

a procedure^{24,27} to estimate the incidence of AIDS-OIs among persons reported based on CD4+ criteria and data from the Adult Spectrum of Disease study²⁸. By the end of 1996, the temporary distortion caused by reporting of prevalent as well as incident cases that met the 1993 criteria had almost entirely waned^{3a} (Figure 2). However, after the end of 1996, trends in AIDS-OIs could no longer be reliably estimated because data are not available to model the effects of therapy on rate of disease progression^{3a}.

4. Evaluation studies and supplemental studies (Attachment E)

Various aspects of the AIDS surveillance system have and will continue to undergo evaluation to ensure continued high quality of the data and reliability of published trends. Each change in the case definition has required careful evaluation to determine the impact on trends^{29,30}. Recently, a study validated the mode of exposure for persons who were reported as having acquired HIV through heterosexual exposure³¹.

Completeness of reporting has been evaluated and estimated to be more than 85% for AIDS case reporting^{32,33} and more than 90% complete for reporting of AIDS deaths³⁴. CDC estimates fewer than 3% of AIDS cases are duplicates based on matching of the national coded surveillance database^{3a}.

CDC also supports two ongoing studies to supplement information collected through routine surveillance: the Adult Spectrum of Disease (ASD) and the Supplement to HIV/AIDS Surveillance (SHAS) project. In the ASD project, detailed medical record reviews are

performed over time on a sample of infected individuals in 11 cities to examine the natural history of the disease, including AIDS opportunistic infections and antiretroviral therapy²⁸. The SHAS project is a cross-sectional study in which a sample of HIV/AIDS cases reported in 12 states are interviewed in depth for their sexual and substance using behaviors, antiretroviral therapy, including adherence, and access to social services³⁵. These studies provide ongoing information to enhance the information collected from routine surveillance activities.

5. Results of case surveillance and dissemination of data (Attachment D)

The cumulatively reported AIDS cases by exposure category is shown in Table 3. The AIDS case database has individual case information on all these cases including date of diagnosis; date of report; state, county, and city of report; age, race gender; risk exposure; date of death; laboratory test information (e.g., CD4+ count).

CDC regularly updates and publishes the HIV/AIDS Surveillance Report Numerous twice a year^{3,3a}. In addition, numerous reports of HIV/AIDS trends have been published in CDC's publications, *Morbidity Mortality Weekly Report* and in peer-reviewed scientific journals and books. Recent examples include declines in AIDS incidence and deaths in the USA due widespread use of highly effective antiretroviral therapy³⁶; trends of AIDS in women³⁷; trends in HIV/AIDS among men-who-have sex-with-men (MSM)³⁸; and trends in heterosexually transmitted AIDS³⁹. Incidence among men who have sex with men had leveled in 1994 and has been declining^{3,38} (Figure 3). Trends among injection drug users also leveled in 1995^{3,40}. However, trends among persons whose risk was

heterosexual contact was increasing at the end of 1996^{3,39}. After 1996, trends AIDS cases and deaths due to AIDS declined steeply due to the widespread use of highly effective antiretroviral therapy (Figure 3). As stated earlier, these trends no longer reflect trends in incidence.

Increasingly AIDS trends will reflect persons who have not accessed therapy and those who have failed therapy.

[Additional detailed tables and trends figures will be excerpted from the surveillance report and other publications for the presentation and will be added to the final draft of the report.]

Many ad hoc data requests are performed on AIDS surveillance important. Among the most important of these are requests from other federal agencies, such as, the Health Resources Services Administration (HRSA). Because the United States does not have a uniform national health care plan, government allocation of funding for medical care and social services must be made to states specifically for care of HIV/AIDS patients. In the past, HRSA has relied on AIDS surveillance data to make these important funding decisions. CDC also provides a public use data set for analysis of national data⁴⁰.

6. Problems and future perspectives

Because trends in AIDS cases will no longer be useful for monitoring trends in disease incidence, HIV case reporting will become increasingly important in fulfilling this role. Therefore, widespread implementation of HIV case reporting is a high priority.

