

17-ID-07

Committee: Infectious Disease**Title:** Standardized Case Definition for Extrapulmonary Nontuberculous Mycobacteria Infections**I. Statement of the Problem**

Nontuberculous mycobacteria (NTM) are opportunistic pathogens that can be difficult to treat. While pulmonary NTM infection is a well-recognized cause of illness among those with underlying lung disease, extrapulmonary NTM infections appear to be increasing and are often associated with severe disease and poor outcomes. Extrapulmonary NTM infections are a cause of both sporadic and healthcare-associated infections in the United States. Outbreaks have been associated with medical devices, cosmetic procedures, contaminated parenteral medications, and medical tourism, as well as with community exposures such as tattoo parlors and nail salons. The true burden and incidence of NTM infections is unknown. Extrapulmonary NTM infection is not nationally notifiable and is currently reportable in a few jurisdictions, such as Oregon and Tennessee. Given the insidious nature of extrapulmonary NTM infections, i.e. nonspecific symptomatology and prolonged time between exposure and symptom onset, detecting outbreaks of extrapulmonary NTM infections can be challenging, which poses barriers to the identification and elimination of sources of infection. Establishing a case definition for extrapulmonary NTM infections will help to identify populations at risk and detect outbreaks in a timely manner to allow for early public health intervention.

II. Background and Justification

NTM are Mycobacterial species other than *M. tuberculosis* complex species and *M. leprae*. NTM are generally free-living organisms and are ubiquitous in the environment, particularly soil and water (1). Over 150 NTM species exist. In the U.S., the species most commonly linked to human disease are *M. avium* complex and *M. kansasii*. Other human-pathogenic NTM species include slow-growing species, such as *M. marinum*, *M. xenopi*, *M. simiae*, *M. malmoense*, and *M. ulcerans*, and rapid-growing species such as *M. abscessus*, *M. fortuitum*, and *M. chelonae*. NTM are not typically transmitted from human-to-human. Disease in humans is thought to be acquired from environmental exposures (1).

Pulmonary disease is the most common clinical manifestation of NTM and occurs most frequently among those with underlying lung disease such as chronic obstructive pulmonary disease (COPD), bronchiectasis, and cystic fibrosis. Extrapulmonary NTM infections, however, are less common and include infections with culture-positive specimens obtained from normally sterile body sites. Clinically, these infections present as lymphadenitis (primarily in children), disseminated disease (most commonly in severely immunocompromised patients), and skin and soft tissue infection (usually due to direct inoculation) (2).

Symptoms of NTM infection are dependent on the site of infection. In many instances, onset of symptoms can occur months to years following exposure. Given the long duration to symptom onset and the nonspecific symptomatology of many extrapulmonary NTM infections, diagnosis and treatment are often delayed. Treatment may involve a combination of surgical intervention and extended antibiotic therapy.

Although NTM have historically been considered opportunistic infections, NTM infections are emerging in new settings among immunocompetent individuals (1). Outbreaks of extrapulmonary NTM infections have been reported in a number of settings. In almost all cases, outbreaks are due to the introduction of water sources. Settings with increased risk of NTM infections include tattoo parlors, nail salons, and hot tubs or spas. Outbreaks have also been reported in the healthcare setting due to contaminated water and the ability of NTM to form biofilms in hospital waterlines and on medical devices (3,4). Healthcare setting outbreak examples include surgical site infections among plastic surgery patients (5), injection site abscesses due to contaminated medications, eye infections following Lasik surgery due to operating room humidifier use (6), and cervical lymphadenitis in children undergoing dental procedures due to contaminated dental waterlines (7).

Establishing a standardized case definition for extrapulmonary NTM infections will allow jurisdictions to make NTM infections reportable and lead to more timely outbreak detection and public health interventions to decrease risk of new infections. Because extrapulmonary NTM infections are reportable in Oregon, public health has been able to analyze surveillance data to identify and promptly respond to NTM outbreaks. An example in which a standardized case definition might have led to timely detection of a national outbreak is the identification of NTM-contaminated heater-cooler devices used during cardiac surgery; delayed patient infection identification placed hundreds of thousands of patients at risk for extrapulmonary *M. chimaera* infections over many years (8, 9).

States making NTM reportable will find operational guidance in CSTE's publications library.

