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Misclassification of the Stages of Syphilis: Implications for Surveillance

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Abstract

Background: Uncertainty when staging latent syphilis should lead clinicians to call it late latent (requires more treatment) and disease investigators to call it early latent (priority for partner investigation). Accurate surveillance requires consistent case definitions.

Objective: Assess validity of reported syphilis stages.

Methods: Record reviews in 6 jurisdictions to determine if reported cases met the Centers for Disease Control and Prevention case definitions.

Results: Nine hundred seventy-three records from 6 jurisdictions in 2002 showed excellent agreement for reported primary (94.0%) and secondary (95.4%), good agreement for late latent (80.2%), and poor agreement for early latent (48.4%) and unknown duration (49.7%). Unknown duration (age ≥ 35 and nontreponemal test titer ≥ 32) was often misinterpreted to mean “not known.” Early latent (within the past year, documented: seroconversion, fourfold titer increase, symptoms, or contact with an independently documented early syphilis case) was often misinterpreted to include patients with risky behavior, young age, or high nontreponemal test titers.

Conclusions: The unknown duration stage should be dropped. Surveillance of latent syphilis would be more consistent if cases were reported as having high or low titers on nontreponemal test. Alternative approaches are solicited from readers.

Short summary:

Syphilis cases were reviewed to see if reported stages met the Centers for Disease Control and Prevention case definition. Classification was excellent for primary and secondary and good for late latent, but half of early latent and unknown duration were misclassified. New surveillance definitions are suggested, comments requested.

SYPHILIS HAS A COMPLICATED natural history with a multitude of possible disease manifestations in the decades following infection.¹ These manifestations have been divided into stages. Primary syphilis occurs 10 to 90 days after infection and is usually characterized by a painless ulcer (chancre) at the site of infection. Secondary syphilis occurs a few weeks or months later, with a variety of possible systemic symptoms, including a general body rash (often including the palmar and plantar surfaces), alopecia, and others. Latent syphilis is detectable only by serologic testing. For the first year (previously 4 years² and still 2 in some countries³) latent syphilis is staged as early latent and may lapse or relapse into the secondary stage. Following this, syphilis is classified as late latent, during which sexual transmission is unlikely, but persons may develop tertiary syphilis, which can include neurologic, cardiovascular, and other life-threatening complications.

These stages of syphilis have important clinical, public health, and surveillance implications. Clinicians treat early infections (primary, secondary, or early latent) with 1 dose of benzathine penicillin G (2.4 million units), while late latent infections are treated with 3 doses, each a week apart.^{3,4} Health department disease-intervention specialists are charged with interrupting syphilis transmission in their communities. Because transmission usually occurs during the primary and secondary stages when lesions are present, effective interruption of transmission requires treating infected persons with early infection. Thus, health departments concentrate on reaching partners of persons who have been infected for a year or less. Syphilis surveillance monitors cases by stage to identify trends in transmission (primary and secondary cases and sometimes also early latent) and how effectively early cases of syphilis are being detected and treated (comparison of primary, secondary, and early latent vs. late latent).

Differentiating between early and late latent syphilis can be difficult because it requires knowing whether a patient has been infected for more or less than a year. Health workers should have conflicting responses when there is uncertainty about the duration of infection. When faced with uncertainty, clinicians should act conservatively and treat latent syphilis as if it were a late infection, with 3 doses of benzathine penicillin. In contrast, disease-intervention specialists acting conservatively should consider the same person to have an early latent infection and search for partners who may have been recently infected. Syphilis surveillance could consider such a case as early or late but above all else should be consistent because inconsistent classification can obscure important changes in disease rates.

Our experience suggested that surveillance stages were not consistently applied. Many people working in surveillance seemed confused by the stage definitions; others, for various reasons, appeared to be using their own definitions. We reviewed syphilis staging in 6 cities to identify and quantify variations from the Centers for Disease Control and Prevention (CDC) case definitions.

Methods

We evaluated syphilis cases reported in New York City; Washington, DC; Puerto Rico (San Juan and Ponce); Chicago; San Diego; and Los Angeles. In each city, syphilis interview records were abstracted beginning with the first case of each stage in January 2002 and moving forward in time. We attempted to review 30 cases for each stage of syphilis at each site.

