24-ID-05

Committee: Infectious Disease

Title: Update to Public Health Reporting and National Notification for Leprosy (Hansen's Disease)

☒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: 12-ID-01.

Synopsis:

- This position statement updates the standardized case definition for leprosy, or Hansen's disease, (previous position statement 12-ID-01) to include primary neural leprosy, leprosy caused by *Mycobacterium lepromatosis,* and nucleic acid detection tests.
- Updates include:
  - Addition of detection of *Mycobacterium leprae* or *M. lepromatosis* by nucleic acid detection to leprosy case ascertainment criteria.
  - Addition of criteria for vital records and healthcare records reporting of leprosy.
  - Removal of disease-specific data elements to be included in the initial report of leprosy.
  - Addition of clinical criteria compatible with primary neural leprosy or diffuse leprosy of Lucio and Latapi to leprosy case classification criteria.
  - Addition of detection of *Mycobacterium leprae* or *M. lepromatosis* by nucleic acid detection to leprosy case classification criteria.
  - Addition of epidemiologic criteria to leprosy case classification criteria.
  - Addition of probable and suspect case classification for leprosy.
  - Addition of criteria to distinguish a new case of leprosy from a recurrence or relapse.

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I. Statement of the Problem

There are two forms of leprosy, or Hansen's disease (HD), not currently accounted for in the 2012 case definition (12-ID-01)[1]. Primary neural leprosy (PNL) is characterized by isolated involvement of peripheral nerve trunks in the absence of skin lesions[2] and is commonly diagnosed without histologic examination of tissue biopsies[3]. A diffuse form of leprosy has been associated with both *Mycobacterium leprae* and another organism in the *M. leprae* complex, *Mycobacterium lepromatosis*[2]. This form requires the same prevention, control, and referral measures as other forms of leprosy. This proposed revision to the 2012 leprosy position statement updates the case definition to include cases of PNL and of leprosy caused by *Mycobacterium lepromatosis* to enable timely public health measures. Additionally, nucleic acid detection tests for *M. leprae* and *M. lepromatosis* are now available and are included in updated laboratory criteria. Finally, the proposed revision recommends the National Hansen's Disease Program encourage healthcare providers to report leprosy cases to their jurisdictional public health authorities, where leprosy or HD is reportable, which is lacking in the 2012 leprosy position statement.

II. Background and Justification

Leprosy, or Hansen's disease (HD) is a chronic bacterial disease of the skin and peripheral nerves caused by bacteria in the *Mycobacterium leprae* complex, comprising *M. leprae* and *M. lepromatosis*. Routes of transmission are uncertain but believed to be by respiratory secretions through close, prolonged contact with untreated patients with leprosy or from prolonged or frequent direct contact with infected armadillos or their environment[4,5]. During 2013–2022, 124 to 216 cases per year were reported in the United States (U.S.)[6], most in people with exposure outside the U.S., although endemic leprosy is found in some states. Leprosy can be cured with early diagnosis and treatment*; in the U.S., case detection, treatment, and contact management have been major control strategies. Ongoing public health surveillance is needed to facilitate case detection and control efforts, which might include post-exposure prophylaxis[7], typically arranged in coordination with public health agencies. Current surveillance case definitions do not include leprosy cases with rare presentations; this may inhibit implementation of control strategies for those cases.

Primary neural leprosy (PNL), also known as pure neural or neuritic leprosy, is one form of leprosy that may not be notifiable under the 2012 leprosy position statement (12-ID-01) because clinical criteria for case classification in 12-ID-01 are based on skin lesions, which are absent in PNL, and, because the diagnosis of PNL is commonly based on nerve enlargement and other neurologic findings without histologic examination of tissue biopsies[3], the confirmatory laboratory evidence required for case classification notification in 12-ID-01 may not be obtained. Among leprosy cases, PNL is more common in Nepal (7% of total HD cases), India (4.3%), and Brazil[2] (7.8%)[8].

Another form of leprosy that may not be notifiable under the 2012 leprosy position statement (12-ID-01) is diffuse leprosy of Lucio and Latapi when the etiologic agent identified is *Mycobacterium lepromatosis* because clinical criteria for case classification in 12-ID-01 only describe those related to *Mycobacterium leprae* infection. Diffuse leprosy of Lucio and Latapi, a diffuse, ulcerative form of leprosy, is common in Mexico (23% of cases) and Costa Rica; this form has been associated with *M. leprae* and *M. lepromatosis*[2].

