



Uses of HIV Laboratory Data in Surveillance, and Challenges with Reporting

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2016 HIV Diagnostics Conference

March 21, 2016

Overview

- Uses of laboratory data
 - Monitoring progress toward goals
 - High Impact Prevention
 - Describing HIV disease burden
- Challenges with laboratory reporting
 - Common themes with laboratory reporting challenges
 - Laboratory Consultation summary
 - Laboratory Consultation recommendations











Laboratory Data Needs for Surveillance

Uses of Laboratory Data

- Measuring progress toward goals
 - National HIV/AIDS Strategy
 - Continuum of Care
- High Impact Prevention
 - Identifying patients potentially not in care
 - Targeting interventions
- Describing HIV disease burden
 - Diagnosing HIV infections
 - Estimating incidence
 - Identifying transmission patterns and growing clusters
 - Monitoring antiretroviral drug resistance

National HIV/AIDS Strategy

INDICATORS AT-A-GLANCE

	INDICATOR 1 Increase the percentage of people living with HIV who know their serostatus to at least 90 percent .
	INDICATOR 2 Reduce the number of new diagnoses by at least 25 percent .
	INDICATOR 3 Reduce the percentage of young gay and bisexual men who have engaged in HIV-risk behaviors by at least 10 percent .
	INDICATOR 4 Increase the percentage of newly diagnosed persons linked to HIV medical care within one month of their HIV diagnosis to at least 85 percent .
	INDICATOR 5 Increase the percentage of persons with diagnosed HIV infection who are retained in HIV medical care to at least 90 percent .
	INDICATOR 6 Increase the percentage of persons with diagnosed HIV infection who are virally suppressed to at least 80 percent .
	INDICATOR 7 Reduce the percentage of persons in HIV medical care who are homeless to no more than 5 percent .
	INDICATOR 8 Reduce the death rate among persons with diagnosed HIV infection by at least 33 percent .
	INDICATOR 9 Reduce disparities in the rate of new diagnoses by at least 15 percent in the following groups: gay and bisexual men, young Black gay and bisexual men, Black females, and persons living in the Southern United States.
	INDICATOR 10 Increase the percentage of youth and persons who inject drugs with diagnosed HIV infection who are virally suppressed to at least 80 percent .

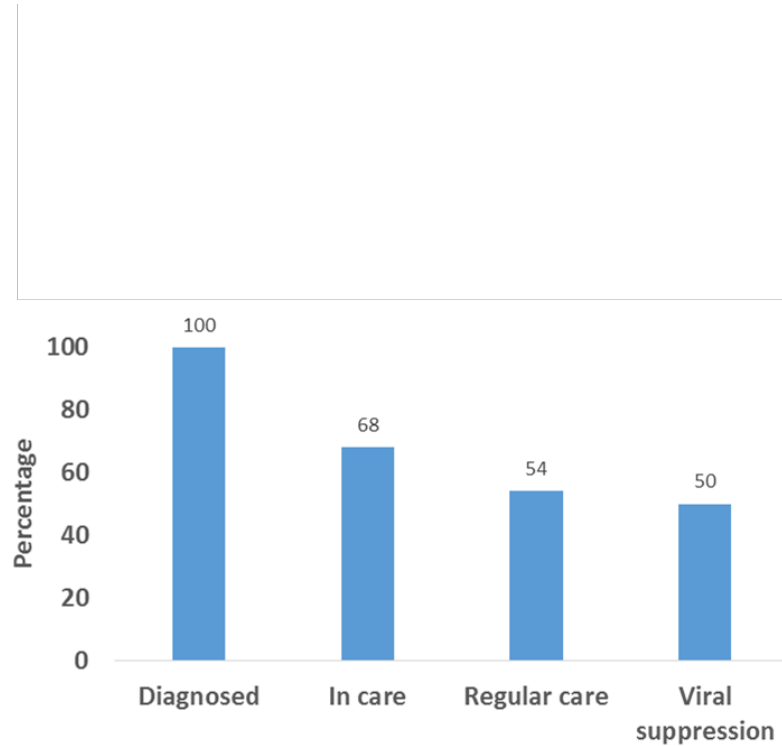
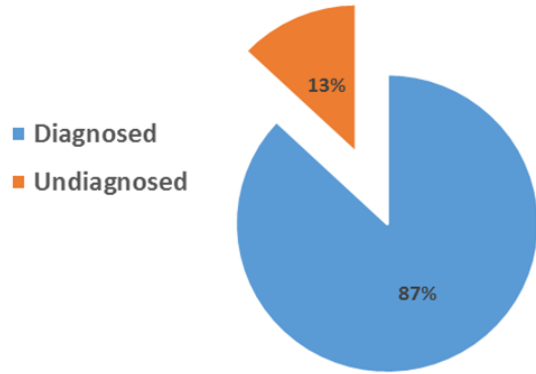
Lab report
required*



