10-ID-06

Committee: Infectious Disease

Title: Public Health Reporting and National Notification for Lyme Disease

I. Statement of the Problem:

CSTE position statement 07-EC-02 recognized the need to develop an official list of nationally notifiable conditions and a standardized reporting definition for each condition on the official list. The position statement also specified that each definition had to comply with American Health Information Community recommended standards to support "automated case reporting from electronic health records or other clinical care information systems." In July 2008, CSTE identified sixty-eight conditions warranting inclusion on the official list, each of which now requires a standardized reporting definition.

II. Background and Justification:

Background[1]
Lyme disease is a tick-borne disease caused by *Borrelia burgdorferi.* 60- 80% of Lyme disease cases have a characteristic rash, *erythema migrans*, typically accompanied by fever, headache and fatigue. Untreated Lyme disease can progress to chronic arthritis, neurological disease and cardiac disease. Lyme disease cases have been identified in most states, but the highest risk areas are in the Northeastern and Midwestern United States. Ongoing surveillance is needed to monitor the demographic geographic and temporal patterns of disease, identify risk factors for transmission and evaluate prevention and control strategies.

Justification
Lyme disease meets the following criteria for a nationally and **standard** notifiable condition, as specified in CSTE position statement 08-EC-02:

- A majority of state and territorial jurisdictions—or jurisdictions comprising a majority of the US population—have laws or regulations requiring **standard** reporting of Lyme disease to public health authorities
- CDC requests **standard** notification of Lyme disease to federal authorities
- CDC has condition-specific policies and practices concerning the agency's response to, and use of, notifications.

III. Statement of the desired action(s) to be taken:

CSTE requests that CDC adopt this standardized reporting definition for Lyme disease to facilitate more timely, complete, and standardized local and national reporting of this condition.

[1] Much of the material in the background is directly quoted from the CDC's Lyme disease Website. See the References for further information on this source.

IV. Goals of Surveillance:
To provide information on the temporal, geographic, and demographic occurrence of Lyme disease to facilitate its prevention and control.

V. Methods for Surveillance:

Surveillance for Lyme disease should use the sources of data and the extent of coverage listed in Table V below.

Table V. Recommended sources of data for case identification and extent of coverage for ascertaining cases of Lyme disease.

	Coverage	
Source of data for case ascertainment	Population-wide	Sentinel sites
clinician reporting	X	
laboratory reporting	X	
reporting by other entities (e.g., hospitals, veterinarians, pharmacies)	X	
death certificates	X	
hospital discharge or outpatient records	X	
extracts from electronic medical records	X	
telephone survey		
school-based survey		
other _____		

VI. Criteria for case identification

A. Narrative: A description of suggested criteria that may be used for case ascertainment of a specific condition.

Report any illness to public health authorities that meets any of the following criteria:

1. Any person with erythema migrans.

2. Any person with laboratory evidence of Lyme disease. Laboratory evidence includes any of the following:
   a. A positive culture of for *B. burgdorferi*
   b. Antibody to *B. burgdorferi* detected in serum by EIA or IFA and confirmed by a Western immunoblot test positive for *B. burgdorferi*-specific IgM or IgG
   c. A Western immunoblot test positive for *B. burgdorferi*-specific IgG
   d. Antibody to *B. burgdorferi* detected in CSF by EIA or IFA

3. A person whose healthcare record contains a diagnosis of Lyme disease.

4. A person whose death certificate lists Lyme disease as a cause of death or a significant condition contributing to death.

Other recommended reporting procedures

- All cases of Lyme disease should be reported.
- Reporting should be on-going and routine.
- Frequency of reporting should follow the state health department's routine schedule.

B. Table of criteria to determine whether a case should be reported to public health authorities:

Table VI-B. Table of criteria to determine whether a case should be reported to public health authorities. Requirements for reporting are established under State and Territorial laws and/or regulations and may differ from jurisdiction to jurisdiction. These criteria are suggested as a standard approach to identifying cases of this condition for purposes of reporting, but reporting should follow State and Territorial law/regulation if any conflicts occur between these criteria and those laws/regulations.