B. HIV case surveillance

1. Legal basis for reporting (Attachment A)

Same as for AIDS surveillance. Concerns about confidentiality and security of data, potential for stigmatization of those identified as infected, and the possibility of decreased testing among high risk populations led to opposition by activists to HIV case reporting by name early in the epidemic^{4,5}. Thus, as of January, 1999, only 30 states/territories had implemented HIV name-based reporting. New York, and the Virgin Islands have passed legislation but not have implemented HIV name-based reporting. Connecticut has confidential HIV reporting for pediatric cases, and Oregon has reporting for children less than 6 years of age (Table 2).

To address some of the privacy concerns of the infected community and others, in November 1998, CDC, the Counsel of State and Territorial Epidemiologists (CSTE), the Association of State and Territorial Health Officers (AS THO), and the National Council of State Legislators (NCSL) convened a meeting to draft model legislation to protect the security and confidentiality of public health information with specific emphasis on HIV/AIDS (CDC, personal communication).

In December 1998, draft guidelines for national HIV case surveillance were published in the *Federal Register* for public comment. This document justifies the needs for integrated HIV and AIDS case surveillance and makes recommendations for surveillance practices and standards for performance⁴¹(Attachment B).

2. Reporting system (Attachments B&H)

The system for HIV case reporting is generally similar that described above for AIDS case reporting. Key differences include the

reporting sources, the ability of health departments to obtain complete information on cases, and the identifying information maintained on cases. Because most HIV cases are asymptomatic, case reporting is largely based on laboratory reports of positive tests for HIV rather than a clinician's diagnosis. HIV cases may be reported from a variety of settings including many where extensive medical records are not available (e.g., counseling and testing sites, military screening, employment screening, etc.). It is more difficult to obtain complete information, especially on risk exposure, from these sources. Therefore, the proportion of HIV cases for which risk cannot be identified will be larger than for AIDS cases.

Because of community opposition to reporting of HIV cases by name, some state health departments have or are discussing legislation that requires reporting of HIV cases using a unique identifier (UI) rather than the patient's name. In an recent study, two states (Maryland and Texas) evaluated the usefulness of UI system using a 12-digit number created from the last 4 digits of the patient's Social Security number, the 6-digit date of birth, a 1-digit code for race/ethnicity, and a 1-digit code for gender⁴². In Maryland, health care providers are required to construct the UI code for each patient being tested for HIV and include it on the laboratory slip. The provider is also required keep a log that matches the UI to patient identifiers (e.g., patient's name and medical record number). In Texas, UI reporting was required, but neither providers nor laboratories were required to keep logs linking the UI to patient identifiers. The full UI could be constructed on only 71% of HIV case reports in Maryland and

62% in Texas. To evaluate the feasibility of case follow up, Texas attempted to identify a medical record for a sample of HIV reports. They could only identify a medical record on only 60% of cases. Texas concluded that the UI system was impractical, costly to implement, and did not meet the desired performance standards for completeness of reporting or unduplication of cases. As a result, Texas implemented name-based HIV reporting beginning in January 1999 (CDC, personal communication). Maryland has continued HIV reporting by UI.

A fully satisfactory UI is also difficult to create. Because the United States does not have nationalized health care, there is no universal health care number as is available in some European countries. In New York City, as many as 25% of AIDS cases do not have Social Security numbers mostly because they are illegal immigrants (CDC, personal communication).

Although reporting is legally mandated, in actual practice, surveillance depends on the voluntary cooperation of providers and laboratories. The increased burden placed on these reporters by a UI system can potentially deter them from reporting.

3. HIV case definition (Attachment B)

Several states passed legislation requiring confidential reporting by name of HTLVIII/LAV (as HIV was then called) cases soon after the antibody tests became widely available. However, a case definition for HIV reporting was not specifically published until the 1993 revision of the AIDS case definition. In these recommendations HIV infection classified based on CD4+ and clinical conditions²¹.

The recently published draft guidelines update the case definition for HIV reporting for adults, adolescents, and children taking into account the advances in virologic testing⁴¹.

