ASSOCIATION OF PUBLIC HEALTH LABORATORIES

AUGUST 2025

Nontuberculous mycobacteria:

An Emerging Public Health Concern

Nontuberculous mycobacteria (NTM) infections are an increasing public health concern. This document establishes the need to improve the public health response with a proposed addition of NTM to the nationally notifiable conditions list. It also describes the current role of public health laboratories and how their role could be enhanced through better early identification of outbreaks and improved surveillance and disease estimates if submission of isolates to public health was mandated.

Background

The genus *Mycobacterium* includes a broad group of bacteria with varying traits. These differing traits include the potential for pathogenicity in humans and animals; the type of disease, epidemiology and reservoirs and their ability to grow in culture, including growth at different temperatures and at different growth rates. Mycobacteria are slow growers relative to other bacteria—sometimes requiring up to eight weeks to grow in culture. There are four major groupings of mycobacteria:

- *Mycobacterium tuberculosis* complex (MTBC), the causative agent of tuberculosis
- *Mycobacterium leprae*, the causative agent of Hansen's disease (previously referred to as leprosy)
- *Mycobacterium ulcerans*, the causative agent of the tropical disease Buruli ulcer
- NTM

Within NTM there are over 200 distinct mycobacterial species. In North America, the most common NTM isolated from patients with a pulmonary infection are organisms within the *Mycobacterium avium* complex,[1,2] followed by *Mycobacterium abscessus* and its subspecies in the United States (US)[2,3,4] and *Mycobacterium xenopi* in Canada.[5] *Mycobacterium kansasii* has also been frequently reported with a potential geographic bias.[2,6,7] Recent data has shown *M. xenopi* to be decreasing, while *M. avium* is increasing in frequency.[8]

NTM are found naturally and ubiquitously in the environment, particularly in soil and water, and are opportunistic pathogens. Similar to other opportunistic pathogens, NTM can infect anyone but those with underlying health issues and compromised immune systems are at greater risk for infection and severe disease.[9] While most clinical cases present as pulmonary infections, NTM can also infect a wide range of other sites including skin and soft tissues, joints, the lymphatic system and bones (**Table 1, page 6**). The clinical significance of an NTM infection cannot be determined by laboratory data alone but must be considered in conjunction with the clinical presentation of the patient.[10,11] NTM identified from a normally sterile body site are almost always considered clinically significant unless it is a proven environmental contamination. Detection of NTM from other body sites does not always indicate the patient has a disease; for example, *Mycobacterium gordonae* is a common NTM identified in the laboratory but is generally not the cause of clinical disease.[11]

Infections caused by NTM can cause significant illness and lead to outbreaks. While incidence of NTM infections in the US varies by state, the overall prevalence is increasing.[12,13,14] However, the true number of outbreaks for NTM—or even the true burden of disease—is difficult to assess due to challenges with insufficient testing, lack of a comprehensive surveillance system and lack of mandated referral of isolates to public health laboratories. Despite the incomplete data, many outbreaks have been identified in recent years (**Table 2, page 7**), and there is no reason to suspect that incidence is decreasing. In recognition of the growing threat, the US Centers for Disease Control and Prevention (CDC) established an NTM surveillance program through the Emerging Infections Program (EIP) in 2021, which included four states and a population of approximately 13 million persons (4% of the US population).[15] However, this is just the beginning of understanding this complex problem.

An additional challenge with NTM infections is that they can have incubation periods that span many years, which can expose others to NTM for extended periods of time before onset of illness, can require prolonged and expensive treatment, and can be very difficult to trace back to a source for mitigation (if at all possible).[16] NTM can be very difficult to eradicate, as they often form biofilms in the water supply; this is especially problematic in healthcare facilities as it can have impacts throughout the facility. For example, NTM have been identified in sinks and showers, hydrotherapy equipment, ice machines and medical equipment, such as heater-cooler devices and bronchoscopes—many of which have been implicated in outbreaks.