For surveillance purposes, the CDC defines a latent infection as early (less than a year) if there is a documented negative serologic test in the previous year followed by a positive test (or if previously infected and adequately treated, a documented fourfold increase in nontreponemal titer).⁵ Alternatively, a person is considered to have early latent infection if they recall symptoms of primary or secondary syphilis within the past year or if a sex partner from the previous year was diagnosed with primary, secondary, or early latent syphilis. In 1990, an additional surveillance category was added to identify persons who likely had recent infections but did not meet the criteria for early latent infection.⁶ This group consists of persons aged 35 years or less who have a titer of 1:32 or higher on a nontreponemal syphilis test and was named “syphilis of unknown duration.”

Cases reported as primary, secondary, early latent, unknown duration, and late latent were evaluated to determine correspondence between the stage assigned locally and staging according to CDC case definitions.⁵ Cases were reviewed by 2 authors (TAP and RHK); questionable cases were discussed before agreeing on a final classification. When the correct classification was unclear from available information, we accepted the classification listed in the chart. For example, a rash was considered to be manifestation of secondary syphilis if the clinician or disease investigator classified it as a syphilis rash but was considered to be due to other causes if the notes on the chart stated that the rash was not secondary syphilis.

The amount of information available for review varied considerably by stage of disease and by jurisdiction. Clinician’s notes were generally available for cases that were diagnosed in public STD clinics (except in Los Angeles). Records from private practitioners were generally not available. Notes from disease-intervention specialists were usually available for early infections but often limited or absent for late latent infections. Disease interventionists recorded notes on signs or symptoms based on conversations with clinicians and patients. Many disease interventionists had shown pictures to patients to help them identify the sores and rashes. Patients were often interviewed to identify partners who might be infected. Notes from these partner investigations were also reviewed. Positive syphilis test results are reportable by law in each jurisdiction and are routinely entered into local databases where comparison to past titers helped us distinguish old from new infections. These old laboratory results were also reviewed.

Adjusted overall case rates for 2002 were calculated by assuming all cases reported during the year were misclassified in the same way as the sample we reviewed. We also estimated the effect of using a titer-based reporting system for latent syphilis by assuming the titers for cases we reviewed were representative of all cases from the jurisdiction and considering high titer to be 16.

We compared syphilis treatment regimens used for persons in different stages who did or did not have documented HIV infection, using the stage reported by the health departments.

Results

We reviewed 973 records from the 6 jurisdictions (Table 1). Primary and secondary cases almost always (>94%) met the CDC definitions. Early latent cases met the CDC definitions only about half of the time, with 14.4% meeting the CDC definition for unknown duration and 31.6% considered late latent. Cases classified by sites as unknown duration also met the CDC definition only half of the time, with 41.3% meeting the case definition for late latent. Most (80.2%) of the cases called late latent by the sites met the CDC definition, though 11.8% did not meet the CDC definition for any stage of syphilis. Overall, 40 cases did not meet the definition for syphilis because nontreponemal tests were negative (26), the patient was previously treated for syphilis and there was no subsequent increase in titer (10), or treponemal tests were negative or not done (4).

Classification also varied by site (Table 2). Many (28.6%) of the cases called primary in Puerto Rico did not meet the CDC definition, because there was no mention of a lesion in the chart. In San Diego, 4 cases were called primary syphilis based on an ulcer, but there were no positive laboratory tests, so they did not meet the CDC case definition.

For latent syphilis, the San Diego and Los Angeles programs used a form for recording the stage and the rationale for the classification and had more records that agreed with the CDC definition than the other sites. However, the Los Angeles cases had only 68.8% agreement with the CDC definition for early latent. The Los Angeles program had intentionally changed their definition for early latent to include patients who had a fourfold titer decrease in the year after treatment. Many cases at the other sites were apparently called early latent because they seemed to be recently infected due to a high titer, young age, or a history of many recent partners, but they did not meet the CDC case definition.

The unknown duration category was not used in Puerto Rico. The New York program began using it midway through the year and had their own definition, including cases as old as 45. Others apparently thought that “unknown” meant “not known” because many cases had low titers, were over 35 years old, or both. Although the forms used in San Diego and Los Angeles increased the accuracy of this classification, all the health department personnel we talked to thought this stage was confusing, unhelpful, and should be dropped.

Finally, some of the cases that were called late latent in Washington, DC, met the CDC definitions for each of the other stages. In New York, most discrepancies were cases that had positive treponemal tests but negative RPRs or were previously treated and did not have evidence of a rising titer, so would not be considered a case of syphilis by the CDC.