Criterion	Reporting
Clinical evidence	
Erythema migrans	S
Healthcare record contains a diagnosis of Lyme Disease	S
Death certificate lists Lyme Disease as a cause of death or a significant condition contributing to death	S
Laboratory evidence	
Culture positive for *B. burgdorferi*	S
Serum antibody positive for *B. burgdorferi* by EIA or IFA	S
Western immunoblot positive for *B. burgdorferi*-specific IgM	S
Western immunoblot positive for *B. burgdorferi*-specific IgG	S
CSF antibody positive for *B. burgdorferi* by EIA or IFA	S

Notes:
S = This criterion alone is sufficient to report a case

C. Disease-specific data elements:

Disease-specific data elements to be included in the initial report are listed below.

Epidemiological Risk Factors
Counties where tick exposure could have occurred in the month before the onset of acute illness

VII. Case Definition for Case Classification

A. Narrative: Description of criteria to determine how a case should be classified.

Clinical presentation

A systemic, tick-borne disease with protean manifestations, including dermatologic, rheumatologic, neurologic, and cardiac abnormalities. The most common clinical marker for the disease is *erythema migrans* (EM), the initial skin lesion that occurs in 60%-80% of patients.

For purposes of surveillance, EM is defined as a skin lesion that typically begins as a red macule or papule and expands over a period of days to weeks to form a large round lesion, often with partial central clearing. A single primary lesion must reach greater than or equal to 5 cm in size across its largest diameter. Secondary lesions also may occur. Annular erythematous lesions occurring within several hours of a tick bite represent hypersensitivity reactions and do not qualify as EM. For most patients, the expanding EM lesion is accompanied by other acute symptoms, particularly fatigue, fever, headache, mildly stiff neck, arthralgia, or myalgia. These symptoms are typically intermittent. The diagnosis of EM must be made by a physician. Laboratory confirmation is recommended for persons with no known exposure.

For purposes of surveillance, late manifestations include any of the following when an alternate explanation is not found:

- *Musculoskeletal system.* Recurrent, brief attacks (weeks or months) of objective joint swelling in one or a few joints, sometimes followed by chronic arthritis in one or a few joints. Manifestations not considered as criteria for diagnosis include chronic progressive arthritis not preceded by brief attacks and chronic symmetrical polyarthritis. Additionally, arthralgia, myalgia, or fibromyalgia syndromes alone are not criteria for musculoskeletal involvement.

- *Nervous system.* Any of the following, alone or in combination: lymphocytic meningitis; cranial neuritis, particularly facial palsy (may be bilateral); radiculoneuropathy; or, rarely, encephalomyelitis. Encephalomyelitis must be confirmed by demonstration of antibody production against *Borrelia burgdorferi* in the cerebrospinal fluid (CSF), evidenced by a higher titer of antibody in CSF than in serum. Headache, fatigue, paresthesia, or mildly stiff neck alone, are not criteria for neurologic involvement.

- *Cardiovascular system.* Acute onset of high-grade (2nd-degree or 3rd-degree) atrioventricular conduction defects that resolve in days to weeks and are sometimes associated with myocarditis. Palpitations, bradycardia, bundle branch block, or myocarditis alone are not criteria for cardiovascular involvement.

Laboratory evidence

For the purposes of surveillance, the definition of a qualified laboratory assay is

1) Positive Culture for *B. burgdorferi, or*

2) Two-tier testing interpreted using established criteria [1], where:
    a. Positive IgM is sufficient only when ≤30 days from symptom onset
    b. Positive IgG is sufficient at any point during illness
3) Single-tier IgG immunoblot seropositivity using established criteria [1-4].
4) CSF antibody positive for *B. burgdorferi* by EIA or IFA, when the titer is higher than it was in serum

Exposure

Exposure is defined as having been (less than or equal to 30 days before onset of EM) in wooded, brushy, or grassy areas (i.e., potential tick habitats) in a county in which Lyme disease is endemic. A history of tick bite is not required.

