**National HIV Surveillance System (NHSS)**

Attachment 4c.

Supplemental Surveillance Activity 1: HIV Incidence Surveillance Technical Guidance

# Technical Guidance for HIV Surveillance Programs

## HIV Incidence Surveillance

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## Contents

# Background

The Centers for Disease Control and Prevention (CDC), in conjunction with the state and local health departments, conducts HIV incidence surveillance (HIS) (a component of the National HIV Surveillance System [NHSS]) to generate reliable and scientifically valid national, state, and local estimates of the number of new HIV infections—diagnosed and undiagnosed. HIV incidence reflects transmission patterns and trends, as well as the impact of HIV on the public's health. Using the stratified extrapolation approach (SEA) [1], CDC calculated the first national HIV incidence estimate based on a direct measure of recency of infection during 2006 [2]. In 2011, on the basis of a refinement of the SEA, the 2006 estimates were updated for 2007–2009 [3]. In 2012, CDC published a surveillance supplemental report of HIV incidence data for 2007–2010 [4]. CDC expects to produce annual estimates to provide updated data on trends in HIV incidence.

Since 2001, CDC has funded selected state and local health departments to conduct HIS. In addition to information collected for case surveillance, information is collected on testing and antiretroviral (ARV) use history and the results of serologic testing for recent HIV infection (i.e., the serologic testing algorithm for recent HIV seroconversion [STARHS] [5], which is a method for testing remnant specimens to classify new diagnoses of HIV infection as recent or longstanding). In 2004, STARHS used a detuned version of a commercially available HIV diagnostic test, the Vironostika HIV-1 EIA (enzyme immunoassay), which made the test less

sensitive. Because the Vironostika HIV-1 EIA had been approved for diagnostic purposes by the United States Food and Drug Administration (FDA), the less-sensitive version of the test (VironostikaLS) required individual consent. Testing history and ARV use information and consent were collected during interviews with persons seeking HIV testing (pretest) or with persons who had received a new HIV diagnosis (posttest).
In March 2005, the FDA allowed the use of a second assay for recency testing (only for surveillance purposes, thus eliminating the need for patient consent). The BED assay is an EIA that detects increasing levels of anti-HIV IgG after seroconversion and can be used for detecting recent HIV infection. (The abbreviation BED refers to a capture enzyme immunoassay in which a branched peptide, constructed from gp41 sequences from HIV-1 subtypes B, C, and D allows similar performance with antibodies against various B and non-B subtypes.) This assay was used for cases diagnosed from 2005 through 2013.

Beginning in 2014, specimens from cases newly diagnosed are tested by using the Bio-Rad HIV1/HIV-22*PLUS O* EIA (Bio-Rad Avidity assay), modified by the DHAP Laboratory Branch for detection of recent HIV-1 infections. (See Appendix B for further information about tests for recent HIV infection for HIV incidence surveillance.)

For surveillance purposes, specimens from newly diagnosed cases are tested for detection of recent HIV-1 infection at a CDC-funded centralized laboratory (STARHS laboratory). The STARHS laboratory is responsible for receiving and storing specimens, conducting tests for recent infection, and communicating results of tests for recent infection to the jurisdictions conducting HIS. Results from tests for detection of recent HIV-1 infection are not returned to patients, providers, or laboratories; therefore, no individual consent for testing is required.

Jurisdictions conducting HIS may require reporting of results of recency testing or submission of samples for recency testing as part of reportable disease regulations.

In 2007, CDC reduced the number of data elements required for testing history and ARV use information and expanded modes of collection of testing and ARV use history data elements to include health care provider reports, medical record review, other databases, and the National HIV Monitoring & Evaluation System (NHME), formerly Program Evaluation and Monitoring System (PEMS). CDC will adjust the program requirements as technology and data sources improve.

The primary functions of HIS are as follows:

- Describe demographic and behavioral characteristics of populations and subpopulations with newly diagnosed HIV infection
- Monitor trends in transmission
- Provide data for national, state, and local HIV prevention planning
- Monitor the outcomes of national, state, and local HIV prevention programs and strategies

The tasks to achieve the functions of HIS include the following:

