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Transmission of *Mycobacterium tuberculosis* to Healthcare Personnel Resulting From Contaminated Bone Graft Material, United States, June 2021–August 2022

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Abstract

A nationwide tuberculosis outbreak linked to a viable bone allograft product contaminated with *Mycobacterium tuberculosis* was identified in June 2021. Our subsequent investigation

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Supplementary Data

Supplementary materials are available at *Clinical Infectious Diseases* online. Consisting of data provided by the authors to benefit the reader, the posted materials are not copyedited and are the sole responsibility of the authors, so questions or comments should be addressed to the corresponding author.

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identified 73 healthcare personnel with new latent tuberculosis infection following exposure to the contaminated product, product recipients, surgical instruments, or medical waste.

Keywords

tuberculosis; bone transplantation; healthcare-associated infections; surgical procedures; contact investigation

A multistate tuberculosis (TB) outbreak linked to a viable bone allograft product contaminated with *Mycobacterium tuberculosis* was identified in June 2021 [1,2]. Bone tissue retrieved from a deceased donor with undiagnosed TB disease was implanted into 113 patients during orthopedic surgeries at 35 hospitals and ambulatory surgical centers in 18 US states. At least 83 (73%) recipients developed extrapulmonary TB disease at a surgical site, and 27 (24%) had pulmonary disease. Fifty-five (50%) were rehospitalized, and 48 (43%) underwent further surgeries.

Within healthcare settings, *M. tuberculosis* is a known hazard. Transmission can be prevented through administrative measures, environmental controls, and respiratory protection [3]. Although extrapulmonary TB is rarely contagious, transmission of *M. tuberculosis* from cutaneous, muscular, and genitourinary lesions has been documented in hospital settings [4–6]. Both the high bacillary load within tuberculous wounds and the hydrophobic nature of *M. tuberculosis* bacilli can lead to aerosolization during wound manipulation or disposal of liquid wound drainage [7,8]. This outbreak added concerns about potential novel transmission routes, including exposures to the contaminated product itself or to infected surgical sites. To characterize the full extent of the nationwide outbreak, we investigated *M. tuberculosis* transmission from bone graft recipients to healthcare personnel (HCP).

METHODS

On 8 June 2021, the Centers for Disease Control and Prevention (CDC) recommended contact investigations with post-exposure testing in healthcare settings where the 113 patients sought care. Based on observations of patient care during the initial cluster investigation in Delaware [1] and CDC guidelines [9], CDC defined exposed HCP as those present during surgical implantation with the contaminated bone graft, revision surgeries, or during provision of inpatient or outpatient medical care during which they shared airspace or had contact with patients with infectious TB without appropriate CDC-recommended airborne precautions for patients with pulmonary disease and airborne and contact precautions for patients with draining tuberculous wounds. The CDC provided an outbreak-specific healthcare risk assessment to assist in the evaluation of HCP potentially exposed through novel exposures (Supplementary Materials). Recommended screening included a TB symptom screen and, for HCP with no known history of TB disease or latent TB infection (LTBI), a tuberculin skin test (TST) or interferon-gamma release assay (IGRA) [10].

In July 2021, the Indiana Department of Health requested assistance in prioritizing HCP contacts for screening. The CDC provided onsite assistance at 2 affected hospitals within health network A. We observed storage, delivery, and use of uncontaminated bone graft product in spinal fusion and other orthopedic surgeries, instrument reprocessing, and patient care. Medical records did not include documentation of all HCP who may have performed or assisted with relevant activities (eg, wound care). Therefore, health network A expanded the contact investigation to include screening of broad categories of potentially exposed HCP based on occupational roles and spatial and temporal overlap with TB patients not continuously maintained under recommended transmission-based precautions.

In September 2021, the CDC requested that state health departments in the 18 affected states voluntarily report all HCP contact investigations associated with the bone graft product. Data requested included aggregate counts routinely reported by state health departments to the CDC [11,12]: cases investigated and contacts identified, evaluated, and diagnosed with LTBI or TB disease. Affected health departments and healthcare facilities used medical charts and staff rosters to identify HCP contacts for TB testing. We did not require submission of the type of testing (ie, IGRA or TST) or prior TB testing results; however, we actively sought information regarding prior results for HCP reported as testing positive during these contact investigations.

RESULTS

Contact Investigations at 46 Facilities Nationwide

State health departments shared HCP contact investigation data received from 31 (89.0%) of the 35 acute care or ambulatory surgical centers that had performed the initial bone graft implantations. Of the 31 centers, 26 (83.8%) reported the locations of HCP exposures; 16 (62.5%) did not extend the HCP contact investigation beyond the operating suite and post-anesthesia care units. Additionally, 15 other healthcare facilities that cared for affected patients following their surgery submitted data: 5 skilled nursing facilities, 4 acute care facilities, 3 home health agencies, 2 free-standing inpatient rehabilitation centers, and 1 hospice care facility.

In total, 5985 HCP were identified as exposed (Table 1). As of April 2022, 4884 (81.6%) HCP had been screened, with 73 (1.5%) testing positive for TB infection; all were determined to have LTBI and all reported prior negative testing for *M. tuberculosis* infection. The primary locations at which HCP who tested positive had been exposed included operating suites (9 of 919, 1.0%), sterile processing departments (3 of 133, 2.3%), post-anesthesia care units (4 of 272, 1.5%), inpatient or long-term care units (35 of 2655 1.3%), and other/unknown locations (22 of 905, 2.4%).

