indicated that their UI-based HIV surveillance systems were limited by the ability of providers to forward UI-based reports and by the proportion of persons with HIV infection reported without a Social Security number. These limitations affected the quality of HIV surveillance data by lowering the completeness of case reporting and by precluding the reliable removal of duplicate case reports from the surveillance systems. The UI-based HIV data could not be linked to other public health data such as tuberculosis surveillance and also did not include HIV risk information. HIV risk information is typically not available in laboratory records, a major source of HIV case reports, and may not be included in initial reports from other health care facilities. Public health follow-up with providers is often necessary to collect this information. For the follow-up of cases reported in a UI-based surveillance system, providers must maintain logs or other forms of documentation linking the UI to the name-based medical records. This process complicates efforts to collect reliable and complete HIV risk and other public health information and increases the number of lists of HIV-infected persons at risks in a breach of confidentiality.

Confidentiality of HIV surveillance data

In 1994, CDC and CSTE also sponsored a review of state confidentiality laws that protect HIV surveillance data (37). All states and many localities have legal safeguards of confidentiality of governmentally maintained health data, and these laws were found to provide greater protection than laws that protect the confidentiality of health information held by private

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health care providers in clinical records. State and local governments use a variety of legal protections of the health data collected by their agencies. Most states have specific statutory protections for the collection, use, and disclosure of data related to HIV and other sexually transmitted diseases. In 1998, CDC initiated a collaborative project to promote strong and uniform legal protections of confidentiality at the state and local level through the development of model confidentiality language for state and local legislation.

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 (38). CDC has previously issued technical guidance for security procedures and includes confidentiality and security safeguards as evaluation criteria for federal funding of state HIV/AIDS surveillance activities (39). The receipt of federal surveillance funding is dependent on the recipient's ability to ensure the physical security and confidentiality of case reports.

At the federal level, HIV/AIDS surveillance data are protected by (i) a limited right to informational privacy under the U.S. Constitution; (ii) federal statutes that protect the privacy of federal records, including the Privacy Act and exemptions to the Freedom of Information Act; and (iii) an assurance of confidentiality under Public Health law 308(d). Privacy is also ensured by the removal of names and the encryption of data transmitted to CDC, and by strict guidelines for the release of aggregate data.

HIV AND AIDS SURVEILLANCE GUIDELINES

HIV/AIDS Surveillance Case Definitions for Children and Adults

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CDC, in collaboration with CSTE, has established new HIV and AIDS case definitions that include revised surveillance criteria for HIV infection and that incorporate the surveillance criteria for AIDS (9,40) (Appendix). HIV and AIDS surveillance reports forwarded to CDC should be based on these surveillance criteria. The HIV and AIDS surveillance case definition for adults, adolescents, and children ≥ 18 months of age includes 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 by using recent data on the sensitivity and the specificity of HIV diagnostic tests, and in the recent clinical guidelines for *Pneumocystis carinii* pneumonia (PCP) prophylaxis for children (19,41-50). 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 will become effective the date of this publication.

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 (18,39).

Surveillance methods

- 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 (i) earliest date of diagnosis for HIV infection, (ii) earliest date of diagnosis

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of an AIDS-defining condition, (iii) demographic information (date of birth, race/ethnicity, sex) and residence (city, state) at diagnosis of HIV and AIDS, (iv) HIV risk exposure, (v) facility of diagnosis, and (vi) 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.

Depending on the availability of resources and local information needs, local surveillance programs may 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 for the enhanced planning and evaluation of prevention services and for referrals to health care services. Surveillance information, without patient identifiers, should be encrypted and forwarded to CDC through the HIV/AIDS Reporting System as is current practice.

- 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.
- The current AIDS surveillance infrastructure should be used for HIV case surveillance. 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

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the laboratory reporting criteria for HIV infection and AIDS. Reports from laboratories should be used by local programs to initiate the reporting process by health care providers and clinicians and to update records on previously reported cases. Statistics regarding persons who are tested anonymously should continue to be reported through the counseling and testing data collection system, but not through the HIV and AIDS case surveillance system. HIV-infected persons tested anonymously should be reported when they enter clinical care and have test results or clinical conditions that meet the HIV and AIDS reporting criteria.

- 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 meet the performance criteria typically used to evaluate public health information systems. HIV and AIDS surveillance systems should provide complete ($\geq 85\%$) and timely ($\geq 66\%$ of cases reported within 6 months of diagnosis) case reporting, with less than 5% duplicate case reporting; at least 85%, or a representative sample, of cases should have HIV risk information after epidemiologic follow-up is completed, and HIV and AIDS case data should be able to be linked with other data bases of public health importance such as tuberculosis and sexually transmitted disease surveillance systems. All HIV and AIDS surveillance systems should collect the recommended standard data in a reliable and valid manner, and to allow identification and follow-up of individual cases of public health importance. These designated performance criteria have been achieved

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by state and local AIDS surveillance programs evaluated by CDC (51-53). CDC recommends that state and local surveillance programs use the same name-based approach for HIV surveillance as is currently used for AIDS surveillance. Some states have adopted, and others may elect to adopt, non-name case identifiers for the public health reporting of HIV and AIDS. However, evaluations of HIV and AIDS surveillance systems suggest that name based surveillance systems are the most likely to meet the necessary performance criteria including the reliable collection of HIV risk data and other epidemiologic information. CDC will evaluate and award proposals for federal surveillance funding of state and local surveillance programs based on their capacity to meet these performance criteria.

