Committee: Infectious Disease

Title: Update to Public Health Reporting and National Notification of Melioidosis

☒Check this box if this position statement is an update to an existing standardized surveillance case definition and include the most recent position statement number here: 11-ID-16.

Synopsis: This position statement updates the melioidosis case definition (previous position statement 11-ID-16) and recommends that melioidosis be made a Nationally Notifiable Condition.

I. Statement of the Problem
The purpose of this position statement is to add melioidosis to the Nationally Notifiable Conditions list. Melioidosis, or Whitmore’s Disease, is a potentially severe and fatal disease caused by Burkholderia pseudomallei, which is predominantly found in tropical and subtropical regions. This bacterium is designated a Tier 1 Select Agent by the National Select Agent Program (NSAP) because it presents the greatest risk for deliberate misuse. Although B. pseudomallei is a Select Agent and falls under the reporting requirements of both the NSAP and the Laboratory Response Network (LRN), only limited laboratory data are shared with the Centers for Disease Control and Prevention (CDC). These data are insufficient to identify epidemiologic links between cases or to prompt timely investigations into non-travel related cases.

Between 2012 and 2021, 92 confirmed human melioidosis cases were reported to CDC, including eight cases with no travel history to endemic areas (unpublished data, CDC). Compared to the prior decade, this represents a marked increase in reported cases overall, and more significantly, an increase in domestically-acquired cases (including some with novel epi links to imported products). Between 2017 and 2021, there were 304 individuals with laboratory exposures to B. pseudomallei, warranting serological monitoring performed at CDC in partnership with jurisdictions’ health departments.

Although a standardized case definition for melioidosis was approved by CSTE in 2011, the number of cases in the U.S. likely continues to be underreported due to lack of awareness of the disease (1). Delayed reporting has been an issue identified in several jurisdictions where melioidosis is not explicitly on the jurisdiction’s list of reportable conditions. For example, in 2018, a melioidosis case in Texas was initially not reported by a hospital laboratory to the state because B. pseudomallei was not specifically listed on the Texas Notifiable Conditions List and the laboratory was unaware of the reporting requirements to the state LRN.

II. Background and Justification
Melioidosis is caused by the environmental bacterium Burkholderia pseudomallei. Infection typically occurs through direct contact with contaminated soil or water via subcutaneous inoculation, ingestion, or inhalation. Person-to-person transmission is extremely rare. B. pseudomallei infection has been identified in humans and multiple animal species. The median incubation period is 9 days but ranges from a few hours to decades after exposure. There is no vaccine, and even with treatment, case fatality rates range from 10-50% (2).

Melioidosis may present as a localized infection, pneumonia, bacteremia, or disseminated infection. Patients generally present with acute illness, but 15% present with chronic infection, with symptoms lasting over two months (3). Clinical presentation may overlap with other diseases, complicating the diagnosis (4).

An estimated 165,000 human melioidosis cases occur annually, mainly in the highly endemic areas of northeast Thailand, Malaysia, Singapore, and northern Australia (5). Melioidosis is considered an emerging infectious disease in the Americas, with most cases occurring in Brazil (6,7). An increasing number of cases have been identified in Puerto Rico and the U.S. Virgin Islands (8-11). Predictive models of environmental suitability suggest the bacteria may be present in the soil in the U.S. (5). Additionally, the genomic analysis of isolates collected from two Texas and two Mississippi patients with no recent travel history indicate the potential endemcity in North America (12, unpublished communication with CDC/Mississippi State Dept. of Health).*
Approximately twelve melioidosis cases are reported to CDC each year. Reported cases increased over the past few decades, with the sharpest increase occurring over the past five years. Although most cases in the U.S. are exposed while in endemic areas, the number of non-travel associated cases is also increasing. Since 2012, there have been eight U.S. cases without relevant travel history, seven of which were infected by South or Southeast Asia strains based on whole genome sequencing (WGS). A 2019 case was linked to an aquarium housing an imported fish (13). In 2021, an outbreak of four cases in four states was linked to a contaminated aromatherapy room spray manufactured in India and sold nationwide (14). Over 2,800 households across 43 U.S. jurisdictions were potentially exposed to \textit{B. pseudomallei} from this product. The source remains unknown for all the other non-travel related cases. Melioidosis is also a potential lab-acquired infection, so exposed laboratory workers are monitored for development of the disease.