Confirmatory laboratory evidence under the 2012 HD position statement (12-ID-01) was based on finding of acid-fast bacilli in skin or nerves using the Fite method and did not include nucleic acid detection. Nucleic acid-based detection techniques for *M. leprae* complex are becoming the standard for supporting leprosy diagnosis[9,10,11]. A variety of nucleic acid detection tests have been successfully implemented for leprosy diagnosis, including conventional polymerase chain reaction (PCR), semi-quantitative PCR (qPCR), reverse transcriptase-based PCR (RT-PCR), TaqMan real time PCR, and loop-mediate isothermal amplification (LAMP)[12,13]. Inclusion of nucleic acid detection tests in confirmatory laboratory evidence brings case reporting, classification, and notification into alignment with current diagnostic laboratory practices.

Despite leprosy or HD being a reportable condition in 49 states, information about the majority of patients with leprosy or suspected leprosy is communicated by healthcare providers to the Health Resources and Services Administration (HRSA) National Hansen's Disease Program (NHDP) without case reporting to the jurisdictional health authority or notification to the Centers for Disease Control and Prevention (CDC) (personal communication). Notification to CDC is by jurisdictional public health authorities, not by the NHDP, and although a data sharing agreement between CDC and NHDP is in progress, increased effort by the NHDP to encourage healthcare providers to report to their jurisdictional public health authority, where leprosy or HD is reportable, could improve national notification and public health surveillance.

**Note that leprosy cases may be classified into types for treatment purposes using Ridley Jopling or WHO classifications[2]. These are not surveillance case definitions.*

III. Statement of the Desired Action(s) to be Taken

CSTE recommends the following actions:

1. Implement a standardized surveillance case definition for **leprosy** (**Hansen's disease)**.

   A. Utilize recommended reporting* sources for case ascertainment for **leprosy** (**Hansen's disease)**. Surveillance for **leprosy** (**Hansen's disease)** should use the recommended sources of data to the extent of coverage presented in Section V.

   B. Utilize standardized criteria for case ascertainment for **leprosy** (**Hansen's disease)** presented in Section VI and Table VI in Technical Supplement.

   C. Utilize standardized criteria for case classification for **leprosy** (**Hansen's disease)** presented in Section VII and Table VII in Technical Supplement.

2. Utilize standardized criteria for case ascertainment and classification (based on Sections VI and VII and Technical Supplement) for **leprosy (Hansen's disease)** and **update** leprosy (Hansen's disease) on the *Nationally Notifiable Condition List* using the following notification** timeframe:
   - ☐ 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. CSTE recommends that all jurisdictions (e.g., States, Localities, or Territories) with legal authority should conduct public health surveillance and use the case classifications included in this standardized surveillance position statement.

5. 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.

6. CDC should publish data on leprosy (Hansen's disease) as appropriate (see Section IX). CSTE recommends the following case statuses be included in the CDC Print Criteria:
   - ☒Confirmed
   - ☒Probable
   - ☐Suspect
   - ☐Unknown

7. To support more timely and complete reporting to state, tribal, local, and territorial (STLT) public health agencies, the Health Resources and Services Administration (HRSA) National Hansen's Disease Program should encourage providers to report leprosy cases to their jurisdictional public health authority.

** Reporting: process of a healthcare provider, laboratory, 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

To provide information on the temporal, geographic, and demographic occurrence of leprosy (Hansen's disease); to facilitate its prevention and control; and to facilitate referral to the National Hansen's Disease Program for consultation and medical support to treat infection and prevent spread.

V. Recommended Data Sources and Methods for Surveillance

Surveillance for leprosy (Hansen's disease) should use the following recommended sources of data and/or methodologies and the extent of coverage listed in Table V.

Surveillance for leprosy heavily relies on clinician and laboratory reporting, whether the suspected case is seen in an outpatient or inpatient setting. Passive surveillance using vital records (i.e., death certificates), hospital discharge or outpatient records, and data from electronic medical records increases the ability to timely identify suspected cases, enumerate cases, and implement control measures.