The criteria that cases met to qualify as early latent syphilis varied by site (Table 3). In some areas, the most common reason was having had a partner with early syphilis (Chicago; Puerto Rico; Washington, DC). For other programs, the most common reason was a documented change in serology, either seroconversion or an increase in titer (New York, Los Angeles, San Diego).

Restaging all reported cases from 2002 based on the distribution of cases we reviewed had a very large impact on rates in some areas (Table 4). For example, in Washington, DC, early latent decreased from 33.6 to 11.3 per 100,000, while late latent increased from 17.8 to 37.9 per 100,000. Similarly, in New York City, the rate of early latent dropped by 58.2%.

We also considered the impact of changing surveillance definitions to classify latent syphilis cases based on nontreponemal test titers rather than duration of infection. Cases were considered high titer if any nontreponemal titer was $\geq 1:16$. High-titer cases were much more common than low-titer cases in Chicago; Washington, DC; New York City; and San Diego (Table 4).

Treatment of early syphilis for persons who were not known to be HIV infected was usually a single dose of benzathine penicillin G, including 84 (79.2%) of 106 with primary, 92 (71.3%) of 129 with secondary, and 86 (45.3%) of 190 infections listed by the sites as early latent. In contrast, persons with documented HIV infection were less likely to receive a single dose of benzathine penicillin G for early syphilis, including only 17 (40.5%) of 42 with primary, 37 (41.6%) of 89 with secondary, and 18 (30.0%) of 60 with infections listed by the sites as early latent.

Discussion

Classification of primary and secondary syphilis was excellent. However, we found many errors in the classification of latent syphilis, especially syphilis of unknown duration (50.3% misclassified) and early latent syphilis (51.6% misclassified). While all programs had some review of syphilis cases to see that partner management and syphilis staging were done correctly, classification was much more consistent in the 2 programs that used forms for recording the stage and rationale for the classification.

Two programs were intentionally using definitions that differed from the definitions used by CDC and the National Association of STD Directors, and the Council of State and Territorial Epidemiologists.⁵ The New York City program expanded the unknown duration category to include persons up to the age of 45 years. The rationale for this expansion was that the median age for primary and secondary syphilis cases was 35 years,⁷ so a cutoff at age 35 years would be expected to miss half of the early cases. In Los Angeles, the definition of early latent syphilis was expanded to include persons with non-treponemal titers that fell fourfold or more in the year following treatment. The rationale for this was that nontreponemal test titers are known to fall at a faster rate after treatment of early syphilis than for late syphilis. This definition of early latent syphilis has also been used in South Australia.⁸ Although both of these definitions may be rational, they make it difficult to

compare trends between areas that use different definitions and prohibit aggregation of cases at the state or national level.

Variations in case definitions can also make it difficult to interpret surveillance data at the site level. While we did not study differences in classification over time, a misclassification rate of 70% suggests a program will have difficulty identifying real changes in disease rates over time. Surveillance systems can accommodate consistent misclassification to a much greater extent than inconsistent misclassification. Thus, systematically expanding an age cutoff is easier to adjust for than changing a definition to include persons who, for whatever reason, seem to have been infected in the past year. Most of the misclassifications that we observed were not due to systematically applied criteria, so they are likely to be highly variable over time. For example, some staff members told us they classified cases as early latent if they reported risky sexual behaviors in the previous year. The descriptions of what constituted risky behavior were vague and variable. Others classified cases as early latent based on young age. These behavior and age criteria may well be associated to some extent with early infection but would need to be consistently applied to be viable surveillance definitions. They were not written down, so are likely to vary, depending on who reviews the cases, and may even vary in the same reviewer over time.

We saw several instances where there were conflicts between the perspectives of the clinicians, disease investigators, and surveillance. These conflicts are inevitable, and when they occur, both perspectives should be acknowledged and accepted rather than trying to force clinicians to use the surveillance definition or force surveillance to use the clinician's stage. For example, we saw 4 cases that were called primary syphilis by clinicians treating ulcers, but they did not meet the case definition because serologic tests were negative. On the other hand, we reviewed records of patients who returned with secondary syphilis after they had been seen for evaluation of an ulcer; the ulcers had apparently not been considered syphilitic because their serologic tests were negative and neither darkfield microscopy nor direct fluorescent antibody testing was done. Clinicians should treat suspicious ulcers as though they are syphilis, even if serologic tests are negative because serologic tests are insensitive in early primary syphilis.⁹ Such cases should be reported to the health department, and disease investigators should search for partners who may have been exposed, but surveillance should not consider these ulcers to be syphilis, because they do not meet the case definition.