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

1. Utilize standard sources (e.g. reporting*) for case ascertainment for extrapulmonary nontuberculous mycobacteria (NTM). Surveillance for extrapulmonary NTM should use the following recommended sources of data to the extent of coverage presented in Table III.

Table III. Recommended sources of data and extent of coverage for ascertainment of cases of extrapulmonary nontuberculous mycobacteria.

Source of data for case ascertainment	Coverage	
	Population-wide	Sentinel sites
Clinician reporting	X	X
Laboratory reporting	X	X
Reporting by other entities (e.g., hospitals, veterinarians, pharmacies, poison centers)	X	X
Death certificates	X	X
Hospital discharge or outpatient records	X	X
Extracts from electronic medical records	X	X
Telephone survey		
School-based survey		
Other _____		

2. Utilize standardized criteria for case identification and classification (Sections VI and VII) for extrapulmonary NTM but do not add extrapulmonary NTM to the *Nationally Notifiable Condition List*. If requested by CDC, jurisdictions (e.g. States and Territories) conducting surveillance according to these methods may submit case information to CDC.

Terminology:

* Reporting: process of a healthcare provider or other entity submitting a report (case information) of a condition under public health surveillance TO local or state public health.

**Notification: process of a local or state public health authority submitting a report (case information) of a condition on the Nationally Notifiable Condition List TO CDC.

IV. Goals of Surveillance

To identify and stop outbreaks of extrapulmonary NTM, as well as to prevent future outbreaks through the recognition and correction of risk factors such as poor infection control practices. Also, to provide information on the temporal, geographic, and demographic occurrence of outbreak-associated extrapulmonary NTM cases.

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

The primary initial source of data will be from laboratory reporting. In states where extrapulmonary NTM is a reportable condition, laboratories should report extrapulmonary NTM cases to public health authorities. Healthcare facilities, clinicians, and infection preventionists who become aware of patients with extrapulmonary NTM should also report these cases to public health authorities. Other data sources (e.g., death certificates or hospital discharge data) may be used as supplementary case-finding methods.

VI. Criteria for case identification

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

In public health jurisdictions where extrapulmonary NTM is classified as a reportable disease or condition, clinicians and laboratories should report to public health authorities any of the following:

Clinical evidence: Clinician-diagnosed NTM infection

Laboratory evidence: A positive culture or molecular evidence, such as polymerase chain reaction (PCR) or 16S ribosomal RNA gene sequencing (16S), of mycobacteria in any sterile body site (including pleural fluid) or in tissue, or wounds

- Exclude cultures or molecular evidence positive for *M. tuberculosis* complex (MTBC) organisms (including *M. tuberculosis*, *M. bovis*, *M. bovis Bacillus Calmette-Guerin*, *M. africanum*, *M. canetti*, *M. microti*, and *M. pinnepedi*), *M. gordonae*, or *M. leprae*
- Exclude cultures or molecular evidence from lower respiratory samples, including: sputum, bronchial alveolar lavage, tracheal aspirate cultures, or lung tissues
- Exclude stool specimens

Standard reporting of laboratory test results is recommended.

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.

Criterion	Extrapulmonary NTM
<i>Clinical Evidence</i>	
Clinician-diagnosed NTM infection	S
<i>Laboratory Evidence</i>	
A positive culture of mycobacteria species in any sterile body site (including pleural fluid), or in tissue or wounds	O
Molecular evidence, such as PCR or 16S, of mycobacteria, in any sterile body site (including pleural fluid) or in tissue or wounds	O
Exclude cultures or molecular evidence positive for <i>M. tuberculosis</i> complex (MTBC) organisms (including <i>M. tuberculosis</i> , <i>M. bovis</i> , <i>M. bovis Bacillus Calmette-Guerin</i> , <i>M. africanum</i> , <i>M. canetti</i> , <i>M. microti</i> , and <i>M. pinnepedi</i>), <i>M. gordonae</i> * or <i>M. leprae</i>	N
Exclude cultures or molecular evidence from lower respiratory samples, including: sputum, bronchial	N

alveolar lavage, tracheal aspirate cultures, or lung tissues.	
Exclude stool specimens	N

Notes: **M. gordonae* is known to be a contaminant in pulmonary specimens. However, less is known about whether *M. gordonae* is more often a pathogen versus a contaminant in extrapulmonary specimens. Rare case reports of *M. gordonae* causing extrapulmonary disease exist. Health jurisdictions may consider including *M. gordonae* isolates from sterile extrapulmonary sites as clinical cases in order to better understand the clinical significance and epidemiology of these isolates. However, the benefit of *M. gordonae* reporting in identifying outbreaks compared to the resources required to investigate these cases is unclear. Therefore, *M. gordonae* is excluded from the proposed case definition.