- To assess the quality of HIV and AIDS case surveillance as specified in the performance criteria, states and local surveillance programs must conduct periodic evaluations that include the use of at least one appropriate population-based data source (e.g., Medicaid registries, outpatient clinic data) that is not used for routine case-finding. An evaluation must be conducted within 1 year after the implementation of HIV case surveillance. Programs should also review the extent to which surveillance data are being used for planning, targeting, and evaluating HIV prevention programs and services.
- 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 state and local public health agencies, academic institutions,

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providers and institutions that have reported cases, community-based organizations, HIV prevention community planning groups, and members of the general public. Local policies should preclude the release of data for statistical purposes that could directly or indirectly identify any persons reported with HIV or AIDS.

Security and confidentiality

The security and confidentiality policies and procedures of state and local surveillance programs should be consistent with CDC standards for surveillance programs. The required practices included in these standards must be met as a condition of federal HIV surveillance funding.

- CDC *requires* that state and local programs 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.
- CDC *requires* that data from the electronic HIV/AIDS Reporting system be protected by computer encryption before transfer. Laboratories and health care providers that forward electronic reports directly to the health department should also be asked to encrypt data before submission. 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 name-based HIV and AIDS surveillance records be protected by coded

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passwords to limit and control access, located in a physically secured area, and should be isolated from other components of the surveillance registry. For optimal security, name-based data should be maintained on a single electronic HIV and AIDS surveillance registry. In accordance with local laws, other files-- paper and electronic (except for a backup for the central system)-- that contain personal identifying information should be eliminated.

- 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 the access and use of surveillance data. Non-surveillance personnel should not have access to HIV and AIDS surveillance files.
- In accordance with local laws, data from HIV and AIDS surveillance records may be linked with data from other public health surveillance systems (e.g., TB) that have equivalent security and confidentiality protections and penalties for unauthorized disclosure as those for the HIV and AIDS surveillance data. Such linkages should share only the minimum amount of epidemiologic information necessary to accomplish a specific public health activity.

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- 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 analysis 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.
- State and local health departments should review their data retention policies. Local policies should provide the flexibility to remove cases that were reported in error, or that no longer meet the HIV reporting criteria. State and local programs may also consider removing the names from surveillance records that no longer serve a useful public health purpose (e.g., deceased persons) 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. Programs should demonstrate that the alternative methods of identifying these cases reliably identify duplicate case reports of the same individual.
- Breaches of confidential HIV/AIDS surveillance data are to be investigated thoroughly, sanctions imposed when appropriate, and reports of such incidents maintained. All breaches of confidentiality are to be reported to CDC immediately.

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- 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. Ideally, state and local confidentiality laws should include (i) the objectives of the collection of personal identifying information; (ii) the public health officials who have access to surveillance information and the justification for this access; (iii) the procedures including time frame for expunging personal identifiable information when no longer needed for the stated purpose; (iv) the safeguards against disclosing HIV and AIDS case surveillance data through subpoena or court order; and (v) the significant civil or criminal penalties for breaches of confidentiality. The confidentiality assurances should also follow the transmission of surveillance data, and penalties for violation of privacy and security should apply to all recipients of surveillance information. The use of personally identifiable information other than for legitimate public health purposes requires the person's informed consent.

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 law, 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 recommends that states prohibiting anonymous HIV testing reconsider this practice, given the overriding public health objective of encouraging knowledge of HIV serologic status.

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- All HIV testing services should continue to be voluntary and preceded by informed consent in accordance with local laws (54).
- All persons who are diagnosed with HIV infection should be referred to programs that provide HIV care, treatment, and comprehensive prevention case management services.
- The primary function of HIV and AIDS surveillance is the collection of accurate and timely epidemiologic data. State and local HIV and AIDS case surveillance programs are not required 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, HIV prevention programs may operate successfully without such linkages. CDC has previously recommended that interaction between clients and providers is the most effective approach to the timely delivery of prevention services and referrals. Areas that have elected to establish such linkages must require that recipients of surveillance information be subject to the same penalties for unauthorized disclosure as surveillance personnel. Prevention programs that use surveillance case data should evaluate the effectiveness of this public health approach, including acceptability to affected communities as reflected by the concurrence of community planning groups, and the program's policies and practices that protect against breaches of confidentiality. Data from individual HIV and AIDS case reports

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should not be shared with programs that do not have well defined public health objectives or with programs that cannot guarantee confidentiality.

