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Office of HIV/AIDS Policy

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

Deliver To: Wendy Adler

Fax: (___) 456-5557

Phone: (___)_____

From: Deborah von Zinkernagel
Deputy Director for Policy
Phone: (202) 690-5560
Fax: (202) 690-6584
E-mail: DvonZinkernagel@osophs.dhhs.gov

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Comments: California Senate Appropriations estimate for AB1663

Analysis

BILL ANALYSIS

APPROPRIATIONS COMMITTEE FISCAL SUMMARY

AB 1663 (Migden)

Hearing Date: 8/19/98
7/6/98

Amended:
and proposed amendments

Consultant: David Maxwell-Jolly
H&HS 5-0

Policy Vote:

BILL SUMMARY:

AB 1663 requires by 1/1/2000 reporting of HIV cases using a uniform, statewide system that reports cases based on a unique code or other method that does not report the names of individuals infected with HIV. The bill directs the Department of Health Services to use the data collected on the basis of the reports for epidemiological studies, to target HIV prevention activities, and to allocate resources.

Fiscal Impact (in thousands)

Major Provisions		1998-99	1999-2000	2000-01	Fund
Surveillance system and Task force	550	350*	350		General

STAFF COMMENTS:

SUSPENSE FILE.

*Amended to $550,000 due to requirement for Statewide Task Force

Multistate Evaluation of Anonymous HIV Testing and Access to Medical Care

Andrew B. Bindman, MD; Dennis Osmond, PhD; Frederick M. Hecht, MD; J. Stan Lehman, MPH; Karen Vranizan, MA; Dennis Keane, MPH; Arthur Reingold, MD; and the Multistate Evaluation of Surveillance of HIV (MESH) Study Group

Context.—Infection with the human immunodeficiency virus (HIV) is the only infectious disease for which anonymous testing is publicly funded, an exception that has been controversial.

Objective.—To assess whether anonymous HIV testing was associated with earlier HIV testing and HIV-related medical care than confidential HIV testing.

Design.—Retrospective cohort.

Setting.—Arizona, Colorado, Missouri, New Mexico, North Carolina, Oregon, and Texas.

Participants.—Probability sample of 835 new acquired immunodeficiency syndrome (AIDS) cases reported to the state health department's HIV/AIDS Reporting System from May 1995 through December 1996. All had responded to the AIDS Patient Survey; 643 had been tested confidentially for HIV, and 192 had been tested anonymously.

Main Outcome Measures.—First $CD4^+$ cell count; number of days from HIV-positive test result to first HIV-related medical care, from first HIV-related medical care to AIDS, and from first HIV-positive test result to AIDS.

Results.—Persons tested anonymously sought testing and medical care earlier in the course of HIV disease than did persons tested confidentially. Mean first $CD4^+$ cell count was 0.427×10^9/L in persons tested anonymously vs 0.267×10^9/L in persons tested confidentially. Persons tested anonymously experienced an average of 918 days in HIV-related medical care before an AIDS diagnosis vs 531 days for persons tested confidentially. The mean time from learning they were HIV positive to the diagnosis of AIDS was 1246 days for persons tested anonymously vs 718 days for persons tested confidentially. After adjustment for the subject's age, sex, race/ethnicity, education, income, insurance status, HIV exposure group, whether the respondent had a regular source of care or symptoms at the time of the HIV test, and state residence, anonymous testing remained significantly associated with earlier entry into medical care ($P<.001$).

Conclusion.—Anonymous testing contributes to early HIV testing and medical care.

JAMA. 1998;280:1416-1420

BOTH CONFIDENTIAL and anonymous antibody testing for the human immunodeficiency virus (HIV) have been available at public testing sites in the United States since 1985. In confidential testing, a person's name is linked to the specimen, and the test result is recorded in a medical chart with a name. Early in the epidemic, the stigma associated with testing positive for HIV focused attention on the potential for breaches in the confidentiality of an HIV test result. Concerned that anxiety about the potential loss of confidentiality would deter some at-risk persons from voluntarily seeking testing for HIV, many state and local public health departments made this test available on an anonymous as well as a confidential basis. In anonymous testing, a unique identifier (typically a number) rather than a patient's name is used to link the specimen and the result to the patient. Anonymous test results are not recorded in a medical chart that has a patient's name. The availability of an anonymous HIV testing option has differed over time across states and localities. Currently, 40 states have publicly funded anonymous testing sites for HIV, and all 50 states have publicly funded confidential HIV testing sites.

See also p 1421.

Human immunodeficiency virus is the only infectious disease for which anonymous testing is publicly funded, an exception that has been controversial. Proponents of anonymous testing believe that it encourages persons who would not otherwise seek testing to learn their HIV infection status by eliminating the concern about potential loss of confidentiality. Persons tested anonymously who learn that they are HIV positive may be motivated by their test result to seek medical care earlier in the course of the d than they might had only confidential testing been available. Some studies have suggested that anonymous testing increases the number of people who are willing to be voluntarily tested for HIV. In North Carolina, counties that offered anonymous testing experienced greater growth in testing than did counties that continued to offer only confidential testing.[1] Similarly, with the introduction of anonymous testing in Arizona and Oregon,[2,3] more people obtained testing than when only confidential testing was available. However, the findings have not been consistent; the Colorado State Health Department did not detect a meaningful increase in HIV testing with the introduction of anonymous HIV testing.[4]

Because people who test HIV positive anonymously cannot be individually identified, reporting systems that rely on the results of anonymous testing are prone to measurement error. It can be difficult to detect repeat tests, and the potential exists for duplicate reporting. Anonymous testing may undermine partner notification.[5] Furthermore, anonymous testing eliminates the opportunity to recontact persons who do not return for their test results or to assist HIV-infected persons in obtaining medical care.

From the Primary Care Research Center (Drs Bindman and Osmond, Ms Vranizan, and Mr Keane) and AIDS Division (Dr Hecht), San Francisco General Hospital, and Departments of Medicine (Drs Bindman and Hecht, Ms Vranizan, and Mr Keane) and Epidemiology and Biostatistics (Drs Bindman and Osmond), University of California, San Francisco; Division of HIV/AIDS Prevention, Surveillance and Epidemiology, Centers for Disease Control and Prevention, Atlanta, Ga (Mr Lehman); and Department of Epidemiology, University of California, Berkeley (Dr Reingold).

A complete list of the members of the MESH Study Group appears at the end of this article.

Corresponding author: Andrew B. Bindman, MD, San Francisco General Hospital, Bldg 30/Ward 95, 1001 Potrero Ave, San Francisco, CA 94110 (e-mail: bindmana@itsa.ucsf.edu).

Because studies have been small, have performed in only 1 state, or did little to control for differences in the characteristics of persons who used anonymous vs confidential testing, it has been difficult to draw clear conclusions about the value of anonymous HIV testing. We used data collected as a part of a cooperative project between the University of California, Berkeley, the Centers for Disease Control and Prevention (CDC), Atlanta, Ga, and several state health departments to evaluate anonymous HIV testing. We assessed the association of the type of HIV test (anonymous or confidential) with when in the course of the disease persons with acquired immunodeficiency syndrome (AIDS) (1) learned of their HIV infection and (2) sought HIV-related medical care.

METHODS

The AIDS Patient Survey was conducted in Arizona, Colorado, Mississippi, Missouri, New Mexico, North Carolina, Oregon, and Texas. Because nearly all HIV-infected persons are thought to progress to AIDS eventually and because AIDS surveillance is estimated to be 80% to 96% complete,[6] reported AIDS cases provide a population-based sample of the experience of HIV-infected persons that can potentially avoid biases that may be present in venue-based samples.

In each state we sought to interview, after obtaining consent, all persons who were described as having newly diagnosed AIDS in a 1-year period or a probability sample of new cases, depending on the projected incidence of new AIDS diagnoses in the state. The sampling frame was persons newly diagnosed as having AIDS reported to the state health department through the HIV/AIDS Reporting System (HARS) from May 1995 through December 1996, who were alive at time of report, who were at least 18 years old, and whose AIDS diagnosis had been made within 12 months of the date of their report to the health department.

An expected number of persons with newly diagnosed AIDS was estimated from the number reported from the previous year who met the sampling frame criteria. In states with an expected incidence of fewer than 500 cases, all new cases were sampled (Arizona, Mississippi, and New Mexico). In the remaining states, a probability sample was stratified by 4 HIV mode-of-exposure groups based on reported behavioral information in HARS: (1) men who have sex with men (MSM), including those with a reported history of injection drug use; (2) heterosexual injection drug users; (3) cases reported with no identified risk; and (4) all other modes of exposure (heterosexual contact, transfusion, hemophilia). To get adequate numbers in each stratum for analysis, we calculated sampling fractions with the goal of sampling equal numbers from each stratum. Colorado, Missouri, and Oregon sampled MSM and took all cases in the other 3 strata; North Carolina sampled 3 strata and took all in the other stratum; and Texas sampled all 4 strata. Uniform random numbers were generated for each new case in the 4 strata, and a new case with a random number equal to or less than the sampling fraction was selected for the study.

Sampled cases were considered eligible for the study if they were living in the state, English or Spanish speaking, and healthy enough to consent to and complete an interview. To avoid biasing our response rate upward by delaying the performance of the interview, patients who had died before the time of first contact were counted in the denominator of eligibles if contact had not been made within 6 months of report. Public health surveillance personnel in each state developed procedures for contacting and interviewing potential subjects.

All procedures were monitored by the University of California and CDC to ensure uniform methods across the states. Surveillance personnel completed an outcome report form for each sampled case, which indicated the consent process and the final outcome. Subjects were interviewed in either Spanish or English. The instrument was translated into Spanish and then back-translated to English before a final Spanish version was produced. Interviewers and supervisors from the state health departments were trained in joint training sessions in conducting a standard interview. States used between 1 and 4 interviewers to administer the survey and all study sites were visited at least once by University of California and CDC investigators to assess the consistency of their technique. All completed interviews and outcome report forms were stripped of personal identifiers, copied, and mailed to the University of California for data entry and conversion into electronic Statistical Analysis System (SAS Institute Inc, Cary, NC) files for analysis.

We compared the characteristics of respondents who were tested anonymously with those who were tested confidentially and examined whether the type of HIV test was associated with when in the course of the disease a subject sought HIV testing and HIV-related medical care. Date of AIDS diagnosis was extracted from the state HARS databases and combined with the interview data for analysis. Type of HIV testing was classified as anonymous or confidential depending on whether the subject reported giving a number (anonymous) or a name (confidential) to get the HIV test result. Subjects who in response to an explicit question said that they gave a false name were excluded from the analysis. To assess the validity of our method for classifying the type of HIV test, we compared the subject's report of having given a number or a name to obtain their test result with the type of testing site. Assuming that testing in a physician's office, hospital, jail or prison, or blood bank should have been reported as testing by name (confidential testing), we found that 96.4% of subjects tested in those settings reported they had received their results by name. Of those who reported that they had received their test result by number (anonymous testing), only 6.4% reported testing in one of those settings.

We limited our analysis to respondents who first tested HIV positive in the state from which they were sampled, lived in states that offered both anonymous and confidential testing (Mississippi excluded), and voluntarily sought HIV testing as opposed to being required to obtain a test because of regulations associated with prisons, drug treatment programs, the military, insurance plans, or blood banks. Thus, subjects were considered volunteers for testing if they, in response to a checklist of questions, reported that their reason for testing was (1) they felt sick and wanted to find out whether they had HIV, (2) they thought they might have HIV even if they did not feel sick, (3) someone told them that they should get tested, or (4) someone from the health department told them that they had had contact with an infected sex or needle-sharing partner.

In comparing the characteristics of persons tested anonymously vs persons tested confidentially, we tested differences in the proportions by using the χ^2 statistic. We examined the association of anonymous and confidential testing with several intervals: time from HIV-positive test result to AIDS, and this interval's 2 subcomponents: (1) time of HIV-positive test result to first HIV-related medical care and (2) time from first HIV-related medical care to AIDS. We used the date of AIDS diagnosis to anchor comparisons of the HIV-positive test result date and the HIV-related medical care date. Date of first HIV-positive test result and date of first medical care for HIV infection were self-reported as a month and a year. Time intervals used in analysis were constructed from these dates and the date of AIDS diagnosis as reported to HARS. We compared the mean time intervals among HIV testing, HIV-related medical care, and AIDS diagnosis for persons tested anonymously and persons tested confidentially. Time intervals that included an AIDS diagnosis were also stratified by whether the diagnosis was based on an opportunistic infection or a $CD4^+$ cell count of less than 0.20×10^9/L (200/μL).

Table 1.—Characteristics of Persons Voluntarily Tested for Human Immunodeficiency Virus (HIV)

Characteristics	Anonymous (n = 192)	Confidential (n = 643)	P Value
Age, mean, y	36	38	<.001
Male, %	86	84	.33
Race/ethnicity, %			
African American	11	29	.001
Hispanic	17	14	
Other	5	3	
White	65	54	
HIV exposure group, %			
Men who have sex with men	78	58	.001
Injection drug user	6	13	
Blood product	1	4	
Health worker	1	3	
Heterosexual	4	11	
Unknown	8	12	
Education, mean, y	13.1	12.7	.03
Monthly income, mean, $	1390	1450	.41
Insurance, %			
Private/other	48	49	.68
Medicaid	4	9	
None	47	42	
Regular source of care before HIV-positive test result, %	23	51	.001
Symptoms at time of HIV-positive test result, %	50	70	.001

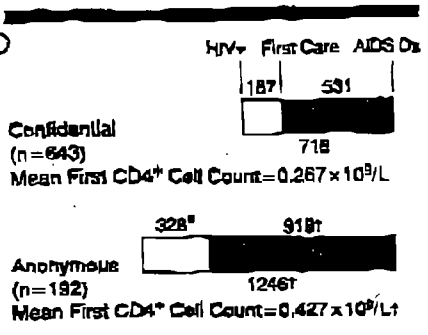

Figure 1.—Mean time in days to first human immunodeficiency virus (HIV)–related care and acquired immunodeficiency syndrome (AIDS) diagnosis by anonymous and confidential testing. Asterisk indicates $P<.01$ for confidential vs anonymous testing; dagger, $P<.001$ for confidential vs anonymous testing; HIV+, date of knowledge of HIV-positive status; first care, date of first HIV-related medical care; and AIDS Dx, date of AIDS diagnosis.

We compared subjects on the basis of whether they had symptoms of weight loss without dieting, fevers, heavy night sweats, diarrhea, oral thrush, frequent vaginal yeast infections, memory problems, shingles, pneumonia, Kaposi sarcoma, lymphoma, meningitis, or tuberculosis at the time they learned they had HIV. Subjects who said yes to any of these conditions were considered symptomatic at the time of the first HIV-positive test result. To estimate HIV disease severity at the time of first HIV-related medical care, we compared the mean self-reported first $CD4^+$ cell counts of persons tested anonymously and persons tested confidentially. To estimate the quality of HIV-related medical care for persons tested anonymously and persons tested confidentially, subjects were asked to report whether their HIV-related medical care had ever included tuberculin skin testing, taking zidovudine for at least 1 day, and taking trimethoprim-sulfamethoxazole (Septra, Bactrim, Cotrim) or aerosolized pentamidine as a measure of *Pneumocystis carinii* pneumonia (PCP) prophylaxis.

To isolate the independent contribution of the type of testing on the time intervals and the first $CD4^+$ cell count, we performed multivariate linear regression analyses that controlled for differences in the characteristics of persons tested anonymously vs confidentially. Marginal differences across states were controlled for using a state of residence indicator in the multivariate analyses. Means from multivariate analyses are the estimated least squares means from linear models. Because the distributions of time intervals and $CD4^+$ cell counts were skewed by some higher values, we repeated our multivariate analyses by using log transformations of the time intervals and $CD4^+$ cell counts. These analyses did not appreciably alter the significance of the results pertaining to anonymous vs confidential testing; therefore, for the purposes of providing measures of effect that are easily interpreted, we have chosen to display the results based on the nontransformed mean time intervals and $CD4^+$ cell counts.

The study was approved by institutional review boards at the University of California, the individual states that required review, and review boards at local institutions as required within some states.

RESULTS

In the 8 participating states, 8321 AIDS cases were sampled from May 1996 through December 1996; of those, 2801 met eligibility criteria. Overall, 1913 (68.3%) of 2801 eligible AIDS cases were interviewed in the AIDS Patient Survey. We excluded 1078 respondents from the analysis because they initially tested HIV positive in a different state from the one in which they were sampled (362), they were from a state that did not have anonymous testing (262), their reason for testing was not voluntary (247), they provided a false name at a confidential testing site (55), or they did not have complete data for all the variables used in the analysis (151). Of the remaining 835 subjects, 192 (23%) reported that their first positive test result had been from an anonymous test (Table 1). Persons tested anonymously tended to be younger, white, slightly more educated than persons tested confidentially, and more likely at risk for HIV because they were MSM. Persons tested confidentially were significantly more likely to have had a regular source of care before their first HIV-positive test result and to have had HIV-related symptoms at the time they received the test; however, half of the persons tested anonymously were also symptomatic.

Persons tested anonymously presented earlier in the course of HIV disease for testing and care than did persons tested confidentially. The mean time from learning they were HIV positive to the diagnosis of AIDS was almost a year and a half longer (529 days) for those tested anonymously than for those tested confidentially (Figure 1). The mean time was 1246 days for persons tested anonymously and 718 days for persons tested confidentially. Most of this difference was in the length of time in HIV-related medical care. Persons tested anonymously received an average of 387 more days in HIV-related medical care before an AIDS diagnosis than did persons tested confidentially. Comparisons of the median times from knowledge of being HIV positive to AIDS were even greater between persons tested anonymously and persons tested confidentially. The median time was 929 days among persons tested anonymously and 90 days among persons tested confidentially. An additional indicator that persons tested anonymously came earlier for testing and medical care than did persons tested confidentially was the significantly higher first $CD4^+$ cell count (0.427×10^9/L vs 0.267×10^9/L) despite the longer unadjusted interval between the HIV-positive test result and medical care.

To isolate the independent contribution of the type of HIV test on the timing of testing and medical care, we adjusted our results to account for differences in the characteristics of persons who sought type of test. In the multivariate analysis, several characteristics were associated with the length of time between a person's learning of a positive HIV test re-

Table 2.—Multivariate Predictors of Number of Days Between Knowledge of Being Human Immunodeficiency Virus (HIV) Positive and Acquired Immunodeficiency Syndrome

Characteristics	No. of Days (95% CI)	P Value*
Age, y	1 (−7 to 9)	.78
Male	−183 (−408 to 44)	.11
Race/ethnicity		
African American	−49 (−234 to 137)	.61
Hispanic	−121 (−332 to 87)	.25
Other	65 (−288 to 418)	.72
White	Referent (. . .)†	. . .
HIV exposure group		
Men who have sex with men	405 (198 to 613)	<.001
Injection drug user	349 (108 to 591)	.005
Other	Referent (. . .)	. . .
Education, y	29 (−4 to 61)	.08
Monthly income, $	−53 (−130 to 23)	.17
Insurance		
Private/other	112 (−52 to 275)	.18
Medicaid	44 (−222 to 311)	.74
None	Referent (. . .)	. . .
Regular source of care before HIV-positive test result	−21 (−173 to 130)	.78
Symptoms at time of HIV-positive test result	−819 (−963 to −675)	<.001
Anonymous test	272 (101 to 443)	.002

*R^2 = 0.24 (including an indicator for respondent's state residence).
†Ellipses indicate data not applicable.

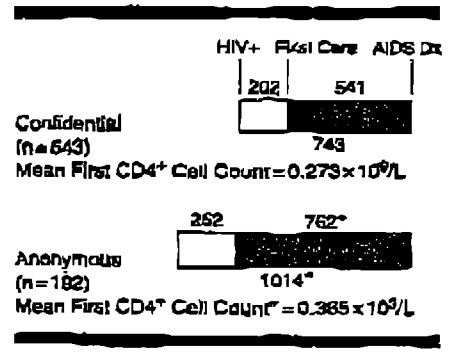

Figure 2.—Adjusted mean time in days to first human immunodeficiency virus (HIV)–related care and acquired immunodeficiency syndrome (AIDS) diagnosis by anonymous and confidential testing. Values are least squares means from a linear regression model and are adjusted for age, sex, race/ethnicity, education, income, insurance status, HIV risk group, regular source of care at the time of testing, symptoms at time of HIV-positive test result, and state residence. Asterisk indicates P<.001 for confidential vs anonymous testing; HIV+, date of knowledge of HIV-positive status; first care, date of first HIV-related medical care; and AIDS Dx, date of AIDS diagnosis date.

sult and receiving an AIDS diagnosis. Among HIV exposure groups, MSM and injection drug users had a significantly longer period of knowing they were HIV positive before their AIDS diagnosis (Table 2). The strongest predictor of the length of time between knowledge of HIV positivity and AIDS was having symptoms at the time of the HIV-positive test result. Having symptoms at the time of the HIV-positive test result decreased the length of time between knowledge of being HIV positive and AIDS by 819 days.

After adjustment for the subject's age, sex, race/ethnicity, education, income, insurance status, HIV exposure group, if the respondent had a regular source of care or symptoms at the time of the HIV-positive test result, and the state of residence, anonymous testing remained significantly associated with earlier medical care (Figure 2). Although the difference in the number of days between the positive test result and first medical care was no longer significant between the 2 groups, the length of time in medical care before AIDS was almost 8 months longer (221 days) for persons tested anonymously compared with persons tested confidentially. The mean adjusted first $CD4^+$ cell count was also 0.092×10^9/L higher for persons tested anonymously than for persons tested confidentially.

Persons tested confidentially were more likely than those tested anonymously (35% vs 16%) to have an AIDS diagnosis based on an opportunistic infection rather than on a $CD4^+$ cell count of less than 0.20×10^9/L. Accounting for this difference in how AIDS was diagnosed in the 2 testing groups further expands the adjusted difference in the duration of HIV-related medical care before AIDS diagnosis from 221 to 290 days.

Comparisons of tuberculin skin testing and the use of zidovudine and PCP prophylaxis suggest that care was similar for the 2 testing groups. Ninety-one percent of persons tested anonymously vs 89% of persons tested confidentially reported that they had received tuberculin skin testing during the course of their HIV-related medical care. Ninety-eight percent of persons tested anonymously vs 95% of persons tested confidentially were offered zidovudine, and 73% in each testing group had been given PCP prophylaxis. None of these testing or treatment differences were significant between the 2 groups.