Testing Practices at State Public Health Laboratories

In 2017 an ad-hoc survey of state public health mycobacteriology laboratories was conducted [APHL and Salfinger, unpublished data]. Among the 43 laboratories that responded:

NAAT Testing

- **98% (42) performed nucleic acid amplification tests (NAAT) for MTBC**
- **21% (9) also performed NAAT for NTM, *M. avium* complex**

Speciation Practices

- **58% (25) performed species level identification**
- **37% (16) reported identification of some NTM**
- **2% (1) did not speciate at all**

NTM Identification Methods

- **40% (17) used MALDI-TOF MS**
- **42% (18) used sequencing**
- **2% (1) performed NGS**

Since this survey was conducted, a widely used product was discontinued in 2019. This left a gap in rapid detection of the most common NTM seen in the US, which has been partially filled by increased implementation of MALDI-TOF MS and PCR-based methods.

While NTM cases are not nationally notifiable, outbreaks of any illness, including NTM, are reportable to state and local public health authorities in the US. Therefore, timely detection and species identification are important not only for clinical management but also to track cases and interrupt transmission to avert larger outbreaks. Despite this need, very few clinical laboratories in the US have the resources to characterize *Mycobacterium* spp. to the level needed for recognition of outbreaks and patient management.

The Role of the Public Health Laboratory

Detection and Identification

Historically, there has been a lack of diagnostic capacity and test methods for accurate identification of most NTM species.[17] The biosafety precautions and specialized methods required for processing clinical specimens and mycobacterial identification often limit testing to large clinical laboratories and public health laboratories. Clinical laboratories receive and process patient specimens, including concentrating and staining to visualize any potential mycobacteria or acid-fast bacilli (AFB) that may be present. Some laboratories can also rapidly screen specimens by PCR to detect MTBC and certain common species of NTM. Many clinical laboratories will stop testing at this stage and report these results without further identification or reflexing to culture and/or antimicrobial susceptibility testing (AST).

Public health laboratories play a critical role in performing this testing by collaborating with clinical laboratories in their jurisdiction to obtain specimens for isolation and additional characterization. Most public health mycobacteriology laboratories in the US have a robust workflow including isolation and identification of MTBC and NTM. It is a core function of the mycobacteriology laboratory to identify MTBC (with subsequent identification as *M. tuberculosis*, *Mycobacterium bovis* or *M. bovis* BCG) or NTM as quickly as possible.[17] Many public health laboratories either perform in-house testing or refer isolates to another public health laboratory for identification and phenotypic and genotypic AST for MTBC and clinically significant NTM to inform treatment. Many public health laboratories have implemented MALDI-TOF MS technology to aid in identification to the species level. The use of molecular methods such as next generation sequencing (NGS) for the accurate and timely detection and diagnosis of NTM could also help alleviate present challenges;[18] NGS can provide information on the relatedness of NTM strains to aid in outbreak identification and source detection, significantly improving public health response.[19] There are also situations where identification of subspecies may have clinical importance, as illustrated by an outbreak linked to heater-cooler units in cardiac surgery (*Mycobacterium intracellulare* subspecies *chimaera*).

Surveillance and Outbreak Investigation

There is no formal or comprehensive surveillance for NTM in the US. To better understand the epidemiology of NTM, the CDC EIP conducted a six-month multi-state pilot of population-based NTM surveillance from October 2019—March 2020,[15] counting pulmonary and extrapulmonary cases based on isolation of an organism from culture. During this time, 299 NTM cases were identified, including 231 pulmonary infections, resulting in an overall NTM incidence of 3.8 per 100,000 (3.1/100,000 for pulmonary infections alone).[15] While short in duration, the study highlighted the importance of active, population-based NTM surveillance for monitoring the burden of disease and characterizing affected populations to inform interventions. Surveillance for extrapulmonary NTM (ENTM) continued in 2021 at the EIP sites, where 1.3 ENTM cases per 100,000 persons were identified. These data found that incidence increased with age, was highest in non-Hispanic Blacks and was associated with skin and soft tissue infections.[20] Continued surveillance will be important for getting closer to an accurate estimate of the burden of disease.

