FOIA Number: 2018-0758-F

FOIA MARKER

This is not a textual record. This is used as an administrative marker by the William J. Clinton Presidential Library Staff.

Collection/Record Group: Clinton Presidential Records

Subgroup/Office of Origin: National AIDS Policy Office

Series/Staff Member: Todd Summers

Subseries:

OA/ID Number: 21089

FolderID:

Folder Title:
Issues - HIV Surveillance-CDC [Centers for Disease Control]-Guidelines-Draft Q and A

Stack:	Row:	Section:	Shelf:	Position:
S	66	6	3	1

OFFICE OF THE SECRETARY
OFFICE OF HIV\AIDS

Office of Public Health and Science
200 Independence Avenue, S.W.
Washington, D.C. 20201
Room 736-E
Tel. (202) 690-5560
Fax. (202) 690-6584
Fax. (202) 690-7560

DELIVER TO: Sondra Thiessen

FAX: 456-2439
TELEPHONE: _____

Comments: FYI - DRAFT

From: **GLEN E. HARELSON**
Deputy Director for Management
Telephone: 202-690-7324
Page: 202-490-2414

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

Talking Points --HIV Surveillance

- On ~~October~~ Dec 10, 1998, the Department published the new draft guidelines for HIV surveillance in the *Federal Register*. As you know, the Department has been working on these guidelines for a long time, and many representatives from community groups participated in a number of discussions CDC held in getting to this point.

- Also on ~~October~~ Dec 10, the Department sponsored a briefing for the NORA coalition groups, where copies of the *Federal Register* notice and our fact sheets were made available. In that meeting, the Department outlined the contents of the guidelines, and what they actually say, in hopes of minimizing misinterpretations.

- The guidelines do recommend that all States move ahead to put in place a system for HIV surveillance, in addition to AIDS surveillance.

- States have the flexibility to choose between unique identifier systems or a name-based system, and CDC is committed to both technical and financial assistance to help States implement the system they choose. There are performance criteria spelled out, which are important to ensuring the quality of the data.

- The document does not provide a formal recommendation from CDC around the use of a name-based reporting system. But it does say that CDC advises that, based on evaluations to date, name-based systems are most likely to meet the necessary performance standards.

- With respect to anonymous testing, these guidelines reflect our strongest position ever on anonymous testing. The Department continues to support anonymous HIV testing and recommends that all states make available anonymous testing options.

- There is also a strong commitment in the guidance to ongoing monitoring to assess if changes in surveillance policies affect HIV testing patterns, and CDC will require all States **receiving prevention funds** to maintain anonymous testing options unless State law prohibits it. In addition, CDC strongly recommends that states not currently offering anonymous testing reevaluate their policies on the issue.

- These guidelines also reflect the Department's strongest statements on handling confidential data. There is a very strong section on confidentiality and security standards, which are the stiffest we have ever put forward. 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. We've also explicitly de-linked HIV surveillance activities from prevention interventions like partner notification.

- I hope we can work together to highlight both the flexibility States have, and the important confidentiality protections and anonymous testing provisions that are vital to keeping people's faith in public health systems. We've worked hard to strike the right balance between getting information important to our prevention and treatment efforts, and respecting individual concerns.

December 1998

Q&A on CDC Draft Guidelines for HIV Surveillance

Q: What is CDC recommending and why?

A. CDC is advising states that name-based systems of surveillance are the most likely to provide the quality data necessary to direct community prevention and treatment programs. But, CDC will also allow states to choose to use alternative tracking systems that rely on codes or "unique identifiers" rather than names, and will provide the technical assistance necessary to help them comply with performance standards. These guidelines address the urgent need for improved data on where and how many new HIV infections are occurring in the U.S. The guidelines also set out strict confidentiality and quality standards and stress the continued importance of anonymous testing.

Treatment advances have slowed the progression from HIV to AIDS for many individuals, so data on AIDS cases alone can no longer be reliably used to direct prevention efforts to communities currently at greatest risk. Without improved data, the nation could soon be blindly fighting an evolving epidemic.

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 surveillance systems. CDC is advising that names-based surveillance systems are the most likely to meet the necessary performance standards. Thirty-two states have already adopted this approach to surveillance. However, CDC will continue to work with states that choose code-based or "unique identifier" systems, and provide technical assistance to help them achieve performance standards, if needed.