Table V. Recommended Sources of Data, Surveillance Methods, and Extent of Coverage for Ascertainment of Cases of Leprosy (Hansen's Disease)

Source of Data/Methodology for Case Ascertainment	Coverage	
	Population-Wide	Sentinel Sites
Clinician reporting	X	
Laboratory reporting	X	
Reporting by other entities, specify: Hospitals	X	
Death certificates	X	
Hospital discharge or outpatient records	X	
Data from electronic medical records	X	
Telephone or online survey		
School-based survey		
Other, specify: National Hansen's Disease Program	X	

VI. Criteria for Case Ascertainment

Case ascertainment is the process through which public health identifies potential cases of a disease or condition using data reported or provided to public health by healthcare, laboratories, and other reporting entities. This public health reporting is triggered by the case ascertainment criteria (a single criterion or a combination of criteria) included in this position statement, and each initial report sent to public health should include common data elements and disease-specific data elements. Case ascertainment criteria are not intended to be used for clinical diagnosis purposes.

A. Narrative: A description of suggested criteria for case ascertainment of a specific condition and recommended reporting procedures.

Leprosy (Hansen's disease) is a highly variable disease. The spectrum of disease ranges from a single macule or plaque on the skin or single nerve thickening to diffuse involvement of skin, multiple nerves, and internal organs.[2] Clinical presentation may change depending on the immune status of the affected individual. Skin signs and symptoms can include pale or reddish patches; decrease or loss of sensation in the skin patches; papules; superficial or deep painful nodules; thickened, stiff, or dry skin; painless ulcers; loss of eyebrows, eyelashes, or body hair; shortening of toes and fingers due to reabsorption; and nasal disfigurement. Signs and symptoms of nerve involvement include numbness or tingling of hands or feet, painless wounds or burns on the hand or feet, muscle weakness or paralysis, deformity (e.g., 'claw hand', inability to abduct the thumb, wrist drop, foot drop, facial palsy), thickened peripheral nerves, painful or tender nerves, burning sensation in the skin, and lagophthalmos. Fatigue, malaise, and fever are possible with immunologic reactions. In diffuse leprosy of Lucio and Latapi, the skin may appear edematous and may have violaceous erythema, especially on the hands and feet; ascending well-defined, angular, jagged, purpuric lesions that ulcerate and heal with atrophic, white scarring may be seen.

A1. Clinical Criteria for Reporting

A clinically compatible illness characterized by:

- Any of the following skin lesions when more common conditions with similar lesions are considered unlikely:
  - an ill-defined hypopigmented or erythematous macule or patch
  - a few well-demarcated, hypopigmented, or erythematous skin lesions with reduced sensation
  - multiple diffuse erythematous papules and nodules on arms and legs, sparing the torso
  - an infiltration of skin, progressing to thickened skin, possibly with reduced sensation
  - diffuse infiltration of the skin and neuropathy (e.g., "glove and stocking") (representing diffuse leprosy)

OR

- The absence of skin lesions AND at least one of the following signs or symptoms:
  - thickening of a peripheral nerve trunk with pain or tenderness of the nerve (representing primary neural leprosy)
  - unexplained peripheral neuropathy with negative markers for inflammatory disease*

**This clinical criterion for reporting must be paired with epidemiologic criteria for reporting to trigger a report to public health.*

A2. Laboratory Criteria for Reporting

- Detection of acid-fast bacilli in skin or a nerve by the Fite-Faraco method,
  OR
- Detection of *M. leprae* or *M. lepromatosis* in skin or a nerve by a nucleic acid detection test**,
  OR
- Detection of non-sarcoid non-caseating granuloma with peripheral nerve involvement.

*** Note that a negative nucleic acid test on a tissue specimen does not rule out* Mycobacterium leprae *or* Mycobacterium lepromatosis *as the cause of illness.*

A3. Epidemiologic Linkage Criteria for Reporting***

- Prolonged, close contact[14,15] with a patient with untreated leprosy,
  OR
- Residency in or repeated travel to a region with higher endemicity (prevalence >1 case per 10,000 population or with new case detection rate ≥ 50 per million population per year) of leprosy,
  OR
- Prolonged or frequent direct contact[†] with armadillos, especially nine-banded armadillos, or with soil in the environment where armadillos live.

**** To trigger a report to public health epidemiologic linkage criteria must be paired with clinical criteria of a clinically compatible illness in the absence of skin lesions with unexplained peripheral neuropathy with negative markers for inflammatory disease.*
[†] Prolonged or frequent direct contact refers to activities such as raising, maintaining, butchering, hunting, field dressing, or consuming armadillos. It does not refer to brief, cursory, or sporadic touching such as might occur with a visitor to a petting zoo.