- Collaborate with CDC, laboratories, HIV testing providers, and affected communities to further develop and ensure the capability to conduct HIV incidence surveillance.
- Obtain HIV testing history and ARV use information on all persons aged 13 years and older with a new diagnosis of HIV infection that has been reported to HIV surveillance.
- Collect results of recency tests (STARHS or other methods as they become available) for persons with new HIV diagnoses. Results from recency testing are obtained from remnant HIV diagnostic blood specimens. In the future, as a protocol becomes available, it may be possible to obtain remnant samples from dried blood spots collected on filter paper.
- Integrate HIV incidence surveillance activities with case surveillance activities.
- Submit data, as specified by CDC, by using eHARS software and by complying with data submission standards established by CDC.
- Conduct systematic evaluation of HIV incidence surveillance.
- Calculate and disseminate annual population-based HIV incidence estimates and promote the use of HIV incidence data for prevention and health services planning.
- Ensure that the security and confidentiality procedures of the program are consistent with the requirements of CDC's Data Security and Confidentiality Guidelines [6].

# Structural Requirements

HIV infection may be detected at various points along the spectrum of disease, and reportable events range from the reporting of HIV infection in otherwise asymptomatic persons to deaths among people with HIV. Jurisdictions conducting HIS are required to incorporate testing and ARV use history variables and the results of recency testing into HIV case reporting of persons aged 13 years and older with a new diagnosis of HIV infection. **Exception:** specimens from persons whose infection was classified as stage 3 (AIDS) at diagnosis are excluded from recency testing.

Data should be collected in accordance with the Technical Guidance for HIV Surveillance Programs. HIV surveillance case report data, in combination with HIS data elements, are used to calculate population-based HIV incidence estimates.

## Policies and Procedures

It is important to document HIS activities and to address the particular needs of HIS in the jurisdiction's HIV surveillance policies and procedures manual to establish standardization, maintain consistency of meaning for data elements, document changes over time, and develop training programs. HIS-specific policies and procedures should include the requirements listed in the technical guidance files and should include information related to the following:

- Obtaining HIV testing history and ARV use information on all persons aged 13 years and older with a new diagnosis of HIV infection that has been reported to HIV surveillance

- Collecting results from tests for recent HIV infection on all persons aged 13 years and older with a new diagnosis of HIV infection. Currently, results are obtained through submission of remnant specimens from HIV diagnostic tests for testing at a STARHS laboratory. Procedures for specimen submission include the following:
    - Establishing and maintaining collaboration and communication with public and private HIV testing laboratories (within and outside the state) to secure remnant specimens from the original diagnostic HIV test or another HIV-related test conducted within 3 months after the initial diagnosis
    - Securing and tracking remnant specimens shipped from public and private HIV testing laboratories (within and outside the state) to the designated laboratory for recency testing
    - Developing a STARHS eligibility list—a list of the diagnostic specimens that represent new diagnoses of HIV infection not known to have progressed to HIV infection, stage 3 (AIDS). The list is used to inform the appropriate laboratory of the need to test the specimens for recent infection or to ship the specimens to a laboratory designated to perform such testing.
- Training all HIV case reporters (e.g., HIV testing providers, HIV care providers) and staff involved in collection of testing history and ARV use information (see Appendix A)
- Managing data and conducting activities to ensure data quality (see Appendixes F and G)
- Conducting systematic evaluations of HIV incidence surveillance by using outcome and process standards and using evaluation results for program improvement
- Calculating and disseminating annual population-based HIV incidence estimates and promoting the use of HIV incidence data for prevention and health services planning
- Ensuring that security and confidentiality procedures of the program are consistent with CDC's Data Security and Confidentiality Guidelines [6]

## Reportable Information

### *STARHS results*

STARHS (serologic testing algorithm for recent HIV seroconversion) is a method for testing remnant specimens to determine whether the infection is long-standing or recent. Recent infection is defined as the period after HIV seroconversion but before an individual has reached an assay-dependent cutoff level that defines the end of the recency period (see Appendix B). Remnant specimens may be obtained from diagnostic specimens or from specimens that are collected after HIV infection has been confirmed.

The HIS program staff collaborate with public and private/commercial laboratories to locate, determine the disposition of, and ship remnant diagnostic blood specimens to the STARHS laboratory for testing for recent HIV-1 infection (see Appendixes C.1, C.2, C.3, and C.4). When the remnant serum/plasma is insufficient or not available from the diagnostic specimen, remnant HIV-positive serum or plasma from a blood draw for an HIV diagnostic or HIV-related test can

be used instead, provided that the blood was drawn within 3 months after the initial HIV diagnosis. No specimen should be drawn solely for recency testing.