COMMENT

In this multistate study, we found that anonymous testing was sought by approximately a quarter of HIV-positive persons who had been tested voluntarily before an AIDS diagnosis. Anonymous testing for HIV infection was associated with earlier testing and medical care. As a result of this earlier testing and care, persons tested anonymously received the potential benefits of a significantly longer period of HIV-related medical care compared with persons tested confidentially.

Although the determination of the type of HIV test, $CD4^+$ cell counts, and the intervals between HIV testing, medical care, and AIDS are in large part dependent on self-report, we suspect that the importance of this information for our respondents makes it reasonably likely that their reporting was accurate. Cunningham et al[7] found that self-reported $CD4^+$ cell counts were accurate when compared with values recorded in the medical record. To the extent that persons are misclassified by type of testing, this would tend to make the 2 testing groups look more similar. Acknowledging that there is also likely to be some error in the self-reported first $CD4^+$ cell count and dates of HIV testing and HIV-related care, we do not have any reasons to suspect that this reporting is biased by the type of HIV test a person received.

Anonymous testing was not available in all the study states in the early years of HIV testing. However, since all the respondents were diagnosed as having AIDS within the same year, there is a bias toward a positive association between confidential testing and the longest intervals between knowledge of being HIV positive and AIDS. When we limited our sample to more recent years in which both anonymous and confidential testing were available, we find a proportionally even greater difference between persons tested anonymously and persons tested confidentially in the length of time between knowledge of being HIV positive and AIDS diagnosis (data not shown).

A question can be raised whether the benefit we observed for anonymous testing is attributable to the availability of this type of testing or to characteristics of persons tested anonymously that make them seek earlier testing and care. For example, among HIV exposure groups, MSM are more likely to seek anonymous testing. From a policy perspective the question is whether the same persons who seek early HIV testing at anonymous sites would do so at confidential sites if anonymous testing sites were eliminated.[8] We cannot rule out the possibility that these same persons would have sought early testing and care even if anonymous test-

ing were not available. However, we designed our analysis to isolate the independent contribution of type of HIV testing to our outcome measures. To avoid a potentially biased comparison of persons who voluntarily sought testing at either anonymous or confidential testing sites with those who were required to be tested in confidential settings, we limited our analysis to those whose reasons for testing suggested that the action was voluntary. To avoid a bias toward confidential testing among sicker persons who sought medical care, we included symptoms at the time of HIV testing in our adjusted analysis. Of the persons tested anonymously, 50% reported that they were symptomatic, suggesting that even sick persons were making testing choices. We also controlled for a wide variety of other characteristics that differentiated persons tested anonymously and those tested confidentially and still found that anonymous testing was independently associated with a substantially higher first $CD4^+$ cell count and a longer period of HIV-related medical care before AIDS.

We explored the possibility that the longer duration of HIV-related medical care for persons tested anonymously could be due to explanations aside from their seeking medical care earlier. For example, if persons tested anonymously were diagnosed as having AIDS more often than persons tested confidentially on the basis of an opportunistic infection as opposed to a $CD4^+$ cell count below 0.20×10^9/L, this would create a bias toward lengthening the duration of HIV-related medical care before an AIDS diagnosis for persons tested anonymously. In general, opportunistic infections occur later in the HIV disease course than detection of a $CD4^+$ cell count below 0.20×10^9/L. However, since more persons testing confidentially than anonymously were diagnosed as having AIDS on the basis of an opportunistic infection, adjusting for this bias merely increases the duration of HIV-related medical care among persons tested anonymously compared with confidentially. A second explanation for the longer duration of HIV-related medical care for persons tested anonymously is that they were receiving better-quality medical care than were persons tested confidentially. However, comparisons between persons tested anonymously and confidentially in their receipt of several effective prevention and treatment services revealed no significant differences.

Some of the individual characteristics associated with earlier HIV testing and HIV-related medical care were expected, but others were not. For example, we had anticipated that persons who were symptomatic would seek care more quickly than persons who were asymptomatic. We found that after controlling for whether persons had HIV-related symptoms at the time they received a positive HIV test result eliminated the significant difference between persons tested anonymously and persons tested confidentially in the length of their delay between learning they were HIV positive and getting HIV-related medical care. However, we were surprised that neither health insurance nor having a regular source of care—2 traditional measures of access—was associated with early HIV testing or HIV-related medical care. This finding suggests that either physicians are not sufficiently identifying their high-risk patients and encouraging them to be tested early or that patients who have insurance or a regular source of care are reluctant to pursue HIV testing at any greater rate than is found among all at-risk individuals.

We found, as other reports have suggested, that black and Hispanic persons tended to have fewer days of knowing that they were HIV positive before AIDS and fewer HIV-related medical care days than whites[5]; however, the comparisons with whites were not significant in the adjusted analyses.

With the development of improved therapies for HIV-infected persons, the rationale for anonymous testing may be waning.[10] In our companion study of persons at high risk for HIV, we found that in the 1990s the annual rate of choosing anonymous rather than confidential testing was 44% to 58% (mean, 48%) (A.B.E., D.O., F.M.H., et al, unpublished data, December 1995-November 1996). This suggests that, at least through 1996, anonymous testing has remained a consistently important testing option for a significant proportion of at-risk persons. It is also possible that more at-risk persons will be interested in anonymous testing now that the Council of State and Territorial Epidemiologists has revised its statement on HIV reporting to favor name reporting[11] and a growing number of states and Congress are actively considering the implementation of HIV name-reporting policies.[12] To the extent that name-reporting surveillance systems create a barrier to HIV testing for some persons, anonymous testing might serve as a "safety valve" for those who fear that confidential surveillance systems cannot adequately protect their privacy.

Observational studies may never be able to fully tease apart the contribution that anonymous testing makes to the timing of HIV testing and to HIV-related medical care. In reality, there is a complex interplay among the characteristics of persons at-risk for HIV, changes over time in the perceived benefit of knowing one's serostatus, the availability of anonymous testing, the implementation of name-reporting policies, the opportunity to circumvent surveillance strategies by using a false name at confidential testing sites, and the availability of anonymous home HIV testing kits. We were able to adjust for many, but not all, of these factors. Nonetheless, we believe that our study provides the strongest evidence to date that anonymous testing contributes at a population level to early HIV testing and medical care. Thus, to achieve the public health goal of providing early access to HIV testing and HIV-related medical care, public health departments should maintain and in some instances enhance the broad availability of anonymous testing options.

Support for this project was provided by the CDC (DHHS 282-92-0048).

The MESH Study Group comprises John Ward, MD, MPH, and Patricia Fleming, PhD, CDC, Atlanta, Ga; Denise K. Boyd, MS, MPH, and Vjollca Berisha, MD, MPH, Arizona Public Health Department, Phoenix; Kenneth Gershman, MD, MPH, and Melanie Matusen, Colorado Public Health Department, Denver; John Newman and Craig Thompson, Mississippi Public Health Department, Jackson; Robert Hamm, MD, MPH, Kristin Wendt, MPH, and Linda Bell, Missouri Public Health Department, Jefferson City; Michael Samuel, DrPH, and Mark Stenger, MS, New Mexico Public Health Department, Santa Fe; Steven Modesitt, RN, MPH, Roger Wirt, PhD, and David Fleming, MD, Oregon Public Health Department, Portland; and Ann S. Robbins, PhD, Sharon A. King, MA, and Douglas Hamaker, Texas Public Health Department, Austin. The participants from the North Carolina Public Health Department requested that their names not be included.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Chief of Staff

Washington, D.C. 20201

FACSIMILE

DATE: DEC 9 1998

TO: Todd Summers

FAX#: 456.2498

FROM: Mary Beth Donahue
Chief of Staff

Phone: 202/690-7431 Fax: 202/401-5783

COMMENTS:

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

3 Pages [including this cover]

(1) FR Notice

Billing Code: 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

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

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

ACTION: Notice and Request for Comments

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

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

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

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

(2) FAX NO. 2

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

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

Dated: _____

Jeffrey P. Koplan, M.D., M.P.H.
Director, Centers for Disease Control and Prevention

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

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

INTRODUCTION

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

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

on: (1) the established practices of AIDS and other public health surveillance systems; (2) reviews of State and local surveillance programs, confidentiality statutes, and security procedures; (3) studies of the performance of surveillance systems; (4) ongoing evaluations of determinants of test-seeking or test-avoidance in relation to State policies and practices on HIV testing and reporting; and (5) discussions at a consultation held by CDC and CSTE in May 1997. A draft of this document was made available for public comment in _____1998.

BACKGROUND

History of AIDS Surveillance

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

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

Current Status of HIV Surveillance

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

In contrast to AIDS case surveillance, HIV case surveillance can provide data to better characterize populations newly diagnosed with HIV, particularly those with evidence of recent HIV infection such as adolescents and young adults (20- to 24-year-olds) (20-21). Of the 52,690

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

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

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

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

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

Concerns Regarding HIV Surveillance

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

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

HIV Surveillance and Testing Behavior

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

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

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

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

HIV Surveillance Based on Non-name Unique Identifiers

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

Confidentiality of HIV Surveillance Data

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

CDC has also reviewed State and local security policies and procedures. Since 1981, States have conducted AIDS surveillance, and few breaches of security have resulted in the unauthorized release of data (43). Because HIV-infected persons are reported earlier in their disease course than persons with AIDS and many such persons are remaining AIDS-free for longer periods as a result of treatment advances, information about them may be maintained by public health surveillance databases for longer periods. This has caused increased concerns about confidentiality of surveillance data among public health and community groups. Therefore, CDC has issued technical guidance for security procedures that include enhanced confidentiality and security safeguards as evaluation criteria for Federal funding of State HIV/AIDS surveillance activities (44). The receipt of Federal surveillance funding is dependent on the recipient's ability to ensure the physical security and the confidentiality of case reports. At the Federal level, HIV/AIDS surveillance data are protected by several Federal statutes, and privacy is also ensured by the removal of names and the encryption of data transmitted to CDC. Based on the importance of maintaining the confidentiality of persons who are diagnosed as HIV-infected by public and private health care providers, CDC is recommending additional practices to enhance the security and confidentiality of HIV and AIDS surveillance data.

HIV AND AIDS SURVEILLANCE GUIDELINES

HIV/AIDS Surveillance Case Definitions for Children and Adults

CDC, in collaboration with CSTE, has established new HIV case definitions for adults and children less than 18 months of age that include revised surveillance criteria for HIV infection and incorporate the surveillance criteria for AIDS (10,13,45) (Appendix). HIV and AIDS surveillance reports forwarded to CDC should be based on these surveillance criteria. The HIV and AIDS surveillance case definitions for adults, adolescents, and children greater than or equal to 18 months of age include laboratory and clinical evidence specifically indicative of HIV infection and severe HIV disease (AIDS). The HIV surveillance case definition for children less than 18 months of age updates the definition in the 1994 revised classification system based on recent data on the sensitivity and the specificity of HIV diagnostic tests and clinical guidelines for *Pneumocystis carinii* pneumonia (PCP) prophylaxis for children (13, 46-55) and for the use of antiretroviral agents for pediatric HIV infection (56). This definition will apply to children less than 18 months of age, except for those who acquired HIV infection through modes of transmission other than perinatal transmission (e.g., blood/blood product recipients). The revised surveillance case definitions for adults and children less than 18 months of age will become effective _____.

HIV and AIDS Case Surveillance Practices

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

Recommended Surveillance Practices

- All State and local programs should collect a standard set of surveillance data for all cases that meet the reporting criteria for HIV infection and AIDS. The standard data set includes the (1) patient identifier, (2) earliest date of diagnosis for HIV infection, (3) earliest date of diagnosis of an AIDS-defining condition, (4) demographic information (date of birth, race/ethnicity, sex) and residence (city, State) at diagnosis of HIV and AIDS, (5) HIV risk exposure, (6) facility of diagnosis, and (7) date of death and state of residence at death. In addition to this information, the date of HIV diagnostic testing and the results of these tests should be collected for all infants with perinatal exposures to HIV. To address specific public health information needs, local surveillance programs may cross-match HIV and AIDS surveillance data with other public health data, such as for tuberculosis, and collect supplemental surveillance data on all or a representative sample of cases. CDC will provide technical assistance and standardized surveillance methods to assist in the collection of supplemental surveillance information. Surveillance information, without patient identifiers, should be encrypted and forwarded to CDC through the HIV/AIDS Reporting System, as is current practice.
- Published evaluations of non-name based HIV surveillance in two States (41) together with results of meetings and consultations with States that have considered or used non-name identifiers have highlighted operational difficulties with these systems. Based on published evaluations, CDC has concluded that name-based HIV/AIDS surveillance systems are the most likely to meet the necessary performance standards (22, 57-61) as well as to serve the purposes for which surveillance data are required. Therefore, CDC advises that State and local surveillance programs use the same name-based approach for HIV surveillance as is currently used for AIDS surveillance nationwide. However, CDC recognizes that some States have adopted, and others may elect to adopt, non-name case identifiers for the public health reporting of HIV infection. CDC will provide technical assistance to all State and local areas to continue or establish HIV and AIDS surveillance systems and to evaluate their surveillance programs regardless of whether they use name or non-name based identifiers.
- HIV and AIDS surveillance should be used to identify rare or previously unrecognized modes of HIV transmission, unusual clinical or virologic manifestations, and other cases of public health importance. CDC will provide technical assistance to State and local health departments conducting such investigations and will revise public health recommendations based on the findings, as appropriate.
- HIV and AIDS case surveillance efforts should be directed toward the collection of data from all private and public sources of HIV-related testing and care services. Laboratory-initiated surveillance methods should be used to collect information for cases that meet the laboratory reporting criteria for HIV infection and AIDS. Statistics regarding persons who are tested anonymously should not be reported through the HIV/AIDS Reporting System. These test results are reported anonymously to the HIV Counseling and Testing database. HIV-infected persons who are initially tested anonymously are only eligible to be reported to HIV/AIDS surveillance after they have been diagnosed by a health care

provider and have test results or clinical conditions that meet the HIV and AIDS reporting criteria.

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

Performance Standards

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

standards following this transition period. At that time, CDC will require that States adopt surveillance methods that will enable them to achieve the standards.

Recommended Security and Confidentiality Practices

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

Security and Confidentiality Standards

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

- CDC *requires* that electronic HIV/AIDS surveillance data be protected by computer encryption during data transfer. Paper or unencrypted electronic case reports forwarded

by providers should be used by surveillance staff to update the central surveillance registry and then should be destroyed.

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

Relationship to HIV Prevention and Care Programs

- The implementation of HIV case surveillance should not interfere with HIV prevention programs, including those that offer anonymous HIV counseling and testing services. Unless prohibited by State law or regulation, CDC *requires* that States and local areas provide opportunities to receive anonymous HIV counseling and testing services as a condition of Federal funding for HIV prevention. CDC strongly recommends that States prohibiting anonymous HIV testing change this practice, given the overriding public health objective of encouraging knowledge of HIV serologic status.
- All HIV testing services should continue to be voluntary and preceded by informed consent in accordance with local laws (62).
- All persons who are diagnosed with HIV infection should be referred to programs that provide HIV care, treatment, and comprehensive prevention case management services. Provider-based referrals of patients to prevention and care services provide a timely, effective, and efficient means of ensuring that individuals who have been diagnosed with HIV receive needed services. The primary function of HIV and AIDS surveillance is the collection of accurate and timely epidemiologic data; therefore, State and local HIV and AIDS case surveillance programs are not directed by CDC to share individual case reports with prevention or care programs, including those that provide partner notification assistance, case management, and other services for individual clients. Although some areas have established direct linkages between surveillance and specific prevention programs, such linkages do not necessarily improve the provision of HIV prevention and care services. Areas that elect to establish such linkages must seek the concurrence of their prevention and care planning groups, require that recipients of surveillance information be subject to the same penalties for unauthorized disclosure as surveillance personnel, and evaluate the effectiveness of this public health approach.

COMMENTARY

The Surveillance Case Definition for HIV Infection and AIDS

The revised HIV case definition for adults and children less than 18 months of age 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 1999 HIV and AIDS case definition includes viral detection tests that were not commercially available when the case definition was revised in 1993. The revised case definition for HIV infection also permits the reporting of cases based on the result of any test licensed for the diagnosis of HIV infection in the United States. Although the reporting criteria generally reflect the recommendations for the diagnosis of HIV infection, the HIV reporting criteria are for public health surveillance and are not designed for making a diagnosis for an individual patient. The laboratory criteria include the serologic HIV tests described in the clinical standards for HIV diagnosis (63-64).

The pediatric HIV reporting criteria include criteria for monitoring all children with perinatal exposures to HIV and reflect recent advances in diagnostic approaches that permit the diagnosis of HIV infection in the first months of life. With 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 (46-55).

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 increases mortality risks. Almost all deaths among persons with HIV infection are caused by AIDS-related opportunistic illnesses (65).

Effect of National HIV Case Surveillance on Reporting Trends

The changes in the HIV reporting criteria will have little effect on reporting trends in States already conducting HIV case surveillance. The number of HIV cases reported nationally will increase primarily because of the implementation of HIV surveillance by the remaining States and local areas. Many of the States that will be implementing HIV case surveillance in the future have high AIDS incidence rates. Similar to the effect on AIDS surveillance trends after the implementation of the revised reporting criteria in 1993, the initiation of HIV surveillance by additional States may result in a sudden and large increase in HIV case reports (66). Based on CDC's estimates that approximately 220,000 HIV-infected persons without AIDS-defining conditions have been diagnosed with HIV in confidential testing settings and reside in States that do not currently conduct HIV case surveillance (30), it is possible that this many persons could be reported with HIV infection from these States in 1999. However, it is more likely that reporting of prevalent HIV infections will be spread over several years and that the annual increases will be more modest. Initially, most case reports will represent persons whose HIV infection was diagnosed before HIV surveillance was implemented. As the reporting of prevalent HIV cases is completed, the number of HIV case reports will decrease and case reports will increasingly represent persons with recent diagnosis of HIV infection.

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

AIDS trends have declined nationally; however, because the AIDS surveillance trends are affected by HIV incidence, as well as the effect of treatment on the progression of HIV disease, it is not possible to predict future AIDS trends. AIDS surveillance will continue to be important in evaluating access to care for different populations and in identifying changes in trends that might signal a decrease in the effectiveness of treatment. The long-term benefits of antiretroviral therapy and antimicrobial prophylaxis for AIDS-related illnesses continue to be defined, and various factors such as access, adherence, treatment costs, and viral resistance will influence the utilization and effectiveness of these therapies and their effects on AIDS incidence and mortality trends (67-69).

HIV and AIDS Surveillance Practices

Laboratories will be an increasingly important source of information from which to initiate reporting. HIV infection is frequently diagnosed in the outpatient clinical setting, and laboratory-initiated reporting will be particularly useful in identifying outpatient sources of HIV testing (60). Although contact with individual providers is necessary to complete the reporting process, the routine collection of data from laboratories and managed care organizations promotes simplicity and efficiency of case reporting to local surveillance programs.

Performance criteria for HIV and AIDS surveillance are necessary to ensure that surveillance data are of sufficient quality to target prevention and care resources and to detect emerging trends in the HIV epidemic. Evaluations of HIV and AIDS surveillance programs have shown that areas should be able to meet these performance criteria (6,22,57-61). According to these evaluations, the completeness of HIV surveillance (79 to 95 percent) and AIDS surveillance (85 to 100 percent) is high, and reporting is timely with nearly one-half of AIDS cases and three-quarters of HIV cases reported to the national HIV/AIDS reporting system within 3 months of diagnosis (6). In 1996, CDC estimated that the duplication rate of HIV and AIDS cases reported from different States to the national surveillance data base was less than 3 percent and 2 percent, respectively (6). The performance criteria also reflect the need for public health surveillance systems to serve as a basis for the identification and follow-up of cases of public health importance. Based on evaluation studies of non-name-based case identifiers and the current infrastructure of State and local health departments, name-based methods for collecting and reporting public health data provide the most feasible and reliable means for ensuring timely, accurate, and complete reporting of persons diagnosed with HIV and AIDS. Name-based reporting facilitates followup of perinatally exposed infants to determine their infection status and of persons reported with HIV to determine progression to AIDS and vital status. (22,28)

The Security and Confidentiality of HIV and AIDS Surveillance

The revision of the HIV reporting criteria provides an opportunity to review and strengthen State and local confidentiality laws and regulations. Although State HIV and AIDS surveillance confidentiality laws and regulations adequately protect privacy compared with the statutory protections of other health care data, State statutes differ in the degree of privacy protections afforded health information and the criteria for permissible disclosures of personal

information. Most State statutes describe some permissible disclosures of public health information. To help ensure uniform confidentiality protections, CDC, CSTE, ASTHO, the National Conference of State Legislatures, and the Georgetown/Johns Hopkins Public Health Law Project are conducting a model State privacy law project. This project is developing model legislative language to protect confidential, identifiable information held by State and local public health departments against unauthorized and inappropriate use while still allowing the use of surveillance information to accomplish legitimate public health objectives. This process is projected to be completed by the end of 1998, and States that plan to implement HIV case surveillance should consider adopting the model legislation.

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

HIV Prevention and Care

CDC has published guidelines concerning the provision and targeting of HIV counseling and testing services (19, 27, 70-72) and provides support for most public sources of HIV testing. The availability of anonymous HIV testing services may be particularly important for persons who delay seeking testing because of a concern that others may learn of their serologic status. Studies have shown that the availability of anonymous HIV testing is associated with increased numbers of persons seeking testing services (73-76). Anonymous HIV testing services are a required element of federally supported prevention programs unless prohibited by State law or regulation. Currently, 39 States, Puerto Rico, and the District of Columbia provide anonymous HIV testing services.

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

surveillance remains the provision of accurate epidemiologic data for public health information, planning, and evaluation.