Some classification errors appear to be due to a conflict between partner notification activities and surveillance. Disease control programs generally will not investigate partners of late latent cases because such investigations are unlikely to interrupt transmission. Although it is not possible to be sure that a case is late latent without interviewing the patient and examining the partners, high case loads may necessitate triaging cases for investigation. In some programs, once a case is labeled as late latent, investigation stops. Thus, some disease investigators who really believed a case should be investigated labeled it as early latent despite the surveillance definitions. In many instances, these erroneous classifications stuck all the way through reporting.

Adjusting the reported rates from the sites to reflect the CDC classification had minor effects on primary and secondary syphilis but very large effects on latent syphilis, causing some rates to fall or rise by more than half. Most analyses of syphilis at the national level have been confined to primary and secondary syphilis, so have not been greatly affected by misclassification. However, early latent cases have often been included in local surveillance reports, program evaluations, and research studies, especially when there were relatively few cases of primary and secondary syphilis.^{10–27} Rates of correctly classified early latent syphilis would help reflect syphilis incidence rates.

Our study was limited to the 6 jurisdictions that had CDC-assigned medical epidemiologists working within the STD control program. Although we reviewed 973 cases, the number from each stage at each jurisdiction was fairly small. Furthermore, our design limited the analysis to how often reported cases met the CDC definition (positive predictive value). We could not measure how often cases that met a particular CDC stage definition were reported as being in that stage (sensitivity). Despite these limitations, our study has important implications for syphilis surveillance in the United States.

The “unknown duration” stage of syphilis is poorly named because it implies it is the stage for all latent cases where the duration is not known. Second, the age cutoff is inappropriate because 35 is now the median age for all cases of primary and secondary syphilis,⁷ and therefore it would miss half of the early cases. Finally, the significance of this category was not clear to anyone we talked with. Most (including the CDC surveillance report) just combine unknown duration cases with late latent cases. Given the confusion and absence of any significant influence on programs, we believe this stage should be dropped.

The early latent stage was also quite confusing and was misclassified as often as the cases of unknown duration. The definition of early latent infection requires identification of a recently infected partner, a history of symptoms, or laboratory evidence of seroconversion. Information on partners is increasingly difficult to obtain. For example, the number of partners contacted and treated for newly identified syphilis fell from 0.55 per case in 1961²⁸ to 0.19 in 1991²⁹ and may be even lower in the recent epidemics among persons with anonymous partners. Documenting seroconversion can also be quite difficult because it requires frequent testing and easily retrievable results. Syphilis testing frequency has declined in many areas. Health departments have very good record systems for tracking positive tests, which are reportable by law, but negative tests are not reportable. Changes in availability of information on partners and past serostatus can lead to artifactual trends in reported syphilis. We suspect, in some areas, most latent infections of less than 1 year’s duration would be erroneously classified as late latent due to the lack of evidence.

We suggest considering a change in syphilis surveillance so that latent syphilis is classified as high-titer or low-titer instead of early, late, and unknown duration. While it would be nice to be able to track trends in early infections, in reality it is too often impossible to accurately determine the duration of an asymptomatic infection. High nontreponemal titers are strongly associated with recent infection.⁹ Thus, we believe this change would facilitate consistent reporting and would also more closely reflect the true duration of infections for persons with incomplete partner evaluations and limited past serologic information. Indeed, we believe

tracking high-titer latent syphilis would more accurately reflect trends in recently acquired infection than the current approach of tracking early latent.

Titer-based surveillance would be subject to some limitations. A definition that depends on a laboratory test would need to change if the test was changed. Also, titers can vary from laboratory to laboratory, VDRL titers are slightly different from RPR titers, and there is some evidence that HIV infection may slightly increase nontreponemal titers.²⁰ However, this variability would only influence classification of cases with titers that are near the cutoff. From a surveillance perspective, we believe these disadvantages are outweighed by the advantages of consistent availability and objectivity of titers.

Treatment of syphilis should not be changed by this change in surveillance definitions. Clinicians who are sure that a latent infection was acquired within a year should continue to treat patients with 2.4 million units of benzathine penicillin G⁴. In practice, clinicians rarely have the dates of previous negative tests or the results of partner investigations needed to determine that an infection was recently acquired. Thus, as seen in our study, many infections reported as early latent by health departments had been treated for late latent syphilis. Many HIV-infected patients with early syphilis were treated with a total of 7.2 million units of benzathine penicillin G regardless of their stage.