### *HIV testing and antiretroviral use history*

The primary purpose of gathering data on HIV testing and antiretroviral (ARV) use history is to calculate a statistical weight corresponding to the probability that a person would be tested for HIV in the STARHS recency period. This weight is used in estimating HIV incidence.

Testing and ARV use history data elements (see Appendix D and the file Adult HIV Confidential Case Report Form) are used to determine testing frequency to classify persons as new testers (i.e., persons whose first HIV test result was positive) or repeat testers (i.e., persons who tested HIV-positive after having previously tested HIV-negative). This distinction is important for incidence estimation because the probability of being classified as recently infected is calculated separately for new testers and repeat testers. In addition, critical testing and ARV use history data elements are used to determine whether treatment (ARV use) might have affected the results of the recency test.

For the standard list of HIV testing and ARV use history data elements needed to estimate HIV incidence, see Appendix D and the file Adult HIV Confidential Case Report Form.

## Staffing Needs

HIS operation requires personnel with specific skills and dedicated time to integrate HIS activities with case surveillance and other program activities (e.g., data collection, data management, data quality assessment, data deduplication, dissemination) to build a seamless surveillance system and maximize efficient use of resources. Generally, HIS staff should have the following:

- Understanding of the general principles of HIV surveillance in the jurisdiction
- Good communication skills
- Strong leadership skills
- Enthusiasm about disease reporting for public health purposes
- Disposition toward meeting HIS process and outcome standards
- Ability to work closely with CDC, other states, local sites, private health care providers, hospitals, and laboratories

CDC recommends that at least 0.5 full-time equivalent (FTE) be dedicated to the incidence surveillance coordinator (ISC) position for monitoring and evaluating the activities of HIS and 0.5 FTE for data management. Other personnel assigned to HIS may vary, depending on program needs, prevalence of HIV, and available resources. Additional staff may include an epidemiologist-trainer (0.5 FTE), a laboratory liaison (0.5 FTE), and field staff for data collection. Finally, because HIV incidence estimation is a highly technical activity, areas conducting HIS should consult with a mathematical statistician as needed. If a person with these

skills is not available within the health department, consult with CDC. Recommended staffing roles and responsibilities of HIS staff are described in the table.

**Table. Recommended roles and responsibilities of HIS staff**

| Position | Responsibilities | Certifications/expertise |
|---|---|---|
| Incidence surveillance coordinator (ISC) | Serve as CDC's primary point of contact regarding HIS<br>Provide overall management of HIS and determine program goals and needs<br>Update HIS policies and procedures manual<br>Oversee processes for the collection of HIV testing history and ARV use information and STARHS data<br>Identify which diagnostic specimens represent new diagnoses of HIV infection not known to have progressed to stage 3 (AIDS)<br>Communicate, as needed, with HIV case reporters and data collectors regarding ascertainment and accuracy of HIS data elements<br>Coordinate the analysis and dissemination of HIV incidence data and assess trends in new infections at the local/state level<br>Evaluate the performance of HIS relative to process and outcome standards<br>Manage any employee or other service contracts related to HIS<br>Participate in CDC site visits, trainings, and workshops<br>Maintain the security and confidentiality of HIS data | SAS (SAS Enterprise Guide [EG]) [*Desired*] |

| Position | Responsibilities | Certifications/expertise |
|---|---|---|

| | | |
|---|---|---|
| Epidemiologist/ trainer | Serve as lead for training HIV testing providers and laboratories regarding HIS, including development/modification of jurisdiction –specific training materials<br>Verify adherence to HIV testing and ARV use history data collection standards and proper submission of testing and ARV use history data elements<br>Conduct quality control activities to address the accuracy of the data collected<br>Provide feedback regarding testing and ARV use history completeness and timeliness to HIV case reporters and data collectors<br>Coordinate the collection of testing and ARV use history data elements from HIV case reporters and data collectors<br>Use evaluation results including process and outcome standards for program improvement<br>Provide consultation and technical assistance on testing and ARV use history data collection<br>Participate, as appropriate, in CDC site visits, trainings, and workshops<br>Maintain the security and confidentiality of HIS data | Training<br>Data collection<br>Data quality<br>SAS (SAS EG) |