COMMENTARY

HIV and AIDS Surveillance Case Definitions for HIV Infection And AIDS

The revised HIV and AIDS surveillance case definition integrates HIV and AIDS reporting criteria in a single case definition and incorporates new laboratory tests in the laboratory criteria for HIV case reporting. For adolescents and adults, the 1998 HIV and AIDS case definition includes viral detection tests that were not commercially available when the case definition was revised in 1993. The revised HIV case definition 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 the diagnosis for an individual patient. The laboratory criteria include the serologic HIV tests described in the clinical standards for HIV diagnosis (55). The other laboratory tests in the criteria (i.e., HIV culture, HIV nucleic acid assays) also provide results that if positive are highly indicative of HIV infection. These other tests may be used by clinicians to identify HIV infection in persons with recent risk exposures who have negative or indeterminate HIV serologic assay results. The HIV nucleic acid assays may also have an increasing role as a supplemental assay for the diagnosis of HIV infection (56).

The pediatric HIV reporting criteria include criteria for monitoring all children with perinatal risk exposures to HIV and reflect recent advances in diagnostic approaches that permit

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the diagnosis of HIV infection in the first months of life. With viral detection tests, HIV infection can be detected in nearly all infants 1 month of age or older. The timing of the HIV serologic and viral detection tests and the number of viral 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 (41-50).

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 AIDS-defining conditions. 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 immunosuppression and the opportunistic illnesses indicative of severe HIV disease. The development of AIDS-related opportunistic illnesses greatly increase mortality risks and almost all deaths among person with HIV infection are caused by AIDS-related opportunistic illnesses.(57)

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

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the implementation of the revised reporting criteria in 1993, the initiation of HIV surveillance by additional states will result in a sudden and large increase in HIV case reports (58). CDC has estimated that approximately 220,000 HIV-infected persons without AIDS-defining conditions have been tested confidentially and reside in states that do not currently conduct HIV case surveillance (59). According to this estimate, as many as 220,000 persons could be reported with HIV infection from these states in 1999. However, it is more likely that this increase will be spread over several years and that the annual increases will be more modest. Initially, most of these 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.

AIDS trends have declined nationally, and these declines are expected to continue. 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 estimate expected changes in AIDS trends. AIDS surveillance will continue to be important in evaluating access to care for different populations and 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 (60-62).

HIV and AIDS Surveillance Practices

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An integrated HIV and AIDS surveillance program promotes the greatest efficiency in surveillance practices. All areas of the country have AIDS surveillance programs, and these programs have established relationships with HIV laboratories and care providers. 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 data from laboratories and managed care organizations will increase the efficiency of local surveillance programs.

CDC has established performance criteria for HIV and AIDS surveillance 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 (51-53, 64). According to these evaluations, the completeness of HIV surveillance (79%-95%) and AIDS surveillance (85%-100%) is high; nearly one half of AIDS cases and three quarters of HIV cases are reported to the national HIV/AIDS reporting system within 3 months of diagnosis (5). In 1996, the duplication rate of HIV and AIDS cases reported from different states to the national surveillance data base, was less than 7% and 2%, respectively (5). 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 conducted to date of alternative case identifiers and the current infra-structure of state and local health departments, name-based methods for collecting

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and reporting public health data provide the most feasible means for ensuring timely, accurate, and complete HIV and AIDS case surveillance. Alternative methods are not currently available that perform at a level comparable to name-based surveillance systems. The CSTE, the Association of State and Territorial Health Officers, the National Alliance of State and Territorial AIDS Directors, and the CDC Advisory Committee for HIV and STD Prevention have all recommended name-based approaches to HIV case surveillance. States should continue the established practice of not including personal identifying information in the HIV and AIDS surveillance data forwarded to CDC.

Although no satisfactory UI currently known to CDC has sufficient performance characteristics to allow it to be recommended as a universal basis for HIV and AIDS surveillance, the adoption of a unique code system to identify patient records across all health care systems would increase the feasibility of this approach for public health surveillance. The Health Insurance Portability and Accountability Act mandates the universal use of a uniquely coded patient identifier system for medical records. A number of UIs have been proposed (65). The adoption of one of these proposed unique identifiers would likely result in a change in the traditional name-based record keeping of providers. If such identifiers were adopted, surveillance methods may need to be revised to reflect a change in health information practices.

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. Many state statutes that mandate the reporting and collection of public health data relating to communicable diseases and other

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reportable conditions typically specify measures to prevent unauthorized access to information and the criteria for the disclosure and use of the information. Although state confidentiality laws and regulations adequately protect privacy compared with the statutory protections of 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 for a variety of purposes. To help ensure uniform confidentiality protections, CDC, CSTE, ASTHO, the National Association 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 should be completed by the end of 1998.