Implementing reporting mandates of melioidosis cases in the U.S. is needed because of the increasing trends in international travel, globalized supply chain leading to continued importation of products from melioidosis-endemic regions, increasing worldwide disease burden (5), increasing evidence of endemicity in the southern U.S., persistently high case-fatality rates, and possibility of its use for bioterrorism. Given the low baseline number of U.S. melioidosis cases, the reporting burden associated with adding this condition to the Nationally Notifiable Conditions list will be low. However, the identification of even one case of melioidosis in an individual without appropriate travel history raises concern for either accidental or intentional introduction of this organism and necessitates a rapid public health response.

* After this position statement was approved by the Council on June 23, 2022, CDC released a Health Alert Network (HAN) Health Advisory confirming the endemicity of melioidosis in Mississippi. (15)

III. Statement of the desired action(s) to be taken
CSTE recommends the following actions:

1. Implement a standardized surveillance case definition for melioidosis.
   A. Utilize standard sources (e.g., reporting*) for case ascertainment for melioidosis. Surveillance for melioidosis should use the recommended sources of data to the extent of coverage presented in Section V.

2. Utilize standardized criteria for case ascertainment and classification (based on Sections VI and VII and Technical Supplement) for melioidosis and add melioidosis to the Nationally Notifiable Condition List
   - Immediately notifiable, extremely urgent (within 4 hours)
   - Immediately notifiable, urgent (within 24 hours)
   - Routinely notifiable
   - No longer notifiable

3. CSTE recommends that all States and Territories enact laws (statute or rule/regulation as appropriate) to make this disease or condition reportable in their jurisdiction. Jurisdictions (e.g., States and Territories) conducting surveillance (according to these methods) should submit case notifications** to CDC.

4. Expectations for Message Mapping Guide (MMG) development for a newly notifiable condition: the National Notifiable Diseases Surveillance System (NNDSS) is transitioning to HL7-based messages for case notifications; the specifications for these messages are presented in MMGs. When CSTE recommends a new condition be made nationally notifiable, CDC must obtain Office of Management and Budget Paperwork Reduction Act (OMB PRA) approval prior to accepting case notifications for the new condition. Under anticipated timelines, notification using the Generic V2 MMG would support
transmission of the basic demographic and epidemiologic information common to all cases and could begin with the new MMWR year following the CSTE annual conference. Input from CDC programs and CSTE would prioritize development of a disease-specific MMG for the new condition among other conditions waiting for MMGs.

5. CDC should publish data on melioidosis as appropriate (see Section IX). CSTE recommends the following case statuses be included in the CDC Print Criteria:
   ☒ Confirmed
   ☒ Probable
   ☐ Suspect
   ☐ Unknown

6. CSTE recommends that all jurisdictions (e.g., States, Localities, or Territories) with legal authority to conduct public health surveillance follow the recommended methods outlined in this standardized surveillance position statement.

*Reporting: process of a healthcare provider or other entity submitting a report (case information) of a condition under public health surveillance to local, state, or territorial public health.
** Notification: process of a local or state public health authority submitting a report (case information) of a condition on the Nationally Notifiable Conditions List to CDC.

IV. Goals of Surveillance
1. To provide information on the temporal, geographic, and demographic occurrence of melioidosis to facilitate its prevention and control.
2. To assist in identification of potential laboratory exposures, conduct risk assessment, and provide post-exposure prophylaxis, if indicated.
3. To detect potential deliberate release of B. pseudomallei.
4. To detect potential imports contaminated with B. pseudomallei.

V. Methods for Surveillance: Surveillance for melioidosis should use the recommended sources of data and the extent of coverage listed in Table V.

Surveillance for melioidosis should use the following recommended sources of data and the extent of coverage listed in Table V.

Melioidosis case reports will derive from laboratory and clinician reporting to state and local health departments, which will conduct individual follow-up based on available resources. CDC will continue to provide national and international assistance/guidance upon request.