| | | |
|---|---|---|
| Laboratory liaison | Coordinate with public and private HIV testing laboratories (within and outside the state) to secure remnant specimens from the original diagnostic HIV test or other HIV-related test conducted within 3 months after the initial diagnosis<br>Coordinate/communicate with public and private HIV testing laboratories (within and outside the state) to arrange transport of remnant specimens to the designated laboratory for recency testing<br>Maintain communication with public health, private, and community laboratories; the STARHS laboratory; and the ISC<br>Establish procedures for tracking specimens<br>Serve as subject matter expert on the preparation and shipping (including quality control procedures) of specimens to the STARHS laboratory<br>Oversee specimen identification and tracking<br>Provide laboratories with feedback on specimen quality and quantity, as well as frequency of specimen shipments<br>Participate, as appropriate, in CDC site visits, trainings, and workshops<br>Maintain the security and confidentiality of HIS data | International Air Transport Association (IATA) training in handling specimens and preparing aliquots<br>Laboratory database experience<br>Encryption software |
| **Position** | **Responsibilities** | **Certifications/expertise** |
| Data manager | Oversee processes for data entry of incidence data elements<br>Conduct data quality assessments, data set creation and transfers, and data management programs<br>Maintain documentation of HIS data management processes in policies and procedures manual<br>Participate in evaluations of process and outcome standards<br>Serve as subject matter expert on HIV incidence data elements, data set preparation for local and national incidence estimation, and daily data management<br>Participate in CDC site visits, trainings, and workshops | SAS (SAS EG)<br>Encryption software |

Maintain the security and confidentiality of HIS data

# Process Standards

HIS involves the following process standards:

- Routine collection of HIV testing history and ARV use information on all persons aged 13 years and older with a new diagnosis of HIV infection that has been reported to HIV surveillance
- Routine collection of results of tests for recent HIV infection in persons aged 13 years and older with a new diagnosis of HIV (excluding those persons whose infection was classified as stage 3 [AIDS] at diagnosis)
- Collection of results from recency testing performed by a STARHS laboratory on remnant specimens from diagnostic HIV tests
- Entry of HIS data in the eHARS database as specified by CDC
- Electronic transfer of HIS data to CDC by using eHARS software in accord with data submission standards established by CDC
- Routine performance of data quality control activities, including data error resolution and monitoring of data completeness
- Calculation and dissemination of annual population-based HIV incidence estimates and promotion of the use of HIV incidence data for prevention and health services planning
- At least annually, performance of a systematic evaluation of HIV incidence surveillance by using outcome and process standards and by using evaluation results for program improvement
- Routine checking of data handling procedures to ensure compliance with CDC's Data Security and Confidentiality Guidelines [6]
- Provision of training (at least annually) in HIV surveillance and HIS methods to HIV reporters and data collectors

## Collection of HIS Data Elements

As a general principle, HIV testing and ARV use history data should be collected for all persons aged 13 years and older with a new diagnosis of HIV infection that has been reported to the HIV surveillance system. Results of tests for recent HIV infection should be collected for persons aged 13 years and older with a new diagnosis of HIV, excluding those whose infection was classified as stage 3 (AIDS) at diagnosis.

### *Diagnoses among persons residing out of jurisdiction*

Jurisdictions funded to conduct HIS should collect HIV testing and ARV use history data and STARHS results for all newly diagnosed HIV infections reported to HIV surveillance and should work with other jurisdictions to exchange needed data. For information about interstate/reciprocal notification of reportable diseases, see the file Date and Place of Residence. For persons whose infection has been reported to an HIS-funded jurisdiction and who reside in any HIS-funded jurisdiction, HIS areas are expected to collect testing and ARV use history data and ensure that a remnant of the diagnostic specimen is tested for recent HIV infection (excluding specimens from persons whose infection was classified as stage 3 [AIDS] at diagnosis). All testing history and ARV use information and STARHS data should be forwarded to the state of residence at HIV diagnosis if that state is conducting HIS. In addition, ARV use data typically collected through HIS are critical to molecular HIV surveillance (MHS) data analyses.

### *STARHS specimen information and results*

Collecting the results of tests for recent HIV infection in persons aged 13 years and older with a new diagnosis of HIV, excluding those whose infection was classified as stage 3 (AIDS) at diagnosis, is required for HIS. HIS staff should perform the following tasks:

- Identify and locate diagnostic specimens that represent diagnoses of HIV infection not known to have progressed to stage 3 (AIDS) at the time of HIV diagnosis
- Secure remnant specimens from the original diagnostic HIV test or other HIV-related test performed by public or private laboratories (within and outside the state) within 3 months after the initial diagnosis
- Determine the disposition of specimens for recency testing (STARHS) by checking the quarterly specimen inventory list submitted by the STARHS laboratory
- Develop a monthly STARHS eligibility list for use by both the public health laboratory and the STARHS laboratory, using the template, standard codes, and formats provided by the STARHS laboratory (see Appendix C.3)
- Establish procedures for tracking shipments and the receipt of results
- Establish regular communication between the public health, private, and commercial laboratories; the STARHS laboratory; the ISC; and HIS staff

Results of tests for recent infection are obtained through locating, and determining the disposition of, specimens; preparing STARHS eligibility lists; and transporting remnant HIVpositive specimens to the STARHS laboratory (see the Background section).