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 surveillance alone. National HIV case surveillance will result in more persons being reported than are reported in AIDS surveillance, and such persons will be reported at an earlier stage of HIV infection. The revised security requirements are based on a CDC review of the security practices of most 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 is evaluating revisions to the current HIV/AIDS reporting system to

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preclude the need for multiple name-based surveillance registries at the state and local level. Based on this evaluation, CDC will provide technical guidance and available resources to facilitate the use of this approach by project areas.

HIV Prevention and Care

Although HIV surveillance is an essential public health activity, HIV surveillance does not take precedence over the established and recommended prevention approaches that promote HIV counseling and testing services and knowledge of HIV infection status. Efforts to facilitate HIV counseling and testing are major components of prevention programs. CDC has published guidelines for targeting HIV counseling and testing services for several populations to whom HIV counseling and testing should be routinely offered (e.g., pregnant women and newborns, persons who have other sexually transmitted diseases, and persons seeking general medical care in areas of high HIV prevalence (17, 26,66-68). CDC also provides support for most public sources of HIV testing services and also sponsors community-based campaigns to encourage persons to seek HIV counseling and 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 and an increase in HIV-infected persons seeking testing services (69-71). In a CDC- sponsored survey of 2,370 high- risk persons, most persons (61%) correctly identified whether anonymous HIV testing services were available in their area and also reported an increased likelihood of seeking HIV testing in the future if anonymous HIV

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testing services were available (33). Anonymous HIV testing services are a required element of federally supported prevention programs unless prohibited by state law or regulation. Currently, 40 states, Puerto Rico, and the District of Columbia provide anonymous HIV testing services.

Because anonymous HIV test results are not captured by the surveillance system, anonymous HIV testing services will affect the completeness of reporting of persons diagnosed with HIV infection. To facilitate the interpretation of HIV surveillance data, 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 enter clinical care for their infection. These evaluations will be useful to determine the quality of HIV surveillance data as well as to determine the effectiveness of program efforts to refer persons into care services after any diagnosis of HIV infection. Persons whose HIV infection was diagnosed at either confidential or anonymous test sites should be promptly referred to facilities that provide confidential HIV care for a medical evaluation that includes CD4+ and viral load testing as well as appropriate antiretroviral therapy and antimicrobial prophylaxis if indicated.

The use of individual HIV surveillance case reports for public health programs such as partner notification is controversial. Communities may have particular concerns about programs based on HIV and AIDS surveillance reports that do not have well defined goals to benefit individual or public health and that use methods lacking stringent security and confidentiality procedures. 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 (72,73). States are required to develop

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standards and implement procedures for HIV prevention partner notification. States are also required to demonstrate a good faith effort to notify spouses of HIV-infected persons and to refer them for testing and prevention services. 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. CDC considers that the decision about linkage between surveillance systems and prevention and care management services should be made at the local level; if established such linkages should not compromise the quality or security of the surveillance system nor compromise the quality, confidentiality, and voluntary nature of HIV prevention services.

Although CDC is not directly responsible for the delivery of medical care for persons with HIV infection and AIDS-defining conditions, 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 Services Administration (HRSA) and the Ryan White CARE Act grantees. CDC has also undertaken a project to develop model contract language for Medicaid programs for people with HIV.