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. CDC will continue to provide technical assistance to states working to design systems that rely on codes or "unique identifiers" (UIs) rather than names.

However, after extensive research and consultation with state and advocacy groups, CDC has determined that name-based HIV surveillance systems are the most likely to provide the quality data necessary to direct community prevention and treatment programs. CDC therefore advises that state and local surveillance programs use the same approach for HIV surveillance as is currently used for AIDS surveillance nationwide. Thirty-two states have already adopted name-based surveillance programs.

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 to ensure

both the quality and confidentiality of the data. CDC will work with states over a period of several years to assist them in the transition, and help them achieve performance standards.

Q: How will surveillance systems be evaluated?

A. The criteria are outlined in detail in the guidance document, but 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 of 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 alone may not be able to accurately depict and predict the course of their epidemics. Eventually, CDC funding will reflect a state's ability to provide accurate and complete surveillance.

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

A. No. As the Nation's prevention agency, CDC has an obligation to ensure that its surveillance systems provide a reliable means of directing and evaluating HIV prevention and treatment efforts at a national, state, and local level. As the epidemic has evolved into multiple, diverse sub-epidemics, the quality of data at a local level is critical. These data are used by HIV community planning groups to plan, direct, and evaluate community-based prevention programs. Moreover, allocation of funding for prevention and care is now based on CDC surveillance data. Without an accurate, reliable picture of the local epidemic, prevention and treatment services may not reach the individuals and communities at greatest risk.

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 XX to XX, 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&A Document)

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 do not need to be linked to be done effectively. CDC already requires states to have 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. 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. However, CDC has studied two unique identifier systems and has not found them to be as accurate, complete, or confidential as a name-based system. An evaluation of two states' UI programs -- published in the January 9, 1997, Morbidity and Mortality Weekly Reports -- revealed several problems with these UI systems, including a high number of reports with incomplete codes (approximately 30-40 percent) and low rates of completeness in reporting (approximately 25-50 percent complete). One of the states involved in this evaluation is now working to implement a name-based system.

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.

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.

###

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 a rapidly evolving epidemic with outdated information.

After extensive work with state health departments and community 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 need 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 advise 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. Alternatives to name-based systems will also be allowed, and CDC will provide technical assistance and funding to those states choosing to implement them.

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 systems that rely on codes or "unique identifiers" rather than names.

CDC is advising 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 breeches.

However, CDC recognizes that some states may choose to design alternative systems that use unique identifiers instead of names. While CDC has evaluated several UI systems and found problems in the quality of data they produced, there remain opportunities for states to either improve upon those systems already designed or to create new systems using different methodologies. CDC will provide technical assistance and support to all States working to implement new HIV surveillance systems, including those that are name-based and those that use unique identifiers.

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

A: No. As the Nation's prevention agency, CDC has an obligation to ensure that its 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 names-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 is most gather quality data. CDC believes that name-based systems have a good track record and can be relied upon to gather quality data. However, some states have expressed an interested 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.

* On the question about **partner notification**, the word "voluntary" should be added to distinguish CDC's support for those systems that are voluntary as opposed to mandatory. Is this as strong as CDC has been on this issue? I thought they were pretty set against any linking of surveillance with notification.

* On the fist question in the UI section, is the statement accurate that tow systems were evaluated, or is it more accurate to say that two attempts to implement one kind of system were evaluated? The wording here and elsewhere seems to imply a more thorough review of a range of UI options instead of just the one (based on social security numbers) attempted by Maryland and Texas.

* I would like a re-working of the UI and names-based sections to make them a little more equal in tone. The names-based system is all about how wonderful they are, and the UI section seems to be saying how bad they are. If in fact we're going to treat them equally and focus instead on the quality of data, then this tone is inconsistent.

FAX TRANSMISSION

U.S. Department of Health and Human Services
Office of the Secretary

DATE: 12/9/98

TO: Todd Summers

FAX: 456-2438 / 546-2352 **PHONE:** _____

FROM: Lauren Shahan

Press Office, OASPA
Phone: (202) 690-6343
Fax: (202) 690-6247

TOTAL NUMBER OF PAGES TRANSMITTED: _____

COMMENTS:

Q+A and AP Story

FOR INTERNAL USE ONLY
December 9, 1998 6:05 p.m.

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.

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.

###