Laboratories that perform routine diagnostic HIV tests or immunologic status tests such as CD4 or viral load counts should report results to the state/local health department surveillance program per current requirements. For the purposes of this guidance, laboratories that are sources of remnant specimens for recency testing have been classified into 3 types:

1. Commercial laboratories that process specimens from many states or jurisdictions (included in this category are Quest Diagnostics Inc., Laboratory Corporation of America [LabCorp], ARUP Laboratories, and Mayo Clinic)

2. Private laboratories, which include smaller private/university/hospital or medical center laboratories that provide service primarily at the state or local level

3. State and local public health laboratories, which collaborate with other components of the nation's public health system to provide clinical diagnostic testing, disease surveillance, environmental and radiological testing, emergency response support, applied research, laboratory training, and other essential services to the communities they serve

To identify all laboratories that perform diagnostic HIV tests and report results to state and local health departments, see the file Reporting. An updated directory of laboratory contacts at all reporting laboratories should be integrated with case surveillance and maintained to facilitate communication in the event that reporting or shipping of specimens is disrupted or that changes in policy or procedures need to be communicated. The laboratories identified should be contacted to request that remnants of HIV-positive diagnostic specimens be made available for recency testing (STARHS). The reports that these laboratories send to the state/local health department surveillance programs, per the established reporting requirements, should include specimen accession numbers (see the file Date and Place of Residence).

Sending specimens from a laboratory that performs the initial HIV immunoassay as part of a diagnostic HIV testing algorithm (originating laboratory) to a second laboratory for supplemental HIV testing (reference laboratory) is a common practice. A specimen may be assigned a different accession number at each laboratory that receives it. Therefore, it is important to ensure that the accession number assigned by the laboratory that ships the specimen to the STARHS laboratory is transmitted to the surveillance program as part of the laboratory reporting process.

HIS staff, using routine HIV surveillance reporting procedures, determines whether the specimen represents the person's first reported positive HIV test result in the HIS jurisdiction or was drawn for an HIV related test within 3 months after the first reported positive HIV test result and is thus eligible for recency testing.

A specimen should be tested for recency of HIV infection if

- the specimen represents the diagnostic specimen (the HIV-positive specimen that led, or should have led, an adolescent/adult HIV case to be reported to HIV surveillance) or

- the diagnostic specimen is unavailable, and the available specimen was drawn within 3 months after the diagnostic specimen and was drawn for an HIV-related test (including viral load, polymerase chain reaction [PCR] test, and CD4 count)

A specimen should not be tested for recency of HIV infection if

- an earlier specimen, drawn closer to the diagnosis date, has already been tested for recency
- the specimen was drawn more than 3 months after the diagnostic specimen
- the person's infection was classified as stage 3 (AIDS) at HIV diagnosis
- the specimen is from a person identified, on the basis of a diagnostic algorithm, as having acute HIV infection (e.g., positive for HIV-1 antigens on the basis of a 4th generation immunoassay, but negative for HIV-1 antibodies on the basis of a supplemental typedifferentiating immunoassay)
- the person has a positive rapid test and an undetectable viral load, and no other diagnostic test results are available to confirm or supplement diagnosis
- the person tested positive for HIV-2 antibody or tested positive for both HIV-1 and HIV2 antibodies (dual infection)

Laboratories (any of the 3 types described earlier) establish whether specimens are classified as HIV-positive. For each positive HIV test result reported to a jurisdiction that conducts HIV incidence surveillance, staff in the jurisdiction must then determine whether each specimen is eligible or ineligible for recency testing. **HIS staff must communicate the outcome of this determination to public health laboratories**. The public health laboratory (regardless whether the public health laboratory performed the testing or received the specimen from another diagnostic laboratory) ships a specimen to the STARHS laboratory only if HIS staff have deemed that specimen eligible for recency testing (see Appendixes C.1 and C.2).

