Challenges in Reporting Laboratory Data from HIV Diagnostic Testing Algorithms in HIV Surveillance

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Outline

- HIV Surveillance Case Definition
- Reporting to HIV Surveillance
- Impact of the New Diagnostic Algorithm on the Case Definition
- Guidance for Surveillance Jurisdictions and Laboratories
- Status of Implementation
- Next Steps
HIV Surveillance Case Definition

- To meet the surveillance case definition for HIV infection among adults and adolescents, laboratory-confirmed evidence of HIV infection is required.

- **Laboratory Criteria:**
  - Positive result from an HIV antibody screening test (e.g., EIA) confirmed by a positive result from a supplemental HIV antibody test (e.g., WB or IFA).
  - OR -
  - Positive result or report of a detectable quantity from any of the following HIV virologic (i.e., non-antibody) tests:
    - HIV nucleic acid (DNA or RNA) detection test (e.g., polymerase chain reaction [PCR])
    - HIV p24 antigen test, including neutralization assay
    - HIV isolation (viral culture)
Reporting to HIV Surveillance

- All state and local HIV surveillance programs use the Enhanced HIV/AIDS Reporting System (eHARS) to collect, manage, or transmit electronic data to CDC
  - eHARS is an application for collecting, organizing, storing, and retrieving the data CDC has identified as necessary to monitor HIV prevalence, incidence and other trends for prevention and care planning efforts.

- Laboratory results are entered into eHARS
  - eHARS allows an unlimited number of laboratory reports to be stored for each case

- Laboratory reporting (including electronic reporting) of an HIV diagnosis triggers a case investigation
Impact of the New Diagnostic Algorithm on the HIV Surveillance Case Definition (1)

  - Recommended laboratory testing procedures for the diagnosis of HIV infection, including testing algorithms in which the Western blot (WB) or indirect immunofluorescence assay (IFA) are not required for a confirmed HIV diagnosis.
The HIV Incidence and Case Surveillance Branch (HICSB) at CDC determined that the new algorithms would be accepted as sufficient criteria for a surveillance case.

- Supplemental HIV antibody tests need not be limited to the WB or IFA.
- Other antibody tests are acceptable as supplemental tests, including some that might alternatively be used as initial screening tests, provided that the initial and supplemental tests are used together as parts of an approved algorithm.
November 2011: HICSB disseminated a letter to clarify how HIV surveillance programs should collect and report data on persons whose HIV infection is diagnosed using new diagnostic algorithms.

- Sent to 65 HIV surveillance jurisdictions and public health laboratories
- Letter affirmed that since a nationally recognized body recommended new diagnostic testing algorithms for HIV, new algorithms would be accepted as sufficient criteria for a surveillance case.
Guidance for Surveillance Jurisdictions and Laboratories (2)

- **Surveillance programs are encouraged to:**
  - Discuss the implementation of new testing algorithms with the laboratory director of public and private laboratories
  - Follow up with health care providers to verify implementation of new testing algorithms
  - Ensure documentation of all test results that lead to a diagnosis of HIV (e.g., both the initial and supplemental test result[s])
    - Work with the staff of HIV testing programs and providers to ensure that test results are documented in the patients’ records and included on HIV case report forms.
    - Work with laboratories to ensure that test results are documented in both paper and electronic reports.
Guidance for Surveillance Jurisdictions and Laboratories (3)

- Entry of test results from the lab-based testing algorithm into the surveillance database (eHARS)
  - Enter/import test results from *all* tests performed as part of an algorithm
  - HICSB provides guidance to ensure that persons diagnosed by a new algorithm are captured in the system as surveillance cases
  - Detailed instructions for data entry/import are provided in an eHARS FAQ document
Status of Implementation

- Several public health laboratories (e.g., FL, MA, IA, IL, MD, MI) have completed validations of the new diagnostic algorithm.

- Other laboratories are planning to implement after one or more of the following occur:
  - The label describing approved uses for the Multispot changes to include its use as a supplemental test.
  - The CDC publishes recommendations for the new diagnostic algorithm.
  - The revised HIV case definition is published with explicit language to capture new diagnostic algorithms.

- Some programs have disseminated letters to educate providers/laboratories.
Next Steps (1)

- **Release the revised HIV case definition**

- **Revise state laws/regulations:**
  - Many state laws/regulations will need to be revised to permit the reporting of positive HIV test results other than the Western blot.

- **Work with laboratories and providers to:**
  - Ensure that laboratory results necessary to establish an HIV diagnosis are reported
  - Determine how results will be reported
    - Paper and electronic reports
    - Standardized use of LOINC codes
Next Steps (2)

- Update eHARS to better accommodate results from the new algorithms

- Surveillance Grantees Meeting in April, 2013
  - Session devoted to the implementation of the new algorithms
Questions?

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The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.