*HIV diagnosis, CD4, and/or VL

<https://www.aids.gov/federal-resources/national-hiv-aids-strategy/overview/index.html>

Continuum of Care



Centers for Disease Control and Prevention. Monitoring selected national HIV prevention and care objectives by using HIV surveillance data—United States and 6 dependent areas—2013. HIV Surveillance Supplemental Report 2015;20 (No. 2).

http://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillancereport_vol20_no2.pdf

High Impact Prevention

- Identifying patients potentially not in care (Data to Care)
 - Patients lacking CD4 or viral load results (as a marker for medical care) within a given period of time
 - Outreach efforts attempt to locate, and link/re-engage and retain these patients in care
 - Initiated by health department, health care provider, or both
- Identifying high burden or high risk populations to target for interventions
 - Disproportionate number of diagnoses or high incidence
 - Geographic, demographic, or risk behavior

HIV Surveillance Case Definition Background

- In June 2011 the Clinical and Laboratory Standards Institute (CLSI) published updated laboratory testing procedures for diagnosis of HIV infection.
- Prior to these alternative diagnostic testing algorithms, a supplemental HIV test was restricted to a Western blot or IFA.
- New diagnostic testing algorithms allow for the use of a NAT or an orthogonal immunoassay as a supplemental HIV test.
 - Orthogonal: Tests with different antigenic constituents or that use different principles to minimize the possibility of concurrent nonspecific reactivity

HIV Surveillance Case Definition

- Multitest algorithm consisting of
 - A positive (reactive) result from an **initial** HIV antibody or combination antigen/antibody test, *and*
 - An accompanying or subsequent positive result from a **supplemental** HIV test different from (orthogonal) the initial test