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

CONCLUSION

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

Appendix

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

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

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

OR

Clinical Criteria (if the above criteria are not met)

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

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

Laboratory Criteria

Definitive

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

OR

Presumptive

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

OR

Clinical Criteria (if the above criteria are not met)

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

Office of HIV/AIDS Policy

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

Deliver To: Todd

Fax: ( ) 456-2438

Phone: ( )

From: **Deborah von Zinkernagel**
Deputy Director for Policy
Phone: **(202) 690-5560**
Fax: **(202) 690-6584**
E-mail: **DvonZinkernagel@osophs.dhhs.gov**

Date: __/__/__

This fax contains _____ **page(s) plus cover**

If transmission problems occur, please call: Shellie Abramson @ 202-690-5560

Comments: final, as we have it

FINAL

December 1998

CDC Fact Sheet

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

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

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

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

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

CDC Recommendations

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

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

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

Criteria for Quality and Confidentiality

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

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

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

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

Evaluation of Unique Identifier Systems

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

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

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

Support for Anonymous Testing

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

Strengthening Systems to Protect Confidentiality

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

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

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

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

Request for Public Comment

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

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Chief of Staff

Washington, D.C. 20201

FACSIMILE

DATE: 12/9/98

TO: Chris Jennings

FAX#: 456-5557

FROM: Mary Beth Donahue
Chief of Staff

Phone: 202/690-7431 Fax: 202/401-5783

COMMENTS:

This is final paper. It just needs to go on CDC letterhead

_____**Pages [including this cover]**

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December 1998

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

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

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

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

Strengthening Systems to Protect Confidentiality

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

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

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

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Effect of HIV Reporting by Name on Use of HIV Testing in Publicly Funded Counseling and Testing Programs

Allyn K. Nakashima, MD; Rosemarie Horsley; Robert L. Frey, PhD; Patricia A. Sweeney, MPH; J. Todd Weber, MD; Patricia L. Fleming, PhD

Context.—Policies requiring confidential reporting by name to state health departments of persons infected with the human immunodeficiency virus (HIV) have potential to cause some of them to avoid HIV testing.

Objective.—To describe trends in use of HIV testing services at publicly funded HIV counseling and testing sites before and after the implementation of HIV reporting policies.

Design and Setting.—Analysis of service provision data from 6 state health departments (Louisiana, Michigan, Nebraska, Nevada, New Jersey, and Tennessee) 12 months before and 12 months after HIV reporting was introduced.

Main Outcome Measure.—Percent change in numbers of persons tested at publicly funded HIV counseling and testing sites after implementation of confidential HIV reporting by risk group.

Results.—No significant declines in the total number of HIV tests provided at counseling and testing sites in the months immediately after implementation of HIV reporting occurred in any state, other than those expected from trends present before HIV reporting. Increases occurred in Nebraska (15.8%), Nevada (48.4%), New Jersey (21.3%), and Tennessee (62.8%). Predicted decreases occurred in Louisiana (10.5%) and Michigan (2.0%). In all areas, testing of at-risk heterosexuals increased in the year after HIV reporting was implemented (Louisiana, 10.5%; Michigan, 225.1%; Nebraska, 5.7%; Nevada, 303.3%; New Jersey, 462.9%; Tennessee, 803.8%). Declines in testing occurred among men who have sex with men in Louisiana (4.3%) and Tennessee (4.1%) after HIV reporting; testing increased for this group in Michigan (5.3%), Nebraska (19.6%), Nevada (12.5%), and New Jersey (22.4%). Among injection drug users, testing declined in Louisiana (15%), Michigan (34.3%), and New Jersey (0.5%) and increased in Nebraska (1.7%), Nevada (18.9%), and Tennessee (16.6%).

Conclusions.—Confidential HIV reporting by name did not appear to affect use of HIV testing in publicly funded counseling and testing programs.

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From the Division of HIV/AIDS Prevention, National Center for HIV, STD, and TB Prevention, Centers for Disease Control and Prevention, Atlanta, Ga.

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Reprints: Allyn K. Nakashima, MD, Centers for Disease Control and Prevention, 1600 Clifton Rd, MS E-47, Atlanta, GA 30333 (e-mail: alnl@cdc.gov).

POLICIES for the confidential reporting by name of persons with acquired immunodeficiency syndrome (AIDS) to health departments exist in all states.[1] The ability to monitor trends in the epidemic due to the human immunodeficiency virus (HIV) has been based on these AIDS case reports. In contrast, confidential reporting by name of HIV-infected adults and adolescents (aged ≥13 years) who do not meet the criteria for AIDS (HIV reporting)[1] has been implemented less completely; by January 1998, only 28 states required physicians and other health care providers, including clinicians, laboratories, and institutions (eg, hospitals, clinics), to report these cases.[2] Until recently, AIDS case reporting met most of the information needs of monitoring and characterizing the HIV epidemic. Because of changes in the epidemic, most notably those related to new therapies, AIDS case reports no longer provide adequate information, and HIV reporting will become increasingly important.[3,4]

See also p 1416.

One barrier to the adoption of HIV reporting has been the concern that such policies might cause some individuals to avoid testing or medical care.[5,6] These concerns have been based on surveys[7-12] of at-risk populations. Although the populations surveyed were at high risk for HIV (eg, men who have sex with men [MSM]), they were limited by small numbers and narrow geographic coverage. Most surveys asked people about their intent to test without verifying testing behaviors after the implementation of HIV reporting.

Large-scale, publicly funded HIV counseling and testing (CT) programs have been in place in all states since 1985.[13]

These programs were initially implemented to provide sites for HIV testing other than blood banks and to offer anonymous or confidential HIV CT services to anyone seeking a test. Approximately 2.5 million HIV tests are furnished by the CT programs each year.[14,15] In areas where HIV reporting legislation was introduced after implementation of CT programs, the data collected by these programs provide a unique opportunity to observe the effect of HIV reporting policies on testing. In this study, we used CT data to compare the changes in use of HIV testing services before and after HIV reporting was implemented.

METHODS

The Centers for Disease Control and Prevention (CDC) has funded 65 project areas in state, city, [illegible] departments for HIV CT services since 1985.[15-16] Since 1990, most project areas have sent to CDC data on individual tests performed. For each test performed, information was collected on month and year of test; sex, race or ethnicity, and HIV risk exposure group (MSM, injection drug use, sex with a person infected with HIV or at risk for HIV) of the person tested; type of testing site (stand-alone counseling and testing site, sexually transmitted disease clinic, drug treatment center, family planning clinic, community health center, prison or jail, other); test result; and type of test (anonymous vs confidential), added after 1992.

In 5 states, HIV reporting was implemented after CT data collection was in place. In Louisiana, HIV reporting was implemented in February 1993; in Nebraska, September 1995; in Nevada, February 1992; in New Jersey, October 1991; and in Tennessee, January 1992. In Michigan, HIV reporting was required by regulation beginning in 1988. However, the health department did not actively solicit HIV case reports from physicians and other providers, including clinicians, laboratories, and institutions (eg, hospitals, clinics), until April 1992. Therefore, for Michigan this date was taken as the date on which HIV name reporting was implemented. In these 6 states, the number of HIV tests, the number of positive HIV test results, and the distribution of these tests by sex, race or ethnicity, type of testing site, and risk exposure group were compared for the 12 months before and the 12 months after the date HIV name reporting was implemented. Data for the [illegible]th when HIV name reporting was introduced were excluded. We excluded CT sites reporting fewer than 50 tests to the client record system during the 25-month period of evaluation. Because of policy changes, changes in funding, or other program issues, sites may be added or eliminated from a state's CT program. To minimize the effect of changes in sites, we excluded sites that reported no tests for any month during the 25-month study period.

Data on type of test were available for Louisiana and Nebraska and the percentages of anonymous and confidential tests before and after HIV name reporting were assessed by sex, race or ethnicity, and risk exposure group for these states.

To account for the variations in autocorrelated data (ie, the underlying statistical distribution of repeated measures over time in the same sites), we used a Poisson log-linear model. For this model, the number of tests was the response variable used to compare the months before and the months after implementation of HIV reporting. Within the model, the generalized estimating equations method was incorporated to fit a correlated response model.[16-18] The trends in the number of tests before and after HIV reporting were also compared by using the model. The 3 variables in the model comparing trends were time (before vs after HIV reporting), trend (linear trend over 12 months), and time by trend interaction (trend same or different before vs after HIV reporting).

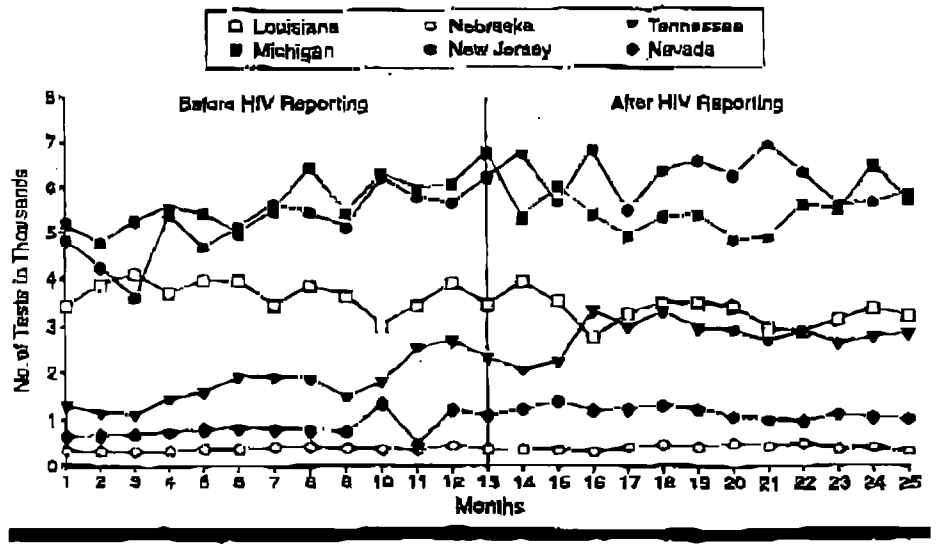
The data used in the analysis were collected to monitor service provision, not for use in a research study; for example, no population sampling was performed. In addition, because of the large numbers of tests performed in most areas, small percentage changes may result in statistically significant differences that are not practically meaningful. Therefore, we present stratified tables as comparisons of numbers of tests and percentage changes without further statistical description.

HIV/AIDS surveillance coordinators and HIV CT program coordinators in each of the 6 study areas were telephoned to obtain qualitative information about the methods used to inform the general public and health care providers such as physicians and other clinicians, laboratories, and institutions about HIV reporting, local HIV CT program characteristics, and occurrences (eg, media events, changes in program funding) that may have influenced counseling and testing trends at the time HIV name reporting was implemented.

Table 1.—Number of HIV Tests Performed in Publicly Funded HIV Counseling and Testing Sites the Year Before and After Implementation of HIV Reporting by State*

	No. of HIV Tests Performed			
	Before Reporting	After Reporting	% Change	P Value†
Louisiana	45 956	38 369	−16.5	.30
Michigan	66 704	65 398	−2.0	.70
Nebraska	4348	5036	15.8	<.001
Nevada	9513	14 264	49.4	<.001
New Jersey	61 440	74 324	21.3	<.001
Tennessee	20 684	33 575	62.8	<.001

*Data exclude tests without site numbers, tests reported from sites with fewer than 50 total tests during the 25-month study period, and sites reporting no tests during any single month. HIV indicates human immunodeficiency virus.
†Data are based on results of Poisson regression modeling.



Number of human immunodeficiency virus (HIV) tests performed per month at publicly funded HIV counseling and testing sites before and after implementation of HIV reporting by state. Dates HIV-reporting-by-name policies were implemented were as follows: for Louisiana, February 1993; Michigan, April 1992; Nebraska, September 1995; New Jersey, October 1991; Tennessee, January 1992; and Nevada, February 1992.

	Who Have Sex With Men			Injection Drug Users					
	Before Reporting	After Reporting	% Change	Before Reporting	After Reporting	% Change	Before Reporting	After Reporting	% Change
Louisiana	1332	1274	−4.3	1938	1562	−16.0	9967	11 009	10.5
Michigan	3806	4113	5.3	3419	2247	−34.3	5756	18 864‡§	225.1
Nebraska	480	574	19.8	238	242	1.7	988	939	6.7
Nevada	744	837	12.5	652	1013	18.9	897	3619	303.3
New Jersey	3242	3968	22.4	7051	7011	−0.6	2284	12 966	467.9§
Tennessee	2734	2622	−4.1	1509	1758	16.6	814	5729	603.9§

*HIV indicates human immunodeficiency virus.
†Includes persons with sexually transmitted diseases, persons who exchanged money or drugs for sex, and persons whose sex partners were at risk for HIV.
‡Large increase in this group was due in part to improved classification of persons initially classified as not at risk.
§Large increase in this group coincided with Earvin "Magic" Johnson's announcement of HIV infection.

RESULTS

During the 25-month period before and after the implementation of HIV reporting, the total numbers of HIV tests provided through the states in the study were as follows: Louisiana, 86 794 tests at 50 sites; Michigan, 138 802 tests at 53 sites; Nebraska, 9749 tests at 8 sites; Nevada, 25 002 tests at 5 sites; New Jersey, 141 946 tests at 84 sites; and Tennessee, 56 721 tests at 29 sites. These tests represented 63% of HIV tests performed in publicly funded CT sites in Louisiana during this period, 95% in Michigan, 77% in Nebraska, 88% in Nevada, 84% in New Jersey, and 79% in Tennessee.

When we compared the total number of tests performed in the year before and the year after HIV reporting, 4 states—Nebraska, Nevada, New Jersey, and Tennessee—had increases in the number of tests performed after implementation (16%, 48%, 21%, and 68%, respectively; Table 1). Louisiana and Michigan had declines of 11% and 2%, respectively, in the total number of tests; however, these declines were not statistically significant.

When linear trends were examined throughout the study period, there were no large or prolonged declines in the number of tests performed in any area in the months immediately after HIV reporting was implemented (Figure). A transient decline in the number of tests in Michigan in the months immediately after implementation of active surveillance for HIV cases had returned to baseline by the end of the 12-month period of study. A declining trend in the number of tests in Louisiana began before HIV reporting was implemented and continued afterward; the Poisson model showed no statistically significant difference in these trends (eg, the slope of a regression line drawn through number of tests per month before HIV reporting and the slope after HIV reporting were the same). A statistically significant difference in the before-and-after trends was found in Nevada, New Jersey, and Tennessee. In these 3 states, the level of testing was higher after HIV reporting.

Table 3.—Number of Anonymous and Confidential HIV Tests in the Year Before and After HIV Reporting for Selected Groups in Louisiana and Nebraska*

	No. of Anonymous HIV Tests			No. of Confidential HIV Tests		
	Before Reporting	After Reporting	% Change	Before Reporting	After Reporting	% Change
Louisiana						
All tests	8551	4987	−23.9	30 895	29 459	−4.6
White MSM	448	348	−22.3	160	174	8.8
African American	2156	1614	−24.7	24 675	22 811	−5.8
Injection drug user	867	288	−37.0	1253	1 146	−8.5
Nebraska						
All tests	1889	2536	34.3	2386	2444	2.5
White MSM	271	385	42.1	169	174	−17.9
African American	106	152	43.8	225	259	19.6
Injection drug user	105	118	11.9	124	121	−2.4

*Data exclude tests for which type of test was unknown or missing (<15% of total tests for Louisiana and <2% for Nebraska). HIV indicates human immunodeficiency virus; MSM, men who have sex with men.

Among whites, the number of HIV tests increased after HIV reporting was implemented in all states but Louisiana, which had a 10% decline. The trends for Hispanic persons were similar to those for whites: a 22% decline for Hispanic persons was seen in Louisiana after HIV reporting. Among blacks, the number of tests performed after HIV reporting declined in Louisiana (10%), Michigan (26%), and New Jersey (2%).

Among MSM, the risk group that reports have suggested would be the most likely to avoid testing if HIV reporting was implemented, the number of tests increased in 4 states in the year after HIV reporting was implemented (Table 2). Louisiana and Tennessee experienced decreases in testing of less than 5% for this group. Among injection drug users, declines in testing occurred in Louisiana and Michigan (Table 2). Among at-risk heterosexuals, which included persons with sexually transmitted diseases, persons who had exchanged money or drugs for sex, and those whose sex partners were at risk for HIV, increases in testing were seen in all areas after HIV reporting was implemented (Table 2). Counseling and testing coordinators in New Jersey and Tennessee attributed the large increases for this group partly to Earvin "Magic" Johnson's announcement of his infection in November 1991,[17] which nearly coincided with the implementation of HIV reporting policies in these states.

In Louisiana, both the number of anonymous tests and the proportion of total HIV tests that were anonymous decreased after HIV reporting was implemented. At the same time, the number and proportion of confidential tests increased (Table 3). Opposite trends were seen in Nebraska (Table 3). In Nebraska, at the time HIV reporting was introduced, counselors were instructed to encourage clients to select anonymous testing. Among white MSMs, in Louisiana, there was a decline in anonymous testing and an increase in confidential testing. In Nebraska, the reverse was true. In Louisiana, declines were seen among blacks both in anonymous and confidential testing after HIV reporting began. The decline in anonymous testing was greater than the decline in confidential testing. Both types of tests increased among blacks in Nebraska. Among injection drug users, confidential testing decreased in Louisiana and Nebraska after HIV reporting whereas anonymous testing increased in Nebraska and decreased in Louisiana.

Surveillance Coordinators and HIV CT Program Coordinators*

	Louisiana	Michigan	Nebraska	New Jersey	Nevada	Tennessee
Media coverage and strategies informing the public HIV reporting				○		
Newspaper articles	X		X	X		X
Press conference				X		X
Evening television news			X			X
Radio news						X
Public and educational television				X		
Public hearings		X	X		X	X
Strategies used to introduce HIV reporting to service providers						
Pamphlets and information sheets	X		X	X		
Public health, epidemiology, or medical society newsletters and bulletins	X	X		X	X	X
Letter campaigns (eg, to physicians, laboratories, clinics)	X	X	X	X		X
Presentations at professional meetings	X	X		X	X	
Training courses	X			X		
Is anonymous testing available?	Yes	Yes	Yes	Yes	No	No
Are health department personnel required to notify partners?	No	No	No	No	No	No
How were publicly funded HIV CT sites notified about HIV reporting?						
Letters to all sites	X	X	X	X		
Training courses	X	X	X	X		X
Involvement in meetings or site visits to discuss HIV reporting		X			X	
How do HIV counselors inform patients about HIV reporting requirements?						
Part of informed consent form	X	X		X	X	
Part of routine counseling	X	X		X		X
Information sheets or pamphlets			X			
Other circumstances coinciding with HIV reporting that influenced CT trends						
Earvin "Magic" Johnson's announcement		X		X		X
Anonymous testing actively encouraged			X			
Expansion of CT programs				X	X	
Outreach efforts to high-risk populations					X	
Efforts to eliminate testing of low-risk populations	X					

*HIV indicates human immunodeficiency virus; AIDS, acquired immunodeficiency syndrome; and CT, counseling and testing.

Counselors informed CT clients about HIV reporting requirements through verbal counseling, informed consent forms, or information pamphlets (Table 4). The methods used to inform health care providers and the public about HIV reporting requirements and the availability of anonymous testing services differed among areas (Table 4).

COMMENT

Confidential reporting of HIV-infected persons by name to health departments has been controversial and many states have been unable to implement HIV reporting policies because of opposition in the community.[3] One of the key concerns about HIV reporting is that it might deter people at risk from being tested or seeking care. In a recent position statement, the American Civil Liberties Union stated that "name reporting is a counterproductive public health measure that will cause individuals to avoid testing."[20] The evidence on which such statements are based consists mostly of surveys such as the one reported by Kegeles et al,[12] in which 60% of 180 persons surveyed in 1987 and 1988 would not be tested if positive results had to be reported to health officials or if partner notification ("contact tracing") were conducted. These surveys on the perceived and hypothetical barriers to testing have been reviewed by Burris,[21] who detected a number of flaws (some of which we discuss later). He concluded that they do not provide an "account of determinants of the underlying social risk [to testing]... and so fail to provide a basis for properly identifying what people are afraid of through research." The evidence showing an effect of HIV reporting on actual testing behavior is scantier. In 1988, Johnson et al[22] showed that the rate of monthly attendance by MSM at an alternative HIV test site decreased 61% in the first 24 months after the reporting of HIV-positive persons by name became mandatory in South Carolina. In contrast with these reports, a multistate survey of high-risk populations conducted in 1996 found that only 2% of people who had not been tested said that concern about HIV reporting was the main reason they were not tested[23]; most could not correctly identify their state's reporting policy.[24] An analysis of data from the 1988 AIDS Knowledge and Attitudes Survey of more than 20 000 people also found no relationship between HIV reporting requirements and previous or planned use of testing.[25] Our results showing no large declines in the number of persons (overall or among high-risk groups) seeking testing at publicly funded CT sites after the implementation of HIV reporting policies complement and confirm these last 2 studies.

One reason for the differences in findings from these studies is the populations studied. The studies that focused on groups (eg, MSM[8,11] or persons seeking anonymous testing[16]) that have a greater interest in confidentiality and discrimination issues were more apt to find significant concerns about HIV reporting. Most of the persons in the 1988 general population survey[25] were low-risk persons who would be less concerned about HIV reporting. Among highly concerned groups, either there must be heterogeneity of opinion or the

perceived risks stated in hypothetical surveys do not actually result in avoidance of testing, as suggested by the lack of declines in testing among MSM in our study. We found declines in testing among blacks and injection drug users in Louisiana, Michigan, and New Jersey after HIV reporting began. In New Jersey, the declines were less than 2% and were within the range expected for routine year-to-year variation. In Louisiana, the declines were consistent with overall declines in testing that were present before HIV reporting was implemented, as evidenced by the lack of significant differences in trends before and after HIV reporting. The declines in Louisiana may have been related to changes in CT program policy that were occurring during the study period. For example, many CT sites in this state had to be excluded from the analysis because they had stopped offering testing due to the low number of HIV-positive persons identified. In addition, many CT sites repeatedly test low-risk clients; over time, these sites may counsel persons at lower risk to return for testing less often.

The declining trends for blacks and injection drug users in Michigan were difficult to interpret because we were not able to define a date of HIV reporting implementation. Legislation on HIV reporting was enacted in Michigan in 1988. However, because the health department had no infrastructure to support additional data collection, HIV case reports were not actively solicited from physicians, clinicians, laboratories, and institutions until April 1992. The active solicitation of case reports was focused mostly on public providers and was not accompanied by publicity. Most clients at CT sites were probably unaware of this change in policy. In addition, Magic Johnson's announcement[19] was especially felt in Michigan because he had once lived there. His announcement was made in November 1991; in our analysis, the data for the year before HIV reporting included the months immediately after the announcement. The decline in the number of tests after HIV reporting could have been an artifact caused by a return to baseline levels of testing after a transient increase following the announcement. To further substantiate this, we examined additional data from Michigan 1 year after the study period; the number of tests for blacks had increased 9% (from 21 792 to 23 726), and the number of tests for injection drug users had increased 16% (from 2347 to 2693). These levels were similar to the levels in the year before the study period: 23 391 tests for blacks and 3158 tests for injection drug users.