One of the main goals of NTM surveillance is to identify and stop outbreaks and to provide information on the temporal, geographic and demographic occurrence of outbreak associated NTM cases.[21] There have been numerous examples of NTM outbreaks associated with medical equipment[22] medical tourism[23,24] tattoo ink[25] and even contaminated hospital water.[26] Outbreak response is a critical function of public health. Even if the pathogen which causes an outbreak is not reportable, the outbreak itself may be reportable. Outbreak identification is performed in public health laboratories for cases of foodborne illness (e.g., PulseNet), healthcare associated infections (e.g., Antimicrobial Resistance Laboratory Network) and influenza, among others. Recognition of an outbreak is facilitated by the reporting of individual cases and characterization of the corresponding isolates. Additional characterization often involves genotyping or genetic sequencing, which is used to demonstrate relatedness between strains, provide information on the genotype of the organism and possible lineage, and can even indicate possible antimicrobial resistance to specific classes of drugs. The acquired data can also help to mitigate future outbreaks through the recognition and correction of risk factors, such as poor infection control practices.

Improving Public Health Response to NTM

Make NTM Nationally Notifiable

As mentioned previously, NTM outbreaks are notifiable, and some information can be gleaned from them—but not all outbreaks involve characterization at a public health laboratory, leaving gaps in our knowledge. Some states have already recognized the utility of this type of surveillance and require laboratory and/or healthcare provider reporting of NTM.[27] Making NTM reportable and nationally notifiable will enable public health officials across the country to collect data, recognize the true burden of NTM disease and have more timely identification of outbreaks, particularly when they cross between states.

As with most other reportable diseases and conditions, laboratory testing data needs to be reviewed in conjunction with the clinical presentation of the patient. This is especially true given that NTM can occur naturally in soil and water. Isolating and identifying NTM and submitting specimens and/or isolates to a public health laboratory will improve public health's ability to identify and respond to outbreaks faster and determine common exposures and potential sources of infections, thereby reducing the possibility of additional cases.

In January 2014, Oregon mandated reporting of ENTM with costs of $6,000 to add NTM to the Oregon reportable diseases list and an estimated annual operating cost of $10,000. In a two-year period (2014–2016), 134 cases were reported including 43 hospitalizations, 18 cases of sepsis and one death. Assisted by this surveillance, public health officials were able to detect and respond to two outbreaks.[16]

Leverage Existing Shared Services

Public health laboratories should coordinate with local clinical and commercial laboratories to ensure isolates or positive clinical specimens are submitted to a public health laboratory for isolation and/or identification and characterization. However, due to the potential variability in incidence of NTM across the country, it may not be realistic for each public health laboratory to perform all necessary NTM testing. One solution for increasing testing support is to utilize established Regional Consortia, which can provide shared workforce development resources, increased capabilities, partnering on funding opportunities and continuity of operations/surge functionality.[28] Alternatively, the public health system could consider establishing reference centers outside of the established consortia to increase overall national capacity.

Environmental Testing Needs

NTM can be present in municipal water systems and difficult to eradicate due to their innate resistance to chlorination.[29] Identifying a reservoir or source of exposure requires testing environmental samples—such as soil or water—as well as unusual specimen types—such as tattoo ink or swabs from medical equipment—and may require modification of typical workflows or SOPs. Any NTM isolated from environmental sources should be sequenced using the same methods used to sequence clinical isolates so the results are directly comparable to assess relatedness.

The US Environmental Protection Agency (EPA) maintains a Contaminant Candidate List (CCL) for drinking water; the drinking water CCL identifies contaminants that are not currently subject to any proposed or promulgated national primary drinking water regulations but are known or anticipated to occur in public water systems. Contaminants listed on the CCL may require future regulation under the Safe Drinking Water Act. EPA uses the CCL to identify priority contaminants for regulatory decision making and information collection needs. *M. avium* and *M. abscessus* are included in the latest Contaminant Candidate List 5 (CCL5).