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 (e.g., clinical evidence and laboratory evidence) in the same column—in conjunction with all "N" criteria in the same column—is required to report a case.

A requisition or order for any of the "S" laboratory tests is sufficient to meet the reporting criteria.

C. Disease-specific data elements

Clinical Information:

None

Laboratory information:

- Mycobacteria species or complex

Epidemiological Information:

None

VII. Case Definition for Case Classification

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

Clinical Criteria

Examples of signs and symptoms of clinical disease include (but are not limited to):

- Fever
- Fatigue
- Weight loss
- Lymphadenopathy
- Surgical site infections
- Wound Infections
- Cellulitis
- Granulomas
- Sepsis
- Failure to thrive
- Osteomyelitis

Laboratory Criteria

Probable Case Laboratory Criteria:

- Positive culture or nucleic acid test (e.g. PCR or 16S) for *Mycobacterium* genus

Exclude cultures from lower respiratory samples, such as: sputum, bronchial alveolar lavage, tracheal aspirate cultures, or lung tissue.

Confirmatory Case Laboratory Criteria:

- Positive culture and identification to the species or complex level of nontuberculous mycobacteria,
or
Positive nucleic acid test specific for a given species or complex of nontuberculous mycobacteria.

Exclude specimens that indicate *M. tuberculosis* complex (MTBC) organisms (including *M. tuberculosis*, *M. bovis*, *M. bovis Bacillus Calmette-Guerin*, *M. africanum*, *M. canetti*, *M. microti*, and *M. pinnepedi*), *M. gordonae*, or *M. leprae*.

Exclude cultures from lower respiratory samples, including: sputum, bronchial alveolar lavage, tracheal aspirate cultures, or lung tissue.

Probable Case:

In a patient with signs or symptoms referable to the area, culture or molecular evidence of infection by a mycobacterial species known not to be an *M. tuberculosis* complex (MTBC) organism but lacking species or complex determination, from at least one of the following extrapulmonary sites:

1. Skin or soft tissue
2. Lymph node
3. Urine
4. A normally sterile body site such as blood, spinal fluid, bone marrow, abdominal fluid, pleural fluid, or bone.

For example, *Mycobacterium* isolates that are PCR negative for MTBC organisms, correspond to probable case classification. MTBC organisms include *M. tuberculosis*, *M. bovis*, *M. bovis Bacillus Calmette-Guerin*, *M. africanum*, *M. canetti*, *M. microti*, and *M. pinnepedi*.

Confirmed case:

In a patient with signs or symptoms referable to the area, nontuberculous mycobacteria species or complex identified in culture or by molecular methods, from at least one of the following extrapulmonary sites:

1. Skin or soft tissue
2. Lymph node
3. Urine
4. A normally sterile body site such as blood, spinal fluid, bone marrow, abdominal fluid, pleural fluid, or bone,

except for *M. gordonae* and *M. leprae* species.

For supplemental information in the form of operational guidance, search CSTE's publications library for "nontuberculous mycobacteria" (https://www.cste2.org/Publications/Extrapulmonary-NTM-PS_Op-Guidance_2017-04-28.docx).

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

Invasive NTM infections often persist for extended periods of time and recurrences can occur after completion of antibiotic therapy. To minimize duplicate counting of chronic infections, illnesses in a given person should be counted no more than once every 24 months, unless a different species is identified.

B. Classification Tables

Table VII-B. Criteria for defining a case of extrapulmonary nontuberculous mycobacterial infection.