4. Evaluation studies (Attachment E)

CDC and others have performed a number of studies to evaluate the impact of confidential HIV reporting by name policies. A frequently stated concern about name-based HIV-reporting is that such policies will cause people to avoid getting tested. The HIV Testing Survey (HITS) was a cross-sectional survey conducted among persons at high risk for HIV infection in nine states⁴³. Men-who-have-sex-with-men were recruited from gay bars, injecting drug users were recruited through street outreach, and sexually active heterosexuals through sexually transmitted disease clinics. Of 2,370 HIV-negative participants, 76% had been tested at least once. Fewer than 20% of participants knew their state's HIV reporting policy. Only 2% said that HIV reporting was the main reason they would not seek testing.

A second study documented the impact of implementation HIV reporting policies on trends in testing in large, publicly funded counseling and testing sites⁴⁴. In this study, trends in HIV testing were compared in the year before and the year after HIV name-based reporting policies were implemented. No significant differences in overall trends in testing were found.

Evaluation of name-based HIV surveillance has shown 74%-97% completeness of reporting (CDC, unpublished), which is similar to 85% completeness of reporting for AIDS cases⁴⁵. Based on the

information from these studies, the performance standard for HIV reporting recommended in the draft guidelines is 85%⁴¹.

5. Results of case surveillance and dissemination of data (Attachment D)

The cumulative HIV cases reported to CDC from 30 states with confidential HIV reporting policies are shown in Table 4³. A recent comparison of HIV and AIDS cases in 25 states showed that HIV cases were younger than AIDS cases⁴⁶. While 83% of AIDS cases were men, 72% of HIV cases were men, reflecting the recent epidemic in heterosexual transmission. Eighteen percent of HIV cases were exposed heterosexually compared with 12% of AIDS cases. The ratio of HIV-to-AIDS cases reported was 2.6.

[Additional HIV surveillance data will be presented in the talk. Some of these figures may be added to the final draft.]

6. Problems and future perspectives

HIV case surveillance will be critical for future monitoring of the epidemic in the United States and to guide prevention programs. Ideally, each state should have a registry of all infected persons who have been diagnosed and are living within its jurisdiction. This registry would provide the best information on which to base funding decisions for medical care and social services. Because of opposition to name-based HIV reporting, this goal will not be achieved for a few years.

III. Sentinel sero-surveillance (Attachment F)

A. Organizational and legal structures for surveillance

Seroprevalence surveys provide a measure of the current prevalence of HIV infection in different segments of the population. CDC in collaboration

with state/local health departments and academic institutions conducts a number of studies to determine HIV seroprevalence and seroincidence in selected populations. These studies are funded by CDC through cooperative agreements with state/local health departments. Because these studies include uninfected persons, they are not routinely exempted from human subjects research ethical considerations as HIV/AIDS case surveillance is. For the unlinked, anonymous surveys, the Office of Protection for Research Risks (OPRR) has determined that such surveys are ethical if no interaction takes place with the survey participant and personal identifying information is not maintained⁴⁷. Protocols of r unlinked surveys are submitted for review and approval by the CDC Institutional Review Board.

B. Sampled populations and sampling procedures

Unlinked, anonymous seroprevalence surveys⁴⁷ have been conducted in a variety of populations and venues: childbearing women⁴⁸⁻⁵⁰, sexually transmitted disease (STD) clinics⁵¹⁻⁵³, drug treatment centers^{54,55}, adolescent medicine clinics^{56,57}, Job Corps entrants^{58,59}, and applicants to military service^{60,61}. Clinic-based surveys are convenience samples. Therefore data are presented as medians.

The survey of childbearing women (SCBW) is a population-based, unlinked anonymous serosurvey of women giving birth to live infants in the United States⁴⁸⁻⁵⁰. Residual dried blood specimens collected from infants for routine metabolic screening are used for this survey. The SCBW is valuable because it indirectly measures the incidence of infection among infants who acquire HIV perinatally from their mothers⁴⁹. HIV prevalence estimates among childbearing women and be used to estimate the expected number of infected

children born each year.

In addition to unlinked, anonymous serosurveys, seroincidence studies are conducted in STD clinics⁶² and cohorts of young men⁶³. A procedure to use a less sensitive enzyme immunoassay to determine recent seroconversions⁶⁴ has been used on blood donor specimens (CDC, unpublished data).

C. Measurements

Unlinked surveys are conducted by using residual specimens collected from eligible survey participants for routine clinical purposes⁴⁷. There is no contact between the persons surveyed and the investigators. Specimens are anonymously tested for HIV after all personal identifying information has been removed.