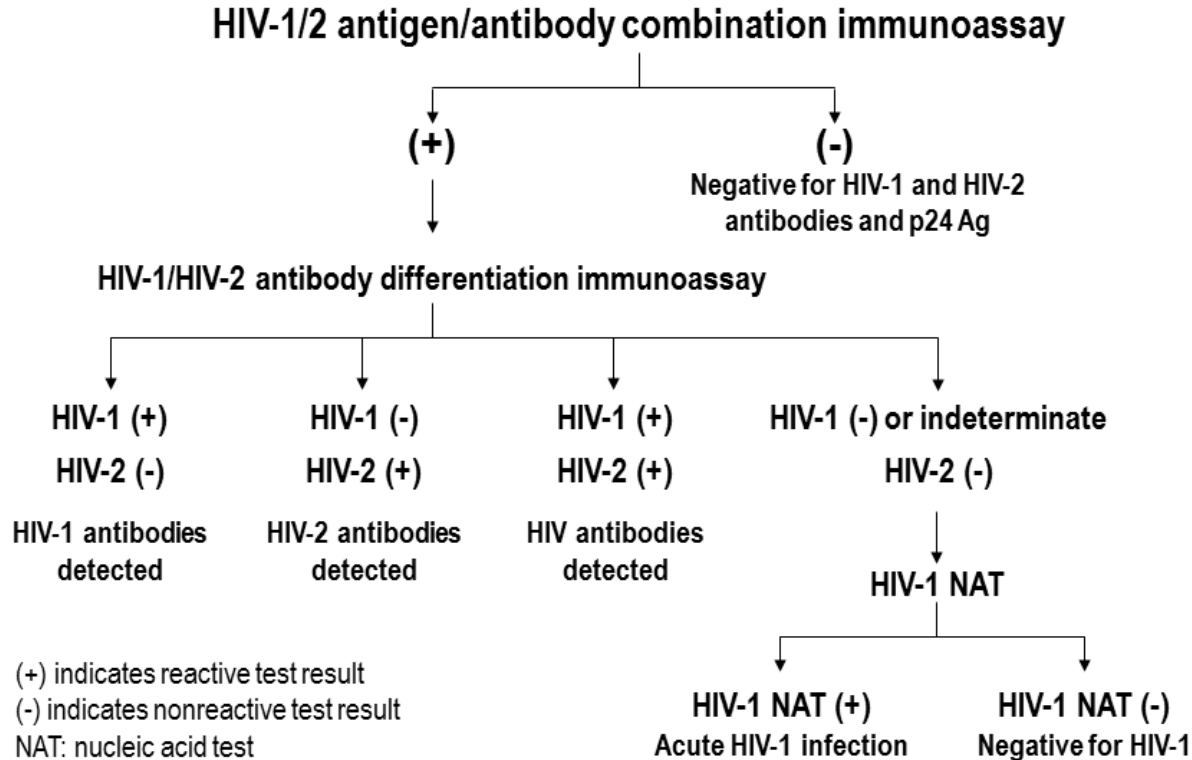
Or

- Positive result of a multitest HIV antibody algorithm from which only the final result was reported, including a single positive result on a test used
 - Only as a **supplemental** test (e.g., HIV Western blot, immunofluorescence assay) *or*
 - As either an initial test or a supplemental test (e.g., HIV-1/2 type-differentiating rapid antibody immunoassay) when it might reasonably be assumed to have been used as a supplemental test

Or

- Positive result of a detectable quantity from any of the following HIV **virologic** tests
 - Qualitative HIV NAT (DNA or RNA)
 - Quantitative HIV NAT (viral load assay)
 - HIV-1 p24 antigen test (standalone)
 - HIV isolation (viral culture)
 - HIV nucleotide sequence (genotype).