Another reason for differences in results may be the timing of the studies. Many of the early studies were conducted before the highly effective antiretroviral therapies became available. As therapies have improved, the advantages to the patient of early diagnosis and treatment can provide a powerful incentive to testing, and those advantages may outweigh concerns about HIV reporting. Since the early years of the epidemic, there has also been considerable experience with the security and confidentiality of AIDS case-reporting data and with issues of discrimination, which may have allayed the concerns of persons considering HIV testing. Case-reporting data for AIDS have been heavily relied on to allocate resources and services for infected patients. Populations who benefit from these services may understand the need for this information and be willing to provide it.[26]

Anonymous testing was available in 4 of the states in our study. Reports have suggested that the introduction of anonymous testing increases testing in high-risk populations[7,27,28] and the elimination of it decreases testing in these groups.[29-31] In Nevada and Tennessee, where anonymous testing was not available, overall testing increased after HIV reporting; however, a small decline in testing occurred among MSM in Tennessee. If there had been no access to anonymous testing in the other states, more declines in testing after HIV reporting policies might have been seen. In the states where we could evaluate anonymous vs confidential testing, the percentage of tests that were anonymous decreased from 15% to 18% in Louisiana and increased from 43% to 50% in Nebraska before and after HIV reporting. From these results we conclude that there may be some persons who wish to test anonymously and concur with the recent recommendation of the Council of State and Territorial Epidemiologists[32] that states considering HIV reporting policies should make anonymous testing available.

The HIV CT data system has a number of limitations because it is designed to measure delivery and use of testing services, not to support a rigorous analysis of testing patterns. The system measures the number of tests rather than the number of persons tested; thus, people may be tested multiple times and the results cannot be identified as coming from repeat tests. Each state CT program is unique and policy changes (eg, in funding, personnel, testing resources, advice given by counselors on when to return for retesting, site selection), media events, availability of other testing services in the community, and many other factors unrelated to HIV reporting may have affected the secular trends of CT coordinators and our site exclusion criteria, to account for some of the main factors that coincided with the implementation of HIV reporting. Finally, these data are not representative of testing trends in the offices of private physicians or other settings where persons may be tested. Despite these limitations, the number and variety of publicly funded CT sites and the large numbers of persons who use those testing services make it unlikely that a large adverse effect of HIV reporting on testing would have been missed.

With the changing trends in clinical AIDS incidence (−6% between 1995 and 1996) and AIDS deaths (−23% between 1995 and 1996) brought about by improved therapies,[4] information on HIV-infected non-AIDS cases obtained through HIV case reporting will be needed for monitoring, planning, and allocation of resources for prevention and clinical services.[5] As states implement confidential HIV reporting policies, these data indicate that the impact of surveillance on those seeking HIV testing will be small and should not hinder HIV prevention efforts.

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Q&A on CDC Draft Guidelines for HIV Surveillance

Q: What is CDC recommending and why?

A. CDC is recommending that states implement HIV surveillance systems to build on their existing AIDS surveillance systems. Treatment advances have slowed the progression from HIV to AIDS for many individuals, so data on AIDS cases alone cannot provide adequate information to direct prevention efforts to communities currently at greatest risk. Without improved data, the nation could be soon fighting an rapidly evolving epidemic with outdated information.

After extensive work with state health departments and community HIV/AIDS organizations, CDC has released draft guidelines to assist states in the design and implementation of effective HIV surveillance systems. These guidelines include very specific standards for both quality and confidentiality, reflecting CDC's responsibility to balance the need for better data with legitimate concerns about confidentiality and security. They also stress the continued importance of anonymous testing as an essential component of any surveillance system.

While the guidelines set out strict confidentiality and quality standards for HIV surveillance data, they do not dictate the type of surveillance system used to gather those data. CDC does believe that, based on its review of currently available studies of name-based reporting systems, that such systems are most likely to provide data that meets the quality standards. However, a state can use any surveillance system that meets the performance criteria specified by CDC. or we can encouraged by state activities to move in the direction.

Q: Will states be required to conduct name-based HIV reporting?

A. No. Our draft policy allows flexibility for states to choose the surveillance systems they deem most appropriate. The focus is on the quality of the data gathered and the security and confidentiality of the surveillance system. CDC will provide technical assistance and funding to states working to design HIV surveillance systems – both those using unique identifiers or name-based systems.

CDC believes that name-based systems have a proven track record of providing quality data in a confidential and secure manner. The AIDS surveillance system, which is in place in all states, is a name-based system that has produced high quality data with only a few instances of security breaches.

However, CDC recognizes that some states may choose to design alternative systems that use unique identifiers instead of names. While CDC has evaluated on type of UI system

and found problems in the quality of data produced, there is currently no evidence suggesting that unique identifier systems cannot be designed and implemented in a manner that consistently provides state public health officials with accurate and reliable data.

CDC therefore encourages states to develop a surveillance system that best protects the confidentiality and privacy of their constituents while providing critical data on the scope of the HIV epidemic. Given the importance of these data for directing services and care to individuals with HIV infection, all states will be required to meet the specified performance criteria regardless of the type of system implemented. CDC will provide technical assistance and support to all the states working to implement new HIV surveillance systems, including those that are name-based and those that use unique identifiers.

Q: How will surveillance systems be evaluated?

A. The criteria include strict confidentiality procedures and protections, quality standards for data to ensure completeness, timeliness, unduplicated reports, and the ability to follow up with providers on cases of public health importance when additional epidemiologic information is needed.

CDC will work closely with states through a transition period over the next several years. When the transition is complete for an individual state, CDC will evaluate and award proposals for Federal funding of state and local surveillance programs based on their capacity to meet the performance standards.

Q: Will states that don't implement HIV reporting lose funding?

A. CDC will continue to fund all states to conduct HIV and AIDS reporting. However, we believe that a state's capacity to accurately monitor and forecast the HIV epidemic on the local level will be less complete without an effective HIV reporting system. States relying solely on AIDS reporting may not be able to accurately depict and predict the course of their epidemics. CDC will work closely with states to help them meet performance standards. Over time, a state's ability to provide accurate and complete surveillance will be reflected in the level of CDC funding.

Q: Is CDC setting its standards for quality too high?

A. No. The goal is to collect the data we need for public health, while protecting privacy and confidentiality. As the nation's prevention agency, CDC must ensure that surveillance systems provide a reliable means of directing and evaluating HIV prevention and treatment efforts at a national, state, and local level. At the same time, CDC must balance the need for data with an equally important obligation to insist that the private information used in these surveillance systems is gathered and maintained under rigorous standards of confidentiality and security. The standards articulated in the guidance reflect that necessary balance. CDC has established standards for the quality of data necessary to

make informed decisions about fighting the epidemic. Setting standards too high might force states to implement more intrusive surveillance systems that might cause resistance to testing and would therefore be counterproductive.

Q. If name-based systems work, why are you allowing states to try unique identifier systems?

A. CDC believes that the issue here is the quality and security of the data, not the system to gather those data. This epidemic varies significantly across the country, and states should have the flexibility to assess their own unique needs and resources and make a determination as to the kind of HIV surveillance system utilized to collect data. CDC believes that name-based systems have a good track record and can be relied upon to gather good data. However, some states have expressed an interest in pursuing systems that use unique identifiers in order to reduce the concerns about confidentiality that might negatively influence testing behaviors. Because it is so critically important for individuals at risk to know their HIV status, and for those that are infected to access care as soon as possible, concerns about confidentiality – whether or not they are justified – must be taken into account. Therefore CDC will work with those states that want to establish unique-identifier-based surveillance systems that they believe will help in maximizing access to HIV testing.

Q: Why are the guidelines being published in draft form?

A. CDC recommendations are often published in draft form to allow for a public comment period. This process is designed to ensure that the recommendations promote the best possible public health approaches. We worked with state health departments and local advocates to draft these guidelines, and we look forward to more input from the public as the process continues. After the public comment period, which runs from December 10, 1998 to January 9, 1999, the guidelines will be modified as needed and published in the Morbidity and Mortality Weekly Report.

Name-Based HIV Reporting

Q: Does name-based HIV reporting mean CDC has a list of names of infected individuals?

A. No. CDC does not now – nor will it in the future – maintain a list of names of individuals in either AIDS or HIV reporting systems. Names are always removed by state health departments before any data are sent to CDC.

Q: How do states that already have name-based HIV reporting use the names?

A. State surveillance staff use the names as the identifier to ensure that HIV data are complete, accurate, and reliable for directing programs and resources. More specifically, the name is used to identify and eliminate duplicate reports on the same individual; to

conduct necessary follow-up with the health care provider if additional epidemiologic information is needed; to link to name-based AIDS and death registries; to link the information with other name-based public health data systems such as tuberculosis registries if necessary; and, in some states, to evaluate referrals to prevention and care services.

Q: Does name-based reporting mean health departments will begin notifying partners of those infected?

A. Partner notification and HIV/AIDS reporting are both important, but separate public health activities. They need not be linked to be done effectively. CDC already requires states to have voluntary partner notification programs in place and partner notification is conducted in all states, including those that do not have name-based HIV reporting.

Additionally, these programs are, by definition, voluntary, since the infected person must choose to participate in discussions about partner notification and provide the names of partners to be contacted. Partner notification is conducted at both anonymous and confidential test sites.

Q: Who will have access to the HIV reports that include names?

A. CDC program guidance specifies that only select staff at state health departments should have access to these data and they should be used only for public health purposes. All of these individuals must be trained in confidentiality procedures and must be made aware of penalties for unauthorized disclosure of reporting information. HIV and AIDS data have the strictest and most comprehensive protections of any health data in the nation, and efforts are underway to strengthen these protections even further.

Q: What protections are in place to ensure confidentiality of name-based reports?

A. HHS and CDC are extremely concerned about HIV data remaining confidential. The draft guidance document outlines performance criteria to ensure the quality and confidentiality of HIV data. These criteria include strict confidentiality procedures and protections such as using a single registry, eliminating paper reports, using computer encryption techniques, setting up physical security and limited access to data, and penalties for abuse.

To date, states have maintained an exemplary record in protecting the confidentiality of HIV/AIDS data. Since 1981 there have been few reported breaches of confidentiality in state AIDS reporting systems. However, concerns about confidentiality of HIV/AIDS status are real, and deserve special consideration.

One important security measure CDC is now making available to states is the option of using a double-keyed encryption program. With this system, names and other identifying

information may only be accessed with both the key (password) held by the state and the key held by CDC.

Additionally, a review of local laws by the Georgetown/Johns Hopkins Public Health Law Project found that laws protecting state-held HIV/AIDS data are stronger than the laws regarding privately held data. CDC is also working with the Georgetown/Johns Hopkins Public Health Law Project to develop model legislative language to protect confidential, identifiable information held by state and local public health departments against unauthorized and inappropriate use, while still allowing the use of surveillance information to accomplish legitimate public health objectives.

Q: Is name-based reporting used for other STDs?

A. Name-based reporting is routinely used for all reportable STDs and other notifiable diseases (i.e., chlamydia, gonorrhea, AIDS, tuberculosis, lyme disease, measles, etc.). For all of these diseases, as well as for AIDS cases, names are collected only at the state level. CDC does not receive names with the data.

Unique-Identifier Systems

Q: Can a unique-identifier (UI) system be used instead of name reporting?

A. Yes. CDC's draft policy allows flexibility for states to choose the surveillance systems they deem most appropriate. CDC will continue to provide technical assistance to states working to design systems that rely on codes or "unique identifiers" (UIs) rather than names.

Q: Are UI systems anonymous and completely confidential?

A. No, a UI system is not completely anonymous. A UI must contain enough information, such as all or part of a Social Security Number in combination with other elements to identify a specific individual. Additionally, for the follow-up of UI-based cases, providers must maintain logs or other forms of documentation linking the UI to the name-based medical records. This process may pose additional confidentiality risks if physician-held surveillance registries are not protected by state confidentiality statutes or are located in non-secure areas. However, CDC will provide states that choose to use UI with any technical assistance they need.

Q: Will CDC assist states who choose to implement UI-based systems?

A. CDC has and will continue to provide technical assistance to states working to design systems that rely on codes or "unique identifiers" rather than names. Over the next several years, CDC will assist all states in implementing HIV surveillance systems, evaluating current performance levels, revising systems as necessary, and reassessing performance.

Testing

Q: Does HIV reporting require the elimination of anonymous testing?

A. No. Not only does CDC continue to strongly support anonymous HIV testing, but it requires states to have anonymous testing systems in place, unless they are forbidden by state law. CDC studies indicate that the lack of anonymous testing options serves as a major deterrent to testing in some high-risk populations. Maintaining anonymous test sites is important for prevention efforts and will not seriously inhibit our ability to track the epidemic. Eleven states currently do not have anonymous testing. CDC has recommended that these states review and reconsider their policies regarding anonymous testing.

Q: What are the 11 states that do not offer anonymous testing?

A. Alabama, Idaho, Iowa, Mississippi, Nevada, North Carolina, North Dakota, South Carolina, South Dakota, Tennessee, and Wyoming.

Q: Does HIV reporting deter people from getting tested?

A. CDC studies conducted to date suggest that name-based HIV reporting has not served as a major deterrent to testing. For example, CDC has worked with six health departments to evaluate HIV testing patterns in the 12 months before and the 12 months after the implementation of HIV reporting. In these areas, the number of HIV tests increased in four states, and declined in two. The declines were not statistically significant and followed a decreasing trend in testing that began before the implementation of reporting.

However, CDC recognizes that for some people name reporting may serve as a deterrent. The agency therefore strongly supports that anonymous testing be made available. As additional areas implement HIV reporting, CDC will continue to conduct evaluations to monitor the impact of policy changes on testing behaviors.

Q: What will be effect of National HIV Case Surveillance on reporting trends?

We expect the number of HIV cases reported nationally will increase primarily because of the implementation of HIV surveillance by the remaining states and local areas. CDC estimates that as many as 220,000 have been diagnosed with HIV in confidential testing settings and reside in states that do not currently conduct HIV case surveillance.

Similar to the effect on AIDS surveillance trends after the implementation of the revised reporting criteria in 1993, the initiation of HIV surveillance by additional states may result in a sudden and large increase in HIV case reports. However, it is more likely that reporting of prevalent HIV infections will be spread over several years and that the annual increases will be more modest.

Privacy

Q. How does this fit in with the Department's overall privacy goals?

The guidelines are consistent with the goals Secretary Shalala outlined in her testimony before Congress on the Health Insurance Portability and Accountability Act (HIPAA). Briefly, these guidelines say that privacy protections must be balanced with the public responsibility to support national priorities -- like public health, research, quality care, and our fight against health care fraud and abuse. Data must be available to those who need it for legitimate reasons, but security measures must be required to protect the information against improper use by employees, or threats from the outside. Organizations hired by providers and payers to process information and complete other tasks should also be bound by these requirements.

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FACSIMILE

DATE: 12/17

TO: Sarah Bianchi / Chris Jennings

FAX#: 456-5557

FROM: Elizabeth Summy
Deputy Chief of Staff

Phone: 202/690-7431 Fax: 202/401-5783

COMMENTS:

HIV/AIDS grant announcement

Please call.

5 **Pages [including this cover]**

#337

DRAFT

DRAFT: FY 1999 TITLE I FORMULA, SUPPLEMENTAL AND CBC AWARDS 12/10/98

FOR IMMEDIATE RELEASE
(once cleared & CLO embargo lifted–12-16 or 17)

Contact: HRSA Press Office
301-443-3376

$479 MILLION AWARDED FOR HIV/AIDS CARE IN HIGH INCIDENCE AREAS

HHS Secretary Donna E. Shalala today announced nearly $479 million in Ryan White CARE Act grants to fund primary health care and support services for low-income individuals and families in 50 eligible metropolitan areas hardest hit by the HIV/AIDS epidemic. Part of these funds are targeted to 47 EMAs with high numbers of affected African American and Hispanic populations under a special Clinton administration initiative with the Congressional Black Caucus to address the greater burden of HIV/AIDS on racial and ethnic minorities.

Under Title I of the Ryan White CARE (Comprehensive AIDS Resources Emergency) Act, 50 EMAs are receiving formula grant awards based on the number of people in the EMA living with HIV disease. Competitive supplemental awards based on severe need and other criteria, also are going to all EMAs except Las Vegas, Nevada and Norfolk, Virginia, which are two newly designated EMAs and will receive supplemental funding early next year.

"The CARE Act helps us reach those who might fall between the cracks, and Title I is our primary mechanism for funding HIV care in urban areas with greatest need," said Secretary Shalala. "Our initiative with the Congressional Black Caucus further targets racial and ethnic minorities by helping us mobilize effective prevention efforts and provide equal benefits for minority populations."

-more-

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Title I grants provide essential HIV/AIDS health care and a wide range of support services to those who lack or are only partially protected by health insurance, including physician visits, case management, assistance in obtaining medications, home-based and hospice care, substance abuse and mental health services and other related services. To qualify for Title I funding, an EMA must have a population of at least 500,000 and have reported more than 2,000 AIDS cases in the most recent five calendar years.

"This marks the first year that we have received extra funds targeted specifically to African Americans and Hispanics," said Claude Earl Fox, M.D., M.P.H., administrator of HHS' Health Resources and Services Administration, which oversees the CARE Act through its HIV/AIDS Bureau. "These funds provide added resources to more than 1,300 HIV care providers. In 1996, more than 60 percent of their clients were African American and/or Hispanic."

Other HRSA-administered CARE Act programs fund HIV/AIDS services in states and eligible U.S. territories (Title II); provide support to public and nonprofit organizations for outpatient early intervention services and planning grants (Title III); fund special programs for improving access to care for women, youth, adolescents and families (Title IV); demonstrate and evaluate innovative models of care for historically underserved populations (Special Projects of National Significance Program); oversee a regional network for educating and training AIDS care providers (AIDS Education and Training Centers Program); and provide reimbursement for uncompensated costs in treating dental patients with HIV (HIV/AIDS Dental Reimbursement

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Program). Title II also supports the AIDS Drug Assistance Program (ADAP), which helps support the cost of medications that prolong and improve the quality of life for uninsured individuals and others unable to pay.

Since FY 1991, the Clinton Administration has awarded close to $6.4 billion in CARE Act funds. It is estimated that more than 400,000 individuals affected by HIV/AIDS access CARE Act services each year.

A list of the 50 EMAs and Title I grant awards, which include the CBC awards, is attached.

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Note: HHS press releases are available on the World Wide Web at: http://www.hhs.gov.

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Ryan White CARE Act
FY 1999 Title I Awards

Eligible Metropolitan Area	Title I Award	CBC Award
Atlanta, Ga.	$13,147,268	($157,991)
Austin, Texas	$3,175,509	($27,997)
Baltimore, Md.	$13,478,549	($202,463)
Bergen-Passaic, N.J.	$4,320,176	($48,163)
Boston, Mass.	$10,647,381	($68,508)
Caguas, Puerto Rico	$1,610,314	($29,348)
Chicago, Ill.	$18,227,884	($191,570)
Cleveland, Ohio	$2,933,058	($31,148)
Dallas, Texas	$10,164,078	($82,552)
Denver, Colo.	$4,150,341	($19,265)
Detroit, Mich.	$6,585,744	($73,909)
Dutchess County, N.Y.	$1,220,662	($12,153)
Ft. Lauderdale, Fla.	$10,810,324	($118,291)
Ft. Worth, Texas	$2,935,543	($21,606)
Hartford, Conn.	$4,019,409	($48,703)
Houston, Texas	$15,489,996	($177,707)
Jacksonville, Fla.	$3,683,146	($41,591)
Jersey City, N.J.	$5,015,785	($63,737)
Kansas City, Mo.	$2,952,910	($16,204)
Las Vegas, Nev.*	$1,800,211	($25,747)
Los Angeles, Calif.	$33,540,737	($261,519)
Miami, Fla.	$21,248,387	($279,163)
Middlesex-Somerset-Hunterdon, N.J.	$2,555,029	($26,467)
Minneapolis-St. Paul, Minn.	$2,548,603	($12,783)
Nassau-Suffolk, N.Y.	$5,632,012	($49,963)
New Haven, Conn.	$6,100,471	($62,746)
New Orleans, La.	$5,695,360	($68,148)
New York, N.Y.	$96,961,856	($1,260,780)
Newark, N.J.	$14,390,269	($192,110)
Norfolk, Va.*	$1,948,137	($49,963)
Oakland, Calif.	$6,218,532	($55,004)
Orange County, Calif.	$4,300,690	($23,586)
Orlando, Fla.	$4,907,180	($54,824)
Philadelphia, Pa.	$16,011,451	($205,884)
Phoenix, Ariz.	$3,865,319	($19,445)
Ponce, Puerto Rico	$2,487,768	($33,849)
Portland, Ore.	$3,115,251	$0
Riverside-San Bernardino, Calif.	$6,463,388	($36,460)
Sacramento, Calif.	$2,578,873	($12,423)
St. Louis, Mo.	$3,664,771	($33,669)
San Diego, Calif.	$8,872,685	($52,934)
San Francisco, Calif.	$36,218,513	($67,788)
San Jose, Calif.	$2,486,136	($15,214)
San Juan, Puerto Rico	$11,912,865	($217,047)

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Santa Rosa, Calif.	$1,127,018	$0
Seattle, Wash.	$5,303,343	$0
Tampa-St. Petersburg, Fla.	$7,236,728	($48,163)
Vineland-Millville-Bridgeton, N.J.	$688,648	($8,732)
Washington, D.C.	$18,322,558	($259,988)
West Palm Beach, Fla.	$6,711,944	($87,953)
TOTAL	**$479,482,810**	

* Includes formula funding and CBC award only.

The Clinton-Gore Administration: A Record of Responding to HIV and AIDS

"Eleven years ago, on the first World AIDS Day, we vowed to put an end to the AIDS epidemic. Eleven years from now, I hope we can say that the steps we took today made that end come about."

-- President Clinton, December 1, 1998 (World AIDS Day)

"We are united in the fight for research, care, and prevention. And we will not stop until all who need it have access to the treatment they need. We will not rest until we have a vaccine -- and a cure."

--Vice President Gore, September 19, 1998

Improving Health Care Quality and Increasing Access

Providing National Leadership. President Clinton has worked hard to invigorate the response to HIV and AIDS, providing new national leadership, substantially greater resources and a closer working relationship with affected communities. Since taking office, funding for AIDS research has increased by over 65 percent, and funding for HIV prevention has increased 34 percent; funding for the Ryan White CARE Act has increased by over 240 percent.

Although much work remains to find a cure, progress has been made. In 1996, the first time in the history of the AIDS epidemic, the number of Americans diagnosed with AIDS declined. And between 1996 and 1997, HIV/AIDS mortality declined 47 percent, falling from the leading cause of death among 25-44 year olds in 1995 to the fifth leading cause of death in that age group. There has been a decline in the number of AIDS cases overall and a sharp decline in new AIDS cases in infants and children.