Challenges

The addition of NTM to the nationally notifiable diseases list presents several challenges, the biggest of which is funding. As NTM are not considered as transmissible or infectious as MTBC, NTM identification is currently unfunded at the federal level and often unfunded at the state and local level. As ubiquitous as NTM are in nature, they are often not fully identified in the clinical laboratory. Many laboratories will test a clinical specimen for the presence of AFB and may use a rapid test, such as a nucleic acid amplification test (NAAT), to detect MTBC and maybe some common NTM, but may not pursue a full identification of less common NTM.

Mycobacterial culture and identification are slow processes. Clinical specimens often require processing such as digestion and decontamination of the specimen to break down human organic material and decrease competing flora prior to performing any screening tests (i.e., AFB smear). This process is ideally performed in a Biosafety Level-3 laboratory or in a Biosafety Level-2 laboratory with Biosafety Level-3 practices and requires trained and competent staff and equipment. Rapid technologies to detect MTBC and certain NTM can be expensive to maintain and often require a large capital expense to purchase an instrument. Bacterial isolation requires specialized media which can be difficult and expensive to purchase and labor intensive to produce in-house. Many laboratories have begun to identify mycobacterial species using MALDI-TOF MS which requires a large capital expense to purchase the instrument plus an extensive validation following optimization of the procedure,[30] but even this method cannot identify all *Mycobacterium* spp.

As shown in workforce surveys, laboratory workforce is shrinking for many reasons.[28] Many mycobacteriology laboratory experts have retired or resigned from their positions, leaving gaps in subject matter expertise and institutional knowledge which cannot be filled. Adding NTM to the nationally notifiable diseases list may open additional necessary funding opportunities such as federal grants or cooperative agreements to support public health laboratories.

Conclusion

NTM are ubiquitous in the environment, are opportunistic pathogens capable of causing a wide variety of diseases and can be the source of significant outbreaks. The limited data we have indicate that the prevalence of pulmonary NTM disease is increasing.[12] To fully understand the burden and recognize outbreaks of NTM disease faster, laboratories should isolate and determine the species of all NTM from clinical specimens. However, a gap in knowledge and resources exists as many laboratories do not fully characterize NTM, nor do they report NTM to public health officials. Laboratory identification of cultured isolates should be completed by trained and competent individuals and isolates should be forwarded to a public health laboratory for further characterization.

Public health laboratories should be funded to fully characterize NTM, including for the purchase of equipment to streamline testing. If it is not feasible for all public health laboratories to maintain competency and proficiency in NTM testing and identification, then referring specimens or isolates to laboratories with the capabilities within their region should be considered. Alternatively, establishing reference centers can be considered.

The addition of NTM to the nationally notifiable diseases list can help to ensure isolates of NTM are forwarded to public health laboratories and reported to public health officials so that prevalence can be determined and outbreaks can be identified faster.

Appendix

Table 1: Diseases caused by NTM and frequently isolated species

Disease		Most Common Mycobacterial Species
Pulmonary Infections	Pulmonary infections, all persons	• *M. avium* complex • *M. abscessus* • *M. kansasii* • *M. xenopi* • *M. malmoense*
	Pulmonary infections in persons with cystic fibrosis	• *M. abscessus* • *M. avium* complex
Extrapulmonary Infections	Skin and soft tissue infections	• *M. marinum* • *M. fortuitum* • *M. chelonae* • *M. abscessus*
	Eye infections	• *M. chelonae* • *M. abscessus*
	Otitis media, mastoiditis	• *M. abscessus* • *M. kansasii* • *M. xenopi*
	Cervical lymphadenitis (mainly in children)	• *M. avium* complex • *M. malmoense*
	Catheter- or device-associated infections	• *M. fortuitum* • *M. abscessus* • *M. chelonae*
	Disseminated disease (with immunosuppression or genetic predisposition)	• *M. avium* complex • *M. kansasii*

