Communicable Disease Case Reporting and Investigation Protocol

LYME DISEASE

I. IDENTIFICATION AND DEFINITION OF CASES

A. Clinical Description:
A multi-systemic disease caused by a spirochete *Borrelia burgdorferi* (or, more rarely, by a new emerging species *Borrelia mayonii*) transmitted through the bite of infected *Ixodes scapularis* (commonly known as the deer tick) in Wisconsin. Due to the status of *B. mayonii* as an emerging pathogen, identified cases must be reported immediately to the Wisconsin Division of Public Health. Within 3-30 days of the tick bite, 70%-80% of infected individuals exhibit a distinctive rash called erythema migrans (EM) that expands in size over a period of days or weeks (see description below in Clinical Criteria for Diagnosis). However, about 25% of patients do not develop EM rash, or the lesion is unnoticed by the patient. The expansion of the EM rash helps to differentiate from an allergic reaction at the site of the bite; unlike the EM rash, the allergic reaction does not expand and disappears within a few days. EM is often accompanied by malaise, fatigue, headache, fever, chills, and swollen lymph nodes. After several weeks to months, untreated patients may develop facial palsy; severe headaches; neck stiffness; migratory pain in joints, tendons, muscles, or bones; neurologic abnormalities; or cardiac disturbances. After several months to years, approximately 60% of untreated patients may develop intermittent bouts of arthritis including pain and swelling in large joints, about 15% may develop neurological symptoms, and 5% may have cardiac manifestations (see Confirmatory Late Manifestations below).

Clinical Criteria for Diagnosis:
Erythema migrans (EM): For the 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 creating a “bull’s-eye” appearance. To meet the case definition, a single primary lesion must reach greater than or equal to 5cm in size across its largest diameter. Secondary lesions may also occur. A hallmark of EM is its gradual expansion over several days. 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.

Confirmatory late manifestations
Confirmatory signs and symptoms include any of the following when an alternate explanation is not found:
1. Musculoskeletal system: Recurrent, intermittent 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.
2. 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 may be confirmed by demonstration of antibody production against *B. burgdorferi* in the cerebrospinal fluid (CSF), but CSF testing is no longer required, since persons with antibodies in CSF should also have sufficient antibodies in blood to yield positive serology. Headache, fatigue, paresthesia, or mildly stiff neck alone is not criteria for neurologic involvement.
3. 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.

Non-confirmatory manifestations
Non-confirmatory signs and symptoms include fever, sweats, chills, fatigue, neck pain, arthralgias, myalgias, fibromyalgia syndromes, cognitive impairment, headache, paresthesias, visual/auditory impairment, peripheral neuropathy, encephalopathy, palpitations, bradycardia, bundle branch block, myocarditis, or other rash.
B. Laboratory Criteria:
For the purpose of surveillance, the definitions of qualified laboratory assays include:

- a positive culture for *B. burgdorferi*, OR
- two-tier testing* with IgM immunoblot seropositive result for specimens collected within 30 days of onset date, OR
- a positive IgG immunoblot interpreted using established criteria, OR
- additional assays, including PCR, which will be considered on a case-by-case basis.

* Two-tier testing includes a positive or equivocal Lyme antibody screen (EIA or IFA) followed by a positive immunoblot result.

C. Wisconsin Surveillance Case Definition:
Adapted from the revised 2017 Council of State and Territorial Epidemiologists (CSTE) Lyme disease national surveillance case definition and was effective on January 1, 2017. This surveillance case definition was developed for national reporting of confirmed and probable Lyme disease cases and is not to be used in clinical diagnosis. Case classification requires laboratory results and clinical signs and symptoms.