Standardized protocols and laboratory procedures are used for each survey. Data are collected includes geographic area, sex, age, race/ethnicity, and behavioral risk group.

D. Results and dissemination of sero-surveillance data

Results of unlinked seroprevalence surveys are published annually⁴⁷. In 1997, prevalence rates in STD clinic attendees were highest among men-who-have-sex-with-men. The median clinic prevalence rate was 19.3% for this group. The median clinic prevalence rate among injecting drug users (IDUs) was 4.8%. Prevalence rates among IDUs attending treatment centers varied widely with an overall median prevalence of 14.8%. Prevalence in Job Corps entrance continued to be low 0.0-0.1%. In addition to the results published in the annual report, data are published in peer-reviewed journals^{49-61,65}.

[Published results of various serosurveys are listed in the reference.]

E. Problems and future perspectives

Serosurveillance data provide an important complement HIV/AIDS surveillance data. They are especially useful for determining the magnitude of HIV disease in high risk populations.

In recent years, there is increasing interest in seroincidence and seroconversion studies. The latter are important because of reports suggesting that recent seroconverters are more likely to transmit HIV^{ref}.

IV. Behavioral surveillance

A. Organizational and legal structures for surveillance

Because HIV-AIDS is spread primarily through sexual activity and drug use, surveillance of these behaviors has been recognized as an integral part of a comprehensive surveillance program. More recently, the availability of protease inhibitors has created interest health care seeking behaviors and adherence to therapy. Information on HIV testing behaviors is important to estimate the percentage of the population that has been tested and to understand barriers to testing.

Behavioral surveillance is different than traditional infectious disease surveillance because interviews are usually required to obtain the desired information. Behavioral surveillance studies are not exempted from human subjects review, and studies funded by CDC require institutional review board approval.

B. Sampled populations and sampling procedures

CDC sponsors a number of behavioral surveys. Some examples are shown in Table 5. There are three main types of behavioral surveillance surveys relevant to HIV. First, there are surveys of infected persons. The Supplement to HIV/AIDS Surveillance (SHAS) Project is a typical example. In this study, infected individuals are interviewed in depth about their sexual and drug using behaviors, access to medical and social services, therapy and adherence to therapy. Six SHAS sites are

population-based and 6 are facility-based.

There are also behavioral studies of persons at high risk for infection. These include the Young Men's Survey (YMS) and the HIV Testing Survey. These surveys attempt to recruit difficult-to-reach persons who are at high risk for HIV from a variety of venues. Therefore, they rely on convenience sampling and outreach methods.

General population surveys are usually population-based and may use complex sampling methods such as multistage probability designs.

C. Measurements

Questionnaire design and careful training of interviewers are critical to accurate, unbiased measurement of behaviors. There are also many behavioral surveys with questions that differ only slightly from each other. Therefore, for the past two years, CDC has been working to standardize core questions for behavioral surveillance that could be used by many surveys.

D. Reporting system

The methods of data collection, data management, data access, and analysis are unique to each behavioral survey.

E. Results of behavioral surveillance

Results from the numerous behavioral surveys are published in the surveillance reports, *MMWR* updates, and peer-reviewed publications.

[May include one or more examples of the more recent surveys here.]

G. Problems and future perspectives

CDC-sponsored behavioral surveillance will continue to play an important role in planning and evaluating behavioral interventions.

V. HIV/AIDS program effectiveness monitored and evaluated by surveillance surveys

HIV/AIDS surveillance data provide the basis for evaluating prevention

program effectiveness and allocation of health care, social service, and prevention resources. The current inability to measure prevalence and trends in incidence in states without HIV reporting may make this task more difficult in the near future.

VI. Conclusion

HIV/AIDS surveillance systems will continue to address a broad range of issues including evaluating the impact of antiretroviral therapy on trends; evaluating access to care and social services; planning, implementing, and evaluating prevention strategies.

Table 1. Evolution of the case definition for surveillance of HIV/AIDS in the United States.