**Commercial and private laboratories** may ship all remnant HIV-positive specimens directly to the STARHS laboratory. The disposition of these specimens must be communicated by HIS staff to the STARHS laboratory. Communication with the STARHS laboratory related to the disposition of remnant specimens is accomplished by using the STARHS eligibility list (see Appendix C.3). The STARHS Data Transfer Network should be used for transferring specimen eligibility lists and shipping manifests from HIS jurisdictions to the STARHS laboratory and transferring untested specimen lists, shipping manifests, and test results from the STARHS laboratory to HIS jurisdictions (see Appendix C.5).

For instructions for shipping remnant HIV-positive diagnostic specimens, see Appendix C.4.

As future tests of recent HIV infection become available, programs must adapt to updated CDC guidance for the collection of these test results.

### *Testing and ARV use history*

The purpose of HIV testing and ARV use history data collection is to obtain the most accurate information available to characterize a person's HIV testing history and ARV use information.

Testing and ARV use history data are reported by HIV testing and health care providers and surveillance staff, who use the jurisdiction's standard reporting procedures or other procedures that meet CDC's Data Security and Confidentiality Guidelines [6].

These data

- should be included for all new case reports of persons aged 13 years and older that have been reported to the HIV surveillance system
- may be collected from multiple sources of information, including patient interview, medical records, laboratory reports, and other databases, including NHME
- should be collected per the tenets of document-based surveillance
- may be collected when investigating a case, completing a case report form, or conducting interviews (e.g., as part of counseling and testing services, partner services)

Testing and ARV use history fields are included in the revised CDC adult case report form (see the file Adult HIV Confidential Case Report Form). It is important to examine all available information and ensure that the collected data accurately reflect the patient's HIV testing history and ARV use. CDC has developed materials for use in training HIV case reporters and data collectors to obtain HIV testing and ARV use history data (see Appendix A).

## Entering Data into Surveillance Databases

HIS data may be entered manually or imported into eHARS but should follow the principles of document-based surveillance. HIV testing and ARV use history data are entered into the eHARS Adult Case Report Form document. Separate eHARS documents are used to enter and store data from different forms or multiple sources or to update information. This important feature allows CDC and the jurisdiction to track the relative proportions and the data quality and completeness of testing and ARV use history documents collected through various reporting methods (e.g., patient interview, medical record review, or passive case reporting) for the purpose of program improvement. Data entry staff are expected to enter data in eHARS as reported on the data collection form. The HIS program should have procedures for resolving conflicting entries on a data collection form (e.g., if the conflict is the result of a typographical error in a single document, the error should be corrected in that document).

All eligible specimens tested by the STARHS lab are assigned a STARHS ID. HIS jurisdictions are sent information linking assigned STARHS IDs to the specimen IDs or accession numbers for the eligible specimens. For more information on the flow of specimens and specimen data between public health, private or commercial, and STARHS labs, see Appendixes C.1, C.2, and C.3.

There are 2 approaches for entering STARHS specimen information and results into eHARS. The approaches are based on whether the jurisdiction uses an external data tracking system to manage STARHS specimen data.

Approach 1 applies to jurisdictions that manually enter or import STARHS specimen data into eHARS before importing STARHS results. STARHS information (required and recommended) on eligible specimens should be entered into eHARS regularly, including STARHS ID; the

person's first, middle, and last names; specimen collection date; STARHS test type; specimen type; relevant specimen IDs or accession numbers; and if necessary, the reasons specimens were not sent for testing for recent infection (e.g., quantity not sufficient). It is important to note that before importing STARHS result files, staff must enter the STARHS specimen data (particularly the STARHS ID, collection date, and test type) into eHARS as a laboratory document. In this approach, when HIS staff receive the STARHS results, they match the results to cases in eHARS by using the previously entered/imported STARHS ID. Some important STARHS specimen information (including specimen collection date, accession number, specimen ID, and the person's first, middle, and last names) will be extracted (by using the CDC-provided SAS program) from the previously entered STARHS specimen laboratory document and included in the STARHS result import file. After the STARHS result file has been imported, a new laboratory document containing the results and specimen collection date, accession number, specimen ID, and the person's first, middle, and last names will be added to each corresponding case. Thus, each case will have at least 2 documents associated with a given recency test. For analysis, the data from all laboratory documents bearing the same STARHS ID should be combined.