Disease control programs should be better off if latent syphilis were tracked in a more consistent fashion that allows comparison with other programs or within a program over time. High-titer latent infections would also provide a more consistent estimate of recently infected persons who were not detected in the primary or secondary stages. Thus, evaluations of syphilis-control strategies such as partner notification or screening would benefit from the proposed surveillance changes. Partner investigations could continue to focus on partners of persons thought to have early syphilis, including persons with primary or secondary, recent seroconversion, recent symptoms, high titer, or other factors that are deemed important based on local evidence.

Changes in surveillance definitions make it difficult to compare rates before and after the new definitions, so any suggestion to change case definitions should be carefully considered. However, for the unknown duration and early latent stages, half of the cases have been misclassified, so trends have already been obscured. We believe changing these definitions would result in more accurate and more consistent staging and will therefore clarify surveillance trends. We would appreciate hearing the thoughts of interested readers.

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TABLE 1.
Stage of Syphilis as Classified by the Sites and Reclassified by the Authors Using the CDC Case Definition

Sites' Stage (n)	Reclassified Stage using CDC Definition (%)				
	Primary	Secondary	Early Latent	Unknown Duration	Late Latent Not Syphilis
Primary (150)	94.0		3.3		2.7
Secondary (218)		95.4	2.8	0.5	0.5
Early L (250)	2.8	1.6	48.4	14.4	31.6 1.2
Unknown duration (143)			4.2	49.7	41.3 4.9
Late L (212)	0.5	1.4	3.8	2.4	80.2 11.8

L = latent.

TABLE 2.

Percent Agreement Between the Local Stage and the CDC Stage Definitions, by Site

	Chicago	Puerto Rico	Washington, DC	New York	San Diego	Los Angeles
Primary	100.0	71.4	100.0	96.8	88.2	100.0
Secondary	100.0	87.5	90.9	100.0	100.0	100.0
Early latent	50.0	51.8	26.3	23.7	85.7	68.8
Unknown duration	12.9	na	23.1	17.2	85.7	82.9
Late latent	80.0	86.1	66.7	71.4	84.6	91.7

TABLE 3.

Characteristics that Qualified Cases as Early Latent Syphilis, by Site (%)

Site (n)	Documented Seroconversion	Documented Titer Increase	Partner With Early Syphilis	History of Symptoms
Chicago (19)	26.3	21.1	52.6	5.3
Puerto Rico (37)	8.1	5.4	73.0	35.1
Washington, DC (20) *	20.0	5.0	45.0	30.0
New York (14) *	21.4	28.6	21.4	28.6
San Diego (33)	42.4	12.1	36.4	24.2
Los Angeles (23)	21.7	43.5	17.4	30.4

* One case had only 1 opportunity for exposure. Cases may meet more than 1 criterion, so row percentages do not add up to 100.

TABLE 4.

Changes in Reported Syphilis Rates (per 100,000) After Adjusting for Differences With the CDC Definitions and After Reclassification of Latent Syphilis as High and Low Titer, by Site

Site	Primary and Secondary	Early	Latent			High Titer	Low Titer
			Unknown duration	Late			
Chicago: reported	11.4	14.2	5.2	4.3			
Adjusted to CDC definition	12.0	7.6	3.3	11.0			
Adjusted, latent classified by titer	12.0				12.8	9.1	
Puerto Rico: reported	7.0	21.0	0.2	14.3			
Adjusted to CDC definition	6.3	11.8	3.5	18.7			
Adjusted, latent classified by titer	6.3				16.1	17.9	
Washington, DC: reported	10.1	33.6	12.2	17.8			
Adjusted to CDC definition	12.6	11.3	8.9	37.9			
Adjusted, latent classified by titer	12.6				41.6	16.5	
New York: reported	5.4	9.1	0.3	28.4			
Adjusted to CDC definition	5.5	3.8	2.9	24.5			
Adjusted, latent classified by titer	5.5				18.1	13.1	
San Diego: reported	1.3	1.2	0.6	2.5			
Adjusted to CDC definition	1.3	1.2	0.6	2.2			
Adjusted, latent classified by titer	1.3				2.9	1.1	
Los Angeles: reported	4.0	3.9	0.9	9.0			
Adjusted to CDC definition	4.4	2.7	1.0	9.0			
Adjusted, latent classified by titer	4.4				5.4	7.3	