07-ID-09

Committee: Infectious Disease

Title: Heterosexual HIV Transmission Classification

Statement of Problem:

Since the beginning of active AIDS surveillance in the early 1980s the Centers for Disease Control and Prevention (CDC) and the jurisdictions reporting AIDS cases (and later HIV infection) have used a virtually unchanged hierarchy to classify the most likely means of HIV transmission. This hierarchy is calculated from the answers to the questions in the patient history section of the case report form[§]. During this time there have been more cases to report as well as increases in cases reported without an identified mode of transmission. These increases result from both 1) death rates dropping dramatically in the mid- 1990's following the introduction of more effective anti-retroviral treatments leading to an increase in prevalence and, 2) increasing use of the laboratory as the initial source of the report. Because laboratories cannot report mode of transmission (they don't collect it), surveillance programs must rely on medical record reviews to complete case report forms. As surveillance funding has decreased and the number of medical records to review has increased it is increasingly difficult to obtain mode of transmission information.

Further compounding the problem is the decentralization of medical care. As more physicians diagnose and care for HIV-infected persons our ability to "train our providers" in how to document risk factors for surveillance purposes decreases. In addition, there has been a decrease in documentation in the medical record on mode of HIV transmission. This decrease is likely to continue as recent CDC HIV testing guidelines are implemented. These guidelines recommend integrating HIV testing into routine medical care and no longer recommend that clinicians conduct pre and post-test counseling[1]. These changes will likely result in more cursory risk behavior information being documented in the medical record.

The number and proportion of cases reported with "No identified Risk" (NIR) cases has increased over time from approximately 20% in 1994 to 35% in 2004[2]. The current standard is that at least 85% of reported cases or a representative sample for a diagnosis year has an identified HIV risk factor within 12 months of the date of the initial HIV/AIDS case report, measured at 12 months after the close of the diagnosis year.[3]

CDC uses the phrase "high risk heterosexual contact" (HRH) to describe transmission attributed to "heterosexual contact with a person known to have, or to be at high risk for, HIV infection."[4] The HIV/AIDS reporting software system that CDC distributes to reporting jurisdictions also categorizes state and city level data using this same definition of "high risk heterosexual contact". This definition is particularly problematic when trying to classify cases reported without a mode of transmission because it requires that, prior to the person's HIV infection diagnosis, at least one heterosexual sex partner was: 1) an injecting drug user (IDU), 2) a bisexual man (this applies only to women), 3) HIV infected from blood or blood products or 4) HIV-infected with no known behavioral risk factor. Condition #4 is the most common way persons are initially classified as "high risk heterosexual contact" cases, requiring knowledge of partner serostatus. The fact that this is the most common way that cases are counted as HRH reflects the person's lack of knowledge of his/her partners' behavioral risk factors or the inability of the medical system to elicit this information. For example, among all cases of HIV infection/not AIDS due to "high risk heterosexual contact" and reported through 2005 (among the 38 states and U.S. dependent areas with confidential name-based HIV reporting), 77% are attributed to *sex with an HIV-infected person, risk not specified.* For AIDS cases reported from all 50 states and Washington, DC the comparable proportion is 66%[4].

In the 1990's, CDC developed a method to address the problem of increasing proportions of cases reported to CDC without a risk factor by using a statistical model to redistribute unreported risk factors based on the distribution of known risk factors. However, risk factor redistribution weights were calculated based on two assumptions: 1) the distribution of risk factors initially reported without risk factors (NIRs) does not change over time and 2) reclassified NIR cases are representative of all NIR cases. Neither of these assumptions is valid. The pattern of risk factors has changed since the beginning of the epidemic[5, 6] and reclassified cases usually represent cases on which risk factors are easiest to find. An additional problem of using the statistical model to redistribute risk is that CDC uses this model when presenting data in the national HIV/AIDS statistical reports, resulting in "artificially" low NIRs published in the national HIV/AIDS statistics. Although the national statistics do include some unadjusted numbers[4] (Tables 17-22), the majority of the presented data have been adjusted. Areas (states and or cities) that choose not to redistribute their NIRs appear to have much higher NIR rates than the national average leading to perceived lower credibility of local data and the erroneous conclusion that they are less able to obtain risk factors than the national average.

Schmidt and Mokotoff[7] conducted a record review and transmission category validation study using Michigan data (1995-1998) from two sources in addition to surveillance data to examine whether additional risk factors were recorded but not captured by the CDC transmission categories. The study led the authors to conclude that the current CDC hierarchy may be inadequate to describe recent trends in HIV transmission in women and they proposed that CDC add a presumed heterosexual category for women.