Leading the Global Fight Against HIV/AIDS. On December 1, 1998 (World AIDS Day), the President announced a new $10 million initiative at USAID to address the growing crisis of children orphaned by AIDS. The United States has invested over $1 billion in international AIDS relief since the start of the epidemic and funds 25% of UNAIDS. In fiscal year 1999, the NIH will invest over $164 million in critical research projects aimed at reducing the number of AIDS orphans by preventing and treating HIV/AIDS internationally.

Historic $156 Million Effort to Address HIV/AIDS in Communities of Color. African Americans and other racial and ethnic minorities make up the fastest growing portion of the HIV/AIDS caseload. As part of the FY99 budget, the Clinton Administration fought for a comprehensive new initiative that invests an unprecedented $156 million to improve the nation's effectiveness in preventing and treating HIV/AIDS in the African American, Hispanic and other minority communities.

Protecting Medicaid and Social Security Coverage. The President fought for and won the preservation of the Medicaid guarantee of coverage which serves more than 50 percent of people living with AIDS -- and 92% of children with AIDS -- who rely on Medicaid for health coverage. He also revised eligibility rules for Social Security Disability Insurance to increase the number of HIV+ persons who qualify for benefits.

Focusing National Efforts on an AIDS Vaccine. In May of 1997, the President challenged the nation to develop an AIDS vaccine within the next ten years. He announced a number of initiatives to help fulfill this goal, including: dedicating an AIDS vaccine research center at the National Institutes of Health and encouraging domestic and international collaboration among governments, medical communities and service organizations. On World AIDS Day 1998, the President announced $200 million in funding for vaccine research at the NIH, a $47 million (33%) increase over the previous fiscal year.

Dramatically Increasing Overall AIDS Funding. The Clinton Administration has responded aggressively to the significant threat posed by HIV/AIDS with increased attention to research, prevention and treatment. President Clinton increased public health spending for major HIV/AIDS programs by over 100 percent, funding for the Ryan White CARE programs has increased 266 percent and support for AIDS-related research has increased by 67 percent.

Increasing AIDS Drug Assistance and Accelerating AIDS Drug Approvals. Funding for AIDS drug assistance has increased from $52 million per year to $385 million per year during the Clinton Administration. This program provides new life-prolonging drugs to people with HIV and AIDS. In addition, President Clinton convened the National Task Force on AIDS Drug Development, and removed dozens of bureaucratic obstacles to the effective and decent treatment of people with AIDS. Since 1993, the Food and Drug Administration has approved more than a dozen new AIDS drugs and important diagnostic tests.

Making Research a Priority. In one of his first acts in office, President Clinton signed the National Institutes of Health Revitalization Act of 1993, placing full responsibility for planning, budgeting and evaluation of the AIDS research program at NIH in the Office of AIDS Research. The Administration has increased

NIH AIDS research funds by 67% in five years.

Focusing on Prevention: Supporting the Centers for Disease Control and Prevention. The Administration has increased funds for HIV prevention at the CDC by 34% in five years. Under the leadership of the Clinton Administration, the CDC reorganized its AIDS prevention efforts to foster greater overall coordination and enhance efforts to reduce sexually transmitted diseases and tuberculosis.

Educating Young People about the Dangers of AIDS. The Clinton Administration launched the Prevention Marketing Initiative, focusing on the risk to young adults (18-25) with frank public service announcements recommending the correct and consistent use of latex condoms for those who are sexually active.

Requiring the Federal Workforce to Understand AIDS. The Administration issued a directive on September 30, 1993, that requires every Federal employee to receive comprehensive education on HIV/AIDS.

Established a White House AIDS Office and Created a Presidential Advisory Council. President Clinton created a White House Office of National AIDS Policy to bring greater direction and visibility to the war on AIDS. Sandy Thurman, the current director of the office, has broad experience in both domestic and international AIDS services. At the same time, the Administration has sharpened the focus of its AIDS programs. The President also created the Presidential Advisory Council on HIV and AIDS to provide him and his Administration with expert outside advice on the ways in which the Federal government should respond to the HIV/AIDS epidemic. Dr. R. Scott Hitt, a California physician specializing in HIV/AIDS care, chairs the panel.

Convened the First Ever White House Conference on HIV and AIDS. On December 6, 1995, the President convened the first White House Conference on HIV and AIDS in the history of the epidemic, bringing together more than 300 experts, activists and citizens from across the country for a discussion of key issues.

SELECTED HIV/AIDS INVESTMENTS	FY99	Increase from FY98	Increase from FY93
Ryan White CARE Act	**$1.4 billion**	**23%**	**266%**
AIDS Drug Assistance	*$461 million*	*61%*	*787%**
HIV Prevention (CDC)	**$657 million**	**5%**	**34%**
AIDS Research (NIH)	**$1.8 billion**	**12%**	**67%**
Vaccine Research	*$200 million*	*33%*	*145%*
Housing (HUD)	**$225 million**	**10%**	**125%**
International (USAID)	**$131 million****	**8%**	**64%**

*since FY96, when separate program established

**includes $10 million emergency funding for AIDS orphan initiative

ATTACHMENTS

REMARKS BY THE PRESIDENT ON WORLD AIDS DAY 1998

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release December 1, 1998

REMARKS BY THE PRESIDENT
AT WORLD AIDS DAY EVENT
Room 450
Old Executive Office Building

THE PRESIDENT: Thank you, Amy, for your magnificent remarks and the power of your example. Thank you, Cynthia, for coming to this big, scary crowd. (Laughter.) She was nervous. I said, well, look at the bright side -- at least you got out of school for a day. (Laughter.)

I thank the other children who are here with us. And I want to thank all the members of our administration who have helped so much in this cause -- Secretary Albright; Brian Atwood; Dr. Satcher; our AIDS Policy Director, Sandy Thurman; members of the Council on HIV and AIDS.
We're glad to have Nafis Sadik here, the Director of the U.N. Population Fund. Richard Socaridies from the White House, I thank you and all the other members of the administration. And I, too, want to join in expressing my appreciation to the members of Congress who Brian
mentioned for their support for AIDS funding.

But I especially want to thank Amy for being here and reminding us of what this is all about. When she was speaking my mind wandered back to an incident that occurred when I was running for President in 1992. Some of you have heard me say this before, but I was in Cedar Rapids,
Iowa, a place largely known for its enormous percentage of Czech and Slovak citizens. And there was in the crowd at this rally where I was speaking a woman who was either Czech or Slovak, probably, holding an African American baby. And I said, whose baby is this? She said, this is my baby. And I said, where is this baby from? She said, Florida, I got her from Florida. (Laughter.)

And it was October in Cedar Rapids and she should have been in Florida, probably. (Laughter.) She said, this baby was born with AIDS and abandoned and no one would take this baby. This woman had her marriage had dissolved, she was raising her own children alone. But

because she heard about children like this wonderful little girl, she adopted this baby.

And every year since, about once a year, I see this young child. I've watched her grow up now and I'm happy to tell you that six years later she's still alive and doing pretty well. She comes to the NIH for regular check-ups and she comes by the White House to see her friend.
And every time I see Jimiya I am reminded of what this whole thing is about.

And I think I should tell you one other thing. When Amy was standing up here with me and I was telling her what a fine job she did, she said, I'm so glad that Cynthia could be here, and that I could say Carla's name in your presence.

This is, I think, very important for people who have not been touched in some personal way -- who have never been at the bedside of a dying friend, who have never looked into the eyes of a child orphaned by AIDS or infected with HIV -- to understand. And I believe, always, that
if somehow we could reach to the heart of people, we would always do better in dealing with problems, for our mind always conjures a million excuses in dealing with any great difficulty.

Let me begin, even in this traumatic moment, to say we have a lot to celebrate on this AIDS Day. We celebrate the example of Amy and Cynthia. Just think, a decade ago people really believed that AIDS was unstoppable; the diagnosis was a virtual death sentence; there was an
enormous amount of ignorance and prejudice and fear about HIV transmission. Most of us knew people who couldn't get into apartment houses or were being kicked out or otherwise -- their children couldn't be in school because of fears that people had about it.

Every day, for people who had HIV or AIDS and their families -- every day was a struggle a decade ago. A struggle for basic information, for treatment, for funding, and all too often, for simple compassion.

For six years, thanks to many of you, we have worked hard to change this picture -- and so have tens of thousands of other people across our country and across the globe. We've worked hard to draw attention to AIDS and to better direct our resources by creating the Office of National AIDS Policy and the President's Council on HIV and AIDS. We had the first ever White House conference on AIDS. We helped to ensure that people with HIV and AIDS cannot be denied health benefits for preexisting conditions. We accelerated the approval of more than a
dozen new AIDS drugs, helping hundreds of thousands of people with AIDS to live longer and more productive lives.

Working together with members of both parties in the Congress, we increased our investment in AIDS research to an historic $1.8 billion. This year we secured $262 million in new funding for the Ryan White CARE Act, providing medical treatment, medication, even transportation to families coping with AIDs. This October we declared that AIDS had reached crisis proportions in the African American, Hispanic American and other minority communities, and fought for $156 million initiative to address that. Today the Vice President is announcing $200 million in new grants for communities around the country to provide housing for people with AIDS.

The results of these and other efforts have been remarkable. For the first time since the epidemic began, the number of Americans diagnosed with AIDS has begun to decline. For the first time, deaths due to AIDS in the United States have declined. For the first time, therefore, there is hope that we can actually defeat AIDS.

But all around us there is, as we have heard from all the previous speakers, fresh evidence that the epidemic is far from over, our work is far from finished, that there are rising numbers of AIDS in countries like Zimbabwe, where 11 men, women, and children become infected every minute of every day. There are still too many children orphaned by AIDS, tens of thousands here in America, tens of millions in developing nations around the world.

And when so many people are suffering, and with HIV transmission disproportionately high, still, among our own young people here in America, it's all right to celebrate our progress, but we cannot rest until we have actually put a stop to AIDS. I believe we can do it -- by developing a vaccine, by increasing our investment in other forms of research, by improving our care for those who are infected and our support for their families.

Last year at Morgan State University, I declared that we should redouble our efforts to develop an AIDS vaccine within a decade. Today I am pleased to announce a $200 million investment in cutting edge research at the NIH to develop a vaccine. That's a 33 percent increase over last year. With this historic investment, we are one step closer to putting an end to the epidemic for all people.

I'm also pleased to say that there will be more than $160 million for other new research critical to fighting AIDS around the world, from new strategies to prevent and treat AIDS in children, to new clinical trials to reduce transmission.

And as hard as we are working to stop the spread of AIDS we cannot forget our profound obligation for the heartbreaking youngest victims of the disease -- the orphaned children left in its wake. Around the world, as we have heard, millions of children have lost their parents.
Their number is expected to rise to 40 million over the next 10 to 15 years. Some of them are free of AIDS, others are not. But sick or well, too many are left without parents to protect them, to teach them right from wrong, to guide them through life and make them believe that
they can live their lives to the fullest.

We cannot restore to them all they have lost, but we can give them a future -- a foster family, enough food to eat, medical care, a chance to make the most of their lives by helping them to stay in school. Today, through Mr. Atwood's agency, we are committing another $10 million in emergency relief that will, though seemingly a small amount, actually make a huge difference for many thousands of children in need around the world.

I'm also directing Sandy Thurman to lead a fact-finding mission to Africa, where 90 percent of the AIDS orphans live. Following the mission she will report back to me with recommendations on what more we can do to help these children and give them something not only to live for, but to hope for.

Eleven years ago, on the first World AIDS Day, we vowed to put an end to the AIDS epidemic. Eleven years from now, I hope we can say that the steps we took today made that end come about. If it happens, it will be in no small measure because of people like you in this room, by your unfailing, passionate devotion to this cause -- a cause we see most clearly expressed in the two people sitting right behind me.

Thank you all, and God bless you. (Applause.)

END 1:26 P.M. EST

REMARKS BY THE PRESIDENT ON HIV CRISIS IN MINORITY COMMUNITIES

THE WHITE HOUSE
Office of the Press Secretary

For Immediate Release October 28, 1998

REMARKS BY THE PRESIDENT ON HIV CRISIS IN MINORITY COMMUNITIES

Old Executive Office Building

5:16 P.M. EST

THE PRESIDENT: Thank you and welcome, every one of you. I'd like to begin by welcoming the Mayor of Baltimore, Kurt Schmoke, and the Mayor of East St. Louis, Gordon Bush. I'd like to thank the members of Congress here behind me who are so responsible for the purpose for which we are called today. (Applause.)

I want to acknowledge Congresswoman Donna Christian Green, Congressman Elijah Cummings, Congresswoman Eleanor Holmes Norton, Congressman Donald Payne. I will say more about Congresswoman Maxine Waters and Representative Lou Stokes in a moment. (Laughter.) But I want to thank them and all the members of the Congressional Black Caucus, including all the House members and Senator Carol Moseley Braun, for what they did.

And then I would like to offer a special word of appreciation to senator Arlen Specter and Congresswoman Nancy Pelosi, who helped us so much to get this done. Thank you very much. (Applause.)

I want to thank everyone in our administration who has worked so hard on the issue of HIV and AIDS, beginning with the Vice President who couldn't be here today, but who has worked very hard on all these issues; and Secretary Shalala; our wonderful Surgeon General, David Satcher; the Director of our AIDS Policy Office, Sandy Thurman, who has literally spent months sounding the alarm about the growing crisis in communities of color, and working to help achieve these dramatic funding increases. There is no stronger or more effective advocate. And I think we ought to thank Sandy Thurman for what she's done. (Applause.)

Finally, I want to thank Denise Stokes for being here. As you will hear in a few moments, she has been living with HIV for 15 years, and has been giving so much

of herself to educate others. If we are to stop this cruel disease we'll have to have brave people like Denise to reach out with candor and compassion to those at risk. I really admire her very much. And you'll hear from her in a moment, but I think we ought to give her a hand for showing up today. (Applause.)

We have good reason to feel encouraged that so many HIV-positive men and women are living longer and healthier lives. We should be proud that we've helped to speed the development of lifesaving therapies and nearly tripled to support those with HIV and AIDS.

But the AIDS epidemic is far from over in any community in our country. Today, we're here to send out a word loud and clear:

AIDS is a particularly severe and ongoing crisis in the African-American and Hispanic communities and in other communities of color. African Americans represent only 13 percent of our population, but account for almost half the new AIDS cases reported last year. Hispanics represent 10 percent of our population; they account for more than 20 percent of the new AIDS cases. And AIDS is becoming a critical concern in some Native American and Asian American communities, as well.

Like other epidemics before it, AIDS is now hitting hardest in areas where knowledge about the disease is scarce and poverty is high. In other words, as so often happens, it is picking on the most vulnerable among us.

The fact is HIV infection is one of the most deadly health disparities between African Americans, Hispanics, and white Americans. And just as we have committed to help build one America by ending the racial and ethnic disparities in infant mortality and cancer and other diseases, we must use all our power to end the growing disparities in HIV and AIDS.

The AIDS crisis in our communities of color is a national one, and that is why we are greatly increasing our national response. Today I am proud to announce we are launching an unprecedented $156 million initiative to stem the AIDS crisis in minority communities. (Applause.)

It is one of the greatest victories in the balanced budget law I just signed. It never could have happened without the passionate and compassionate leadership of Maxine Waters, Lou Stokes, and the rest of the Congressional Black Caucus -- (applause) -- or the support of senator Specter and Congresswoman Pelosi and so many others.(Applause.)

Now, this initiative will allow thousands of cities, churches, schools, and grass-roots organizations to expand prevention efforts and target them to the

specific needs of specific minority communities such as young men, students, pregnant mothers. It will allow minority communities to expand treatment for substance abuse.

It will increase access to protease inhibitors and other new therapies, because lifesaving therapies cannot be a luxury reserved only for the rich.(Applause.) It will increase access to skilled doctors and other health care providers. And finally, it will help us to assemble teams of public health experts from the Centers for Disease Control and other federal agencies to visit individual communities and provide whatever technical assistance those communities need. (Applause.)

This new initiative will build on the other historic funding increases in HIV/AIDS funding we won in the new balanced budget, which Secretary Shalala will talk about in greater detail in a moment. I'm also pleased that it will build on our race and health initiative. Congress has taken a first step to fund this initiative, but we must do more. We are not one America when some of our communities lag so far behind in health.

Of course, this room looks nothing like a house of worship except for a few collars I see. (Laughter.) But I'd like to end my remarks today with what I think is quite an appropriate passage from the First letter of Paul to the Corinthians. "The body is a unit, though it is made up of many parts. And though all its parts are many, they form one body. If one part suffers, every part suffers with it. If one part is honored, every part rejoices with it."

So it is with the body of Americans, and a nation that strives tone one America. Every one of our communities is inextricably linked, in suffering and rejoicing, in sickness and in health. And that is why we must work together in every community to stop this cruel disease. Black or white, gay or straight, rich or poor, you name it, we have to stop it.

Now I'd like to present America's Surgeon General, our nation's family doctor, whose deep commitment to advancing our country's health is embodied in the 200-year-old guiding principle of our public health service that you best protect the health of the entire nation when you reach out to the most vulnerable people.

Dr. David Satcher. (Applause.)

END 5:30 P.M. EST

PRESS RELEASE ON 1998 WORLD AIDS DAY EVENT

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release December 1, 1998

PRESIDENT CLINTON COMMEMORATES WORLD AIDS DAY BY UNVEILING NEW STEPS TO ADDRESS THE GROWING CRISIS OF CHILDREN ORPHANED BY AIDS

Today, President Clinton will join Secretary of State Madeleine Albright and Brian Atwood, Administrator of the U.S. Agency for International Development (USAID), to commemorate World AIDS Day by launching a series of new initiatives to address the growing crisis of HIV/AIDS around the world, particularly the millions of children orphaned by AIDS. The President will unveil historic increases in funding for research at the National Institutes of Health (NIH) designed to develop an effective AIDS vaccine and prevention strategies to help address the problem of HIV/AIDS throughout the world. He will announce new emergency funding from USAID to support international AIDS orphan programs. In addition, he will direct his AIDS policy advisor, Sandra Thurman, to lead a delegation to Sub-Saharan Africa to assess the growing problem of AIDS orphans and recommend new strategies for responding to the crisis.

USAID projects that up to 40 million children will be orphaned by HIV/AIDS by the year 2010, over 90 percent of whom live in developing countries with few resources to provide for their care and support. Over 33 million people around the world are now living with HIV or AIDS, with another 5.8 million becoming infected every year. As with so many epidemics, children and young people bear much of the terrible burden of AIDS. In the United States, as many as 80,000 children already have been orphaned by AIDS.

Increases in funding by the National Institutes of Health for research to prevent and treat HIV around the world. The National Institutes of Health will undertake the largest single public investment in AIDS research in the world by supporting a comprehensive program of basic, clinical, and behavioral research on HIV infection and its related illnesses. This program will include:

- $200 million -- a 33 percent increase from last year's funding -- for research on AIDS vaccines to prevent transmission around the world. The development of a safe and effective AIDS vaccine is critical to stemming the growing problem of HIV/AIDS and AIDS orphans internationally. The President will announce that NIH will dedicate $200 million to vaccine research in Fiscal Year (FY) 1999, a $47 million or 33 percent increase over FY 1998 and an 100 percent increase over FY 1995. This investment is critical in meeting the President's challenge to develop an effective AIDS vaccine.

- $164 million for other research critical to addressing the HIV/AIDS epidemic around the world. The President also will announce that NIH will invest $164 million in FY1999, a $38 million increase over last year, in critical research projects aimed at reducing the number of AIDS orphans by preventing and treating HIV/AIDS internationally. These projects will include: a new prevention trials network to reduce adult and perinatal transmission of HIV/AIDS; new strategies to prevent and treat HIV infection in children; funding to train more foreign scientists to collaborate on this epidemic; research on the prevention and treatment of the opportunistic infections, such as tuberculosis, that commonly kill people with HIV/AIDS; and research on topical microbicides and other female-controlled barrier methods of HIV prevention.

- $10 million in USAID emergency relief funding to provide support for AIDS orphans. USAID will make available $10 million in emergency funding to support community-based efforts for orphans in the countries most affected by this problem. These efforts will include training and support for foster families, initiatives to keep children in school, vocational training, and nutritional enhancements. In addition, USAID will take steps to help prevent the spread of HIV from mothers to children and to improve medical care for children already infected with HIV.

- AIDS Policy Advisor Sandra Thurman to lead fact-finding delegation to raise awareness and make recommendations to address growing problem of AIDS orphans. President Clinton will ask Sandra Thurman, Director of the Office of National AIDS Policy, to lead a fact-finding delegation early next year to Sub-Saharan Africa, where 90 percent of AIDS orphans reside. The delegation will include representatives from key Congressional offices. Its goal will be to raise awareness of this emerging problem and to develop recommendations for action.

- New steps to address the continued needs of those living with HIV/AIDS in the United States. While the problem of HIV/AIDS is particularly acute internationally, the President will underscore the impact of HIV/AIDS on families in this country as well. The President will highlight an announcement today by Vice President Gore of more than $200 million in funds this year for the Housing

Opportunities for People With AIDS (HOPWA) program to prevent individuals affected by HIV/AIDS and their families from becoming homeless. The Vice President will announce these grants at a meeting with local community leaders who provide housing and other support services for people living with HIV/AIDS and with several individuals and families who have benefited from these services.

- A solid record of achievement in HIV/AIDS. Today's announcements build on a deep and ongoing commitment by the Clinton Administration to respond to the AIDS crisis both in the United States and across the world. The Administration has fought for other critical investments in HIV/AIDS. This year alone, the President:

  - Declared HIV/AIDS in racial and ethnic minority communities to be a severe and ongoing health care crisis and unveiled a new $156 million initiative to address this problem. This initiative included crisis response teams, enhanced prevention efforts, and assistance in accessing state-of-the-art therapies.

  - Worked with Congress to secure historic increases in a wide range of effective HIV/AIDS programs. Increases this year alone include: a $262 million increase in the Ryan White CARE Act; a 12 percent increase in AIDS research funding at the NIH, totaling nearly $1.8 billion; a $32 million increase for HIV prevention programs at the Centers for Disease Control and Prevention; and a $21 million increase in the Housing Opportunities for People With AIDS (HOPWA) program at HUD.

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PRESS RELEASE ON 1998 WORLD AIDS DAY EVENT VICE PRESIDENT GORE

THE WHITE HOUSE
Office of the Vice President

For Immediate Release December 1, 1998

VICE PRESIDENT GORE ANNOUNCES $220 MILLION TO PROVIDE HOUSING, OTHER CRITICAL SUPPORT SERVICES FOR OVER 65,000 PEOPLE WITH HIV/AIDS

Washington, DC -- Vice President Gore commemorated World AIDS Day today by announcing that the federal government will provide $220 million in grants for housing and support services for over 65,000 low-income people with HIV/AIDS and members of their households.