Disease endemic to county

A county in which Lyme disease is endemic is one in which at least two confirmed cases have been acquired in the county or in which established populations of a known tick vector are infected with *B. burgdorferi*.

Case classification

Confirmed: a) a case of EM with a known exposure (as defined above), or b) a case of EM with laboratory evidence of infection (as defined above) and without a known exposure or c) a case with at least one late manifestation that has laboratory evidence of infection.

Probable: any other case of physician-diagnosed Lyme disease that has laboratory evidence of infection (as defined above).

Suspected: a) a case of EM where there is no known exposure (as defined above) and no laboratory evidence of infection (as defined above), or b) a case with laboratory evidence of infection but no clinical information available (e.g. a laboratory report).

Lyme disease reports will not be considered cases if the medical provider specifically states this is not a case of Lyme disease, or the only symptom listed is "tick bite" or "insect bite."

B. Classification Tables:

Table VII-B. Table of criteria to determine whether a case is classified.

	Case Definition												
Criterion	Confirmed								Probable			Suspected	
Clinical Evidence													
Physician diagnosed Lyme disease									N	N	N		
Erythema migrans	N	N	N	N								N	
Arthritis with objective joint swelling					O	O	O						
Chronic arthritis					O	O	O						

Aseptic meningitis					O	O	O						
Cranial neuritis					O	O	O						
Facial palsy					O	O	O						
Radiculoneuropathy					O	O	O						
Encephalomyelitis								N					
AV conduction defects					O	O	O						
Myocarditis					O	O	O						
Laboratory Evidence													
Culture positive for *B. burgdorferi*			N		N				N				O
Serum antibody positive for *B. burgdorferi* by EIA or IFA				N		N		N		N			O
Western immunoblot positive for *B. burgdorferi*-specific IgM (onset ≤30 days)				O		O				O			O
Western immunoblot positive for *B. burgdorferi*-specific IgG		N		O		O	N			O	N		O
CSF antibody positive for *B. burgdorferi* by EIA or IFA (titer higher than serum antibody)								N					O
Epidemiologic Evidence													
Having been in an endemic area	N												

Notes:
N = This criterion in conjunction with all other "N" and any "O" criteria in the same column is required to classify a case.
O = At least one of these "O" criteria in each category in the same column (e.g., clinical presentation and laboratory findings)—in conjunction with all other "N" criteria in the same column—is required to classify a case.

VIII. Period of Surveillance:

Surveillance should be on-going.

IX. Data sharing/release and Print criteria:

- Notification to CDC of confirmed, probable and suspected cases is recommended for cases of Lyme disease.

- Provisional data on Lyme disease cases reported through NETSS/NNDSS are summarized weekly in the MMWR, and finalized data are published annually in the Summary of Notifiable Diseases. Longer articles describing and interpreting national trends are published in the MMWR on an ad-hoc basis (approximately

once every other year). Summary data are also made available through the CDC Lyme disease website.

- State-specific compiled data will continue to be published in the weekly and annual MMWR.

- Provisional state-specific compiled data on confirmed and probable cases will continue to be published in the weekly reports. Finalized data on confirmed and probable cases will be published in the annual MMWR Summary of Notifiable Diseases, following verification by each state. The frequency of release of additional publication of this data will be dependent on the current epidemiologic situation in the country. These publications might include annual epidemiologic summaries in the MMWR or manuscripts in peer-reviewed journals.

- No specific plans for re-release. However, CDC may re-release finalized data on ad hoc basis for research or public health activities in accordance with the Data Release Guidelines for the National Notifiable Diseases Surveillance System.