In response to the publication by Schmidt and Mokotoff, Lee and colleagues analyzed national AIDS and available HIV data[8]. The Michigan results could not be duplicated on a national level. The authors concluded that "Our inability to reduce substantially the proportion of NRR (No Reported Risk) cases in the national database simply by creating additional categories or assigning cases to presumed heterosexual based on currently available data suggests a measurement or information ascertainment issue" (page 406). Further exploration of the issue reveals that, on a national level, there is a large proportion of cases where no answer is recorded to the basic questions "sex with male" and "sex with female" on the case report form[§] and therefore most remained as NIRs. Based on these results, Lee and colleagues concluded that more should be done to improve risk factor ascertainment rather than add additional risk factor categories. For example, they proposed that with improved documentation of standard CDC-defined risk factors in the medical record, additional investigations (involving more time and other resources) would be unnecessary.

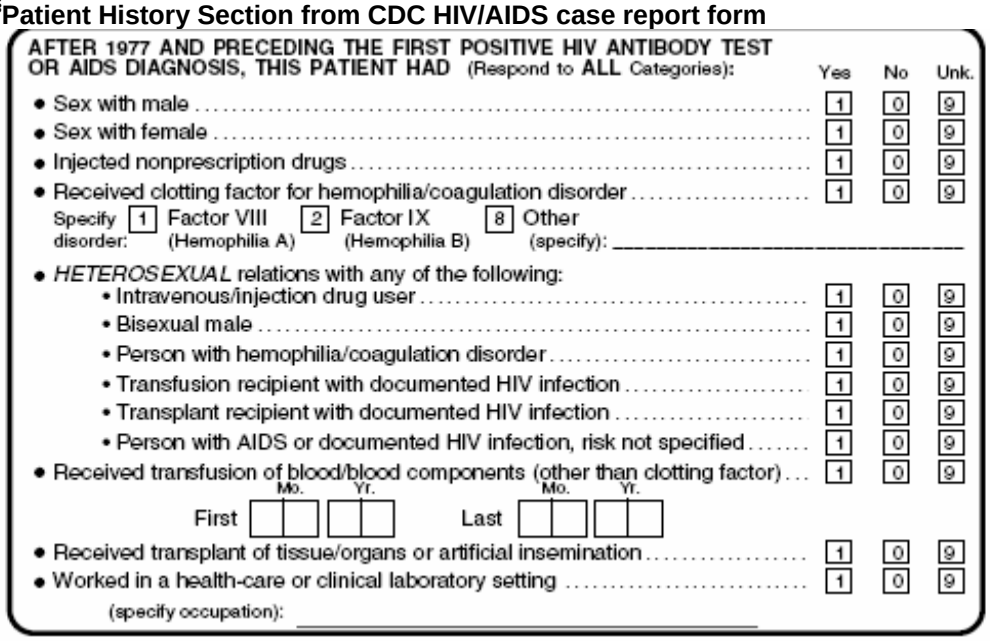
Since that time CDC and CSTE have worked to respond to Lee et al's recommendations. More specifically they have written the Risk Factor Ascertainment Technical Guidance[3]. CDC has been engaged in a process of assisting states to implement this Guidance which includes the goal of increasing ascertainment of "yes", "no" or "unknown" answers (and not having blank boxes with no option checked) for individual risk factor questions, including answers to the variables "sex with male" and "sex with female" on the case report form[§]. However, at the same time, demands on surveillance programs have increased as the funding available to support them has decreased and the NIR rate has increased.

This position statement is proposing the addition of a presumed heterosexual category for females. Several large cities and states have already begun using some version of a presumed heterosexual category in the presentation of their local data*. Proposing this category for females is relatively uncomplicated since there is no other likely mode of transmission for heterosexually active, non-injection drug using women. For males, however, the question is less straightforward. The most common mode of HIV transmission for men in the United States, regardless of race, has always been and continues to be, having sex with other men. Strong societal stigma against this behavior exists in virtually all race and ethnic groups, although the strength of it varies, making elicitation of MSM behavior by medical care providers difficult at best. This social stigmatization of male-to-male sex is likely to produce under-reporting of MSM transmission,

making a presumed heterosexual category for men potentially less accurate. Given the likely confounding factor presented by male-male sex this Position Statement recommends further exploration of the issue for males and does not recommend applying the Presumed Heterosexual category to males at this time.

In December 2001 CDC held a Risk Consultation. The summary of this Consultation states “Dr Fleming (the Branch Chief at the time) ended by outlining that there is more work to be done. The category of “probable heterosexual” must be defined with additional input from health department surveillance experts……..and there is a need to strike a balance between national needs and local level realities through flexible protocols.”[9] The authors of this Position Statement believe that the actions proposed here meet Dr Fleming’s challenge.