Approach 2 applies to jurisdictions that manage STARHS specimen information by using a locally designed data tracking system outside of eHARS. Approach 2 combines the locally stored specimen data (from the tracking database) with the STARHS results (from the STARHS laboratory) outside eHARS and allows both to be imported (on a single document) into eHARS. The external data tracking system should include the following required and recommended information: STATENO; first, middle, and last names; STARHS ID; laboratory specimen IDs or accession numbers; specimen collection date; and specimen type. To combine STARHS results with the specimen data, one needs to first extract the specimen data from the external tracking system as a CSV (comma-separated values) file (see tabulation, which provides the structure of the CSV file, along with variable names, descriptions, types, and acceptable values) and then run the SAS import preparation program provided by CDC.

The SAS import preparation program combines the specimen data and STARHS result data by STARHS ID and prepares an auto-import STARHS data file based on STATENO. Importing the auto-import STARHS data file into eHARS will add a STARHS laboratory document containing both specimen and STARHS result data for a given specimen. If the jurisdiction uses the CDCprovided SAS program, the eHARS auto-import file will contain only specimen data for the specimens that have a matching STARHS ID in the STARHS result file. The specimen data without a matching STARHS ID in the STARHS result file are likely to be specimens for which STARHS results are pending and therefore will be matched to future STARHS results. Most surveillance areas also maintain in their tracking system the data on specimens that are not sent for recency testing. Information on the reason specimens were not sent for recency testing cannot be imported into eHARS; therefore, data on these specimens should be manually entered into eHARS, along with required or recommended specimen information (e.g., specimen collection date, STARHS test type, specimen type, and relevant specimen IDs). In approach 2, surveillance staff can enter data into eHARS manually when necessary.

CSV file structure for STARHS specimen data is as follows:

| STATENO | FIRST | MIDDLE | LAST | SSTARHSID | SSTATEID | LSrceID | LDteObt | LSpecTy |
|---|---|---|---|---|---|---|---|---|

| State number | First name | Middle name | Last name | STARHS specimen ID | State lab or other specimen ID | Source lab specimen ID | Specimen collection date | Specimen type |
|---|---|---|---|---|---|---|---|---|
| Char(35) | Char(50) | Char(50) | Char(50) | Char(15) | Char(50) | Char(50) | mm/dd/yyyy | Char(10)<br>Valid values are:<br>URN<br>BLD<br>OTH<br>SAL<br>UNK |

*Note.* Maintaining the order of the variables is REQUIRED; however, the header row with variable names is not necessary. For additional information regarding HIS data entry and eHARS variables that are required or recommended for HIS, see Appendix D.

## Transferring Data to CDC

Since 2011, eHARS has been configured to allow the entry, management, and transmission of HIS data to CDC. All HIS data collected from other databases should be manually entered or imported into eHARS. The HIS data include the data from the STARHS laboratory on the Excel spreadsheet, which contains STARHS results identified by STARHS ID, the testing and ARV use history data collected through NHME, and other local sources.

Jurisdictions should follow CDC guidance for creating and transferring HIS data to CDC. Data transmitted to CDC must not include personal identifiers and must be encrypted and password protected according to CDC's Data Security and Confidentiality Guidelines [6].

## Data Quality

CDC has developed programs that generate reports to be used to improve the quality of incidence data. The 2 data quality monitoring tools for HIV incidence are the completeness report and the error report (see Appendixes F and G).

The HIV incidence completeness report provides a snapshot of the proportion of HIV cases diagnosed within a 3-year period, by year, that have required testing and ARV use history data elements and STARHS results. Completeness is based on all HIV cases diagnosed in a specific year. Percentages are based on persons reported from each HIS area and residing in any area funded for HIS. The HIV incidence completeness report not only monitors data completeness but also identifies problems with data transfer and monitors progress toward target performance levels and data quality standards. A high level of completeness helps HIS programs meet outcome standards. If problems are identified, CDC will provide technical assistance to improve the completeness of data.

The HIV incidence error report is used to monitor data entry errors and data inconsistencies between variables. It is based on data about persons reported from, and residing in, areas that conduct HIS. The validity and accuracy of the HIV incidence estimates are limited if the data contain errors or a large proportion of information is missing or unknown. If errors and inconsistencies are routinely checked and corrected, programs can more easily and quickly detect and correct problems with data entry and data collection and thus improve data quality.

Completeness and error reports serve as data quality monitoring tools for CDC epidemiologists and state/local HIS staff to use in understanding HIS data and in working together to improve the validity and accuracy of the data. HIS sites investigate and resolve errors on the basis of CDC recommendations (see Appendixes F and G).