A4. Vital Records Criteria for Reporting

- A person whose death certificate lists leprosy or Hansen's disease as an underlying cause of death or a significant condition contributing to death.

A5. Healthcare Record Criteria for Reporting

- A person whose healthcare record contains a diagnosis of leprosy or Hansen's disease.

[*continued*]

B. Disease-Specific Data Elements to be Included in the Initial Report
Disease-specific data elements should be included in addition to the common data elements that are to be reported for all initial individual case reports (see CSTE Position Statement 09-SI-01 "Common Core Data Elements for Case Reporting and Laboratory Result Reporting" https://cdn.ymaws.com/www.cste.org/resource/resmgr/PS/09-SI-01.pdf). Public health authorities do not expect that an initial report will contain all the information necessary for case investigation and case classification.

No additional disease-specific data elements are needed for initial individual case reports of leprosy.

VII. Case Definition for Case Classification

This case definition for case classification is intended solely for public health surveillance purposes and does not recommend criteria for clinical diagnosis purposes. Once a public health agency has ascertained data on potential cases of a disease or condition from reporting entities, the public health agency assigns case statuses based on the case classifications included within this position statement.

A. Narrative: A description of criteria to determine how public health should classify a case of leprosy (Hansen's disease).

A1. Clinical Criteria
A clinically compatible illness characterized by:

- Any of the following skin lesions:
  - an ill-defined hypopigmented or erythematous macule or patch
  - a few well-demarcated, hypopigmented, or erythematous skin lesions with reduced sensation
  - multiple diffuse erythematous papules and nodules on arms and legs, sparing the torso
  - an infiltration of skin, progressing to thickened skin, possibly with reduced sensation
  - diffuse infiltration of the skin and neuropathy (e.g., "glove and stocking") (representing diffuse leprosy)

OR

- The absence of skin lesions and thickening of a peripheral nerve trunk with pain or tenderness of the nerve (representing primary neural leprosy).

A2. Laboratory Criteria*
Confirmatory Laboratory Evidence:

- Detection of acid-fast bacilli in a nerve by the Fite-Faraco method,
  OR
- Detection of acid-fast bacilli in skin by the Fite-Faraco method, without growth of mycobacteria on culture** (if done),
  OR
- Detection of *M. leprae* or *M. lepromatosis* in skin or a nerve by a nucleic acid detection test***.

Presumptive Laboratory Evidence:
N/A

Supportive Laboratory Evidence:

- Detection of non-sarcoid non-caseating granuloma with peripheral nerve involvement, without growth of mycobacteria on culture** (if done)

** 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.*
*** If acid-fast bacilli are detected in skin only, mycobacterial culture negativity is highly recommended to rule out infection with mycobacteria other than those in the* M. leprae *complex. To rule out* M. haemophilum*, hemin or iron-citrate containing medium would be needed. To rule out* M. xenopi *or* M. marinum*, incubation at 42 and 30 degrees centigrade, respectively, would be needed.*
**** Note that a negative nucleic acid test on a tissue specimen does not rule out* Mycobacterium leprae *or* Mycobacterium lepromatosis *as the cause of illness.*

A3. Epidemiologic Linkage Criteria

- Prolonged close contact[14,15] with an untreated person with new or recurring leprosy,
  OR
- Residency or repeated travel in a region with higher endemicity (prevalence >1 case per 10,000 population or new case detection rate ≥ 50 per million population per year) for leprosy[16],
  OR
- Prolonged or frequent, direct contact[†] with armadillos, especially nine-banded armadillos, or soil in the environment in which they live.

[†] Prolonged or frequent direct contact refers to activities such as raising, maintaining, butchering, hunting, field dressing, or consuming armadillos. It does not refer to brief, cursory, or sporadic touching such as might occur with a visitor to a petting zoo.

A4. Case Classifications

Confirmed:

- Meets clinical criteria AND confirmatory laboratory evidence.

Probable:

- Meets clinical criteria for primary neural leprosy AND meets epidemiologic linkage criteria.

Suspect:

- Meets clinical criteria for a clinically compatible illness with skin lesions AND meets epidemiologic linkage criteria, OR
- Meets clinical criteria for a clinically compatible illness with skin lesions AND meets supportive laboratory evidence.