Adults and Adolescents >13 years of age

Year	Reference	Key changes in the case definition
1982	6	Person with a disease moderately predictive of a defect in cell-mediated immunity and no known cause for diminished resistance to that disease. Examples: <i>Pneumocystis carinii</i> pneumonia (PCP), Kaposi's sarcoma (KS), and other serious opportunistic infections.
1985	17	Inclusion of cases with other opportunistic infections if they had a positive serologic or virologic test for the human T-cell lymphotropic virus type III/lymphadenopathy-associated virus (HTLV-III/LAV). (Persons with serologic evidence of HTLV-III/LAV infection but who had no evidence of an opportunistic infection indicative of AIDS were not included.)
1986	18	Classification system for HTLV-III/LAV infections based on CD4+ count and opportunistic infections.
1987	21	Simplification and clarification of the case definition to reflect changes in diagnostic practices. Inclusion of HIV encephalopathy, HIV wasting syndrome and other AIDS indicative diseases; inclusion of patients with presumptively diagnosed indicator diseases; and elimination of cases with other causes of immunodeficiency.
1993	22	Inclusion of symptomatic and asymptomatic HIV cases with CD4+ cell count of <200 cells/ μ L.
1999	41	The draft guidelines for HIV case surveillance, including an updated HIV case definition for reporting, were published in the Federal Register on December 10, 1998, for a 30-day public comment period. The final draft is expected to be published sometime in 1999.

Children

Year	Reference	Key changes in the case definition
1987	19	Classification system for HIV infection in children <13 years of age
1994	18	Updated case definition based on improved knowledge about progression of HIV disease among children.
1999	41	HIV case definition and guidelines for reporting.

Table 2. Current status of HIV infection reporting policies by state--United States, January 1999.*

Name-based reporting required (Date implemented) [†]	Non-name-based reporting required [‡]	Reporting not required
<i>Alabama</i> (January 1988)	Georgia	Alaska
Arizona (January 1987)	Illinois	California
Arkansas (July 1989)	Kansas	Connecticut ¹
Colorado (November 1985)	Kentucky	Delaware
Florida (July 1997)	Maine	Hawaii
<i>Idaho</i> (June 1986)	Maryland ²	Massachusetts
Indiana (July 1988)	Montana	Pennsylvania
<i>Iowa</i> (October 1998)	New Hampshire	Puerto Rico
Louisiana (February 1993)	Oregon ³	Vermont
Michigan (April 1992)	Rhode Island	Washington ²
Minnesota (October 1985)		District of Columbia
<i>Mississippi</i> (August 1988)		
Missouri (October 1987)		
Nebraska (September 1995)		
<i>Nevada</i> (February 1992)		
New Jersey (January 1992)		
New Mexico (January 1998)		
New York (pending)		
<i>North Carolina</i> (February 1990)		
<i>North Dakota</i> (January 1988)		
Ohio (June 1990)		
Oklahoma (June 1988)		
<i>South Carolina</i> (February 1986)		
<i>South Dakota</i> (January 1988)		
<i>Tennessee</i> (January 1992)		
Texas (January 1999)		
Utah (April 1989)		
Virginia (July 1989)		
West Virginia (January 1989)		
Wisconsin (November 1985)		
<i>Wyoming</i> (June 1989)		
Virgin Islands (pending)		

rw15*States in *italics* offer only confidential and not anonymous HIV testing in publicly-funded test sites. All other states and territories offer both anonymous and confidential testing.

†“Pending” indicates that legislation has been passed, but implementation has not yet occurred.

¹ Maryland conducts HIV case surveillance using a 12-digit unique identifier (UI) and attempts to complete missing information using active follow-up. Providers, hospitals, and labs in the other states in this column send health departments individual-level HIV data using a variety of non-name-based identifiers, e.g., initials, date of birth, or test number. No follow-up is attempted.

² Has implemented HIV name-based reporting for children <13 years of age.

³ Requires name-based reporting of symptomatic HIV infection as defined in CDC classification of Group IV, non-AIDS (CDC, 1986).

³ Requires name-based reporting for children <6 years of age.