The Vice President announced the new funds, which the Housing and Urban Development Department (HUD) will distribute under its Housing Opportunities for Persons with AIDS (HOPWA) program, at a meeting with people who receive and provide these critical housing and support services in Washington DC.

"For too many Americans living with AIDS, poverty is nearly as much of a threat as the disease itself," Vice President Gore said. "Without our help, many would be forced to live in unfit housing or become homeless. These grants will mean that people fighting AIDS won't have to also fight to keep a roof over their heads."

HUD Secretary Andrew Cuomo added, "We all know about the terrible toll of illness and death caused by the AIDS virus. On top of this, AIDS often destroys the financial health of those with the disease as well, hitting them with huge medical bills and leaving them too sick towork."

Today, the Vice President:

Unveiled new HOPWA grants that provide critical support to communities in need. Studies show that people with HIV/AIDS are at increased risk for homelessness and have more problems obtaining access to affordable housing. This $220 million in HOPWA funding, a 10 percent increase over last year, provides critical housing and other support services that:

- help people with HIV/AIDS remain in their homes by providing rental

assistance and supportive services such as meals, transportation, and counseling; and

- provide housing to people with HIV/AIDS and their families facing homelessness. By providing housing and other critical support services, this program helps keep families intact, and assures that individuals with HIV/AIDS have the support they need. Most people that HOPWA serves have incomes of under $1,000 a month.

Of the $220 million, $200 million will go to states, cities, and communities to develop effective programs. The remaining $20 million will go to programs nationwide that have developed particularly effective and innovative approaches to providing housing and other necessary support services for people with HIV/AIDS. For example, an innovative program in Savannah, GA enables people with HIV/AIDS to receive home-based care, and one in Illinois provides innovative services, including effective mental health services and daily livingservices.

Highlighted Clinton/Gore Administration's ongoing progress in fighting HIV/AIDS. The Vice President underscored other Administration efforts to improve prevention, treatment, and research for people with HIV/AIDS. He noted that the President is unveiling historic new steps
today to help the up to 40 million children who will be orphaned by HIV/AIDS by 2010, including new emergency funding from USAID to support international, community-based AIDS orphan programs and historic new increases in AIDS research at the National Institutes of Health (NIH) dedicated to help address the global problem of HIV/AIDS.

These steps build on the historic progress to combat HIV/AIDS for which the Administration fought in this year's balanced budget, including: a new $156 million initiative to address the severe, ongoing health care crisis of HIV/AIDS in racial and ethnic minorities, including crisis response teams and enhanced prevention efforts across the nation; a $262 million increase in the Ryan White CARE Act; a 12 percent increase in AIDS research funding at the NIH, a $32 million increase HIV prevention programs at the CDC; and a $21 million increasein HOPWA.

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1998 WORLD AIDS DAY PROCLEMATION

THE WHITE HOUSE
Office of the Press Secretary

For Immediate Release December 1, 1998

WORLD AIDS DAY, 1998
BY THE PRESIDENT OF THE UNITED STATES OF AMERICA
A PROCLAMATION

On World AIDS Day, we are heartened by the knowledge that our unprecedented investments in AIDS research have resulted in new treatments that are prolonging the lives of many people living with the disease. Thousands of scientists, health care professionals, and patients themselves have joined together to advance our understanding of HIV and AIDS and improve treatment options. Because of the heroic efforts of these people, fewer and fewer Americans are losing their lives to AIDS, and for that we are immensely thankful.

But the AIDS epidemic is far from over. Within racial and ethnic minority communities, HIV and AIDS are a severe and ongoing crisis. While the number of deaths in our country attributed to AIDS has declined for 2 consecutive years, AIDS remains the leading killer of African American men aged 25-44 and the second leading killer of African American women in the same age group. African Americans, who comprise only 13 percent of the U.S. population, accounted for 43 percent of new AIDS cases in 1997 and 36 percent of all AIDS cases. Hispanic Americans represent just 10 percent of our population, but they account for more than 20 percent of new AIDS cases; and AIDS is also becoming a critical concern to Native American and Asian American communities. Young people of every racial and ethnic community are also disproportionately impacted by AIDS, both in the number of new AIDS cases and in the number of new HIV infections. In fact, the Centers for Disease Control and Prevention estimate that approximately half of all new HIV infections in the United States occur in people under age 25 and that one-quarter occur in people under age 22.

Across the world, the situation is even more grim. As with other epidemics before it, AIDS hits hardest in areas where knowledge about the disease is scarce and poverty is high. Of the nearly 6 million people newly infected with HIV each year, more than 90 percent live in the poorest nations of the world. Entire communities are threatened by

December 16, 1998

MEETING WITH THE
PRESIDENT'S ADVISORY COUNCIL ON HIV/AIDS

TALKING POINTS FOR CLOSING COMMENTS

- Thank you for all of the good work that you have been doing.

- We have made a lot of progress, and I appreciate your recognition of that. Together, we have helped get the resources that have made an incredible difference in the lives of so many.

- Yet I know that there is much more to do, particularly on prevention and international support. I especially understand the importance of the HIV vaccine and will make sure that everyone in this Administration understands that it is a top priority for us.

- You've made a number of good suggestions, and I'm going to ask Sandy to help us move forward on them.

- You have a lot of friends here - the First Lady, the Vice President, Mrs. Gore, Secretaries Shalala and Cuomo, and certainly Sandy - you have lots of advocates here who have done a tremendous amount to increase awareness of AIDS. I want you to know that we are committed to the fight.

- We may not always agree on how to get there, but you can be assured that we all share your determination to bring an end to this epidemic both here and across the globe.

December 16, 1998

MEETING WITH THE
PRESIDENT'S ADVISORY COUNCIL ON HIV/AIDS

QUESTIONS AND ANSWERS

Q: **Current HHS guidelines encourage early treatment of HIV to forestall the onset of AIDS, yet access to Medicaid coverage for that treatment is generally restricted to those who have progressed to AIDS. How are you going to help increase access to treatment?**

A: This is a difficult challenge and we are taking steps to address it. You know I tried to solve this problem with universal health care. We wouldn't be talking about this problem and a lot of other problems had that been successful.

The Vice President has taken leadership in this area, asking HCFA to look at solutions. Unfortunately, what we thought might be fixed quickly has turned out to be more difficult than expected. While we are committed to continuing our work to look at increasing Medicaid coverage, we've also been working on interim solutions:

- Sandy Thurman has set up an internal task force to develop solutions
- we've succeeded in getting significant increases in the AIDS Drug Assistance Program--$175 million (61%) increase in FY99--and the Ryan White CARE Act overall--$271 million (23%) increase in FY99 and 266% since FY93
- we strongly supported the Jeffords-Kennedy legislation, which includes a demonstration program that helps states provide Medicaid coverage to people with HIV before they get AIDS - I hope you'll continue to work with us to get legislation like this passed in the coming year
- HCFA has been working with States that are seeking to develop waivers to expand their coverage to people living with HIV. We have talked with HCFA, and they have assured us that they will continue to aggressively provide support and assistance to States that want to develop demonstration programs that work.

I recognize the need and promise you that I and the Vice President will stay on top of this issue and do everything in our power to see that people with HIV don't have to get sick before they get treatment.

Q: **We are concerned that our national effort to stop the spread of HIV is not working, and that the number of new HIV infections in this country has**

stayed at 40,000 per year. In addition, at least 30% of those that are HIV positive don't know it, which means they are likely to continue the activities that spread the infection. The Council would like to recommend a new national "get tested" campaign to encourage people at risk to seek HIV counseling and testing services. Will you support that request?

A: I think it sounds like a good idea. Let me ask Sandy to take a look at the proposal and give me her recommendations. I do believe we need to do a better job with our work on prevention, not only for HIV but for a variety of preventable illnesses. Secretary Shalala and Surgeon General Satcher have been focusing a great deal of energy on prevention, particularly in racial and ethnic minorities. Dr. Satcher has been helping to lead their Race and Health Disparities initiative, which includes HIV and AIDS as one of six targeted illnesses.

Young people are also in need of greater attention. I believe that some of the impact of the anti-drug campaign by our Office of National Drug Control Policy will help since the abuse of drugs and alcohol plays a key role in young people taking risks with HIV.

Q: **Last March, you announced your commitment to finding a vaccine for HIV within ten years. That was 18 months ago. The Council is concerned that the effort to develop a vaccine is not progressing fast enough. NIH has yet to hire a director for its new vaccine center and the different Federal agencies that are involved in vaccine research aren't coordinated. Will you encourage NIH Director Varmus to get the vaccine center director position filled? Will you support Sandy Thurman's office in facilitating cross-agency coordination?**

A: I certainly appreciate the need for an HIV vaccine. This past World AIDS Day we did an event here that focused on the international epidemic, and I am just staggered by the impact that AIDS is having on so many nations around the world. I have asked Sandy to go to Africa in January to look at the AIDS orphan issue and to report back to me with recommendations on further actions we might consider. I know that a vaccine is our best and maybe only hope of stopping this terrible disease.

As for the vaccine center director, we have talked with Dr. Varmus and he has assured us that he is being very aggressive in his efforts to find just the right person for the position. Part of the delay has been his commitment to finding the very best person. He also assures us that the vaccine research effort has not been slowed down by this vacancy, and that in fact they are very pleased with their progress. NIH is increasing its vaccine research funding this year, up $47 million (33%) to $200 million. I also know that Dr.

Nathanson, the new director of the Office of AIDS Research at NIH, is very committed to vaccine research and is providing great leadership.

As for the interagency coordination, Sandy and Dr. Varmus have talked about that. I understand that they're initiating regular vaccine research meetings that will be open to all the different agencies, and the community groups working on this issue. I will talk with Sandy about this and see if there is more that we can do.

Q: **While we have had great success in AIDS funding with your leadership, the Council is concerned that there are still a great many unmet needs. We are particularly concerned that HIV prevention activities at the CDC and international assistance through USAID have not received needed increases. Will you commit to increasing AIDS funding in FY2000, particularly in prevention and international relief?**

A: We are working on developing the FY2000 budget now, so it is a work-in-progress. I do know that you have a great team of advocates at OMB. Jack Lew, Josh Gotbaum, Sylvia Matthews, and Dan Mendelson are all committed to doing the best that we can in addressing the need for additional AIDS funding.

With respect to prevention funding, I can say that we fully understand the need to increase and improve our HIV prevention activities, and to pay particular attention to communities of color, to women, and to young people who are at highest risk. We're taking a look not only at the need for increased funding, but making sure that what we are already investing is being used most effectively.

As for international funding, we've gotten good support from USAID although I know Brian Atwood would like more. This is going to be a very challenging budget year for us, and I don't want to be overly optimistic about our ability to repeat the kind of increases we were able to obtain in FY99. Nevertheless, we will do our very best to support appropriate funding levels for our international AIDS efforts, and the other AIDS programs as well.

SELECTED HIV/AIDS INVESTMENTS	**FY99**	**Increase from FY98**	**Increase from FY93**
Ryan White CARE Act	**$1.4 billion**	**23%**	**266%**
AIDS Drug Assistance	*$461 million*	*61%*	*787%**
HIV Prevention (CDC)	**$657 million**	**5%**	**34%**
AIDS Research (NIH)	**$1.8 billion**	**12%**	**67%**
Vaccine Research	*$200 million*	*33%*	*145%*

Housing (HUD)	**$225 million**	**10%**	**125%**
International (USAID)	**$131 million****	**8%**	**64%**

*since FY96, when separate program established

**includes $10 million emergency funding for AIDS orphan initiative

this epidemic, and the growing number of children who will lose parents to AIDS will have a devastating impact on these societies. By the year 2010, there may be as many as 40 million children who will have been orphaned by AIDS, and developing nations will have to struggle to deal with the overwhelming needs of a generation of young people left withoutparents.

This year's World AIDS Day theme, "Be A Force For Change," is a reminder that each of us has a role to play in bringing the AIDS epidemic to an end. Our response must be comprehensive and ongoing. It must also be a collaborative one, bringing together governments and communities in a shared effort to expand prevention efforts, raise awareness among young people of the risks of HIV infection and how to avoid it, increase access to lifesaving therapies, and ensure that those who are living with HIV and AIDS receive the care and services they need.

Developing a vaccine for HIV is perhaps our best hope of eradicating this terrible disease and stemming the tide of pain and desolation it has wrought. The global community has joined together in making the development of an HIV vaccine a top international priority. Within the next decade, we hope to have the means to stop this deadly virus, but until we reach that day we must remain strong in our crusade to prevent the spread of HIV and AIDS and to care for those living with the disease. In this way we can best honor the memory of the many loved ones we have lost to AIDS.

NOW, THEREFORE, I, WILLIAM J. CLINTON, President of the United States of America, by virtue of the authority vested in me by the Constitution and laws of the United States, do hereby proclaim December 1, 1998, as World AIDS Day. I invite the Governors of the States, the Commonwealth of Puerto Rico, officials of the other territories subject to the jurisdiction of the United States, and the American people to join me in reaffirming our commitment to defeating HIV and AIDS. I encourage every American to participate in appropriate commemorative programs and ceremonies in workplaces, houses of worship, and other community centers and to reach out to protect and educate our children and to help and comfort all people who are living with HIV and AIDS.

IN WITNESS WHEREOF, I have hereunto set my hand this first day of December, in the year of our Lord nineteen hundred and ninety-eight, and of the Independence of the United States of America the two hundred and twenty-third.

WILLIAM J. CLINTON

DRAFT

December 17, 1998

MEETING WITH THE PRESIDENT'S ADVISORY COUNCIL ON HIV/AIDS

DATE: December 18, 1998
LOCATION: Vice President's Ceremonial Office (OEOB)
BRIEFING TIME: 5:15 pm to 5:30 pm
EVENT: 5:45 pm to 6:15 pm
FROM: Bruce Reed/Chris Jennings/Sandy Thurman

I. PURPOSE

You will be meeting with members of the President's Advisory Council on HIV/AIDS to discuss the Administration's progress on addressing the AIDS epidemic.

II. BACKGROUND

The Council requested a meeting with you to address its recommendations on ways to improve the Administration's response to the HIV/AIDS epidemic. Over the past few months, the Council has been publicly critical of the Administration, particularly its commitment to HIV prevention. Most recently, several key Council members reacted strongly to the release of draft guidelines by the CDC advising states to begin reporting HIV infections using name-based systems. This meeting would provide an opportunity for you to personally reaffirm your commitment to the Council and the seriousness with which you take the issue.

Questions from the Council will focus on four areas:

-- **Access to Treatment**: The Council will seek your leadership on expanding access to treatment for indigent persons with HIV who must wait until they get AIDS to qualify for Medicaid, which covers the treatments that would likely have forestalled their progression to AIDS. Initial reviews, prompted by a request by the Vice President, determined that such an expansion is not cost neutral and therefore cannot be done administratively. Pending further analysis, the Administration has supported susbstantial increases in the AIDS Drug Assistance Program. In addition, the Jeffords-Kennedy legislation includes a demonstration

program that would substantially increase access to Medicaid by persons who would become disabled but for care. Support of this legislation by the Council and the AIDS community would be very beneficial.

-- **Promoting HIV Testing**: Approximately 30% of persons infected with HIV do not now they are infected, complicating prevention efforts and delaying helpful treatments. The Council will ask for your support of a national "get tested" campaign focusing on higher-risk populations (youth, persons of color, women). This is a reasonable proposal, and one which is already under consideration.

-- **Vaccine Research**: Last spring, you announced your desire to find a vaccine for HIV within ten years. Two weeks ago, on World AIDS Day, you announced a 33% increase in vaccine research funding at the NIH (up $47 million to $200 million). The Council is highly supportive of your leadership on this issue, but has some concern about the 18 months its taking find a director for NIH's new vaccine research center and about the need for increased inter-agency coordination. NIH has assured us that they are aggressively searching for the best person for the job and that vaccine research has not been delayed by this vacancy.

-- **Increased AIDS Funding**: Funding for HIV/AIDS programs has more than doubled during your Administration, with Ryan White funding up 266% and AIDS research up 67%. The Council is concerned that prevention and international funding have not benefited from similar increases. CDC's prevention budget is over $640 million and has increased 34% since you took office; the Administration is focusing on insuring that prevention funds are used effectively and are targeted to those at highest risk. As for international funding, USAID's AIDS budget has increased 64% during your Administration. You also just announced on World AIDS Day a new $10 million effort to help developing countries respond to the needs of children orphaned by AIDS.

In your closing remarks, you may highlight recent Administration activities on HIV/AIDS, including:

-- World AIDS Day event at which you announced an AIDS orphan initiative at USAID, increased vaccine research funding from the NIH, and a delegation to Africa led by Sandy Thurman.

-- Minority initiative announcement on October 28th at which you declared HIV/AIDS to be an ongoing and severe crisis in racial and ethnic minorities and announced $156 million in additional funding to address the crisis.

-- Historic HIV/AIDS funding achievements in the FY99 budget negotiations

with Congress.

III. PARTICIPANTS

Briefing Participants:
Bruce Reed
Virginia Appuzo
Karen Tramontano
Chris Jennings
Sandy Thurman
Richard Socarides

Program Participants:
YOU
Sandy Thurman
Bruce Reed
Virginia Appuzo
Karen Tramontano
Chris Jennings
Sandy Thurman
Richard Socarides
Dr. Scott Hitt, Council Chairperson
Members of the Council

IV. PRESS PLAN

Pool still before start of meeting; closed press thereafter. Transcript to be provided to press following end of meeting.

V. SEQUENCE OF EVENTS

-- Sandy Thurman will introduce **YOU** to members of the Council.
-- Dr. Scott Hitt will make a brief opening statement.
-- Council member Rabbi Joseph Edelheit will provide an overview of the message of the Council to you.
-- Four members of the Council will provide brief background statements and identify specific issues on which they seek Administration action. (You will have the option to seek clarification or respond--see attached Q & A.)
-- **YOU** will make brief closing remarks, thanking the Council for its hard work and reaffirming your commitment to continuing the fight against AIDS--see attached talking points.

VI. REMARKS

Talking points provided by the Office of National AIDS Policy.

VII. ATTACHMENTS

-- Talking points for closing remarks.
-- Q & A for discussion purposes.
-- List of Council members and brief biographies.

Withdrawal/Redaction Sheet
Clinton Library

DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001. list	re: President's Advisory Council on HIV/AIDS (5 pages)	n.d.	P6/b(6)

COLLECTION:
Clinton Presidential Records
Domestic Policy Council
Devorah Adler
OA/Box Number: 20464

FOLDER TITLE:
HIV/AIDS [Folder 2]

2012-0463-S
rc771

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

P1 National Security Classified Information [(a)(1) of the PRA]
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P3 Release would violate a Federal statute [(a)(3) of the PRA]
P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [a)(5) of the PRA]
P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

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b(1) National security classified information [(b)(1) of the FOIA]
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b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

FAX

Date: *January 8, 1999*

To: *Technical Information and Communications Branch*

cc: *See Below*

Phone: *Various*
Fax: *Various*

From: *Lisa Schneider*
San Francisco AIDS Foundation
P.O. Box 426182
San Francisco, CA 94142

Phone: *415/487-3034*
Fax: *415/487-3089*

Total Pages: *6*

Remarks: ☐ *Urgent* ☒ *For your review* ☐ *Reply ASAP* ☐ *Please Comment*

404/639-7111 Jeffrey Koplan, MD, Director, Centers for Disease Control and Prevention
404/639-8600 Helene Gayle, MD, Director, National Center for HIV, STD, and TB Prevention, CDC
404/639-0910 Kevin DeCock, MD, Director, Division of HIV/AIDS Prevention, Surveillance and Epidemiology, NCHSTP, CDC
202/690-7755 Kevin Thurm, Deptuy Secretary for Health and Human Services
202/456-2437 ~~Sandy Thurman~~, Director, Office of National AIDS Policy
202/456-7431 Chris Jennings, Deputy Assistant to the Presiden for Health Policy
202/225-8259 ~~Congresswoman~~ Nancy Pelosi, U.S. House of Representatives
202/690-7560 Eric Goosby, MD, Director, Office of HIV/AIDS Policy, HHS
202/690-7098 Marsha Martin, PhD, Special Assistant to the Secretary, HHS

SAN FRANCISCO AIDS FOUNDATION 995 MARKET STREET, SUITE 200, SAN FRANCISCO, CALIFORNIA 94103
VISITORS' ENTRANCE: ONE 6TH STREET AT MARKET

January 8, 1999

Technical Information and Communications Branch
Mailstop E-49
Division of HIV/AIDS Prevention
National Center for HIV, STD and TB Prevention
Centers for Disease Control and Prevention (CDC)
Atlanta, GA 30333

FAX: 404/639-2007
Email: hivmail@cdc.gov

RE: Comments on the Draft CDC Guidelines for National HIV Case Surveillance

To Whom It May Concern:

The San Francisco AIDS Foundation appreciates the opportunity to comment on the recently released "Draft Guidelines for HIV Case Surveillance." We are pleased that the draft guidelines state that flexibility will be given to states to design and implement HIV reporting systems that best meet the needs of their jurisdictions. However, we believe that the draft guidelines should be revised to better reflect the scientific research findings on the impact of names-based reporting on HIV testing and to address the needs of individuals living in communities that are profoundly affected by HIV.

The Foundation's concerns are as follows:

1. The CDC inappropriately advises states to use names reporting.

Although states are given a choice of using either names or unique identifier (UI) systems, both the language and the presentation of scientific evidence in the guidelines clearly reflect the CDC's bias towards names reporting. The guidelines state: "CDC advises that State and local surveillance programs use the same name-based approach for HIV surveillance as is currently used for AIDS surveillance nationwide" (p. 8). Such advice is scientifically unfounded (see below). The guidelines should be revised so as not to favor one system over another in order to provide state health officials true flexibility in designing the system that best meets their community's needs. To this end, the sentence "advising" names reporting should be eliminated.

Although the draft guidelines appropriately pledge technical assistance regardless of the type of HIV surveillance implemented, the CDC's preference for names reporting, while not being overtly stated, appears to be linked to the provision of funds. This bias is apparent in statements such as: "based on published evaluations, the CDC has concluded that name-based HIV/AIDS surveillance systems are the most likely to meet the necessary performance standards as well as to serve the purposes for which surveillance data are required" (p. 8). The CDC actually stated in a letter to Washington State that supplemental funding for HIV/AIDS surveillance was contingent upon the implementation of names-based reporting. While the statement was later re-

tracted, there is an underlying and pervasive impression among states that federal funding is contingent upon names-based reporting. The CDC should work to reverse this impression by presenting unbiased information and support to states implementing non-names based systems.