<table>
<thead>
<tr>
<th>Source of data for case ascertainment</th>
<th>Coverage</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Population-wide</td>
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<td>Sentinel sites</td>
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<td>Clinician reporting</td>
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<td>Laboratory reporting</td>
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<td>Reporting by other entities: outpatient healthcare facilities, veterinary laboratories</td>
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<tr>
<td>Hospital discharge or outpatient records</td>
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<td>Data from electronic medical records</td>
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<td>Telephone survey</td>
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<tr>
<td>School-based survey</td>
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<td>Other, specify: N/A</td>
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</table>
VI. Criteria for case ascertainment

A. Narrative: A description of suggested criteria for case ascertainment of a specific condition.

Recommended reporting procedures
- All cases of melioidosis should be reported.
- Reporting should be on-going and routine.
- Reporting should be immediate.

A1. Clinical Criteria for Reporting
In the absence of a more likely diagnosis, a person with at least one of the following signs or symptoms*:
- Fever (temperature > 38.0°C [100.4°F])
- Muscle aches
- Ulcer
- Nodule
- Skin abscess
- Pneumonia
- Headache
- Chest pain
- Anorexia
- Respiratory distress
- Abdominal discomfort
- Joint pain
- Disorientation
- Weight loss
- Seizure
- Organ abscess (liver, lung, spleen, prostate, or brain)
- Encephalomyelitis/meningitis/extra-meningeal disease

* Clinical criteria must be paired with EITHER serologic evidence of a single B. pseudomallei total antibody titer ≥1:40 from one or more serum specimens OR epidemiologic linkage criteria to trigger a report to public health.

A2. Laboratory Criteria for Reporting
- Isolation of B. pseudomallei from blood, sputum, urine, pus, throat swab, or swabs from organ abscesses or wound, or any other clinical source, OR
- Evidence of a fourfold or greater rise in B. pseudomallei antibody titer by indirect hemagglutination assay (IHA) between acute- and convalescent-phase serum specimens obtained at least two weeks apart, OR
- Detection of B. pseudomallei in a clinical specimen by nucleic acid amplification test, OR
- Single B. pseudomallei total antibody titer of greater than or equal to 1:40 by serology in one or more serum specimens obtained from person with compatible clinical symptoms

A3. Epidemiologic Linkage Criteria for Reporting
A person with clinically compatible illness and one of the following findings:
- History of travel to or residence in a region endemic for melioidosis, OR
- Known exposure to B. pseudomallei as a result of intentional release or known product/source exposure (outside of laboratory), OR
- Known exposure to B. pseudomallei as a result of an occupational risk (i.e., laboratory exposure).
A4. Vital Records Criteria for Reporting

- A person whose death certificate lists melioidosis as a cause of death or a significant condition contributing to death.

A5. Other Criteria for Reporting

- A person whose healthcare record contains a recent diagnosis of melioidosis.

B. Disease-specific data elements to be included in the initial report

In addition to patient demographics and geographic information, the following disease-specific data elements are expected to be included in all reports to public health agencies:

- Clinical information
  - Description of clinical symptoms/signs of illness
  - Date of symptom onset
  - Date of hospitalization
  - Timing of antimicrobial therapy and collection of specimens

- Laboratory information
  - Date of specimen collection
  - Specimen type
  - Results

- Epidemiological information
  - International military service
  - Microbiological laboratory work
  - Travel information (especially travel to a melioidosis-endemic region)
  - Soil or water contact especially during travel to a melioidosis-endemic region
  - Animal (mammal, reptile, bird, fish) contact
  - Exposure to product or source known to be contaminated with the bacteria
  - Suspected deliberate bioterrorism-associated exposure

VII. Case Definition for Case Classification

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

A1. Clinical Criteria

In the absence of a more likely diagnosis, at least one of the following signs or symptoms:

- Fever (temperature > 38.0°C [100.4°F])
- Muscle aches
- Ulcer
- Nodule
- Skin abscess
- Pneumonia
- Headache
- Chest pain
- Anorexia
- Respiratory distress
- Abdominal discomfort
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- Disorientation
- Weight loss
- Seizure
- Organ abscess (liver, lung, spleen, prostate, or brain)
- Encephalomyelitis/meningitis/extra-meningeal disease
A2. Laboratory Criteria

