

CALDA CDC Survey Results (182 Respondents) by Lorraine Johnson, JD, MBA and Theresa Denham

Misuse of the Centers for Disease Control and Prevention (CDC) surveillance criteria for diagnostic purposes is a significant problem for patients with Lyme disease, causing misdiagnosis and treatment delays that may permit the disease to advance from the more easily treated acute infection to a chronic treatment resistant infection. As part of an informal study, a survey questionnaire was distributed to patients with persistent Lyme disease through the Lyme Times publication nationally and through selected doctors' offices throughout the nation during the last quarter of 2003 and throughout 2004. The study was completed in January 2005. Preliminary results suggest widespread misuse of the CDC surveillance criteria for diagnostic purposes resulting in significant diagnostic delays. Respondents were asked to provide a unique patient identifier to ensure that no duplication of results occurred. This article reflects the responses of the 182 respondents that were diagnosed with Lyme disease.

ELISA Misdiagnoses

Seventy-three percent (73%) of respondents were denied a diagnosis for Lyme at least once due to a negative ELISA by CDC criteria. Of these, 31% were denied access to a Western blot (WB) by their physicians due to a negative ELISA.

Western Blot Misdiagnosis

Sixty-one percent (61%) of respondents were denied a diagnosis for Lyme at least once due to a negative WB blot by CDC surveillance band criteria.

ELISA and Western Blot: Misuse of CDC Surveillance Criteria for Diagnostic Purposes			
	ELISA	Western blot (CDC surveillance criteria)	Total (non-duplicated)
Misdiagnosis basis	73%	61%	81%
Doctor refused to do Western blot	31%		
Medical Reimbursement Denials	16%	19%	

Method of Diagnosis

Of the diagnostic methods surveyed, only 13% of those responding were diagnosed by ELISA. The WB supported 67% of the Lyme disease cases, with significant bands present and not necessarily falling into the CDC surveillance criteria. Diagnosis by Polymerase Chain Reaction (PCR) and spinal tap were 12 and 3%, respectively. Clinical diagnosis, without supporting lab tests, accounted for 24%.

Diagnosis and Treatment Delays

The misapplication of CDC surveillance criteria (either ELISA or WB) for diagnostic purposes resulted in a delay in diagnosis of one year or more for 49% of responding patients. The average period of delay in diagnosis was almost 4-1/2 years. A full 81% of patients had physicians fail to diagnose their Lyme disease because of misapplication of the CDC surveillance criteria for diagnosis. Many of these patients incurred treatment delays as well. Delayed diagnoses in Lyme disease can allow the disease to progress from one that is generally treatable to one that is more resistant or unresponsive to treatment, with devastating consequences to the patient.

The table below summarizes the diagnostic delays caused by misuse of the CDC surveillance criteria.

Patients with Lyme disease	182 (100%)
Patients with at least one diagnosis failure due to misuse of CDC criteria	148 (81%)
Patients with treatment delays of at least one year due to misuse of CDC criteria	90 (49%)
Range of delayed treatment duration	0 to 18 years
Average delayed treatment duration	4.4 years

The take home message of this survey is that 49% of those responding had a delay in diagnosis of one year or greater, with the average delay almost 4-1/2 years. A recent study equated the disability caused by persistent Lyme disease to that of congestive heart failure. Early detection and treatment is key to Lyme disease. The CDC should not tolerate the misuse of surveillance criteria for diagnostic purposes.

CDC Miscommunication will Further Misdiagnosis Problems

In November 2003, doctors, scientists and representatives of several patient education and advocacy groups met with officials from the department of U.S. Human and Health Services (HHS) and the Centers for Disease Prevention and Control (CDC) to discuss misuse of the surveillance criteria for diagnosis. As a result of that meeting, the CDC notified physicians that the surveillance case definition was developed for national reporting and is not intended as a surrogate for sound clinical judgment through its Mortality and Morbidity Weekly Report (MMWR).^{1, 2}

Surveillance and diagnostic criteria have distinctly different goals,³ which were explained by Paul Mead in his testimony before the Connecticut Attorney General regarding Lyme disease:

A clinical diagnosis is made for the purpose of treating an individual patient and should consider the many details associated with that patient's illness. Surveillance case definitions are created for the purpose of standardization, not patient care; they exist so that health officials can reasonably compare the number and distribution of "cases" over space and time. Whereas physicians appropriately err on the side of over-diagnosis, thereby assuring they don't miss a case, surveillance case definitions appropriately err on the side of specificity, thereby assuring that they do not inadvertently capture illnesses due to other conditions....⁴

However, in a recent MMWR, the CDC emphasized its two-tiered testing recommendation and failed to underscore the clinical nature of the diagnosis.⁵ Unfortunately, this publication will undoubtedly lead to more misdiagnosis and treatment delays for patients.

¹ Centers for Disease Control and Prevention (1996). "Lyme Disease Surveillance Case Definition (revised September 1996)."

² Centers for Disease Control and Prevention (2004). "Lyme Disease--United States, 2001--2." *MMWR* **53**((17)): 365-9.

³ Centers for Disease Control and Prevention (1997). "Case definition for infectious conditions under public health surveillance (Lyme disease surveillance case definition) <http://www.cdc.gov/ncidod/dvbid/lyme/casedef2.htm>." *MMWR* **46**(RR10): 1-3, 15-16.

⁴ Mead, P. "Statement by Paul Mead, MD, MPH, Medical Epidemiologist, Division of Vector-Borne Infectious Diseases, National Center for Infectious Diseases, Center for Disease Control and Prevention, U.S. Department of Health and Human Services on Hearing: CDC's Lyme Disease Prevention and Control Activities before the Connecticut Department of Public Health and the Connecticut Attorney General's Office on January 29, 2004."

⁵ Centers for Disease Control and Prevention, "Notice to Readers: Caution Regarding Testing for Lyme Disease." *MMWR*, February 11, 2005. 54((05)): p. 125.