Case classification for required reporting:

- **Confirmed:** Erythema migrans (EM) in a Wisconsin resident that has been diagnosed by a physician or a medical professional and is greater than or equal to 5cm in size. Note that although the national case definition requires a known “exposure” as defined below, the Centers for Disease Control and Prevention (CDC) considers Wisconsin to be a high-incidence state. Thus, any Wisconsin resident is considered exposed.
  - **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 high-incidence state (i.e., Wisconsin). A history of tick bite is not required. For the purpose of surveillance, the Wisconsin Department of Health Services (DHS) considers all Wisconsin residents to be exposed.
  - **High-incidence state:** A state in which there is an average of 10 or more confirmed Lyme disease cases per 100,000 persons for the previous three reporting years. CDC considers Wisconsin to be a high-incidence state.

Case classifications for optional reporting:

- **Confirmed:** At least one confirmatory late manifestation (as described above in the Clinical Criteria for Diagnosis) and laboratory evidence of infection that meets criteria listed in Section B above.
- **Probable:** Any other physician-diagnosed Lyme disease with laboratory evidence of infection that meets criteria listed in Section C above, with only non-confirmatory signs and symptoms (as described above in the Clinical Criteria for Diagnosis).
- **Suspect:** Any positive laboratory test with no clinical information available (e.g., a laboratory report without a case report form).
  
  **Note:** Please document in the notes section of the Wisconsin Electronic Disease Surveillance System (WEDSS) if unable to obtain clinical information after contacting the patient provider.
- **Not A Case:** Any case report that does not meet the confirmed, probable, or suspect category.

D. Lyme Disease Estimate Calculation

- Since the change in Lyme disease reporting criteria in 2012, DHS has calculated estimated Lyme disease cases based on the number of reported Lyme disease laboratory results. Statistical analysis of past surveillance data was used to determine the percentages for confirmed and probable cases and projections are calculated based on the number of total laboratory reports for each year since 2012.
- DHS analyzed Lyme disease surveillance data for the period 1991-2011. During this period, the annual proportion of cases with EM was fairly consistent, averaging 65.1% of total reported confirmed cases annually (range 50.5%-75.9%), and statewide trends in the number of cases with EM reported annually were similar to trends in total cases. At the county level, total confirmed cases and cases with EM were highly correlated, and maps of the three-year average county incidence provide a very similar picture of the spread of Lyme disease across the state, whether based on total confirmed cases or cases with EM only.
II. REPORTING

- **Wisconsin Disease Surveillance Category II – Methods for Reporting:** This disease shall be reported to the patient’s local health officer or to the local health officer’s designee within 72 hours of recognition of a case or suspected case, per Wis. Admin. Code § DHS 145.04 (3) (b). Report electronically through the Wisconsin Electronic Disease Surveillance System (WEDSS), or mail or fax a completed Acute and Communicable Disease Case Report (F-44151) to the address on the form.

- **Responsibility for Reporting:** According to Wis. Admin. Code § DHS 145.04(1), persons licensed under Wis. Stat. ch. 441 or 448, laboratories, health care facilities, teachers, principals, or nurses serving a school or day care center, and any person who knows or suspects that a person has a communicable disease identified in Appendix A.

- **Clinical Criteria for Reporting:** Clinically compatible illness.

- **Laboratory Criteria for Reporting:** Laboratories must continue to report all Lyme disease positive test results.

- **Optional Reporting:**
  - Providers: Unless requested by the Local Health Department (LHD), reports of cases with confirmatory and non-confirmatory clinical signs and symptoms without EM rash are optional. See Section A for definition and clarification of confirmatory and non-confirmatory clinical signs and symptoms. Unless requested by the LHD, reporting of signs and symptoms other than EM rash, exposure, and treatment information is now optional.
  - LHDs: LHDs will not be expected to review incoming laboratory reports or call providers for clinical signs and symptoms when a positive laboratory report is received. Lyme laboratory results that are received electronically at the LHDs or at the state will be auto-imported into WEDSS as a “Lyme laboratory report.” Paper copy of the laboratory reports received at the LHD can be entered at the LHD or forwarded to the state for entry. All laboratory results that have been entered into WEDSS will be accessible to LHDs.

