THE OFFICIAL NEWSMAGAZINE OF THE AMERICAN ACADEMY OF PEDIATRICS
AAP News
DEDICATED TO THE HEALTH OF ALL CHILDREN
Volume 35 • Number 7
July 2014
www.aapnews.org

MMWR in Review

by **Larry K. Pickering, M.D., FAAP**

New test to diagnose Lyme disease raises concerns

Editor's note: *These articles summarize key points from two Centers for Disease Control and Prevention (CDC) reports published in* Morbidity and Mortality Weekly Report (MMWR). *The background and comment sections might include additional information that did not appear in the original publications. To subscribe to* MMWR, *visit www.cdc.gov/MMWR.*

◆ "Concerns Regarding a New Culture Method for *Borrelia burgdorferi* Not Approved for the Diagnosis of Lyme Disease." *MMWR*. 2014;63(15):333, www.cdc.gov/mmwr/preview/mmwrhtml/mm6315a4.htm?s_cid=mm6315a4_w.

Background

Lyme disease occurs most commonly in the northeast and Midwest regions of the United States.

Lyme disease, transmitted by certain ixodid ticks (see photo) and caused by the spirochete *Borrelia burgdorferi*, is the most commonly reported vector-borne disease in the United States and is one of the top 10 Nationally Notifiable Infectious Diseases (http://1.usa.gov/UfLVQO) reported to the CDC.

Clinical manifestations of Lyme disease are divided into three stages: early localized, early disseminated and late.

Early localized disease presents with erythema migrans, a distinctive rash at the site of a recent tick bite. Early disseminated disease most commonly presents with multiple erythema migrans lesions. Late disease is characterized most often by arthritis that usually is pauciarticular and involves large joints, particularly the knees, or other extracutaneous manifestations. Accurate and timely diagnosis of illness is critical for proper therapy.

Results

Laboratory-developed tests that are manufactured and used within a single laboratory and that have not been cleared or approved by the Food and Drug Administration (FDA) are known as "home brew" tests. The CDC has received inquiries regarding a laboratory-developed test that uses a novel culture method to identify the spirochete that causes Lyme disease. Review by the CDC of published methods and results using this test has raised serious concerns about false-positive results caused by laboratory contamination as well as potential for misdiagnosis.

Public health implications

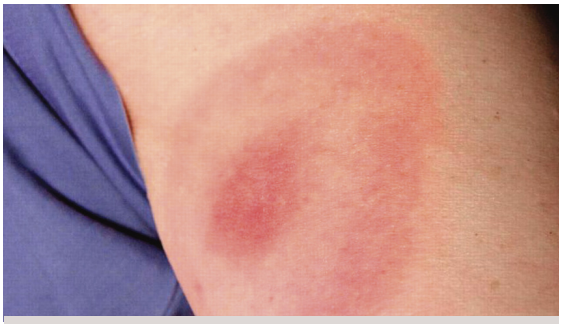
When evaluating testing options for Lyme disease, the following should be considered:

- Clinical Laboratory Improvement Amendments (CLIA) certification of a laboratory indicates the facility meets a set of basic quality standards.
- The CLIA program does not address the clinical validity of a specific test.
- FDA clearance/approval of a test provides assurance that the test itself has adequate analytical and clinical validation and is safe and effective.
- Diagnosis of Lyme disease requires two-tier serologic testing for antibodies to *B. burgdorferi*. If an FDA-cleared enzyme immunoassay is positive or equivocal, it is followed by an FDA-cleared immunoblot ("Western blot") test. Only when both are positive are results considered positive. However, in early stages of disease in patients with erythema migrans without dissemination, sensitivity is only 25%-40%.
- Culture and polymerase chain reaction of clinical specimens are recommended only in rare circumstances.

Comment

For any diagnostic test, including those for diagnosis of Lyme disease, it is critical that the tests have adequate analytical and clinical validation to facilitate accurate diagnosis, enabling proper treatment. The CDC recommends that laboratory tests cleared or approved by the FDA be used to aid in the routine diagnosis of Lyme disease. A complete searchable list of such tests is available at www.cdc.gov/ncidod/dvbid/lyme/ld_humandisease_diagnosis.htm and www.cdc.gov/lyme/diagnosistesting/index.html.

Dr. Pickering is editor of the 2012 AAP Red Book.



Erythema migrans is most often associated with which tick-borne associated condition?

a. Babesiosis
b. Ehrlichiosis
c. Lyme disease
d. Relapsing fever
e. Tularemia

Answer: c. Lyme disease

RESOURCE

Red Book Online, http://aapredbook.aappublications.org/content/1/SEC131/SEC212.body.