**Confirmatory laboratory evidence:**
- Isolation of *B. pseudomallei* from a clinical specimen

**Presumptive laboratory evidence:**
- Evidence of a fourfold or greater rise in *B. pseudomallei* antibody titer by indirect hemagglutination assay (IHA) between acute- and convalescent-phase serum specimens obtained at least two weeks apart, OR
- Evidence of *B. pseudomallei* DNA (for example, by LRN-validated nucleic acid amplification test) in a clinical specimen

**Supportive laboratory evidence:**
- Single *B. pseudomallei* total antibody titer of greater than or equal to 1:40 by serology in one or more serum specimens

*Note: The categorical labels used here to stratify laboratory evidence are intended to support the standardization of case classifications for public health surveillance. The categorical labels should not be used to interpret the utility or validity of any laboratory test methodology.*

A3. Epidemiologic Linkage

A person with at least one of the following findings:
- History of travel to or residence in a region endemic for melioidosis, OR
- Known exposure to *B. pseudomallei* as a result of intentional release or known product/source exposure (outside of laboratory), OR
- Known exposure to *B. pseudomallei* as a result of an occupational risk (i.e., laboratory exposure)

A4. Vital Records Criteria

- A person whose death certificate lists melioidosis as a cause of death or a significant condition contributing to death

A5. Other Criteria

- A person whose healthcare record contains a recent diagnosis of melioidosis

A6. Case Classifications

**Confirmed:**
- Meets confirmatory laboratory evidence.

**Probable:**
- Meets clinical criteria AND presumptive laboratory evidence AND epidemiologic linkage.
- Meets vital records criteria AND presumptive laboratory evidence AND epidemiologic linkage.
- Meets other criteria AND presumptive laboratory evidence AND epidemiologic linkage.

**Suspect:**
- Meets clinical criteria AND supportive laboratory evidence AND epidemiologic linkage.
- Meets vital records criteria AND supportive laboratory evidence AND epidemiologic linkage.
- Meets other criteria AND supportive laboratory evidence AND epidemiologic linkage.
B. Criteria to distinguish a new case of this disease or condition from reports or notifications which should not be enumerated as a new case for surveillance
An infection would be counted as a new infection if a person is culture-positive within an 18-month time period with an isolate that is distinct from the previous infection by whole genome sequencing.

Note: Recurrent melioidosis can be defined as a re-presentation with *B pseudomallei* culture-positive clinical disease occurring <18 months following initial diagnosis and after the time designated for treatment completion (both intravenous and oral phases) for the previous episode, irrespective of whether the patient was adherent to the therapy or initially lost to follow-up. Recurrent cases will not be counted as a new case for surveillance purposes. Epidemiological and exposure information can be used to determine if it is a new or recurrent infection, as can whole genome sequencing, if an isolate is available.

VIII. Period of Surveillance
This surveillance should be on-going.

IX. Data sharing/release and print criteria
CSTE recommends the following case statuses* be included in the ‘case’ count released outside of the public health agency:

- □ Confirmed
- □ Probable
- □ Suspect
- □ Unknown

* Which case statuses are included in the case counts constitute the “print criteria.”

Jurisdictions (e.g., States and Territories) conducting surveillance under this case definition can voluntarily submit de-identified case information to CDC, if requested and in a mutually agreed upon format. Production of national data summaries and national data re-release for non-NNCs:

- Prior to release of national data summaries CDC should follow the CDC/ATSDR Policy on Releasing & Sharing Data, issued on April 16, 2003 and referenced in 11-SI-01 and custodians of such data should consult the CDC-CSTE Intergovernmental Data Release Guidelines Working Group report (www.cste2.org/webpdfs/drgwgreport.pdf) which contains data release guidelines and procedures for CDC programs re-releasing state, local, or territorial-provided data.
- CDC programs have a responsibility, in collaboration with states, localities, and territories, to ensure that CDC program-specific data re-release procedures meet the needs of those responsible for protecting data in the states and territories.