Adapted from "Nontuberculous Mycobacterial Disease—A Comprehensive Approach to Diagnosis and Management."[31]

Table 2: Outbreaks of NTM in the US

Title	Facility	Organism (Cases)	Year(s)
Outbreak of nontuberculous mycobacteria joint prosthesis infections, Oregon, USA, 2010-2016[32]	Four hospitals	• *M. goodii* (2) • *M. fortuitum* (8)	• 2010 • 2013-2014
Clusters of nontuberculous mycobacteria linked to water sources at three Veterans Affairs medical centers[33]	Veterans Affairs medical centers	• *M. conceptionense* (41) • *M. porcinum* (4)	• 2012-2017 • 2018
Mycobacterium chimaera infections associated with heater-cooler unit during cardiopulmonary bypass surgery—Los Angeles County, 2012-2016[34]	Hospital	*M. chimaera* (20)	2013-2016
Use of statistical process control methods for early detection of healthcare facility-associated nontuberculous mycobacteria outbreaks: a single-center pilot study[35]	Tertiary care hospital	• *M. abscessus* (58) • *M. abscessus* (105) • *M. avium complex* (165)	• 2013-2014 • 2013-2016 • 2014-2016
Outbreak of tattoo-associated nontuberculous mycobacterial skin infections[25]	Tattoo studio	*M. fortuitum*, *M. abscessus* and *M. chelonae* (38)	2015
Mycobacterium avium pseudo-outbreak associated with an outpatient bronchoscopy clinic: lessons for reprocessing[36]	Outpatient clinic, tertiary care hospital	*M. avium* (N/A)	2015-2016
Invasive *Mycobacterium abscessus* outbreak at a pediatric dental clinic[37]	Pediatric dental clinic	*M. abscessus* subsp. *abscessus* (71)	2016
A bronchoscopy-associated pseudo-outbreak of *Mycobacterium mucogenicum* traced to use of contaminated ice used for bronchoalveolar lavage[38]	Tertiary care hospital	*M. mucogenicum* (15)	2017
Hospital water contamination associated with pseudo-outbreak of *Mycobacterium porcinum*—Wisconsin, 2016-2018[26]	Hospital	*M. porcinum* (16)	2017-2018
Mycobacterium porcinum skin and soft tissue infections after vaccination—Indiana, Kentucky, and Ohio, September 2018—February 2019[39]	Contractor providing vaccinations at workplaces	*M. porcinum* (101)	2018-2019
A bronchoscopy-associated pseudo-outbreak of *Mycobacterium chelonae* and *Mycobacterium mucogenicum* associated with contaminated ice machine water and ice[40]	Teaching community hospital	*M. chelonae* and *M. mucogenicum* (15)	2019
A cluster of three extrapulmonary *Mycobacterium abscessus* infections linked to well-maintained water-based heater-cooler devices[41]	Tertiary care hospital	*M. abscessus* (3)	2020
Nontuberculous mycobacteria infections after cosmetic surgery procedures in Florida—nine states, 2022-2023[42]	Plastic surgeon office	*M. abscessus* (15)	2020-2023
Mycobacterium abscessus outbreak related to contaminated water among ventilator-dependent residents of a pediatric facility[43]	Ventilator-dependent residents of a pediatric facility	*M. abscessus* (3)	2022

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Association of Public Health Laboratories

The Association of Public Health Laboratories (APHL) works to strengthen laboratory systems serving the public's health in the US and globally. APHL's member laboratories protect the public's health by monitoring and detecting infectious and foodborne diseases, environmental contaminants, terrorist agents, genetic disorders in newborns and other diverse health threats.

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This project was 100% funded with federal funds from a federal program of $1,241,161. This publication was supported by Cooperative Agreement #NU60OE000104 from the US Centers for Disease Control and Prevention (CDC). Its contents are solely the responsibility of the authors and do not necessarily represent the official views of CDC.