



## Peer Review Plan for “Revised Surveillance Case Definition for HIV Infection — United States, 2014”

**Title:** Revised Surveillance Case Definition for HIV Infection — United States, 2014

**Subject of Planned Report:** Changes in the national surveillance case definition for HIV infection to become effective in 2014

**Purpose of Planned Report:** The purpose of the planned report is to revise the national surveillance case definition for HIV infection to align it with changes recommended in Position Statement 12-ID-05 approved at the 2012 annual meeting of the Council of State and Territorial Epidemiologists (CSTE) [available at <http://www.cste.org/ps2012/12-ID-05FINAL.pdf>], and to disseminate the revised definition to HIV surveillance

**Type of Dissemination:** ISI

**Timing of Review (including deferrals):** June – August 2013

**Type of Review (panel, individual or alternative procedure):** individual

**Opportunities for the Public to Comment (how and when):** At a consultation that took place February 7-8, 2012, subject matter experts, including health care providers, academic institutions, health department surveillance staff and public health and commercial laboratories, participated in the revision of the surveillance case definition for HIV infection. Additional public engagement occurred at the annual CSTE meeting in June 2012 when CSTE members were given an opportunity to review the proposed revisions and suggest modifications; CSTE members approved the Position Statement mentioned above.

**Peer Reviewers Provided with Public Comments before the Review:** No

**Number of Reviewers:** 5

**Primary Disciplines or Expertise:** HIV infection case surveillance by health departments, HIV infection clinical care for adult patients, HIV infection clinical care for pediatric patients, clinical immunology in HIV infection, laboratory tests for HIV infection (including antibody tests and nucleic acid tests) programs in state and local health departments that will report cases to CDC. The most important revision is the expansion of laboratory criteria for defining a confirmed case to accommodate new multi-test algorithms approved by the Clinical and Laboratory Standards Institute (CLSI) in 2011 (CLSI guideline M53-A), which accept antibody immunoassays in the role of confirmatory tests, and include criteria for defining acute HIV infection and for differentiating between HIV-1 and HIV-2. This revision is mainly a response to changes in how health care providers and laboratories are diagnosing HIV infection, and is not intended to provide recommendations on how HIV infection should be diagnosed. Other revisions are intended to streamline and standardize surveillance practices or to align the case definition more closely with clinical practice, and are listed below in items #4 through #11 in the charge to peer reviewers.



**Reviewers Selected by (agency or designated outside organization):** CDC

**Public Nominations Requested for Reviewers:** No

**Charge to Peer Reviewers:** The document that you will review is a draft MMWR article entitled “Revised Surveillance Case Definition for HIV Infection — United States, 2014.” A summary of the revisions of the case definition follows:

1. Laboratory criteria for defining a confirmed case have been revised to accommodate new multi-test algorithms approved by CLSI, which do not require the Western blot or immunofluorescence assays that are required by the current definition.
  2. Criteria have been added for differentiating between HIV-1 and HIV-2.
  3. The staging system has been expanded by the addition of “stage 0”, which is based on a sequence of negative and positive test results indicative of early (including acute) HIV infection.
  4. Criteria for stage 3 have been simplified by eliminating the need to differentiate between definitive and presumptive methods of diagnosing a stage-3-defining condition (opportunistic illness).
  5. Lymphoid interstitial pneumonia has been removed from the list of opportunistic illnesses indicative of stage 3 in children because it is associated with moderate rather than severe immunodeficiency.
  6. The requirement that a case in a child less than 18 months of age must have evidence that the child’s biologic mother was HIV-infected has been eliminated because it is incorrect and was never implemented in surveillance data.
  7. The distinction has been eliminated between definitive and presumptive diagnoses of HIV infection among children less than 18 months of age because it is not useful for surveillance purposes.
  8. The use of CD4 T-lymphocyte counts and percentages for determining the surveillance stage of HIV infection has been extended to children as well as adults and adolescents, and the stage in children aged 6—12 years will be determined the same way as in adults and adolescents. Previously only the presence or absence of opportunistic illnesses had been used to determine the stage in children aged <13 years.
  9. The use of CD4 T-lymphocyte counts and percentages for determining the stage of HIV infection has been modified by using only the count if both the count and the percentage are known, and using the percentage only if the count is unknown. This avoids exaggerating the proportion of cases in the more severe stages, which occurred when the stage was based on whichever test (the count or the percentage) indicated the more severe stage.
  10. The requirement that a “physician-documented” diagnosis must be based on laboratory evidence has been eliminated, because such a requirement is at odds with the purpose of allowing clinical evidence to be sufficient when it is impractical to retrieve laboratory test information on the initial diagnosis
  11. The date of a physician-documented diagnosis is defined as the diagnosis date recorded in a medical record note, rather than the date the note was written. (Previously the diagnosis date was not mentioned in the case definition, but was defined as the date the note was written in separate instructions to surveillance programs.)
- We request your expert opinion about the various changes made in the surveillance case definition, as compared with the previous case definition, entitled “Revised Surveillance Case Definitions for HIV Infection Among Adults, Adolescents, and Children Aged <18 Months and for HIV Infection and AIDS Among Children Aged 18 Months to <13 Years. MMWR 2008;57:1-8.” As you review the various sections of the definition, we would appreciate your thoughts on whether the findings of key studies that you can cite should be added to the reasons for the revisions, whether any studies on which the revisions were based were insufficient or misinterpreted, and whether the revisions were justified and appropriate. After we review your comments, they will be posted without attribution along with our responses on this page at a later date.



**Peer Reviewers:**

Archibald, Chris P., MDCM, MHSc, FRCPC

Director, Surveillance and Epidemiology Division

Centre for Communicable Diseases and Infection Control

Public Health Agency of Canada

Areas of expertise: HIV medicine, particularly in surveillance and epidemiology

Dunn, David, PhD

Clinical Trials Unit,

Medical Research Council,

United Kingdom

London, United Kingdom

Areas of expertise: HIV medicine, particularly in pediatric immunology and statistics for HIV infection

Fowler, Mary Glenn, MD, MPH

John Hopkins University School of Medicine

Baltimore, Maryland

Areas of expertise: pediatric HIV infection

Gulick, Roy M., MD, MPH

Professor of Medicine

Chief, Division of Infectious Diseases

Weill Medical College of Cornell University

Areas of expertise: HIV medicine, clinical studies

Liberti, Thomas

Former Bureau Chief for HIV/AIDS for State of Florida Dept. of Health

Areas of expertise: HIV surveillance and policy

*Additional elements to be added to the public posting as they become available:*

- Peer Reviewers' Comments
- CDC/ATSDR's Response to Reviewers' Comments
- The ISI/HISA Dissemination Itself

Updated 12/9/2013

Reviewed 5/14/2014

Published 4/11/2014

Link: <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6303a1.htm>