X. Revision History

<table>
<thead>
<tr>
<th>Previous PS ID</th>
<th>Section of Document</th>
<th>Revision Description</th>
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</thead>
<tbody>
<tr>
<td>11-ID-16</td>
<td>I. Statement of Problem</td>
<td>EDITED to make relevant to recommending national notifiability</td>
</tr>
<tr>
<td>11-ID-16</td>
<td>II. Background and Justification</td>
<td>EDITED to include recent data and cases</td>
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<tr>
<td>11-ID-06</td>
<td>III. Desired Actions to be Taken</td>
<td>Recommends ADDITION of melioidosis to the NNC list</td>
</tr>
<tr>
<td>11-ID-16</td>
<td>VII. Case Definition for Case Classification</td>
<td>Added “or known product/source exposure” to epidemiological evidence</td>
</tr>
<tr>
<td>11-ID-16</td>
<td>VII. Case Definition for Case Classification and Table VII. Classification Table: Criteria for defining a case of melioidosis.</td>
<td>ADDED suspect case definition and criteria</td>
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<tr>
<td>N/A</td>
<td>11-ID-16</td>
<td>Created standardized surveillance case definition for melioidosis.</td>
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</tbody>
</table>
XI. References


XII. Coordination

Subject Matter Expert (SME) Consultants:

PRIMARY SME

(1) Julia Petras
Epidemic Intelligence Service Officer (B. pseudomallei epi SME)
Bacterial Special Pathogens Branch
Centers for Disease Control and Prevention
1600 Clifton Rd.
Atlanta, GA 30329
978 335 3814
rhu2@cdc.gov
ADDITIONAL SME(s)

(1) Mindy Elrod  
Microbiologist (B. pseudomallei lab SME)  
Centers for Disease Control and Prevention  
Bacterial Special Pathogens Branch  
(404) 639-4055  
wzg0@cdc.gov

(2) Jay Gee  
Research Biologist (B. pseudomallei genome SME)  
Centers for Disease Control and Prevention  
Bacterial Special Pathogens Branch  
1 (404) 639-4936  
xzg4@cdc.gov

(3) William Bower  
Epidemiologist Team Lead  
Centers for Disease Control and Prevention  
Bacterial Special Pathogens Branch  
(404) 639-0376  
wab4@cdc.gov

Agencies for Response

(1) Centers for Disease Control and Prevention  
Rochelle Walensky, MD, MPH  
Director  
1600 Clifton Road, NE  
Atlanta GA 30329  
(404) 639-7000  
aux7@cdc.gov

CC: Dr. William Bower, Epi Team Lead, Bacterial Special Pathogens Branch, Division of High-Consequence Pathogens and Pathology, wab4@cdc.gov

XIII. Author Information

Submitting and Presenting Author:

(1) Maria Bye, MPH  
Epidemiologist  
Minnesota Department of Health  
625 Robert St N  
St. Paul, MN 55155  
(651) 201-4085  
Maria.Bye@state.mn.us

Co-Authors:

(1) Active Member  
Danielle Stanek, DVM, DACVPM  
State Public Health Veterinarian / Medical Epidemiologist  
Florida Department of Health  
4052 Bald Cypress Way, Bin A-12  
Tallahassee, FL 32399  
850-245-4117  
danielle.stanek@fldh.gov

2) Active Member  
Jessica Pavlick, DrPH, MPH  
Epidemiology Preparedness Director  
Georgia Department of Public Health  
2 Peachtree St NE  
Atlanta, GA 30303  
404-357-0862  
Jessica.Pavlick@dph.ga.gov
Table VI. Table of criteria to determine whether a case should be reported to public health authorities.

