DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention

February 14, 2011

Dear STD Program Directors and Managers,

Recent press coverage of the CDC MMWR from the Associated Press and other major media organizations has focused on the fact that approximately 18% of positive results from the newer syphilis antibody test (EIA/CIA) were not verified when they were retested with older syphilis tests (RPR, TP-PA). The coverage asserted that as a result of these positive results patients may have been falsely diagnosed and "may have been given unnecessary treatment."

There are two problems with this assertion. First, the current report does not document whether or not treatment was provided. Second, in those cases where treatment was provided, it may have been justified based on sexual risk and findings on clinical evaluation. The MMWR analysis, while important, does not allow us to conclude that the newer tests led to inaccurate syphilis diagnoses or inappropriate treatment.

Key messages for syphilis control efforts remain the same:

1. Patients at high risk should continue to be tested at regular intervals
2. Medical providers should conduct comprehensive sexual risk assessments and clinical evaluations in order to diagnose and treat syphilis correctly. The CDC recently published its 2010 treatment guidelines which include comprehensive information regarding management of all STDs, including syphilis. It is available at www.cdc.gov/std/treatment/2010.

In addition, we have created a question and answer document to address some other anticipated programmatic questions you may have.

1) Question: Should DIS follow-up on any of the EIA pos/RPR neg/TP-PA neg?

Answer: No because disease intervention follow-up should focus on cases likely to be actively contributing to transmission of syphilis in a community. An EIA pos/RPR neg/TP-PA neg result is not likely a case of infectious syphilis contributing to further transmission. If clinicians ask, they should be told that high-risk patients with these test results should have repeat serologic testing in several weeks to ensure that they had not recently acquired syphilis. Also, clinicians should ask these patients about symptoms to rule out primary syphilis at the time of the initial test where the RPR test was not yet reactive.

2) **Question: Should DIS follow-up on any of the EIA pos/RPR neg/TP-PA pos?**

Answer: No. An EIA pos/RPR neg/TP-PA pos result is either a previously treated case or a patient with latent syphilis of unknown duration. Because latent syphilis is generally not infectious, DIS follow-up is not recommended.

3) **Question: What and how do states report these cases and serologic results to CDC via NETSS (National Electronic Telecommunications System for Surveillance), other systems, in STD*MIS, and state reactor registries?**

Answer: Serologic test results for persons who do not meet the surveillance case definition should not be sent to CDC since they are not related to a reportable case. According to the CDC/CSTE case definition, a reportable case of latent syphilis must have a reactive treponemal result and a reactive non-treponemal result. So, an EIApos/RPR neg–/TP-PA pos would not be a reportable case of latent syphilis. Secondary syphilis requires a (non-treponemal) titer of ≥ 4 and concurrent secondary symptoms. Only primary syphilis allows for a reactive treponemal test or a reactive non-treponemal test (along with clinically compatible lesions). For adult cases of syphilis, only non-treponemal results, including titers, should be reported to CDC as part of the morbidity report. For cases of congenital syphilis, serologic test results should be reported for mothers and babies.

4) **Question: If we just have an EIA result should we spend time tracking down the RPR and (if neg) the TP-PA results or should we wait for these results and if so how long and what do we do if we don't get them?**

Answer: The issue of actively following EIA positives whose RPRs have not been reported is a local programmatic issue. An accompanying reactive RPR should be reported by the laboratory but a nonreactive RPR may not be. Efforts to follow-up on EIA positives should depend on the local epidemiology and circumstances of the individual patients as well as program resources. Given the severe resource challenges that most STD programs are facing, in general, efforts should not be spent finding RPR results if an isolated EIA positive test result is received. Efforts should focus on the reactive RPRs titers reported for surveillance purposes and DIS action according to local procedures tailored to local epidemiology.

Additional program questions can be directed to Kevin O'Connor at 404 639-8193 and surveillance questions to Hillard Weinstock at 404-639-2059

Best Regards,

Gail

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