

Summary of the 2012 Consultation on Revision of the HIV Surveillance Case Definition.

Introduction:

During 2008 through 2011, CDC convened several workgroups to consider revision of various aspects of the HIV surveillance case definition. The topics addressed included:

1. new HIV diagnostic testing algorithms that the current case definition might not recognize as valid;
2. criteria for differentiating HIV-2 infection from HIV-1 infection;
3. expansion of the staging system to include acute HIV infection;
4. the role of opportunistic illnesses in defining stage 3 HIV infection;
5. use of CD4 T-lymphocyte counts for staging ;
6. the requirement of maternal HIV infection for diagnosis in children <18 months of age;
7. criteria for "physician-documented diagnosis" (when laboratory test documentation is insufficient).

On February 7 and 8, 2012, CDC hosted a consultation to consider the recommendations of the workgroups. As in the workgroups, participants were experts in HIV case surveillance, laboratory testing, or clinical care. In addition, the consultation included representatives from relevant national and international organizations.

Synopsis:

Consultants were presented an overview of the recommendations from each of the workgroups. Consultants then participated in one of two breakout sessions focused on either topics 1-3 or 4-7 listed above. The recommendations from each breakout session were then summarized and discussed by the entire group of consultants on the second day to finalize them. The following is a summary of those recommendations.

1. New HIV testing algorithms:

- a. The HIV surveillance case definition should include cases diagnosed by any of the testing algorithms recommended in the *Criteria for Laboratory Testing and Diagnosis of Human Immunodeficiency Virus Infection: Approved Guideline*, [CLSI document M53-A, ISBN 1-56238-758-8], published in June 2011 by the Clinical and Laboratory Standards Institute, including algorithms in which HIV antibody tests other than the Western blot or indirect immunofluorescence assay are used to verify positive/reactive results on initial tests. Presumptive and definitive cases should not be distinguished in tabulations of surveillance data.
- b. A workgroup should be convened with representatives from jurisdictions with established laboratory reporting systems to discuss how reporting laws and surveillance practices should change to implement reporting of all test results needed to recognize cases diagnosed by the new algorithms.

2. HIV-2 infection: The case definition should include criteria for differentiating between HIV-1 and HIV-2 infections. The following criteria should be accepted for diagnosis of HIV-2 infection:

- a. a positive initial/screening test that can detect HIV-2 antibody (e.g., HIV-1/HIV-2 antibody immunoassay), AND:
- b. one or more of the following:
 - 1) An FDA-approved HIV-1/HIV-2 type-differentiating antibody test positive for HIV-2 and negative for HIV-1,
 - or
 - 2) A positive HIV-2 nucleic acid test (NAT),
 - or
 - 3) A positive HIV-2 Western blot/immunoblot (WB) and negative HIV-1 WB,
 - or
 - 4) A diagnosis made after expert lab consultation in case of positive HIV-2 WB and positive or indeterminate HIV-1 WB.

3. Stage 0 HIV infection: The staging system in the HIV surveillance case definition should be expanded to include a "Stage 0," defined by the following criteria, regardless of CD4 T-lymphocyte test results:

a. Virologic criteria:

First positive HIV NAT or antigen test (specimen collection date, if known) was:

- 1) on same date or no more than 180 days after or before a non-reactive/negative or indeterminate HIV antibody test,

or

2) on same date or no more than 180 days after a negative HIV NAT result;

or

b. Serologic criteria:

Initial positive HIV antibody test, confirmed by subsequent positive HIV antibody test in same algorithm or confirmed by positive HIV NAT result, was on same date or no more than 180 days after:

1) a non-reactive, negative, or indeterminate HIV antibody test,

or

2) a negative/undetectable NAT.

If the above criteria for Stage 0 are not met or more than 180 days have elapsed after serologic criteria for Stage 0 were met, the stage should be classified as 1, 2, 3, or Unknown, depending on CD4 test results at that time, as in the current definition.

4. **Use of opportunistic illnesses (OIs) as criteria for Stage 3:** Criteria for Stage 3 among adults and adolescents should no longer include opportunistic illnesses, because CD4 test results are adequate for this purpose. OIs should remain as criteria for Stage 3 among children, but lymphoid interstitial pneumonia should no longer be one of them, and whatever method was used to make the OI diagnosis should be accepted as sufficient (eliminating requirement that some OIs be “definitively” diagnosed). These changes should be applied only to cases reported after implementation, not retroactively to previously reported cases.
5. **Use of CD4 T-lymphocyte test results for staging in adults and adolescents:**
 - a. The CD4 count should take precedence over the CD4 percentage as a criterion for staging; the CD4 percentage should be used as a criterion only if the CD4 count is missing.
 - b. The CD4 percentage used as the threshold between stage 1 and stage 2 (corresponding to a CD4 count of 500 cells/microliter) should be changed from 29% to 26% if data supporting this change are published.
6. **Other recommendations regarding staging for surveillance purposes:**
 - a. The term “acquired immunodeficiency syndrome” (AIDS) should no longer be used as a synonym for “stage 3” HIV infection in surveillance reports.
 - b. The staging system should be permitted to be applied in alternative ways. In particular, the user should be allowed to define the stage as:
 - 1) the stage at initial diagnosis, or
 - 2) the most severe stage ever experienced (for which changes in the stage could be in only one direction--from less to more severe), or
 - 3) the stage based on the most recent CD4 test results (for which changes could be in either direction, including from more to less severe).
7. **HIV infection surveillance case definition for children:** The current case definition's requirement of an HIV-infected mother should be removed for diagnosis of definitive HIV infection and presumptive HIV infection among children less than 18 months of age because laboratory test results are sufficient to make those diagnoses, but should be kept for indeterminate HIV infection, in which required laboratory test results are unavailable for diagnosis.
8. **Physician-documented diagnosis:**
 - a. If a physician's written statement says the patient had a positive result on a particular type of HIV test in a specific year (excluding information stated to be only what the patient said), then the diagnosis should be classified as laboratory-test-documented rather than physician-documented.
 - b. If the initial diagnosis is not laboratory-test-documented, but is supported by a physician's written statement that the patient has HIV infection (excluding information stated to be only what the patient said), and:
 - 1) a subsequent diagnosis is laboratory-test-documented,

or

 - 2) there is circumstantial evidence of HIV infection (e.g., receipt of care clearly HIV-related, an otherwise unexplained low CD4 count or OI),then the initial diagnosis should be classified as physician-documented.
 - c. The official date of a physician-documented diagnosis should be defined as the date of diagnosis reported in the content of the physician's note, regardless of possible inaccuracy or

inexactness, not necessarily the date on which the note was written unless the diagnosis date was not reported in the note.

Next Steps

1. Submission of recommendations in a position statement to the June 2012 meeting of the Council of State and Territorial Epidemiologists (CSTE).
2. Revision of the proposed case definition based on further recommendations from the CSTE.
3. Publication of the accepted revisions in an MMWR in 2012.
4. Implementation of the revisions by changing case report forms, database software, and reporting laws and practices by 2013.