Table 3. AIDS cases by age group exposure category and sex, reported through June 1998,

United States*

Adult/Adolescent exposure category	Males No. (%)	Females No. (%)	Total No. (%)
Men who have sex with men	317,862 (57)	--	317,862 (48)
Injecting drug use	122,933 (22)	45,075 (43)	
168,008 (26)			
Men who have sex with men and inject drugs	42,093 (8)	--	
42,093 (6)			
Heterosexual contact	21,855 (4)	40,744 (39)	
62,599 (10)			
Hemophilia/coagulation disorder	4,559 (1)		222 (0)
4,781 (1)			
Receipt of blood transfusion, Blood components or tissue	4,752 (1)	3,559 (3)	
8,311 (1)			
Other/risk not reported or identified	38,994 (7)		14,428 (14)
53,423 (8)			
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Adult/adolescent subtotal	553,048 (100)	104,028 (100)	657,077 (100)
Pediatric (<13 years old) exposure category			
Hemophilia/coagulation disorder	227 (5)		7 (0)
234 (3)			
Mother with HIV infection or at risk for HIV infection	3,737 (87)	3,775 (94)	
7,512 (91)			
Receipt of blood transfusion, blood components of tissue		235 (5)	140
(3) 375 (5)			
Risk not reported or identified		77 (2)	82 (2)
159 (2)			
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Pediatric subtotal	4,276 (100)	4,004 (100)	
8,280 (100)			

Total	557,324	108,032	665,357
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*from *HIV/AIDS Surveillance Report* (reference 3a)

Table 4. HIV cases by age group exposure category and sex, reported through June 1998, United States, from 31 states with confidential HIV infection reporting by name policies*

Adult/Adolescent exposure category	Males No. (%)	Females No. (%)	Total No. (%)
Men who have sex with men (33)	32,225 (45)	--	32,225
Injecting drug use (17)	10,832 (15)	5,707 (23)	16,539
Men who have sex with men and inject drugs 42,093 (6)	42,093 (8)	--	
Heterosexual contact (0)	4,421 (6)	9,793 (39)	14,214 (15)
Hemophilia/coagulation disorder 448 (0)	426 (1)		22
Receipt of blood transfusion, Blood components or tissue 8,311 (1)	349 (0)	3,559 (3)	
Other/risk not reported or identified 28,348 (29)	18,871 (26)		9,469 (37)
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Adult/adolescent subtotal 97,113 (100)	71,743 (100)	25,362 (100)	
Pediatric (<13 years old) exposure category			
Hemophilia/coagulation disorder 96 (5)	94 (11)		2 (0)
Mother with HIV infection or at risk for HIV infection 1,544 (86)	730 (82)		814 (90)
Receipt of blood transfusion, blood components of tissue (2) 33 (2)		11 (1)	22
Risk not reported or identified 118 (7)	56 (6)		62 (7)
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Pediatric subtotal 1,791 (100)	891 (100)	900 (100)
Total 98,904	72,634	26,262

*Includes only persons reported with HIV infection who have not developed AIDS; see Table 2 for list of states with confidential HIV reporting; from the *HIV/AIDS Surveillance Report* (see Reference 3).

Table 5. Examples of CDC-sponsored surveys and studies of behaviors related to HIV infection.

A. Infected populations

<u>Survey</u>	<u>Description</u>
Supplement to HIV/AIDS Surveillance (SHAS) Project	Cross-sectional interview survey of reported HIV/AIDS cases ≥ 18 years of age in 12 states. Information on sexual and drug using behaviors; access to medical and social services; therapy and access to therapy.

B. High Risk Populations

<u>Survey</u>	<u>Description</u>
HIV Testing Survey (HITS)	Cross-sectional interview survey of MSM, IDUs, and STD clinic attendees on HIV testing behaviors.
Young Men's Survey (YMS)	Survey of young men between 15 and 22 years of age recruited from public venues to estimate prevalence of HIV infection and related risk behaviors in this population.

C. General Population Surveys

<u>Survey</u>	<u>Description</u>
Behavioral Risk Factor Surveillance System (BRFSS)	Population-based, telephone survey of person ≥ 18 years of age conducted in all states. Questions on AIDS-related knowledge and attitudes and HIV testing behaviors.
National Health Interview Survey (NHIS)	Population-based, household sample of U.S. population ≥ 18 years of age. Questions on AIDS-related knowledge and attitudes and HIV testing behaviors.
Youth Behavioral Risk Factor Surveillance System (YRBS)	School-based survey of 9-12th grade. Questions on HIV-specific risky behaviors

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