[§]Patient History Section from CDC HIV/AIDS case report form



AFTER 1977 AND PRECEDING THE FIRST POSITIVE HIV ANTIBODY TEST OR AIDS DIAGNOSIS, THIS PATIENT HAD (Respond to ALL Categories):

	Yes	No	Unk.
• Sex with male	1	0	9
• Sex with female	1	0	9
• Injected nonprescription drugs	1	0	9
• Received clotting factor for hemophilia/coagulation disorder	1	0	9
Specify disorder: 1 Factor VIII (Hemophilia A) 2 Factor IX (Hemophilia B) 8 Other (specify): _____			
• *HETEROSEXUAL* relations with any of the following:			
• Intravenous/injection drug user	1	0	9
• Bisexual male	1	0	9
• Person with hemophilia/coagulation disorder	1	0	9
• Transfusion recipient with documented HIV infection	1	0	9
• Transplant recipient with documented HIV infection	1	0	9
• Person with AIDS or documented HIV infection, risk not specified	1	0	9
• Received transfusion of blood/blood components (other than clotting factor)	1	0	9
First Mo. Yr. Last Mo. Yr.			
• Received transplant of tissue/organs or artificial insemination	1	0	9
• Worked in a health-care or clinical laboratory setting	1	0	9
(specify occupation): _____			

*New York City, Florida, Michigan, North Carolina, Indiana, Massachusetts, Virginia, Los Angeles County, New Jersey

Statement of desired actions to be taken:

CSTE:

1. Recommends that CDC add the category "Presumed Heterosexual" to the categories used to describe HIV infected females with both HIV and AIDS. These cases are currently classified as No Identified Risk but will be moved into the new category when all of the following statements are true:

-- The case is not already classified in one of the existing categories IDU, Heterosexual (as defined by CDC and described above), Blood, or Perinatal.
-- The case is a female.
-- Negative history of Injection drug use – i.e., the "No" option must be checked on the case report form for this risk factor question.
-- Positive history of sex with a male prior to diagnosis of HIV is documented and/or reported by the woman—i.e., the "Yes" option must be checked on the case report form for the question "sex with a male" prior to infection. This box can be checked following report by the female case or a health care provider - it does not have to be documented in the medical record nor be present on the first submitted case report form.
-- There is no other known information that would suggest a likely alternative source of HIV infection (for example, occupational exposure).

These cases are considered heterosexual transmission in the absence of information to show otherwise. Presumed heterosexual female cases should be displayed either as their own category or be included with the existing Heterosexual category when presenting data. They should not be displayed as a subset of NIRs. Note that all reported HIV/AIDS cases are open to future reclassification based on better or more complete behavioral information.

2. Recommends that additional information be collected on female presumed heterosexual cases in areas for which this is feasible in order to better qualify and understand heterosexual HIV transmission. However, this information is not required for classification as presumed heterosexual transmission. Such information could include:

-- History of sexually transmitted infections
-- History of non-injection drug use
-- History of alcohol abuse
-- Exchanging sex for money, drugs, shelter or other items/services of value
-- Having sex under the influence of drugs or alcohol
-- History of incarceration or history of heterosexual partner with history of incarceration

3. Recommends that CDC and CSTE convene one or more workgroups to:

a) Select and standardize the data elements listed in recommendation #2 above;
b) Begin the process of changing the current hierarchical system to one that is mutually exclusive and allows for multiple categories of risk factor classification. This work should build upon use the work already completed by the December 2001 Risk Consultation[9] summarized in the Risk Factor Ascertainment Technical Guidance and included here as Appendix 1;
c) Evaluate the impact of adding this presumed heterosexual category for females;
d) Explore the issues related to, and the feasibility of, creating a presumed heterosexual category for males in the future.

This Workgroup should contain HIV/AIDS Surveillance Coordinators along with subject matter experts from CDC and other informed and interested parties.

Fiscal Impact on CSTE:

None.

Public Health Impact:

The current CDC risk factor hierarchy under-represents the contribution of heterosexual transmission to women and does not serve the prevention needs of women and people who make prevention policy and allocate prevention resources to preventing infection in women. Public health programs will benefit from increasing the number and proportion of cases classified with a mode of transmission. This change will result in data that are more believable to our data users and produce data that are more useful for planning prevention programs.