CONCLUSION

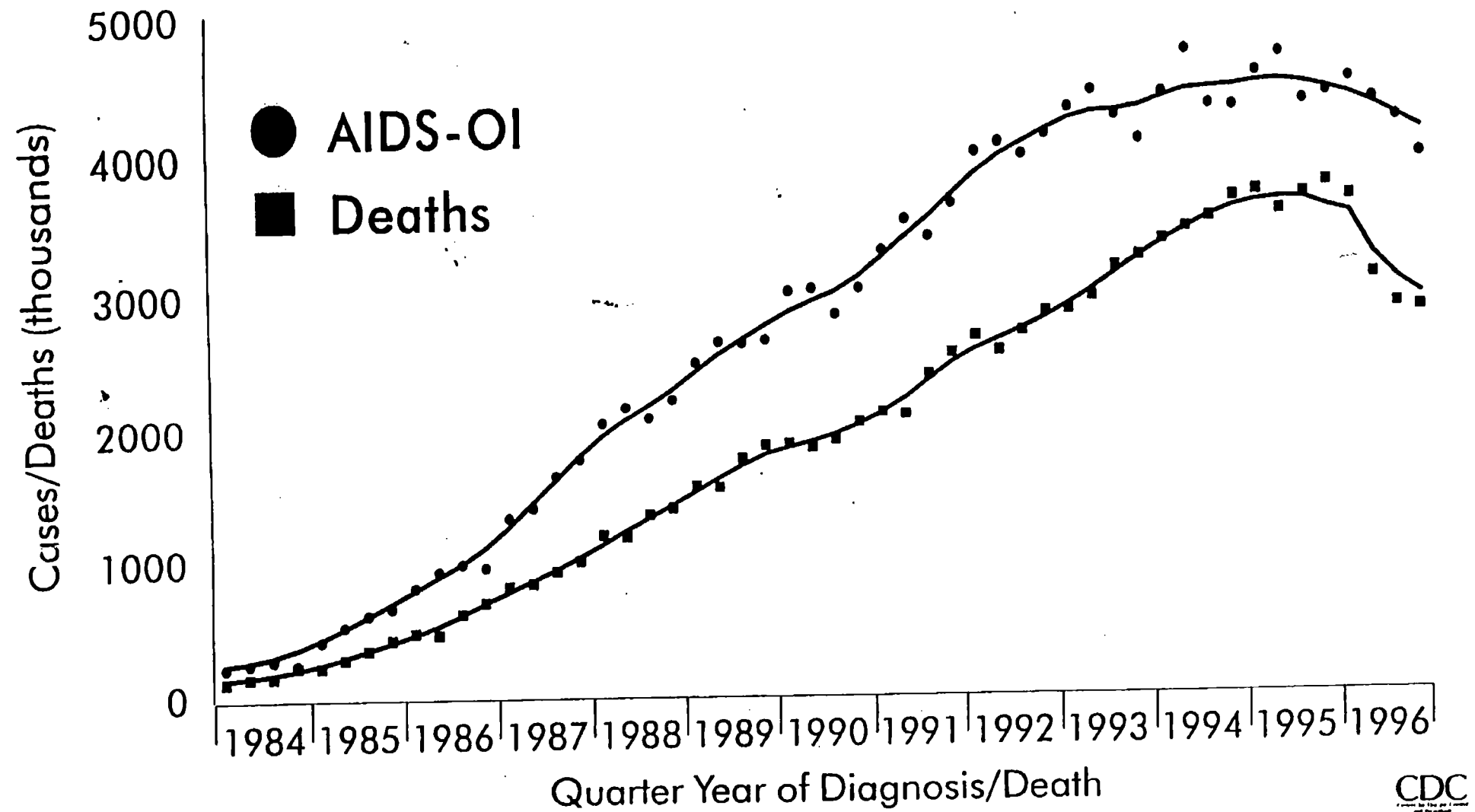
The HIV and AIDS surveillance network is the national system for monitoring HIV and AIDS trends in all communities throughout the United States. An expansion of this national surveillance network to include both HIV and AIDS surveillance in all areas of the country is a