B. Criteria to Distinguish a New Case of Leprosy from Reports or Notifications which Should Not be Enumerated as a New Case for Surveillance

For surveillance purposes, a new case of leprosy should be enumerated by public health based on the following criteria:

- A person should be enumerated as a case if not previously enumerated as a case,
  OR
- A person was previously enumerated as a case, followed by adequate treatment with current, standard, multidrug therapeutic regimen and newly meets the criteria for a confirmed or probable case,
  OR
- A person was previously enumerated as a case, but genetic sequencing results are distinctly different in a new positive specimen from a previous positive specimen,
  OR
- A person was previously enumerated as a case, but the *M. leprae* complex species identified (e.g., *M. leprae* vs. *M. lepromatosis*) in a new positive specimen is different than identified in a previous specimen in the same person.

VIII. Period of Surveillance

Surveillance should be ongoing.

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 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

Position Statement ID	Section of Document	Revision Description
24-ID-05	24-ID-05	Changes condition name to: leprosy (Hansen's disease)
24-ID-05	V. Recommended Data Sources and Methods for Surveillance, Table V.	Added death certificates.
24-ID-05	VI. Criteria for Case Ascertainment	Clinical criteria UPDATED to include symptoms of pure neural leprosy and diffuse leprosy. Reference to anti-leprosy drug regimen REMOVED.
24-ID-05	VI. Criteria for Case Ascertainment	Laboratory criteria UPDATED to include nucleic acid detection and *Mycobacterium lepromatosis.*
24-ID-05	VI. Criteria for Case Ascertainment	Epidemiologic criteria ADDED.
24-ID-05	VI. Criteria for Case Ascertainment	Vital records criteria for reporting ADDED
24-ID-05	VI. Criteria for Case Ascertainment	Healthcare record criteria for reporting ADDED
24-ID-05	VI. Criteria for Case Ascertainment	Disease-specific data elements for initial report REMOVED
24-ID-05	VII. Case Definition for Case Classification	Clinical criteria UPDATED to include symptoms of pure neural leprosy and diffuse leprosy
24-ID-05	VII. Case Definition for Case Classification	Laboratory criteria UPDATED to include nucleic acid detection and *Mycobacterium lepromatosis.*
24-ID-05	VII. Case Definition for Case Classification	Epidemiologic linkage criteria ADDED.
24-ID-05	VII. Case Definition for Case Classification	Probable and suspect case definitions ADDED.
24-ID-05	VII. Case Definition for Case Classification	Criteria for distinguishing a new case ADDED.
12-ID-01	N/A	Updated the case definition for Hansen's disease
10-ID-12	N/A	• Established standardized surveillance position statement for Hansen's disease • Added Hansen's disease to the NNC List

XI. References

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Technical Supplement

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

Criterion	Leprosy (Hansen's disease)			
Clinical Criteria for Reporting				
Ill-defined hypopigmented or erythematous macule or patch		O		
A few well-demarcated, hypopigmented, or erythematous skin lesions with reduced sensation		O		
Multiple diffuse erythematous papules and nodules on arms and legs, sparing the torso		O		
Infiltration of skin, progressing to thickened skin, possibly with reduced sensation		O		
Diffuse infiltration of the skin and neuropathy (e.g., "glove and stocking")*		O		
More common conditions with similar skin lesions are considered unlikely		N		
Absence of skin lesions			N	N
Thickening of a peripheral nerve trunk with pain or tenderness of the nerve**			N	
Unexplained peripheral neuropathy with negative markers for inflammatory disease				N
Laboratory Criteria for Reporting				
Detection of acid-fast bacilli in skin using the Fite-Faraco method	S			
Detection of acid-fast bacilli in a nerve using the Fite-Faraco method	S			
Detection of *M. leprae* in skin by a nucleic acid detection test^	S			
Detection of *M. leprae* in a nerve by a nucleic acid detection test^	S			
Detection of *M. lepromatosis* in skin by a nucleic acid detection test^	S			
Detection of *M. lepromatosis* in a nerve by a nucleic acid detection test^	S			
Detection of non-sarcoid non-caseating granuloma with peripheral nerve involvement	S			
Epidemiologic Linkage Criteria for Reporting				
Prolonged, close contact with a patient with untreated leprosy				O
Residency in or repeated travel to a region with higher endemicity (prevalence >1 case per 10,000 population or with new case detection rate ≥ 50 per million population per year) of leprosy				O
Prolonged or frequent direct contact† with armadillos, especially nine-banded armadillos, or with soil in the environment where armadillos live				O
Vital Record Criteria for Reporting				
A person whose death certificate lists leprosy or Hansen's disease as an underlying cause of death or a significant condition contributing to death	S			
Healthcare Record Criteria for Reporting				
A person whose healthcare record contains a diagnosis of leprosy or Hansen's disease	S			