Criterion	Probable	Confirmed	
<i>Clinical Evidence</i>			
Fever	O	O	O
Fatigue	O	O	O
Weight loss	O	O	O
Lymphadenopathy referable to the area from which the specimen in which mycobacteria were identified	O	O	O
Surgical site infections referable to the area from which the specimen was obtained, in which mycobacteria were identified	O	O	O
Wound infections referable to the area from which the specimen was obtained, in which mycobacteria were identified	O	O	O
Cellulitis referable to the area from which the specimen was obtained, in which mycobacteria were identified	O	O	O
Granulomas referable to the area from which the specimen was obtained, in which mycobacteria were identified	O	O	O
Sepsis	O	O	O
Failure to thrive	O	O	O
Osteomyelitis referable to the area from which the specimen was obtained, in which mycobacteria were identified	O	O	O
Other infection signs or symptoms referable to the area from which the specimen was obtained, in which mycobacteria were identified	O	O	O
<i>Laboratory evidence</i>			
Specimen from skin, soft tissue, a lymph node, urine or a normally sterile body site (e.g., blood, spinal fluid, bone marrow, abdominal fluid, pleural fluid, or bone)	N	N	N
Positive culture for <i>Mycobacterium</i> genus	O		
Positive nucleic acid test for <i>Mycobacterium</i> genus	O		
Positive culture for mycobacteria, identified to species		O	
Positive nucleic acid test for mycobacteria, identified to species		O	
Positive culture for mycobacteria, identified to complex			O
Positive nucleic acid test for mycobacteria, identified to complex			O
Culture or molecular evidence that the infecting mycobacterial species is not a <i>Mycobacterium tuberculosis</i> complex (MTBC) organism (such as <i>M. tuberculosis</i> , <i>M. bovis</i> , <i>M. bovis Bacillus Calmette-Guerin</i> , <i>M. africanum</i> , <i>M. canetti</i> , <i>M. microti</i> , and <i>M. pinnepedi</i>)	N	N	N
Absence of identification of the mycobacterial species or complex involved	N		
Identification of the mycobacterial species or complex involved		N	N
Exclude <i>M. gordonae</i> * or <i>M. leprae</i> species		N	N

Exclude cultures from lower respiratory samples, such as: sputum, bronchial alveolar lavage, tracheal aspirate cultures, or lung tissue	N	N	N
<i>Criteria to distinguish a new case:</i>			
At least 24 months have lapsed since last reported onset of NTM of the same species in same individual, unless a different species is identified	N	N	N

Notes:

* *M. gordonae* is known to be a contaminant in pulmonary specimens. However, less is known about whether *M. gordonae* is more often a pathogen versus a contaminant in extrapulmonary specimens. Rare case reports of *M. gordonae* causing extrapulmonary disease do exist. Health jurisdictions may consider including *M. gordonae* isolates from sterile extrapulmonary sites as clinical cases in order to better understand the clinical significance and epidemiology of these isolates. However, the benefit of *M. gordonae* reporting in identifying outbreaks compared to the resources required to investigate these cases is unclear. Therefore, *M. gordonae* is excluded from the proposed case definition.

S = This criterion alone is Sufficient to classify a case.

N = All “N” criteria in the same column are Necessary to classify a case. A number following an “N” indicates that this criterion is only required for a specific disease/condition subtype (see below). If the absence of a criterion (i.e., criterion NOT present) is required for the case to meet the classification criteria, list the Absence of criterion as a Necessary component.

O = At least one of these “O” (One or more) criteria in each category (e.g., clinical evidence and laboratory evidence) in the same column—in conjunction with all “N” criteria in the same column—is required to classify a case. (These “O” criteria are alternatives, which means that a single column will have either no O criteria or multiple O criteria; no column should have only one O.) A number following an “O” indicates that this criterion is only required for a specific disease/condition subtype.

VIII. Period of Surveillance

Surveillance should be ongoing.

IX. Data sharing/release and print criteria

Data will be used to detect outbreaks, determine the burden of illness due to extrapulmonary NTM, and characterize trends of illness over time. Data may also enable comparing extrapulmonary NTM cases across jurisdictions.

Data are not currently nationally notifiable, and will not be collected at CDC or any other national agency as a result of the propagation of this case definition. Individual jurisdictions where reporting or surveillance of NTM is mandated should be governed by their own data sharing and usage agreements.

X. Revision History

Past Position Statement Number	Section of Document	Revision Description
17-ID-07	Table VIIB	National Office removed “pleural fluid” from excluded cultures from lower respiratory samples to reflect Section VII narrative (April 2018).

XI. References

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