References

1) Centers for Disease Control and Prevention. *Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings*. MMWR 2006;55(RR-14):1-17.
2) McDavid and McKenna, *HIV/AIDS Risk Factor Ascertainment: A Critical Challenge*; AIDS Patent Care and STDs Vol 20, No. 4, 2006 285-292.
3) Centers for Disease Control and Prevention and Council of State and Territorial Epidemiologists. *Technical Guidance for HIV/AIDS Surveillance Programs, Volume I: Policies and Procedures*. Atlanta, Georgia: Centers for Disease Control and Prevention; 2005. The document is available at https://team.cdc.gov/team/cdc/dispatch.cgi. Risk Factor Ascertainment chapter.
4) Centers for Disease Control and Prevention. *HIV/AIDS Surveillance Report, 2005*. Vol 17. Atlanta: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention; 2006: Page 37.
5) MMWR January 17, 1992; *The Second 100,000 cases of Acquired Immunodefficiency Syndrome—United States, June 1981-December 1991*. Vol 41 No.02; 28-9
6) MMWR November 28, 2003; *Increases in HIV Diagnoses—29 states, 1992-2002*. Vol 52 No. 47;1145-1148.
7) Schmidt MA and Mokotoff ED. *HIV/AIDS Surveillance and Prevention: Improving the Characterization of HIV Transmission.* Public Health Rep May-June 2003;118:197-204
8) Lee LM, McKenna MT and Janssen RS. *Classification of Transmission Risk in the National HIV/AIDS Surveillance System.* Public Health Rep September-October 2003;118:400-407
9) McKenna, MT. Dear Colleague summary of the Risk Consultation held December 3-4, 2001 by the Surveillance Branch of the Division of HIV/AIDS Prevention-Surveillance and Epidemiology of the Centers for Disease Control and Prevention (CDC) and dated December 20, 2002. Copy is available from the submitting author.

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None

Appendix 1

From Risk Factor Ascertainment Technical Guidance:

Page 27: **"Transmission category"** should be the term for summarizing the multiple risk factors (as defined in risk factors) that an individual may have had by selecting the one through which HIV was most likely to have been transmitted. The selection of the most likely route of transmission is based on a presumed hierarchical order of transmission that was developed in the early years of the AIDS epidemic, and was based on what was known at the time about how HIV was transmitted. The hierarchy has not changed even though our understanding of the most efficient ways of HIV transmission has changed.

Pages 28-29: **"Exposure category"** should be the term for a new classification (or any of the categories in it) that summarizes the multiple risk factors that an individual may have had by including combination categories of the three most common ones (MSM, IDU, HTC). The exposure category classification was developed in response to the "Risk Consultation" of December 3-4, 2001, as an alternative to the transmission category classification. The consultants stated that the assumption on which the current hierarchical classification ("transmission category") is based—that sufficient information is collected to allow accurate selection of the most likely mode of transmission from among multiple possible routes of exposure—is probably not true, and that the resulting concealment of routes of exposure lower in the hierarchy by those that are higher is therefore unjustified and misleading. They therefore recommended a classification that would be less hierarchical, particularly so that HTC would not be concealed as a risk factor when it occurred in combination with MSM or IDU.

The exposure category still is hierarchical with respect to risk factors other than the primary three groups (e.g., receipt of a blood transfusion), which appear only in single categories ranked lower hierarchically than the combinations of MSM, IDU, and HTC.

Unlike transmission category, exposure category adheres strictly to the rules for "cases of public health importance" (COPHI), which require that certain rare routes of exposure not be accepted unless they are confirmed by a special investigation, and that, if they are confirmed, should then take hierarchical precedence in the classification over other possible routes of exposure in the same individual. Thus, if the COPHI investigation confirms that HIV transmission probably resulted from sexual abuse of a child or from a blood transfusion that became contaminated with HIV despite the screening of blood donors for HIV antibody, then this rare route of exposure should be selected as the single most likely mode of transmission. In contrast, transmission category, as it exists currently, does not adhere strictly to the COPHI rules. For example, transmission category attributes some cases to a risk factor like receipt of blood transfusions after screening of blood donors for HIV antibody had begun, despite lack of confirmation that the blood donor had been HIV-infected. For that reason, many cases that are classified in the transmission category for transfusion recipients are classified in the exposure category for no identified risk factor. Also, unlike transmission category, exposure category eliminates the age distinction between adult/adolescent and pediatric categories for receipt of blood products, transfusion, or transplant, and for absence of reported/identified risk factors. Finally, the exposure category classification distinguishes between cases reported without any risk factor within the preceding 12 months and those remaining with no identified risk factor for 12 or more months.

THE FOLLOWING ITEMS WERE LEFT BLANK ON THIS POSITION STATEMENT:

- Agencies for Information – Contact Name(s) and Information