2. Regarding the performance standards, the guidelines do not contain discussion of sufficient time for implementation.

The guidelines should contain a reasonable transition period for implementation of reporting systems before any evaluation for funding purposes is completed. Based on the experience of several states implementing HIV surveillance systems, *five years* appears to be an adequate amount of time to establish a system and ensure that it is functioning at the levels set out in the guidelines.

In addition, at least one of the performance standards must be modified—the requirement that risk information be gathered on 85% of cases. Most states with names reporting have not met this criterion and there is little evidence that they will be able to do so, even with years of experience. Risk information – which is often very difficult for providers to secure—would be better obtained through representative sample surveys and sentinel studies. This should be discussed in detail in the guidelines and the 85% requirement should be eliminated.

3. The presentation of research on testing behavior is biased.

The scientific evidence presented to discount the impact of names-based reporting on individuals' willingness to seek HIV testing is both biased and flawed. Key studies that demonstrate that HIV names reporting deters individuals from seeking testing are not mentioned anywhere in the guidelines (Myers et al 1993; Reed 1996; Kegeles et al 1990; Kegeles et al 1989; Fordyce 1989; Johnson et al 1988; Judson and Vernon 1988).

Not only are these studies not discussed, but those studies that are cited draw questionable conclusions that are not justified by the data and methods used (Nakashima et al 1998; Hecht et al 1997). For example, while the Nakashima study examines testing patterns in states that implemented names reporting, the study did not include comparisons to states that did not implement such a policy. It is thus impossible for the authors to prove that testing rates might not have increased *more dramatically* had names reporting not been instituted in those states. In addition, the study's authors do not examine carefully the experience of *key subpopulations* that are most at risk for HIV infection. While Nakashima and colleagues do show that testing increased or remained stable overall in some states, changes in testing frequency across *high-risk groups* did not correspond to the *overall* change. Contrary to the conclusions drawn by the CDC, Nakashima's results suggest that the highest risk groups may be reluctant to test with names reporting. These results have very important public health ramifications and raise serious concerns about the deterrent effect of names reporting for African Americans and, in some cases, injection drug users. If this study is going to be used in the guidelines, it should be presented fairly, and the population-specific trends should be presented in greater detail.

The draft guidelines also reference the Hecht study, in which 19% of respondents reported that "fear of reporting to the government" was a concern that contributed to their decision to delay testing. Again, the language used to describe the findings reflects bias. This finding is pre-

sented as "less than 20%" (versus, for example, "nearly 1 in 5") which intentionally minimizes the importance of these data. This is especially important because the Hecht study targeted high-risk populations, which make up a greater percentage of the populations in the states that have not yet instituted HIV surveillance. In fact, only 6 of the 32 states currently collecting HIV data with names-based reporting systems have higher-than-average AIDS case rates in their populations.

Encouragement of names reporting may be particularly dangerous for the remaining states that have yet to introduce an HIV reporting system. In many of these states, reported AIDS cases are disproportionately among high-risk groups (as evidenced by figures from 1997). For example, the proportions of AIDS cases in California and Washington among men who have sex with men (64% and 55%) are much higher than the national average (35%). Similarly, in Illinois (30%), Massachusetts (34%) and Pennsylvania (43%), the proportions of cases associated with injection drug use are greater than the national average of 24%. The proportion of cases among African Americans in Georgia (72%), Illinois (56%) and Pennsylvania (60%) are greater than the 45% national average. These discrepancies indicate that encouraging names reporting among these states may be irresponsible, since their populations may be more likely to be deterred by these policies.

Finally, while the CDC's attention to the importance of anonymous testing in the guidelines is to be applauded, it is inherently contradictory to recognize the importance of anonymous testing while at the same time call for names-based systems over unique identifier systems. The CDC acknowledges that anonymous testing has been clearly associated with earlier testing and treatment (Bindman et al 1998). These results prove that some segments of the population are extremely concerned about the confidentiality of their HIV status. This suggests that these same individuals would be reluctant to seek testing and or treatment if HIV names reporting was implemented and, in fact, the draft guidelines should make the provision of anonymous testing a condition of funding.

4. Discussion of ineffectiveness of UI and purported superiority of names-based systems is biased.

The presentation of the evaluation findings on the efficacy of unique identifier systems for HIV reporting is misleading and outdated. The CDC's criticisms of Maryland's system are based on evaluation data from 1994-1996. These data do not reflect the progress and evolution of Maryland's UI system, or the fact that Maryland was not funded by the CDC to implement their UI system. In reality, recent evidence indicates that Maryland's system provides complete data at a reasonable cost, comparable to rates found in states that use names-based reporting. Criticisms of the Texas system must be considered in light of the fact that health officials in the state were never particularly committed to the implementation of a unique identifier system and therefore had little incentive to work for the program's success. Reference to "published evaluations of non-name based HIV surveillance" (p. 8) thus presents an incomplete picture of the available data on UI systems. Maryland has much more updated information available about their system that reflects their ability to meet the CDC's criteria and this data should be incorporated into the guidelines.

The CDC's biased use of conclusions on the efficacy of names reporting is also evident in the guidelines. The CDC is "advising" names reporting based on what appears to be anecdotal evidence from the 32 states that currently use names based systems. The CDC does not report

performance data on names-based systems that may in fact reflect "operational difficulties" in those states. The CDC seems to be reasoning that because names based systems are ubiquitous and because they require fewer contingencies to implement, that they are better. The notion that ease of implementation is equivalent to superiority is highly problematic because the concerns about names reporting far outweigh ease of use.

5. The language regarding the linkage of HIV reporting systems and partner notification is weak.

The draft guidelines do not send a clear and compelling enough message to states that they *should not link partner notification and HIV surveillance systems*. The draft guidelines state that the CDC "does not direct" states to link partner notification and HIV surveillance systems and that doing so "does not necessarily improve the provision of HIV prevention and care services" (p. 12). This language should be strengthened considerably to encourage states not to link these distinct systems. The CDC should also discuss research findings that suggest that HIV names reporting does not improve partner notification or access to care (findings presented by D. Osmond to the CDC Consultation on HIV Reporting, May 1997, Atlanta, GA).

6. The guidelines refer narrowly to community representatives concerns' with HIV reporting.

The draft guidelines inaccurately suggest that concerns regarding confidentiality and fear of illegal disclosure of HIV information is only of concern to community groups. In fact, a number of state and local public health officials share this concern. Positioning these considerations as merely "community concerns" suggests that there are not legitimate public health consequences to names-based reporting. The language should be revised to reference the concerns of both the community and public health officials regarding the deterrent effect of names-based systems.

Thank you for the opportunity to comment on the guidelines. I hope that our comments will assist the CDC in working to ensure that the important goal of securing improved HIV data is implemented thoughtfully and responsibly. If you have any questions, please do not hesitate to contact me.

Sincerely,

Regina Aragón

Regina Aragón
Public Policy Director

cc: Jeffrey Koplan, MD, Director, Centers for Disease Control and Prevention
Helene Gayle, MD, Director, National Center for HIV, STD, and TB Prevention, CDC
Kevin DeCock, MD, Director, Division of HIV/AIDS Prevention, Surveillance and Epidemiology, NCHSTP, CDC
Kevin Thurm, Deputy Secretary for Health and Human Services
Sandy Thurman, Director, Office of National AIDS Policy
Chris Jennings, Deputy Assistant to the President for Health Policy
Congresswoman Nancy Pelosi
Eric Goosby, MD, Director, Office of HIV/AIDS Policy, HHS
Marsha Martin, PhD, Special Assistant to the Secretary, HHS

References:

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until it's over
AIDS ACTION

November 24, 1999

President Bill Clinton
The White House
1600 Pennsylvania Avenue
Washington, DC 20500

Dear Mr. President:

As we approach the last World AIDS Day of the century, I want to take this opportunity to thank you for your extraordinary efforts to enhance AIDS research and AIDS health care as well as your recent efforts to make the fight against the global epidemic a top national foreign policy imperative.

Until your presidency, the fight against AIDS was virtually absent at the White House. President Reagan wouldn't even say the word "AIDS" and President Bush only spoke softly.

Since your Administration began, you have spoken forcefully about the need to fight AIDS and ensured significant and meaningful investments in AIDS research as well as the Ryan White CARE Act. This leadership contributed to the development of the first effective treatments for HIV and a subsequent reduction in the AIDS death rate.

Your work to secure better health care access has helped to bring these drugs to low-income people and we are grateful for your success in securing $250 million for a demonstration project of AIDS Action's Reinventing Medicaid plan.

In short, your leadership has saved thousands of lives from the ravages of HIV disease.

Your leadership was supported and carried out with great valor by AIDS Czar Sandy Thurman, Chief of Staff John Podesta and Chris Jennings. In addition, AIDS Action is grateful for the hard work of the Office of Management and Budget including Jack Lew, Dan Mendelsohn, and Bob Kyle. Their countless hours of hard work, dedication and commitment have helped to ease the pain of an epidemic.

Now, in the remaining fourteen months of your presidency and the beginning of the third decade of the epidemic, we hope you will work to complete your legacy on AIDS by committing to fight the crisis spot of today's epidemic: HIV prevention and education.

Every hour, two young people are newly infected with HIV. Everyone in the fight against AIDS is haunted by this statistic and we hope you will end four years of flat-funding at the CDC by committing to new investments in prevention. There is no shortage of innovative and proven prevention proposals and there is no shortage of need. But there is a shortage of funds to make reinvigorated prevention a reality.

1906 Sunderland Place, NW Washington, DC 20036 P 202 530 8030 F 202 530 8031 www.aidsaction.org

Thank you again for your leadership in the war on AIDS and we hope you commit to providing the same kind of leadership for reinvigorated HIV prevention. For our kids.

Sincerely,

Daniel Zingale

Daniel Zingale
Executive Director

Time Line and Roll-out Implementation Plan for the Final HIV Reporting Guidelines

1998

November

- HIV surveillance guidelines package to CDC OD.
- HIV surveillance guidelines package to the Department.
- Meeting with OS Staff Divisions (including but not restricted to ASL, ASL, ASPA, CDC, IGA, OPHS) to coordinate Congressional and other communication related to the guidelines.
- Briefing with Secretary Shalala.

December

- Briefing for Congressional staff, public health organizations, and advocacy groups.
- Letter announcing the publication of the guidelines mailed/ faxed to key CDC partners.
- Mail-out of comprehensive briefing materials to State health department personnel and other key stakeholders. Material available through National Prevention Information Network (NPIN).
- Notice of publication of the final "Guidelines for National HIV Case Surveillance" published in the *Federal Register*. Guidelines will also be made available on the Worldwide Web.
  Target month for publication, June 1999.
- Notice to readers in *Morbidity and Mortality Weekly Report (MMWR)*.

1999

January

- Comment period closed January 11.
- Receive and review public comments.

February

- Summarize comments; prepare response; revise *Guidelines* . . . document.

March - September

- Revised *Guidelines* package to CDC/OD and the Department.

November - December

- On December 9, at *10:00 a.m., CDC will conduct briefings for the Office of National AIDS Policy (ONAP) and Office of Management and Budget (OMB) staff.
- On December 9, at *11:00 a.m., CDC will conduct briefings for the members of the House of Representatives and Senate.
- On December 9, at *12:00 p.m., CDC will conduct briefings for partner organizations, including public health organizations, and advocacy groups (see list below.)

- On December 10, 1999, the *Guidelines* are scheduled to be published in the *MMWR Recommendations and Reports* series. **Guidelines are effective immediately.**
- A letter announcing the publication of final *Guidelines* will be mailed/faxed to key CDC partners immediately following publication. Briefing materials will also be mailed to State health department personnel and other key stakeholders and will be available through the National Prevention Information Network and on the Worldwide Web.

All times are tentative and are to be confirmed the week of 11/29/99.

Plan to brief key Congressional Contacts on the HIV Reporting Guidelines

HHS (specifically ASL and ASMB) and CDC will make necessary arrangements to brief key congressional members and staff. These briefings will take place the week before the *MMWR Reports and Recommendations* is published (see above). Below is a proposed list of key congressional members.

House of Representatives:

Commerce Committee

Chairman: Representative Tom Bliley, Jr. (R-VA.); Ranking Member: Representative John D. Dingell (D-MI)

Staff of Commerce Subcommittee: Health & Environment

Chairman: Representative Michael Bilirakis (R-FL); Ranking Member: Representative. Sherrod Brown (D-OH)

Others

Representative Connie Morella (R-MD); Representative Gary Ackerman (D-NY); Representative Tom Coburn (R-OK); Representative Henry Waxman (D-CA); Representative Barney Frank (D-MA); Representative Donna Christian-Greene (D-Virgin Islands)

Senate:

Labor & Human Resources

Chairman: Senator James Jeffords (R-VT); Ranking: Senator Edward Kennedy (D-MA)

Staff of Labor & Human Resources Subcommittee: Public Health & Safety Subcommittee

Chairman: Senator William Frist (R-TN); Ranking: Senator Edward Kennedy (D-MA)

Other Congressional Members:

Congressional Black Caucus:

Chair: Representative Maxine Waters (D-CA)

Congressional Hispanic Caucus:

Chair: Xavier Becerra (D-CA)

Committee on Indian Affairs

Chair: Ben Nighthorse Campbell (R-CO)

There will also be a briefing offered to staff of members who have a particular interest in matters related to privacy of health information and/or the use of unique identifiers. This briefing would occur within 1 week after publication of the final *Guidelines* in the *MMWR*.

Key staff from the Office of National AIDS Policy and Office of Management and Budget:

OMB: Dan Mendelson, Richard Turman, and Melanie Nakagira
ONAP: Sandy Thurman and Todd Summers

Key partners:
AIDS Action Council
American Public Health and Human Services Association
Asian Pacific Islander Partnership for Health, Inc.
Association of State and Territorial Health Officers
Council of State and Territorial Epidemiologists
National Alliance of State and Territorial AIDS Directors
National Association of City and County Health Officials
National Association of Counties
National Association of Latino Elected and Appointed Officials
National Association of Persons with AIDS
National Association of State Alcohol and Drug Abuse Directors
National Black Caucus of State Legislators
National Conference of Black Mayors
National Conference of State Legislatures
National Governors Association
National League of Cities
National Native American AIDS Prevention Center
National Organization of Black County Officials
National Organizations Responding to AIDS
U.S. Conference of Mayors

Plan to distribute the R&R to other key partners:

In addition to making the *R&R* document available on CDC's web page, many partners will receive copies of the document directly from CDC. This list includes but is not limited to:
CDC Advisory Committee on HIV/STD Prevention
Council for State and Territorial Epidemiologists
HIV/AIDS Surveillance Coordinators
HIV Prevention Community Planning Co-Chairs
HIV Prevention Consultants
National Public Health Information Coalition
STD Project Directors
(Many of the partners listed above will in turn disseminate information through their own communication systems)

[Federal Register: December 10, 1998 (Volume 63, Number 237)]
[**Notices**]
[Page 68289]
From the Federal Register Online via GPO Access [wais.access.gpo.gov]
[DOCID:fr10de98-107]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

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

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

ACTION: Notice and Request for Comments.

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

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

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

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

In response to these changes in **HIV** treatment practices and new information needs of public health programs, CDC, the Council of State and Territorial Epidemiologists (CSTE), and most other public health and AIDS organizations have recommended that all States and territories conduct **HIV** case surveillance in addition to AIDS surveillance. In this manner, the AIDS/**HIV** epidemic can be tracked more accurately, and appropriate information about **HIV**/AIDS can be made available to policymakers. As of July 1998, a total of 32 States were conducting **HIV** case surveillance using the same methods as surveillance for AIDS. Because some States (many with large numbers of AIDS cases) do not report **HIV** case numbers, interpretations of available **HIV** data are difficult. To gain more reliable information about the prevalence,

incidence, and future directions of **HIV** infection and the impact on specific populations such as racial and ethnic minorities and women, CDC is proposing that the current surveillance system be expanded to include **HIV** case reporting for all States and is publishing guidelines that States can use to implement **HIV** surveillance.

Dated: December 3, 1998.
Jeffrey P. Koplan,
Director, Centers for Disease Control and Prevention (CDC).
[FR Doc. 98-32617 Filed 12-9-98; 8:45 am]
BILLING CODE 4163-18-P

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

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

INTRODUCTION

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

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

The recommended program practices and program performance and security standards are based on: the established practices of AIDS and other public health surveillance systems; reviews of State and local surveillance programs, confidentiality statutes, and security procedures; studies of the performance of surveillance systems; ongoing evaluations of determinants of test-seeking or test-avoidance in relation to State policies and practices on HIV testing and reporting; and discussions at a consultation held by CDC and CSTE in May 1997. A draft of this document was made available for public comment in _____1998.

BACKGROUND

History of AIDS Surveillance

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

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

Current Status of HIV Surveillance

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

In contrast to AIDS case surveillance, HIV case surveillance can provide data to better characterize populations newly diagnosed with HIV, particularly those with evidence of recent HIV infection such as adolescents and young adults (20- to 24-year-olds) (20-21). Of the 52,690

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

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

Not all persons infected with HIV are tested, and of those that are, testing occurs at different stages of their infection. Therefore, HIV surveillance data provide a minimum estimate of the number of infected persons and are most representative of persons who have been diagnosed with HIV infection in medical clinics and other confidential diagnostic settings. The data represent the characteristics of persons who recognize their risk and seek confidential testing, who are offered HIV testing (e.g. pregnant women, clients at sexually transmitted disease clinics), who are required to be tested (e.g. blood donors, military recruits), and who are tested because they present with symptoms of HIV-related illnesses. CDC estimates that more than two-thirds of all infected persons in the United States have been diagnosed with HIV in such settings (30). HIV surveillance data do not represent untested persons or those who seek testing at anonymous test sites or with home collection kits; such persons cannot be reported through confidential HIV surveillance systems. However, the availability of these testing venues is highly important in promoting knowlege of HIV status among at-risk populations and provides an opportunity for counseling and referrals to appropriate medical diagnosis and care.

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

AIDS surveillance nationally and HIV surveillance in 32 States is conducted using the

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

Concerns Regarding HIV Surveillance

Since 1985, many States have implemented HIV case surveillance as part of their comprehensive surveillance programs. The implementation of the 1993 expanded AIDS surveillance case definition prompted discussions of the rationale and need for data representing HIV-infected persons who did not meet the AIDS-defining criteria. Because many States considered implementing HIV reporting, in 1993, CDC held a consultation with public health and community representatives to discuss issues and concerns regarding HIV surveillance. Community representatives' main concerns were that the security and confidentiality standards of surveillance programs may not be sufficient to prevent disclosures of information, and that many persons at risk for HIV infection may delay seeking HIV counseling and testing because of these confidentiality concerns. The consensus of the consultants was that there were few, if any, published studies of sufficient scientific quality to provide objective answers to these concerns. Therefore, the consultants identified several areas that required additional research and policy development before CDC and CSTE should consider recommending further expansion of HIV surveillance efforts. These areas included: the impact of reporting policies on testing practices, including the decreased availability of anonymous testing in some States; the role of surveillance data in linking reported persons to prevention and care programs; the development of recommended uses and standards for the confidentiality of publicly-held HIV and AIDS surveillance data; and determining whether alternatives to reporting of patient names would reduce confidentiality risks while meeting the needs for surveillance data. In response to the consultants' recommendations, CDC initiated several research projects: 1) to assess the effect of name-based HIV surveillance on persons' willingness to seek HIV testing; 2) to evaluate the performance of non-name-based surveillance systems; and 3) to review program practices and legal requirements for the security and confidentiality of State and local HIV/AIDS surveillance data. Findings from these projects and expert advice from participants at numerous technical meetings and consultations held during the intervening period have informed the policies and practices recommended in this document. The interim findings from these projects are summarized in the following three sections:

HIV Surveillance and Testing Behavior

To determine the effect of changes in reporting policies on actual testing behaviors

among persons seeking testing at publicly funded HIV counseling and testing sites, CDC and six State health departments reviewed data routinely collected from these sites to compare HIV testing patterns in the 12 months before and the 12 months after the implementation of HIV case surveillance (36). In these areas, the number of HIV tests increased in four States, and decreased in two States, however, these declines were not statistically significant (Figure 4). Thus, these data do not suggest that, in these States, the policy of expanding HIV case surveillance adversely affected test-seeking behaviors. CDC recognizes that careful attention to providing accurate public education and factual mass media messages will be important to ensure that adverse outcomes do not occur in States that implement HIV case surveillance based on these Guidelines.

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

Preliminary data from surveys of high-risk persons about their perceptions and knowledge of HIV testing and HIV reporting practices found that few respondents' had knowledge of the HIV reporting policy in their State (37-38). In these settings, respondents reported high levels of testing, with approximately three-fourths reporting that they have had an HIV test. The most commonly reported factors that contributed to delays in seeking testing or not getting tested were fear of being diagnosed as having HIV, or belief that they were not at risk for HIV infection, factors reported by nearly half of respondents. About one-fifth responded that "reporting to the government" was a concern that may have delayed their seeking HIV testing; 2 percent of the respondents indicated that this was their main concern. Among different risk groups, the level of concern about name-based reporting of HIV infections to the health department, as the main reason for delaying or avoiding HIV testing, varied slightly; for men who have sex with men, the risk group that had the highest level of concern, "reporting to the government" was the main concern for 4%. In the context of current changes in State policies, the relative importance of various determinants of testing behaviors could change, and CDC will continue to assist States to evaluate the impact of policy changes on HIV testing patterns and HIV/AIDS surveillance data.

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

HIV Surveillance Based on Non-named Unique Identifiers

To assess the feasibility of using alternatives to name-based methods for HIV surveillance, several States implemented reporting of HIV cases or CD4 laboratory results using

a variety of numeric codes. Other States considered or tried to conduct case surveillance without name-identifiers by using codes that were designed for non-surveillance purposes, e.g. codes that were intended for use in tracking patients in case management systems (40). CDC convened a meeting of these States in May 1995 that identified operational, technical, and scientific challenges in conducting surveillance using non-name codes. In addition, CDC supported research to evaluate the performance of a coded unique identifier (UI) in two States that implemented a non-name-based HIV case reporting system while maintaining name-based surveillance methods for AIDS (41). The evaluations conducted by these States from 1994 to 1996 indicated that social security number-based UI HIV surveillance systems were limited by the ability of providers to complete and forward UI-based reports, resulting in incomplete reporting. The evaluations were also unable to demonstrate that duplicate case reports could be reliably eliminated. For the follow-up of UI-based cases to collect risk and other epidemiologic data, providers maintained logs or other forms of documentation linking the UI to the name-based medical records. This process may pose additional confidentiality risks if physician-held surveillance registries are not protected by State confidentiality statutes or are located in non-secure areas. One of the States is continuing to collect case reports and to review and evaluate the performance of the UI HIV case surveillance system; the other is seeking to amend its regulations to begin name-based reporting of HIV infected persons.