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, laboratory, epidemiologic linkage, vital records, etc.) in the same column—in conjunction with all "N" criteria in the same column—is required to report a case.
** Represents diffuse leprosy*
*** Represents primary neural leprosy in the absence of skin lesions*
^ *Note that a negative nucleic acid test on a tissue specimen does not rule out* Mycobacterium leprae *or* Mycobacterium lepromatosis *as the cause of illness*
†*Prolonged or frequent direct contact refers to activities such as raising, maintaining, butchering, hunting, field dressing, or consuming armadillos. It does not refer to brief, cursory, or sporadic touching such as might occur with a visitor to a petting zoo.*

[*continued*]

Table VII.A. Classification Table: Criteria for defining a case of Leprosy (Hansen's disease).

Criterion	Confirmed				Probable	Suspect	
Clinical Evidence							
Ill-defined hypopigmented or erythematous macule or patch	O		O			O	O
A few well-demarcated, hypopigmented, or erythematous skin lesions with reduced sensation	O		O			O	O
Multiple diffuse erythematous papules and nodules on arms and legs, sparing the torso	O		O			O	O
Infiltration of skin, progressing to thickened skin, possibly with reduced sensation	O		O			O	O
Diffuse infiltration of the skin and neuropathy (e.g., "glove and stocking")*	O		O			O	O
Absence of skin lesions		N		N	N		
Thickening of a peripheral nerve trunk with pain or tenderness of the nerve**		N		N	N		
Laboratory Evidence							
Detection of acid-fast bacilli in skin using the Fite-Faraco method			N	N			
Detection of acid-fast bacilli in a nerve using the Fite-Faraco method	O	O					
Detection of *M. leprae* in skin by a nucleic acid detection test^	O	O					
Detection of *M. leprae* in a nerve by a nucleic acid detection test^	O	O					
Detection of *M. lepromatosis* in skin by a nucleic acid detection test^	O	O					
Detection of *M. lepromatosis* in a nerve by a nucleic acid detection test^	O	O					
Detection of non-sarcoid, non-caseating granuloma with peripheral nerve involvement							N
Mycobacterial culture not done			O	O			O
Absence of growth of mycobacteria on culture†			O	O			O
Epidemiologic Linkage Evidence							
Prolonged close contact with an untreated person with new or recurring leprosy					O	O	
Residency or repeated travel in a region with higher endemicity (prevalence >1 case per 10,000 population or new case detection rate ≥ 50 per million population per year) for leprosy					O	O	
Prolonged or frequent direct contact†† with armadillos or with soil in the environment where armadillos live					O	O	

Notes:
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.
** Represents diffuse leprosy*
*** Represents primary neural leprosy in the absence of skin lesions*
^ *Note that a negative nucleic acid test on a tissue specimen does not rule out* Mycobacterium leprae *or* Mycobacterium lepromatosis *as the cause of illness.*
† *To rule out* M. haemophilum*, hemin or iron-citrate containing medium would be needed. To rule out* M. xenopi *or* M. marinum*, incubation at 42 and 30 degrees centigrade, respectively, would be needed.*
††*Prolonged or frequent direct contact refers to activities such as raising, maintaining, butchering, hunting, field dressing, or consuming armadillos. It does not refer to brief, cursory, or sporadic touching such as might occur with a visitor to a petting zoo.*

Table VII.B. Classification Table: Criteria to distinguish a new case of Leprosy from reports or notifications which should not be enumerated as a new case for surveillance.

Criterion	Confirmed	Probable	Suspect
Criteria to distinguish a new case			
A person should be enumerated as a case if not previously enumerated as a case	S	S	S
A person was previously enumerated as a case, followed by adequate treatment with current, standard, multidrug therapeutic regimen and newly meets the criteria for a confirmed or probable case	S	S	
A person was previously enumerated as a case, but genetic sequencing results are distinctly different in a new positive specimen from a previous positive specimen	S		
A person was previously enumerated as a case, but the *M. leprae* complex species identified (e.g., *M. leprae* vs. *M. lepromatosis*) in a new positive specimen is different than identified in a previous specimen in the same person	S		

S = This criterion alone is SUFFICIENT to enumerate as a new case.