X. References:

1. Centers for Disease Control and Prevention (CDC). Case definitions for infectious conditions under public health surveillance. MMWR 1997; 46(No. RR-10):1–57. Available from: http://www.cdc.gov/mmwr/

2. Centers for Disease Control and Prevention (CDC). National notifiable diseases surveillance system: case definitions. Atlanta: CDC. Available from: http://www.cdc.gov/ncphi/disss/nndss/casedef/index.htm Last updated: 2008 Jan 9. Accessed:

3. Council of State and Territorial Epidemiologists (CSTE). CSTE official list of nationally notifiable conditions. CSTE position statement 07-EC-02. Atlanta: CSTE; June 2007. Available from: http://www.cste.org.

4. Criteria for inclusion of conditions on CSTE nationally notifiable condition list and for categorization as immediately or routinely notifiable. CSTE position statement 08-EC-02. Atlanta: CSTE; June 2008. Available from: http://www.cste.org.

5. Council of State and Territorial Epidemiologists (CSTE). Revised National Surveillance Case Definition for Lyme disease. 07-ID-11 Atlanta: CSTE; June 2007. Available from: http://www.cste.org.

6. Council of State and Territorial Epidemiologists (CSTE). Data Release Guidelines of the Council of State & Territorial Epidemiologists for the National Public Health System. Atlanta: CSTE; June 1996.

7. Council of State and Territorial Epidemiologists, Centers for Disease Control and Prevention. CDC-CSTE Intergovernmental Data Release Guidelines Working Group (DRGWG) Report: CDC-ATSDR Data Release Guidelines and Procedures for Re-release of State-Provided Data. Atlanta: CSTE; 2005. Available from:

http://www.cste.org/pdffiles/2005/drgwgreport.pdf or
http://www.cdc.gov/od/foia/policies/drgwg.pdf.

8. Heymann DL, editor. Control of communicable diseases manual. 18th edition. Washington: American Public Health Association; 2004.

9. Steere AC. *Borrelia burgdorferi* (Lyme Disease, Lyme Borreliosis) In: Mandell GL, Bennett JE, Dolin R, editors. Principles and Practice of Infectious Diseases, 6th edition. Philadelphia: Churchill Livingstone; 2005.

(References specifically referred to in case definition for case classification:)

1. Centers for Disease Control and Prevention. Recommendations for test performance and interpretation from the Second National Conference on Serologic Diagnosis of Lyme Disease. MMWR MMWR Morb Mortal Wkly Rep 1995; 44:590–1.

2. Dressler F, Whalen JA, Reinhardt BN, Steere AC. Western blotting in the serodiagnosis of Lyme disease. J Infect Dis 1993; 167:392–400.

3. Engstrom SM, Shoop E, Johnson RC. Immunoblot interpretation criteria for serodiagnosis of early Lyme disease. J Clin Microbiol 1995; 33:419–27.

4. Centers for Disease Control and Prevention. Notice to readers: caution regarding testing for Lyme disease. MMWR Morb Mortal Wkly Rep 2005; 54:125–6.

XI. Coordination:

Agencies for Response:

(1) Thomas R. Frieden
Director
Centers for Disease Control and Prevention
1600 Clifton Road, NE
Atlanta, GA 30333
404-639-7000
txf2@cdc.gov

XII. Submitting Author:

(1) P. Bryon Backenson
Director, Investigation and Vector Surveillance
New York State Department of Health
Bureau of Communicable Disease Control
ESP—Corning Tower Room 651
Albany, NY 12237
518-473-4439
bpb01@health.state.ny.us

Co-Authors:

(1) Katherine Feldman
State Public Health Veterinarian
Maryland Department of Health and Mental Hygiene
201 W. Preston Street, 3rd Floor
Baltimore, MD 21201
410-767-5649
KFeldman@dhmh.state.md.us

(2) Harry F. Hull
Medical Epidemiologist
HF Hull & Associates, LLC
1140 St. Dennis Court
St. Paul, MN 55116
651-695—8114
hullhf@msn.com