Confidentiality of HIV Surveillance Data

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

CDC has also reviewed State and local security policies and procedures. Since 1981, States have conducted AIDS surveillance, and few breaches of security have resulted in the unauthorized release of data (43). Because HIV-infected persons are reported earlier in their disease course than persons with AIDS and many such persons are remaining AIDS-free for longer periods as a result of treatment advances, information about them may be maintained by public health surveillance databases for longer periods. This has caused increased concerns about confidentiality of surveillance data among public health and community groups. Therefore, CDC has issued technical guidance for security procedures that include enhanced confidentiality and security safeguards as evaluation criteria for Federal funding of State HIV/AIDS surveillance activities (44). The receipt of Federal surveillance funding is dependent on the recipient's ability to ensure the physical security and the confidentiality of case reports. At the Federal level, HIV/AIDS surveillance data are protected by several Federal statutes, and privacy is also ensured by the removal of names and the encryption of data transmitted to CDC. Based on the importance of maintaining the confidentiality of persons who are diagnosed as HIV-infected by public and private health care providers, CDC is recommending additional

practices to enhance the security and confidentiality of HIV and AIDS surveillance data.

HIV AND AIDS SURVEILLANCE GUIDELINES

HIV/AIDS Surveillance Case Definitions for Children and Adults

CDC, in collaboration with CSTE, has established new HIV and AIDS case definitions that include revised surveillance criteria for HIV infection and that incorporate the surveillance criteria for AIDS (10,13,45) (Appendix). HIV and AIDS surveillance reports forwarded to CDC should be based on these surveillance criteria. The HIV and AIDS surveillance case definitions for adults, adolescents, and children greater than or equal to 18 months of age 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 based on recent data on the sensitivity and the specificity of HIV diagnostic tests and clinical guidelines for *Pneumocystis carinii* pneumonia (PCP) prophylaxis for children (13, 46-55) and for the use of antiretroviral agents for pediatric HIV infection (56) . 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 _____.

HIV and AIDS Case Surveillance Practices

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

Recommended Surveillance Practices

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

through the HIV/AIDS Reporting System, as is current practice.

- Published evaluations of non-name based HIV surveillance in two States (41) together with results of meetings and consultations with States that have considered or used non-name identifiers have highlighted operational difficulties with these systems. Based on published evaluations, CDC has concluded that name-based HIV/AIDS surveillance systems are the most likely to meet the necessary performance standards (22, 57-61) as well as to serve the purposes for which surveillance data are required. Therefore, CDC advises that State and local surveillance programs use the same name-based approach for HIV surveillance as is currently used for AIDS surveillance nationwide. However, CDC recognizes that some States have adopted, and others may elect to adopt, non-name case identifiers for the public health reporting of HIV infection. CDC will provide technical assistance to all State and local areas to continue or establish HIV and AIDS surveillance systems and to evaluate their surveillance programs regardless of whether they use name or non-name based identifiers.
- HIV and AIDS surveillance should be used to identify rare or previously unrecognized modes of HIV transmission, unusual clinical or virologic manifestations, and other cases of public health importance. CDC will provide technical assistance to State and local health departments conducting such investigations and will revise public health recommendations based on the findings, as appropriate.
- HIV and AIDS case surveillance efforts should be directed toward the collection of data from all private and public sources of HIV-related testing and care services. Laboratory-initiated surveillance methods should be used to collect information for cases that meet the laboratory reporting criteria for HIV infection and AIDS. Statistics regarding persons who are tested anonymously should not be reported through the HIV/AIDS Reporting System. These test results are reported anonymously to the HIV Counseling and Testing database. HIV-infected persons who are initially tested anonymously are only eligible to be reported to HIV/AIDS surveillance after they have been diagnosed by a health care provider and have test results or clinical conditions that meet the HIV and AIDS reporting criteria.
- All State and local surveillance programs should regularly publish, in print or electronically, aggregated HIV and AIDS surveillance data in a format that facilitates the use of these data by Federal, State, and local public health agencies; HIV Prevention Community Planning groups; academic institutions; providers and institutions that have reported cases; community-based organizations; and the general public. The presentation of surveillance data should be consistent with established policies for data release that preclude the direct or indirect identification of a person with HIV or AIDS.
- All State and local surveillance programs should conduct regular ongoing assessments of the performance of the surveillance system and redirect efforts and resources to ensure timely reporting of complete, representative, and accurate data. CDC will provide technical assistance and standardized evaluation methods to assist States in achieving the highest possible level of performance.

Performance Standards

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

Recommended Security and Confidentiality Practices

- State and local programs should have a description of their security policies and procedures available for external review. CDC will require that State and local areas include their security policy in applications for Federal surveillance funds.
- For optimal security, data should be maintained on a single electronic HIV and AIDS surveillance registry. In accordance with local laws, other files--paper and electronic (except for a backup for the central system)--that contain personal identifying information should be eliminated. All States should continue the established practice of not including personal identifying information in the HIV and AIDS surveillance data forwarded to CDC.
- State and local health departments should review their data retention policies. Policies should provide the flexibility to remove cases that were reported in error. State and local programs should also consider removing the names from surveillance records that no longer serve a public health purpose and to identify these cases through other means such as the use of the alpha-numeric code scheme currently used in HIV and AIDS

surveillance, date of birth, and other data routinely collected in case reports.

- State and local health departments should also review their confidentiality statutes to determine whether additional protections should be put in place before the implementation of HIV case surveillance. State and local confidentiality laws should include (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 purposes; (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 laws should protect surveillance data that are transmitted (in a secure and confidential manner consistent with CDC's HIV/AIDS surveillance program requirements) to other public health programs as part of evaluation studies or for follow up of cases of special public health importance. The penalties under law for violation of privacy and security should apply to all recipients of HIV and AIDS case surveillance information.

Security and Confidentiality Standards

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

- CDC *requires* that electronic HIV/AIDS surveillance data be protected by computer encryption during data transfer. Paper or unencrypted electronic case reports forwarded by providers should be used by surveillance staff to update the central surveillance registry and then should be destroyed.
- CDC *requires* that HIV and AIDS surveillance records be located in a physically secured area to limit and control access to surveillance records, and be protected by coded passwords and computer encryption. To further enhance security and confidentiality of the data, the use of a double-key encryption and decryption system, in which identifying information encrypted by the States using the first key can only be decrypted for access using the second key to be held by CDC, can be implemented by States using methods recommended by CDC. The key held by CDC will be protected by an Assurance of Confidentiality under Section 308(d) of the Public Health Service Act. Under this Assurance, the second CDC-held key would preclude States from accessing or releasing the HIV/AIDS surveillance data for non-public-health purposes.
- CDC *requires* that access to the HIV/AIDS surveillance registry be restricted to a minimum number of authorized surveillance staff who have been trained in confidentiality procedures and who are aware of penalties for unauthorized disclosure of surveillance information. The State Health Officer or other designated authorizing official should specify the persons who have access to confidential HIV/AIDS surveillance data and the duties to be conducted. Audit systems should be established to monitor access to and use of surveillance data. Non-surveillance personnel should not

have access to HIV and AIDS surveillance files.

- If State and local health departments develop data bases from the cross-matching of HIV/AIDS surveillance data with other surveillance data, HIV and AIDS surveillance records *must not* be used if the cross-matched data bases do not have equivalent security and confidentiality protections and penalties for unauthorized disclosure as those for the HIV and AIDS surveillance data. Such cross-matched data bases should use the minimum amount of surveillance data necessary to accomplish the specific public health activity.
- The use of HIV and AIDS surveillance data for research purposes *must* be approved by appropriate institutional review boards, and researchers should sign confidentiality statements. HIV and AIDS surveillance data made available for epidemiologic analyses must not include names or other identifying information. State and local data release policies should ensure that the release of data for statistical purposes does not result in the direct or indirect identification of persons reported with HIV and AIDS. If a breach of confidentiality occurs, State and local health departments should impose personnel sanctions and criminal penalties as appropriate.
- State and local health departments *must* investigate potential breaches of confidentiality, and impose personnel sanctions and criminal penalties as appropriate. All breaches of confidentiality are to be reported to CDC immediately. CDC will provide technical assistance to State and local health departments' investigations of such incidents, develop recommendations for improvements in local security measures, and provide oversight to monitor changes in program practices.

Relationship to HIV Prevention and Care Programs

- The implementation of HIV case surveillance should not interfere with HIV prevention programs, including those that offer anonymous HIV counseling and testing services. Unless prohibited by State law or regulation, CDC *requires* that States and local areas provide opportunities to receive anonymous HIV counseling and testing services as a condition of Federal funding for HIV prevention. CDC strongly recommends that States prohibiting anonymous HIV testing change this practice, given the overriding public health objective of encouraging knowledge of HIV serologic status.
- All HIV testing services should continue to be voluntary and preceded by informed consent in accordance with local laws (62).
- All persons who are diagnosed with HIV infection should be referred to programs that provide HIV care, treatment, and comprehensive prevention case management services. Provider-based referrals of patients to prevention and care services provide a timely, effective, and efficient means of ensuring that individuals who have been diagnosed with HIV receive needed services. The primary function of HIV and AIDS surveillance is the collection of accurate and timely epidemiologic data; therefore, State and local HIV and AIDS case surveillance programs are not directed by CDC to share individual case reports with prevention or care programs, including those that provide partner notification assistance, case management, and other services for individual clients. Although some

areas have established direct linkages between surveillance and specific prevention programs, such linkages do not necessarily improve the provision of HIV prevention and care services. Areas that elect to establish such linkages must seek the concurrence of their prevention and care planning groups, require that recipients of surveillance information be subject to the same penalties for unauthorized disclosure as surveillance personnel, and evaluate the effectiveness of this public health approach.

COMMENTARY

The Surveillance Case Definition for HIV Infection and AIDS

The revised HIV 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 1999 HIV and AIDS case definition includes viral detection tests that were not commercially available when the case definition was revised in 1993. The revised case definition for HIV infection also permits the reporting of cases based on the result of any test licensed for the diagnosis of HIV infection in the United States. Although the reporting criteria generally reflect the recommendations for the diagnosis of HIV infection, the HIV reporting criteria are for public health surveillance and are not designed for making a diagnosis for an individual patient. The laboratory criteria include the serologic HIV tests described in the clinical standards for HIV diagnosis (63-64).

The pediatric HIV reporting criteria include criteria for monitoring all children with perinatal exposures to HIV and reflect recent advances in diagnostic approaches that permit the diagnosis of HIV infection in the first months of life. With 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 (46-55).

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 increases mortality risks. Almost all deaths among persons with HIV infection are caused by AIDS-related opportunistic illnesses (65).

Effect of National HIV Case Surveillance on Reporting Trends

The changes in the HIV reporting criteria will have little effect on reporting trends in States already conducting HIV case surveillance. The number of HIV cases reported nationally

will increase primarily because of the implementation of HIV surveillance by the remaining States and local areas. Many of the States that will be implementing HIV case surveillance in the future have high AIDS incidence rates. Similar to the effect on AIDS surveillance trends after the implementation of the revised reporting criteria in 1993, the initiation of HIV surveillance by additional States may result in a sudden and large increase in HIV case reports (66). Based on CDC's estimates 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 (30), it is possible that this many persons could be reported with HIV infection from these States in 1999. However, it is more likely that reporting of prevalent HIV infections will be spread over several years and that the annual increases will be more modest. Initially, most case reports will represent persons whose HIV infection was diagnosed before HIV surveillance was implemented. As the reporting of prevalent HIV cases is completed, the number of HIV case reports will decrease and case reports will increasingly represent persons with recent diagnosis of HIV infection.

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

AIDS trends have declined nationally; however, because the AIDS surveillance trends are affected by HIV incidence, as well as the effect of treatment on the progression of HIV disease, it is not possible to predict future AIDS trends. AIDS surveillance will continue to be important in evaluating access to care for different populations and 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 (67-69).

HIV and AIDS Surveillance Practices

Laboratories will be an increasingly important source of information from which to initiate reporting. HIV infection is frequently diagnosed in the outpatient clinical setting, and laboratory-initiated reporting will be particularly useful in identifying outpatient sources of HIV testing (60). Although contact with individual providers is necessary to complete the reporting process, the routine collection of data from laboratories and managed care organizations promotes simplicity and efficiency of case reporting to local surveillance programs.

Performance criteria for HIV and AIDS surveillance are necessary to ensure that surveillance data are of sufficient quality to target prevention and care resources and to detect emerging trends in the HIV epidemic. Evaluations of HIV and AIDS surveillance programs have shown that areas should be able to meet these performance criteria (57-61). According to these

evaluations, the completeness of HIV surveillance (79 to 95 percent) and AIDS surveillance (85 to 100 percent) is high and reporting is timely with nearly one-half of AIDS cases and three-quarters of HIV cases reported to the national HIV/AIDS reporting system within 3 months of diagnosis (6). In 1996, CDC estimated that the duplication rate of HIV and AIDS cases reported from different States to the national surveillance data base was less than 3 percent and 2 percent, respectively (24). The performance criteria also reflect the need for public health surveillance systems to serve as a basis for the identification and follow-up of cases of public health importance. Based on evaluation studies of non-name-based case identifiers and the current infrastructure of State and local health departments, name-based methods for collecting and reporting public health data provide the most feasible and reliable means for ensuring timely, accurate, and complete reporting of persons diagnosed with HIV and AIDS. Name-based reporting facilitates follow-up of perinatally-exposed infants to determine their infection status and of persons reported with HIV to determine progression to AIDS and vital status.

The Security and Confidentiality of HIV and AIDS Surveillance

The revision of the HIV reporting criteria provides an opportunity to review and strengthen State and local confidentiality laws and regulations. Although State HIV and AIDS surveillance confidentiality laws and regulations adequately protect privacy compared with the statutory protections of other health care data, State statutes differ in the degree of privacy protections afforded health information and the criteria for permissible disclosures of personal information. Most State statutes describe some permissible disclosures of public health information. To help ensure uniform confidentiality protections, CDC, CSTE, ASTHO, the National Conference of State Legislatures, and the Georgetown/Johns Hopkins Public Health Law Project are conducting a model State privacy law project. This project is developing model legislative language to protect confidential, identifiable information held by State and local public health departments against unauthorized and inappropriate use while still allowing the use of surveillance information to accomplish legitimate public health objectives. This process is projected to be completed by the end of 1998, and States that plan to implement HIV case surveillance should consider adopting the model legislation.

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

HIV Prevention and Care

CDC has published guidelines concerning the provision and targeting of HIV counseling

and testing services (19, 27, 70-72), and provides support for most public sources of HIV testing. The availability of anonymous HIV testing services may be particularly important for persons who delay seeking testing because of a concern that others may learn of their serologic status. Studies have shown that the availability of anonymous HIV testing is associated with increased numbers of persons seeking testing services (73-76). Anonymous HIV testing services are a required element of federally supported prevention programs unless prohibited by State law or regulation. Currently, 39 States, Puerto Rico, and the District of Columbia provide anonymous HIV testing services.

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

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

CONCLUSION

The implementation of a national surveillance network to include both HIV and AIDS surveillance is a necessary response to epidemiologic trends and new standards for HIV care. Integrated HIV and AIDS surveillance programs will provide data to characterize persons newly diagnosed with HIV infection, including those with evidence of recent infection, persons with severe HIV disease (AIDS), and those succumbing to HIV and AIDS. The revised HIV surveillance case definitions and the establishment of performance criteria will promote uniform case ascertainment and will ensure that the surveillance data are of sufficient quality for effective planning and allocation of resources for prevention and care programs. The successful implementation of HIV and AIDS surveillance will require that State and local areas further

ensure the security and confidentiality of surveillance data. This can be promoted through enhancements to data systems and confidentiality policies, training and management of public health personnel, and by use of the HIV Prevention Community Planning process to determine the appropriate use of surveillance data by prevention and care programs.

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

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

OR

Clinical Criteria (if the above criteria are not met)

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

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

Laboratory Criteria

Definitive

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

OR

Presumptive

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

OR

Clinical Criteria (if the above criteria are not met)

- Diagnosis of HIV infection documented in a medical record by a physician, OR,
- Conditions that meet criteria included in the 1987 pediatric surveillance case

definition for AIDS (12,13)

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

Laboratory Criteria

Definitive

- At least two negative HIV antibody tests from separate specimens obtained at ≥ 6 months of age, OR,
- At least two negative HIV virologic detection tests** from separate specimens, both of which were obtained 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)

OR

Presumptive

- One negative result from an HIV antibody test performed at ≥6 months of age, OR,
- One negative HIV virologic detection test** performed at ≥4 months of age, OR,
- One positive HIV virologic detection test with at least two later negative tests**, at least one of which is after 4 months of age; or negative HIV antibody test results, at least one of which is at ≥6 months of age.

OR

Clinical Criteria

- Determined by a physician to be 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).

*The revised surveillance criteria for HIV infection were approved and recommended by the membership of the Council of State and Territorial Epidemiologists (CSTE) at the 1998 annual meeting. Draft versions of these criteria were previously reviewed by state HIV/AIDS surveillance staffs, CDC and CSTE laboratory experts; in addition the pediatric criteria were reviewed by an expert panel of consultants.

#Plasma viral RNA nucleic acid tests should **not** be used as screening tests for the purpose of diagnosing HIV infection.

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

DRAFT: December 17, 1999

Dear Addressee:

Human immunodeficiency virus (HIV) case surveillance serves critical public health goals as have been detailed in the Guidelines for National HIV Case Surveillance and accompanying materials. For example, HIV case surveillance enhances local, State, and Federal efforts to prevent HIV transmission. It also helps public health authorities evaluate the impact of public health interventions.

On December 10, 1999, the Centers for Disease Control and Prevention (CDC) published "Guidelines for National HIV Case Surveillance, Including Monitoring for HIV Infection and Acquired Immunodeficiency Syndrome" in the *Morbidity and Mortality Weekly Report (MMWR) Recommendations and Reports*. These Guidelines can be accessed at www.cdc.gov. The Guidelines include a revised case definition for HIV infection in adults and children, recommended surveillance program practices, and performance and security standards for conducting HIV/AIDS surveillance by local, State, and territorial health departments. HIV case surveillance must also protect the confidentiality of personal data. The purpose of this letter is to clarify and emphasize key points in the Guidelines related to confidentiality and security.

As you may be aware, on November 3, 1999, the Department of Health and Human Services (HHS) published a Notice of Proposed Rule Making regarding Standards for Privacy of Individually Identifiable Health Information. This proposed rule is mandated by the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The rule provides privacy protections for personal medical information *held by covered health care providers, health plans, and health care clearinghouses*. The proposed rule would not preempt State public health reporting laws or more stringent State privacy protections.

To help ensure the security and confidentiality of HIV surveillance data under State confidentiality laws, the CDC Guidelines include a recommendation that States and territories consider implementing the "Model Public Health Privacy Act" (Model Act), if necessary, to strengthen their current public health laws. This Model Act was developed by Georgetown University, at the request of the Council of State and Territorial Epidemiologists (CSTE), to promote minimum standards for the protection of *publicly held* public health surveillance data The provisions of the Model Act would enhance the confidentiality of surveillance data, strengthen statutory protections against disclosure, and preclude the unauthorized use of surveillance data.

Additionally, the Model Act contains strong penalties for unauthorized disclosure of personal identifying data by public officials. It also permits access to civil remedies (e.g. compensatory and punitive damages) to any person aggrieved by disclosure of protected health information in violation of the Model Act. As part of the surveillance program, CDC offers to States the option of requesting that CDC and the State jointly restrict access to HIV/AIDS surveillance data through the implementation of a dually-held encryption-decryption code that would be legally protected under a Federal assurance of confidentiality as authorized under Section 308(d) of the Public Health Service Act, 42 U.S.C. §242m(d).

In addition to legal protections of surveillance data, CDC's HIV Surveillance Guidelines set forth minimum standards for the security of HIV/AIDS surveillance data to establish a minimum level nationwide, consistent with individual State laws. The security requirements were developed with input from the States following visits by CDC staff to all State health departments. CDC provided 1998 supplemental funding to States, to help them comply with the standards. States are required to meet these standards in order to receive Federal funds under the HIV/AIDS surveillance cooperative agreement, effective January 1, 2000, the same date the Guidelines become effective. All States have met CDC's minimum security requirements by providing CDC with a written certification and designating an Overall Responsible Party for the security and confidentiality of HIV/AIDS surveillance data.

Two key points in the Guidelines Minimum Security and Confidentiality Standards are highlighted below:

> Access to the HIV/AIDS surveillance registry should be restricted to a minimum number of authorized surveillance staff, who are designated by a responsible authorizing official, have been trained in confidentiality procedures, and are aware of the penalties for unauthorized disclosure of surveillance information. The State Health Office or other designated authorizing official should specify the persons who have access to confidential HIV/AIDS surveillance data and the duties to be conducted. Audit systems should be established to monitor access to and use of surveillance data. Non-surveillance personnel should not have access to HIV and AIDS surveillance files.
>
> State and local health departments must investigate potential breaches of confidentiality, and impose personnel sanctions and criminal penalties as appropriate. All breaches of confidentiality are to be reported to CDC immediately. CDC will provide technical assistance to State and local health departments' investigation of such incidents, develop recommendations for improvements in local security measures, and provide oversight to monitor changes in program practices.

CDC recognizes that some States have elected and others may elect to use patient codes when implementing HIV case reporting. Regardless of the type of patient identifier (names or codes) that States use, CDC will provide funds to any State whose reporting system meets the qualifications set out in the Guidelines. CDC will work with States that wish to develop non-name-based reporting systems that qualify for Federal funding. CDC will also share information on these reporting systems with other interested States. CDC affirms its commitment to the security and confidentiality of personally identifying HIV/AIDS surveillance data by

recommending the Model Act for consideration by States where existing State statutes are less stringent, and by requiring States to meet minimum security standards.

Sincerely,

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

cc:
OD
CDC/W
NCHSTP
NCHSTP/DHAP
Doc. Name: KoplanJenningsHIVletterv1.wpd
Prepared by: P. Fleming, NCHSTP/DHAP-SE/SB, (404) 639-2040:12/13/99
Spelling verifier used by: cmp3:12/13/99
Spelling verifier used by:DAcevedo 12/17/99