Recommended Diagnostic Testing Algorithm



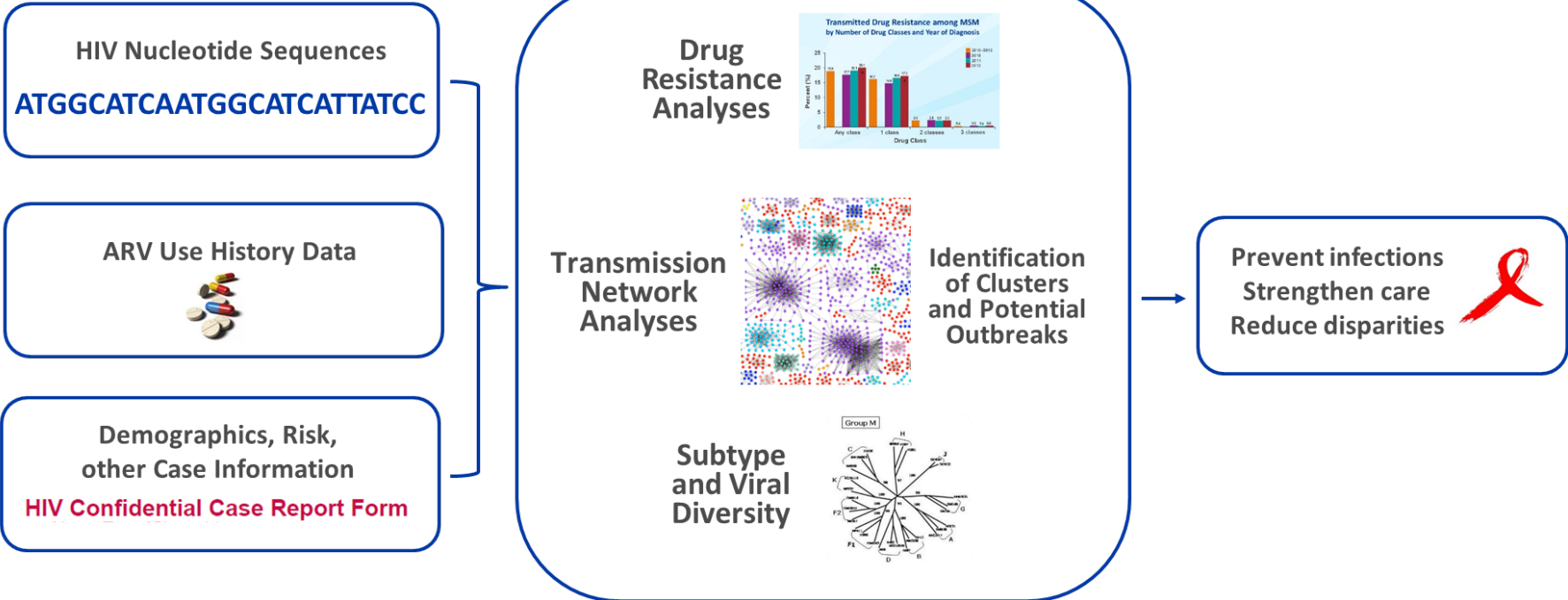
Importance of Negative Test Results

- Negative antibody test results usually sent from a laboratory
 - Important for identifying acute infection and prioritizing those patients for intervention
 - Acute infection (part of Stage 0): Positive interpretation of a testing algorithm which contained a negative antibody test result
- Negative test results usually obtained through case surveillance follow-up
 - Important for ascertaining the date of the person's last negative test result
 - Staging of disease at diagnosis
 - Stage 0: Positive interpretation of a testing algorithm within 180 days of a negative or inconclusive interpretation of a testing algorithm
 - Incidence estimation

Incidence Estimates

- Incidence estimates are calculated with key data elements using a mathematical model and stratified extrapolation approach:
 - laboratory results from recency tests (i.e., BED and Bio-Rad Avidity) performed on specimens from persons newly diagnosed with HIV
 - data collected through case surveillance follow-up:
 - information on testing history (including last known HIV-negative test)
 - antiretroviral drug use

Genotype/Sequence Data



Test Results Necessary to Collect

- All results that are part of an algorithm indicating infection (including negative results)
 - Initial (screening) immunoassay
 - Supplemental immunoassay (e.g., type-differentiating or Western blot)
 - Nucleic acid test (NAT)
- CD4 count/percentage (all values, including those >200/14%)
- Viral load (all results, including undetectable)
- Genotype (gene sequence, not just whether a mutation is found)
- Recency tests (i.e., BED and Bio-Rad Avidity)

Challenges with Laboratory Reporting

Common Themes in Laboratory Reporting Challenges

- Laboratory reports missing sufficient information
 - Patient identifiers
 - Patient or provider address
- Not receiving reports of all tests performed
 - Negative test results part of a positive algorithm
 - Positive initial screening immunoassays
- Confusion interpreting laboratory reports
 - Multispot reported as two separate tests
 - Inconsistent use of LOINC codes
- Health care provider confusion ordering tests
 - Unaware that some procedures do not automatically reflex to the next step in the algorithm
 - Overall lack of understanding of the algorithm and what to order

Laboratory Consultation Background

- A consultation was held in January to address challenges in HIV laboratory reporting that were experienced by surveillance programs.
- The Laboratory Consultation provided HIV surveillance program and laboratory representatives the opportunity to present their respective needs, specific issues, and limitations regarding HIV-related laboratory reporting.
- Representatives from HIV surveillance programs, commercial laboratories, public health laboratories, NASTAD, CSTE, APHL, and CDC participated in the event.

Laboratory Consultation Agenda

- Presentations
 - CDC
 - Surveillance Programs
 - Commercial Laboratories
- Breakout Session Discussions
 - Data Elements on Laboratory Reports
 - Diagnostic Algorithm Continuity
 - Reporting Process
 - Communication and Health Care Provider Education
- Conclusion, Summary, and Recommendations

Laboratory Consultation Recommendations

- Reporting regulations should be consistent for all states.
 - It is recommended that all states require reporting of all HIV-related tests, including CD4, viral load, and genotype sequences, regardless of the test result.
- Reporting regulations should require all test results in a diagnostic algorithm and the overall interpretation to be reported by the index laboratory to the surveillance program for the jurisdiction where the patient resides and also where the health care provider is located (if different).
- An accession number assigned to a specimen at collection could assist in tracking the specimen from health care provider to index laboratory to reference laboratory, and linking all tests in the same algorithm back to the patient.

Laboratory Consultation Recommendations (2)

- The information reported by the index laboratory to the health department should be nationally standardized under authoritative agencies to include
 - Patient identification
 - Healthcare provider identification
 - The type of tests done
 - The test results from each test
 - The overall interpretation of the diagnostic testing algorithm
- Only one LOINC code should be assigned to only one test.

Laboratory Consultation Recommendations (3)

- State reporting rules and regulations should follow HL7 standards and require electronic reporting.
- Guidelines and toolkits should be developed to update electronic health record (EHR) systems to automate test ordering and enable a mechanism to import electronic lab reports.
- A variety of procedures were discussed that could be used to improve dialogue between laboratories and surveillance programs.
- A variety of approaches were discussed that could be used to educate health care providers on the new diagnostic testing algorithms.

Thank you

For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

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.