<table>
<thead>
<tr>
<th>Criterion</th>
<th>Melioidosis</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Clinical Criteria for Reporting</strong></td>
<td></td>
</tr>
<tr>
<td>Fever (temperature &gt; 38.0°C [100.4°F])</td>
<td>O</td>
</tr>
<tr>
<td>Muscle aches</td>
<td>O</td>
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<tr>
<td>Ulcer</td>
<td>O</td>
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<td>Nodule</td>
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<td>Skin abscess</td>
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<td>Pneumonia</td>
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<td>Headache</td>
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<td>Chest pain</td>
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<td>Encephalomyelitis/meningitis/extra-meningeal disease</td>
<td>O</td>
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<tr>
<td>Absence of a more likely diagnosis</td>
<td>N</td>
</tr>
<tr>
<td><strong>Laboratory Criteria for Reporting</strong></td>
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<tr>
<td>Isolation of <em>B. pseudomallei</em> from blood, sputum, urine, pus, throat swab, or swabs from organ abscesses or wound, or from any other clinical source</td>
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</tr>
<tr>
<td>Evidence of a fourfold or greater rise in <em>B. pseudomallei</em> antibody titer by indirect hemagglutination assay (IHA) between acute- and convalescent-phase serum specimens obtained at least 2 weeks apart</td>
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<td>Detection of <em>B. pseudomallei</em> in a clinical specimen by nucleic acid amplification test</td>
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<td>Single <em>B. pseudomallei</em> total antibody titer of greater than or equal to 1:40 by serology in one or more serum specimens</td>
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<tr>
<td><strong>Epidemiologic Linkage Criteria for Reporting</strong></td>
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<tr>
<td>History of travel to or residence in a region endemic for melioidosis</td>
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<td>A person whose death certificate lists melioidosis as a cause of death or a significant condition contributing to death</td>
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<td><strong>Other Criteria for Reporting</strong></td>
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<tr>
<td>A person whose healthcare record contains a diagnosis of melioidosis</td>
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</tr>
</tbody>
</table>

Notes:
- **S** = This criterion alone is SUFFICIENT to report a case.
- **N** = All "N" criteria in the same column are NECESSARY to report a case.
- **O** = At least one of these "O" (ONE OR MORE) criteria in each category (categories=clinical evidence, laboratory evidence, and epidemiological evidence) in the same column—in conjunction with all "N" criteria in the same column—is required to report a case.
## Table VII. Classification Table: Criteria for defining a case of melioidosis

<table>
<thead>
<tr>
<th>Criterion</th>
<th>Confirmed</th>
<th>Probable</th>
<th>Suspect</th>
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<td><strong>Clinical Evidence</strong></td>
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<tr>
<td>Fever (temperature &gt; 38.0°C [100.4°F])</td>
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<td><strong>Laboratory Evidence</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Isolation of <em>B. pseudomallei</em> from a clinical specimen</td>
<td>S</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Evidence of a fourfold or greater rise in <em>B. pseudomallei</em> antibody titer by indirect hemagglutination assay (IHA) between acute- and convalescent-phase serum specimens obtained at least 2 weeks apart</td>
<td>O</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>Evidence of <em>B. pseudomallei</em> DNA (for example, by LRN-validated nucleic acid amplification test) in a clinical specimen</td>
<td>O</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>Single <em>B. pseudomallei</em> total antibody titer of greater than or equal to 1:40 by serology in one or more serum specimens</td>
<td>N</td>
<td>N</td>
<td>N</td>
</tr>
<tr>
<td><strong>Epidemiologic Linkage Evidence</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>History of travel to or residence in a region endemic for melioidosis</td>
<td>O</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>Known exposure to <em>B. pseudomallei</em> as a result of intentional release or known product/source exposure (outside of laboratory)</td>
<td>O</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>Known exposure to <em>B. pseudomallei</em> as a result occupational risk (i.e., laboratory exposure)</td>
<td>O</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td><strong>Vital Records Criteria</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A person whose death certificate lists melioidosis as a cause of death or a significant condition contributing to death</td>
<td>N</td>
<td>N</td>
<td></td>
</tr>
<tr>
<td><strong>Other Criteria for Reporting</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A person whose healthcare record contains a diagnosis of melioidosis</td>
<td>N</td>
<td>N</td>
<td></td>
</tr>
<tr>
<td><strong>Criteria to distinguish a new case:</strong></td>
<td>N</td>
<td>N</td>
<td>N</td>
</tr>
</tbody>
</table>

Notes:
S = This criterion alone is SUFFICIENT to classify a case.
N = All “N” criteria in the same column are NECESSARY to classify a case.
O = At least one of these “O” (ONE OR MORE) criteria in each category (categories=clinical evidence, laboratory evidence, and epidemiologic evidence) in the same column—in conjunction with all “N” criteria in the same column—is required to classify a case.