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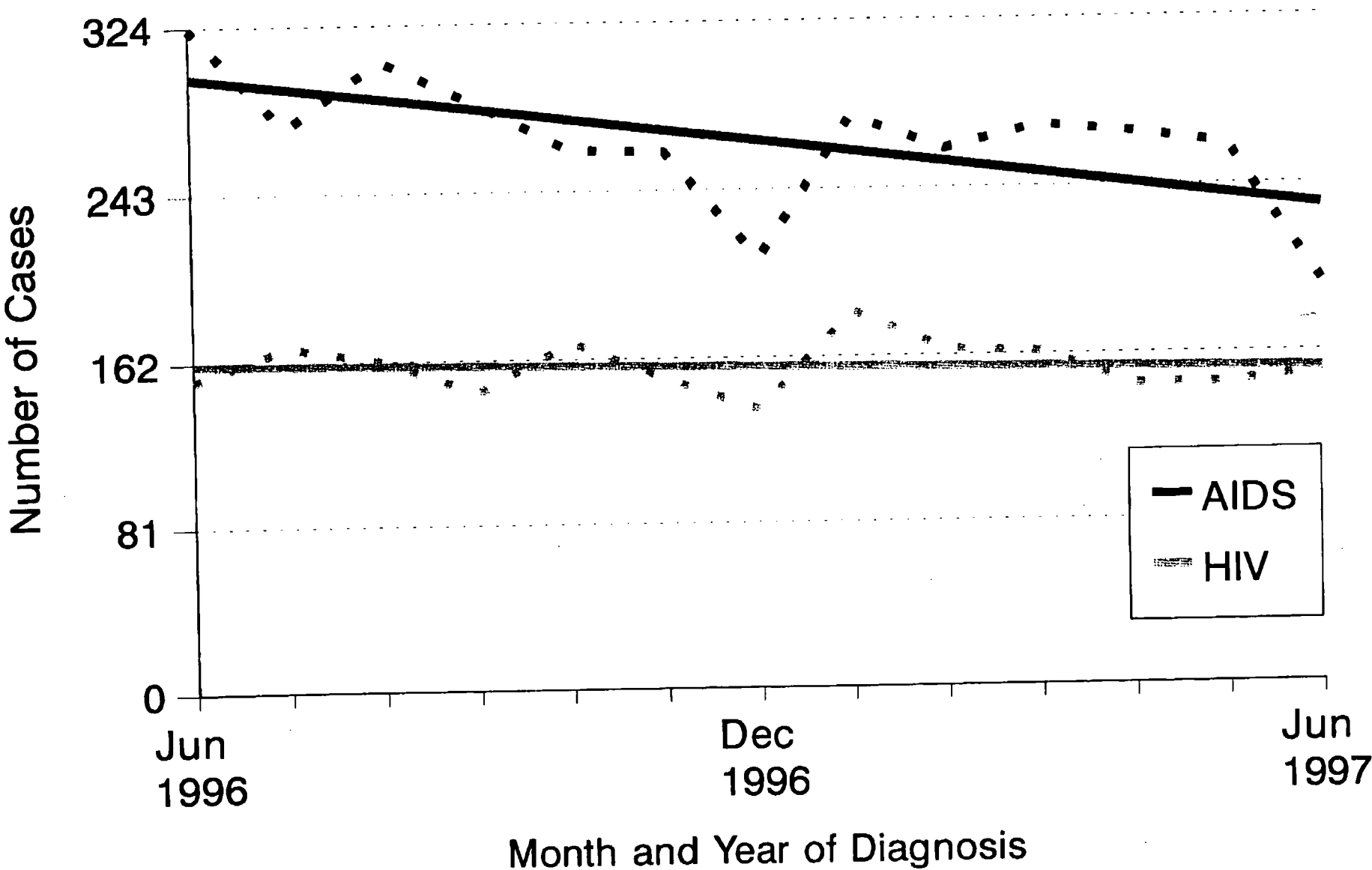
necessary response to new standards for HIV evaluation and care and will more accurately represent all persons infected with HIV. Integrated HIV and AIDS surveillance programs will provide data to characterize persons newly diagnosed with HIV infection, including those with evidence of recent infection, persons with severe HIV disease (AIDS), and those dying with HIV and AIDS. The revised HIV surveillance case definitions and the establishment of performance criteria will promote uniform case ascertainment and will assure that the surveillance data are of sufficient quality for the planning and the allocation of resources for prevention and care programs. The successful implementation of HIV and AIDS surveillance will require that state and local areas further assure the security and confidentiality of surveillance data through enhancements to data systems and confidentiality policies, training and management of public health personnel, and by use of the community planning process to determine the appropriate use of surveillance data by prevention and care programs.

Estimated AIDS-OI Incidence and Estimated AIDS Deaths Among Men who have Sex with Men, U. S., 1984-1996



Kevin DeCock, 12/97 97-647 kdpacha1.cdr cwk

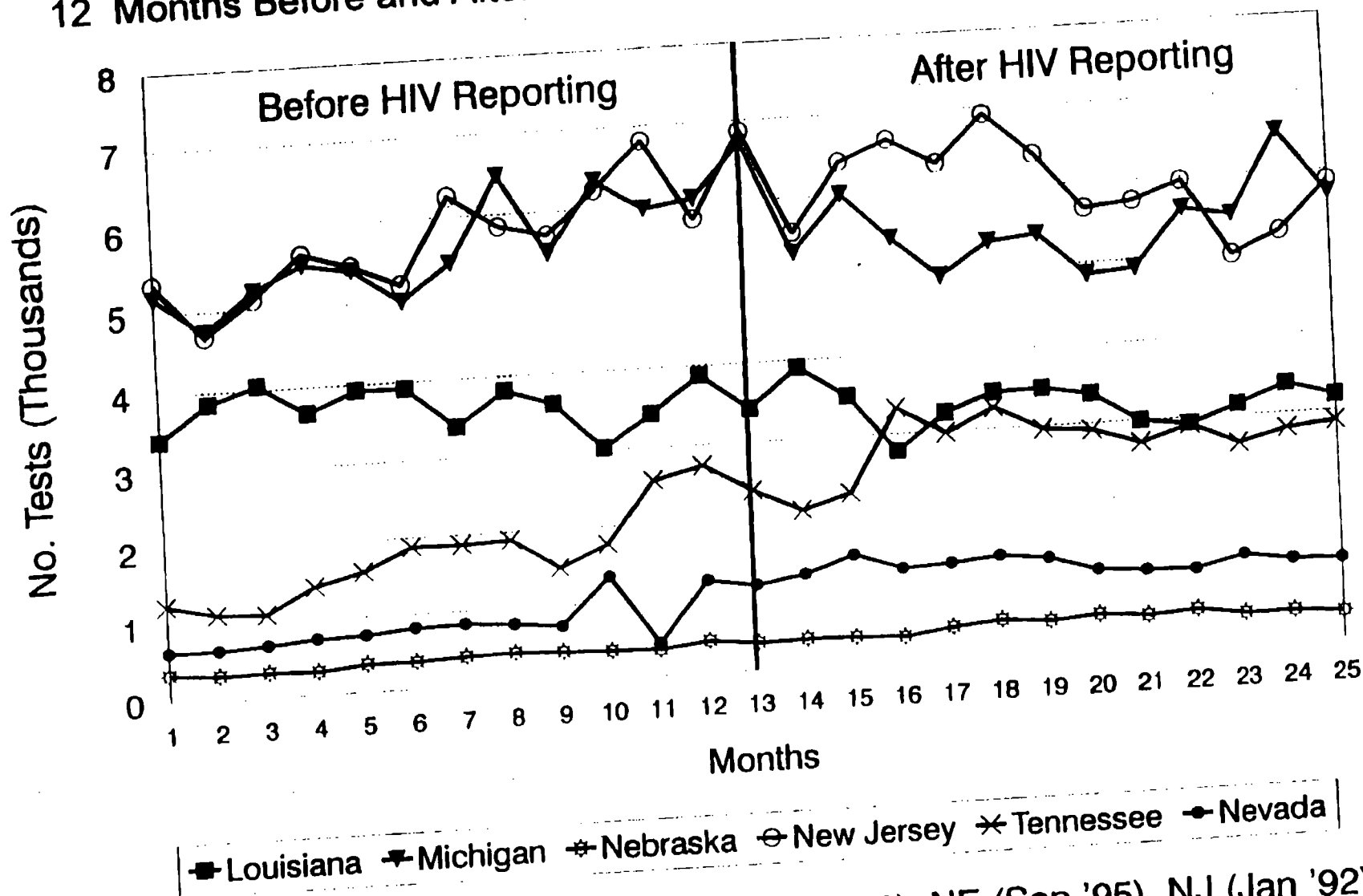
Number of H V and A DS Cases* Diagnosed Among White MSM
in 25 HIV Reporting States, by Month, June 1996 to June 1997