## Ensuring Security and Confidentiality

Data collected for HIV incidence surveillance are considered part of routine surveillance and should be held to the CDC standards of security and confidentiality for HIV surveillance outlined in the CDC's Data Security and Confidentiality Guidelines [6]. Policies and procedures, based on the guidelines and local laws, are already in place at state and local health departments and are used to secure hard copies and electronic data to protect the confidentiality of persons reported as having HIV infection. Specimens and associated information that are carried through US mail or carrier services should be treated as case information and should follow all security and confidentiality requirements that apply to physical and data security. Access by all staff to information in eHARS, HIV testing and ARV use history, and STARHS data is governed by the same security and confidentiality requirements. Recency results are intended for HIV surveillance purposes only (i.e., to support population studies) and cannot be interpreted at the individual level for clinical decisions.

## Analyzing and Disseminating HIV Incidence Estimates

Population-based HIV incidence is estimated by using a statistical approach that is analogous to that used to estimate a population total from a sample survey. Per the sample survey approach, the number of new HIV infections in the population is estimated (from a sample comprising all newly diagnosed HIV infections in the selected period classified as "recent") by assigning a sampling weight to each result in the sample. This weight is the inverse of the estimated probability that a person who has seroconverted would be identified, on the basis of a recency test, as having a recent infection. Data from persons who choose to have a confidential HIV test and who test positive are used to estimate the incidence of HIV infection, both diagnosed and undiagnosed, nationally and locally. The method used to generate the population-based incidence estimate was initially described by Karon et al [1].

HIV prevention programs can use HIV incidence estimates to target resources and to monitor and evaluate prevention activities locally, regionally, and nationally. CDC has the primary responsibility for analyzing, interpreting, and disseminating national HIV incidence estimates, using data from HIS areas. Results will be presented at conferences and published in peerreviewed journals. The number of representative authors from participating areas and CDC will be determined for each presentation or paper. State or local HIS areas should consider developing their own HIV incidence estimates in accordance with Appendix E.

## Training Staff

In accordance with CDC's Data Security and Confidentiality Guidelines [6], HIS staff must receive training in security and confidentiality procedures and must sign a confidentiality statement upon being hired and annually thereafter. Because HIS is a fully integrated component

of HIV surveillance, all HIS staff should receive training in the local policies and procedures for case surveillance, including the following:

- Active and passive surveillance methods
- Laboratory reporting mechanisms
- Data management processes

In addition to the general training mentioned above, the HIS laboratory liaison, data manager, ISC, and epidemiologist should receive specific job-related training. The following are examples:

**Laboratory liaison**

- Role of public health laboratory in incidence surveillance
- Specimen handling (i.e., specimen numbering, storage, and retention)
- Preparing aliquots and shipping specimens to the STARHS laboratory according to guidelines
- Entering data and generating reports for specimen tracking and determining specimen eligibility for recency testing by using STARHS

**Data manager**

- HIS data entry and data quality assessment
- Secure procedures for electronic data transport
- Specimen eligibility and the tracking and maintenance of results (electronic and hard copies)
- Creating reports for HIV care and prevention programs

**ICS or epidemiologist**

- Incidence estimation
- Program monitoring and evaluation
- eHARS

# Outcome Standards

Outcome standards described in the file Introduction to Policies and Procedures and the file Evaluation and Data Quality can be applied to HIS. These files address case ascertainment, completeness, timeliness of reporting, evaluation of standard data edits, and missing/unknown information. Meeting case surveillance standards for case ascertainment and timeliness is essential for HIS to be successful, given the time-sensitive nature of HIS data elements, including HIV testing and ARV use history data and STARHS results. The quality of the HIV incidence estimate depends on the quality and completeness of data included in the HIS system.

All outcome standards for HIS relate only to cases in persons who resided in the surveillance area at the time of diagnosis.

**Data quality**

- At least 97% of case records (target: 100%) pass all selected data edits related to HIS data, measured 12 months after the close of the report year.

**Completeness of testing and ARV use history data**

- At least 85% of case reports of newly diagnosed cases of HIV infection reported for a calendar year should include testing and ARV use history data, assessed 12 months after the end of the diagnosis year.

**Completeness of STARHS results**

- At least 60% of new diagnoses of HIV infection reported for a calendar year, excluding cases classified as stage 3 (AIDS) within 6 months after HIV diagnosis year, have a STARHS result from a specimen obtained at, or within 3 months after, HIV diagnosis, assessed 12 months after the end of the diagnosis year.

# References


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