Contact Investigations at Health Network A

Among the 5985 exposed HCP nationwide, 2197 (36.7%) were identified at the 2 affected hospitals within health network A in Indiana. Among these 2197 exposed HCP, 33 (1.5%) were evaluated and found to have LTBI; all had previous negative TB testing within 1 month to 5 years. Of the 33 HCP with newly identified LTBI in this network, 15 (45.4%) had

exposures limited to surgical sites, wounds, or grossly contaminated procedural or surgical equipment.

Assessment of Exposures and Infection Prevention and Control Practices

Onsite assessments at 3 affected facilities (1 in Delaware and 2 in Indiana) identified multiple novel routes of potential HCP exposure to *M. tuberculosis*. These included stirring graft matrix in an open container prior to surgical implantation, irrigating infected surgical wounds during revision surgeries, rigorous flushing and brushing of cannulated surgical instruments during decontamination, generating a forceful stream of surgical wound drainage to empty Jackson-Pratt drains, flushing of liquid drainage in an open hopper, and the absence or intermittent use of transmission-based precautions during wound and routine care of patients with draining tuberculous surgical wounds.

DISCUSSION

This investigation identified more than 5000 potential TB exposures and 73 latent TB infections among HCP linked to a contaminated bone graft product, expanding the estimated scope and burden of this unprecedented outbreak [2]. Our findings suggest that at least 15 of 73 infections (20.5%) resulted from unusual extrapulmonary exposures, including draining tuberculous wounds and grossly contaminated procedural or surgical equipment.

To our knowledge, this is the largest contact investigation to date involving *M. tuberculosis* transmission from extrapulmonary sources. For 58 of the 73 HCP with new LTBI diagnoses, transmission could not be attributed to extrapulmonary vs pulmonary sources since multiple exposures were possible. We do not know the background or expected annual incidence of LTBI among HCP within all 46 facilities in this investigation. Annual TB screening for HCP is no longer recommended for most healthcare facilities [13], and LTBI is not a nationally reportable condition. However, LTBI is a reportable condition in Indiana, where 4 new LTBI diagnoses were reported among HCP in the county of health network A during the 2 years before this outbreak. This suggests that the 33 HCP with new LTBI identified during this investigation represent a substantial increase above baseline that was at least partially attributable to exposures during the outbreak.

The risk of TB infection in our investigation, 1.5%, might appear low. During a typical contact investigation for an infectious pulmonary TB case, approximately 20% of identified dose contacts develop LTBI [12]. Previous investigations of healthcare-associated *M. tuberculosis* transmission from draining wounds and abscesses have found the risk of tuberculin skin test conversion of 4%–19% among exposed contacts [4–7]. There are several potential explanations for our relatively low observed infection rate. Our investigation took place during a time of recommended universal masking for HCP due to the coronavirus disease 2019 pandemic, which might have attenuated *M. tuberculosis* transmission. In addition, the number of exposed HCP was likely substantially overestimated. For example, in health network A due to imprecise documentation of exposures, broad categories of HCP were tested. Last, the overall 1.5% risk encompasses a heterogeneous set of exposures, some of which are likely of higher risk than others. Some HCP were exposed to contaminated bone allograft once during surgery, while others were repeatedly exposed during patient

care activities, particularly when airborne precautions were not implemented consistently for those with draining tuberculous wounds.

This investigation had limitations. Despite distribution of a HCP risk assessment, our exposure definition was not applied homogeneously across all 46 healthcare facilities that submitted contact investigation data. Some might have inadvertently included persons without exposure to *M. tuberculosis* due to difficulties identifying HCP who were truly exposed, while others investigated only the surgical staff exposed during the initial graft implantations. Four surgical facilities did not share data from their investigations. As a result of these limitations, we have likely underestimated both the number and percentage of exposed HCP who were infected during this outbreak. Finally, we did not consistently receive information about the type of TB testing (TST or IGRA) or quantitative test results. However, when the pretest probability is moderate or high, as is true for any contact with recent exposure to an infectious TB case, the positive predictive value of both TSTs and IGRAs is high. Thus, we believe the positive tests among contacts in this investigation are more likely to represent true-positives than false-positives.

Our findings reinforce the importance of adhering to the CDC's recommendations for the maintenance of airborne and contact precautions for patients with draining tuberculous wounds in healthcare settings. In situations where novel or unusual exposures are implicated, collaboration between public health authorities and healthcare facilities is essential for timely and effective implementation of appropriate infection control measures and contact investigations.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments.

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Table 1.
Tuberculosis Testing for Exposed Healthcare Personnel by Location of Exposure, 46 Healthcare Facilities, 2021

Healthcare Personnel	Total	Operating Suite	Sterile Processing	Post-Anesthesia Care	Inpatient or Long-Term Care Unit	Other ^d /Unknown
Exposed	5985	1150	189	303	3116	1227
Tested > 8 wk after last exposure (% of total exposed) ^b	4884 (82%)	919 (80%)	133 (70%)	272 (90%)	2655 (85%)	905 (74%)
Latent tuberculosis infection ^c (% of tested)	73 (1.5%)	9 (1.0%)	3 (2.3%)	4 (1.5%)	35 (1.3%)	22 (2.4%)

The 46 healthcare facilities included 35 acute care and ambulatory surgical centers, 5 skilled nursing facilities, 3 home health agencies, 2 inpatient rehabilitation facilities, and 1 hospice facility.

^aOther locations include personnel at home health agencies, inpatient rehabilitation facilities and those who work on multiple units such as environmental services, radiology, or respiratory therapy.

^bTuberculin skin test or interferon-gamma release assay.

^cPersonnel had at least 1 negative tuberculin skin test or interferon-gamma release assay in the previous 1 month to 5 years. There were no cases of tuberculosis disease among exposed healthcare personnel.