*HIV and AIDS cases adjusted for reporting delays.

Number of HIV Tests Performed in Publicly-Funded HIV Counseling and Testing Sites 12 Months Before and After HIV Name Reporting Laws Were Implemented*

Figure 3



*Name Reporting Began: LA (Feb '93), MI (Apr '92), NE (Sep '95), NJ (Jan '92), TN (Jan '92), NV (Feb '92)

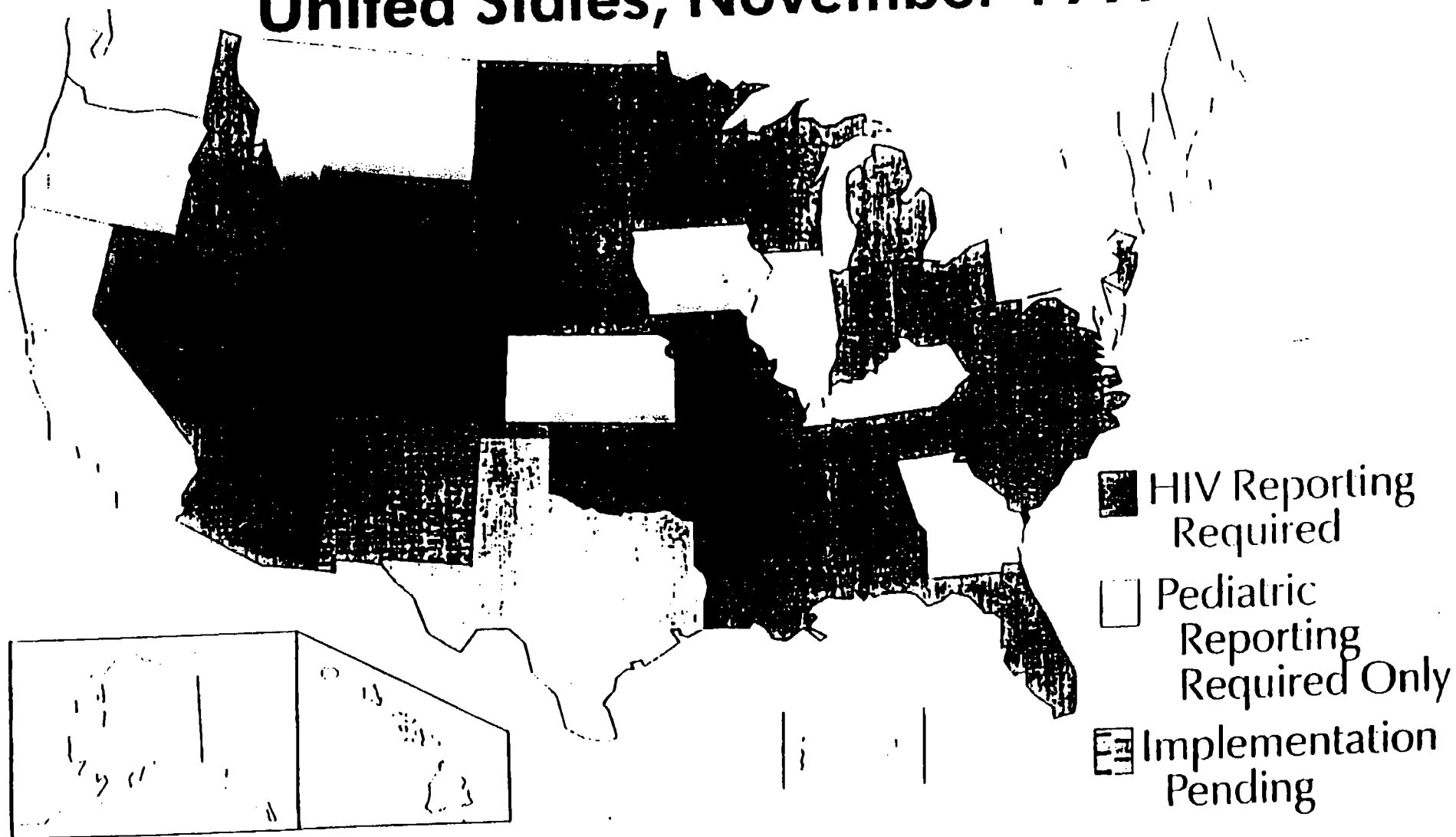
HIV and AIDS Among Persons 16 Years of Age and Older January 1996 through October 1997