E. Lyme Disease Modified Reporting Memo:
The following letter was sent to Wisconsin health care providers, infection preventionists, and public health officials in May of 2012:

On January 1, 2008, the Wisconsin Division of Public Health (DPH) began using the Lyme disease national surveillance case definition adopted by the Council of State and Territorial Epidemiologists (CSTE) and Centers for Disease Control and Prevention (CDC) in accordance with the 2007 CSTE position statement. This revision permits states and territories to follow a standardized method of surveillance by providing guidance on qualified laboratory procedures and clinical manifestation to classify cases into confirmed, probable, and suspect categories. DPH began reporting confirmed and probable cases of Lyme disease to the CDC on January 1, 2008; prior to that date only confirmed cases were reported. Since implementing the revised Lyme disease national surveillance case definition, it has become apparent that the current Lyme disease surveillance system places a substantial burden on reporters of diseases and public health agencies and is no longer sustainable in Wisconsin.

**Effective June 1, 2012,** the Wisconsin Division of Public Health is modifying the requirements of Lyme disease reporting in Wisconsin to reduce the Lyme disease surveillance burden.

**Required reporting via Wisconsin Electronic Disease Surveillance System (WEDSS) or paper copy:**
- Continue to report all cases of erythema migrans (EM) rash occurring in Wisconsin residents that have been diagnosed by a physician or a medical professional. For surveillance purposes, EM rash is defined as a red macule or papule that expands during a period of days to weeks to a diameter that is greater than or equal to 5 cm. The skin lesion often has partial central clearing.
- Continue to report date of illness onset and patient demographic information including address, birth date, gender, race and ethnicity.
- Laboratories must continue to report all Lyme positive laboratory results.

**Optional reporting (change to current reporting procedure):**
• Unless requested by the local health department, reporting of cases without EM rash is now optional.
• Unless requested by the local health department, reporting of signs and symptoms other than EM rash is now optional.

If you have further questions, please contact the Vectorborne Program at the Wisconsin Division of Public Health at 608-267-9003.

III. CASE INVESTIGATION
A. Responsibility for case investigation: It is the responsibility of the LHD to investigate or arrange for investigation of suspected or confirmed cases as soon as is reasonably possible. A case investigation may include information collected by phone, in person, in writing, or through review of medical records or communicable disease report forms, as necessary and appropriate.

B. Required Documentation:
1. Complete the WEDSS disease incident investigation report, including appropriate, disease-specific tabs.
2. Upon completion of investigation, set WEDSS disease incident process status to “Sent to State.”

C. Additional Investigation Responsibilities: If a provider reports incomplete clinical information, LHDs will be expected to follow up for the missing information needed to complete the investigation, even if there was no EM rash.

D. WEDSS Protocol:
• Lyme laboratory reports will be automatically imported from staging.
• If your LHD has made the decision to educate your providers to report all EM rash cases, and to no longer actively follow up on all positive laboratory results, then you do NOT need to do anything with the Lyme Laboratory results.
• To remove them from your task list: change the Process Status to Follow-Up Complete
• Do not add follow-up information into Lyme Laboratory Reports (in either the filing cabinet or notes section). If you decide to follow up with the patient or receive incomplete clinical information from a provider, change the Disease Being Reported to Lyme disease so you can enter the clinical information in the Lyme-LabClinical tab.

IV. PUBLIC HEALTH INTERVENTIONS AND PREVENTION MEASURES

B. LHDs should train their local providers to report all cases of EM rash meeting surveillance criteria and encourage their local providers to report via WEDSS instead of submitting cases by paper copy.

C. Patient education as needed to minimize future tick exposure.

V. CONTACTS FOR CONSULTATION
A. Local health departments and tribal health agencies: https://www.dhs.wisconsin.gov/lh-depts/index.htm

B. BCD, Communicable Diseases Epidemiology Section, Vectorborne Epidemiologists: 608-267-9003

C. Wisconsin State Laboratory of Hygiene: 1-800-862-1013

D. Tick Identification: The public can send in ticks or pictures electronically for identification at no charge through the University of Wisconsin, Department of Entomology. Please contact DHS for further information.

VI. RELATED REFERENCES