Table 1

	HIV (not AIDS) N=22,358 %	AIDS N=28,185 %
Female	30	21
Black, Non-Hispanic	55	50
White, Non-Hispanic	35	41
Hispanic	7	8
Age		
13-24	17	4
25-34	41	36
35-44	30	40
45+	12	20

* Reported from 26 states with HIV case surveillance

States with Confidential HIV Case Surveillance United States, November 1997



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Draft Surveillance Case Definition for HIV infection (including AIDS)

Appendix

This definition of HIV infection, which applies to any type of HIV (e.g., HIV-1, HIV-2), is intended for public health surveillance only. It is not presented as a guide to clinical diagnosis or for other uses (1,2).

- I. In adults, adolescents, or 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 (repeatedly reactive enzyme immunoassay) followed by a positive result on a confirmatory (sensitive and more specific) test for HIV antibody (Western blot or immunofluorescence antibody test)
- Positive result on any of the following HIV detection (non-antibody) tests:
 - HIV nucleic acid (RNA or DNA) detection (e.g., by PCR, nucleic acid sequence-based amplification, or branched DNA assay, including viral load determination)
 - p24 antigen test
 - Virus isolation (culture)

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Clinical Criteria (if the above criteria are not met)

- Diagnosis of HIV infection documented in a medical record by a physician
- Conditions included in the case definition for AIDS (3,4),

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

Laboratory Criteria

Definitive

- Positive results on two separate determinations (excluding cord blood) from one or more of the following HIV virologic tests:
 - Detection of HIV nucleic acid (RNA or DNA) (e.g., by DNA polymerase chain reaction [PCR], reverse transcriptase (RT) - PCR, RNA amplification, nucleic acid signal amplification
 - HIV virus isolation (culture)
 - HIV p24 antigen

Presumptive

- Positive results on only one (excluding cord blood) of the definitive HIV detection tests AND has NO subsequent negative detection* or HIV antibody tests;

Clinical Criteria

- Diagnosis of HIV infection documented in a medical record by a physician

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- Conditions included in the 1987 pediatric surveillance case definition for AIDS
(1, 2)

III. A child <18 months of age born to an HIV-infected mother will be categorized for surveillance as not infected with HIV according to the following criteria

Laboratory Criteria

Definitive

- Documented evidence of negative HIV-antibody test results (i.e., two or more negative EIA tests performed on separate specimens at or after 6 months of age)
- At least two negative HIV virologic test results (specifically, HIV culture or detection of DNA PCR *), both of which were drawn at ≥ 1 month of age and one of which was drawn at ≥ 4 months of age

AND

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

Presumptive

- One negative result from an EIA performed at ≥ 6 months of age

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- One negative HIV virologic test result (specifically HIV culture or DNA PCR *) performed at ≥ 4 months of age

OR

- One positive HIV virologic test result with at least two later negative test results (i.e., specifically, culture or DNA PCR*), at least one of which is after 4 months of age; or negative EIA antibody test results, at least one of which is at ≥ 6 months of age

Clinical Criteria

- Determined by a physician to be uninfected 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 test results, if tests were 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 the absence of HIV infection (III).

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*A positive HIV RNA PCR in plasma can be used to define HIV infection. A negative HIV RNA assay will not be used to rule out HIV infection in an infant at this time. Similarly, standard and immune-complex dissociated p24 antigen tests are very specific for HIV infection. However, the sensitivity is less than other virologic tests and, therefore, will not be used to exclude HIV infection.

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