



# BULLETIN 23-6

## Requirements and Recommendations for Reducing Risk of Mycobacterium tuberculosis Transmission

**AUGUST 7, 2023**

AATB is issuing this Bulletin to update and clarify our current understanding of the risk of transmission of *Mycobacterium tuberculosis* (MTB) from our tissue donor population. AATB accredited establishments and their Medical Directors must comply with the requirements in this Bulletin and are advised to review the recommendations set forth within it. The requirements in this Bulletin will be fully in effect September 4, 2023.

**FREQUENTLY ASKED QUESTIONS (FAQS) REGARDING AATB BULLETIN 23-6 ABOUT MTB (/MTB\_FAQ) -**

*updated August 18, 2023*

**PHYSICIANS COUNCIL MTB WORKING GROUP- INTERIM MYCOBACTERIUM TUBERCULOSIS (MTB) DONOR SCREENING REQUIREMENTS**

([HTTPS://ATTENDEE.GOTOWEBINAR.COM/RECORDING/7188335876338384384](https://attendeegotowebinar.com/recording/7188335876338384384)) (<https://attendeegotowebinar.com/recording/7188335876338384384>) WEBINAR RECORDING ([HTTPS://ATTENDEE.GOTOWEBINAR.COM/RECORDING/7188335876338384384](https://attendeegotowebinar.com/recording/7188335876338384384)) (<https://attendeegotowebinar.com/recording/7188335876338384384>) - August 21, 2023

**UNIFORM DONOR RISK ASSESSMENT INTERVIEW ADDENDUM TO ASSIST WITH SCREENING FOR RISK OF MTB (/SITES/DEFAULT/FILES/2023/ADDENDUM\_FOR\_A\_UNIFORM\_DRAI\_MTB\_2023\_08\_02.PDF)**

### A. BACKGROUND

In May 2021, a tuberculosis (TB) outbreak was linked to a contaminated bone graft product containing live cells used in spinal surgery:

[https://www.cdc.gov/mmwr/volumes/70/wr/mm7036a4.htm?s\\_cid=mm7036a4](https://www.cdc.gov/mmwr/volumes/70/wr/mm7036a4.htm?s_cid=mm7036a4) ([https://www.cdc.gov/mmwr/volumes/70/wr/mm7036a4.htm?s\\_cid=mm7036a4](https://www.cdc.gov/mmwr/volumes/70/wr/mm7036a4.htm?s_cid=mm7036a4))

While the investigation of the 2021 transmission events was ongoing, the AATB Physicians Council worked with an independent contractor to review the literature and the information available at the time. This culminated in an advisory Bulletin (**AATB Bulletin 22-2 (/bulletin-22-2)**) published March 22, 2022) along with a **companion document**

(<https://www.aatb.org/sites/default/files/2022/AATB%20Mtb%20Nerac%20Literature%20Review%20122921.pdf>) with more medical and scientific details.

In August 2022, **Schwartz**

(<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9605268/>), et al published the

details of the investigation and findings. In May 2023, further investigation of additional transmission to healthcare workers was published by Li, et al. In September 2022, after review of details provided in the Schwartz et al manuscript, the Physicians Council formed a Working Group. This group has been meeting on an ongoing basis, at least twice a month, to carefully consider the Mycobacterium tuberculosis (MTB) science and medical literature, and develop more specific and binding requirements for AATB members regarding screening potential donors for MTB.

In July 2023, the same tissue processor announced **another investigation** (<https://www.aziyo.com/aziyo-biologics-announces-voluntary-recall-of-viable-bone-matrix-products/>) of post-surgical MTB infections in two patients treated with viable bone matrix products from a different single donor lot.

Due to the urgency of putting into place donor screening requirements regarding MTB for AATB members, the Physicians Council MTB Working Group has deemed it necessary to publish the current consensus donor screening requirements that represent the highest risks for tissue transplantation, particularly among products containing viable cells.

Please see **AATB Bulletin 22-2 (/bulletin-22-2)** and the references below for additional information about MTB.

## B. REQUIREMENTS

Potential donors with the following are ineligible to donate **tissues**:

1. Individuals with a history (ever) of tuberculosis disease (sometimes referred to as “active” or “clinically active” tuberculosis)
2. Individuals with a history of latent tuberculosis infection initially diagnosed within the past two (2) years (i.e., the individual has had a positive test for tuberculosis).

Note: Tests for tuberculosis include TB skin test (other names used interchangeably—TST, PPD or Mantoux) and Interferon Gamma Release Assay (IGRA) blood tests (e.g., QuantiFERON-TB Gold, T-SPOT).

Potential donors with the following are ineligible to donate **tissues containing viable cells** (i.e., all products comprising or containing tissues that are processed in a manner to retain live cells—including reproductive cells)

1. Exposure to an individual with tuberculosis disease in the past 2 years
2. Latent tuberculosis infection > 2 years ago, i.e., positive TB test > 2 years ago
3. Chronic renal failure on dialysis
4. Age > 65
5. Solid organ transplant recipients

Below are additional risk factors for MTB exposure or reactivation or both. Medical directors are urged to strongly consider all the MTB risk factors in combination, and along with any clinical signs, symptoms, or radiological evidence of MTB during review of donor eligibility:

Individuals with history of

1. Birth, travel, or residence >3 months cumulative in a country with most current available tuberculosis incidence of >20 (rate per 100,000 population), available on WHO TB country profile website:

**[https://worldhealthorg.shinyapps.io/tb\\_profiles/](https://worldhealthorg.shinyapps.io/tb_profiles/)  
([https://worldhealthorg.shinyapps.io/tb\\_profiles/](https://worldhealthorg.shinyapps.io/tb_profiles/))**

2. Homelessness, or residence or employment in a homeless shelter
3. Residence or employment in a long-term care facility
4. Incarceration or employment in a jail/prison
5. Diabetes mellitus
6. Alcoholic liver disease or cirrhosis
7. Use of TNF alpha inhibitors and other immunosuppressive drugs

These risk factors, among many issues including testing, are still under review by the Physicians Council MTB Working Group.

### C. CONCLUSION AND IMPLEMENTATION

It is the consensus of the MTB Physicians Council Working Group that the combined required donor exclusions and consideration of the additional risk factors above should reduce the risk for transmission of MTB via tissues.

While additional recommendations and/or requirements are anticipated in the future, along with a Standards Compliance Supplement, the recommendations in this Bulletin are not anticipated to change and should be implemented as soon as possible, and **no later than 4 weeks after publication of this Bulletin**. An MTB addendum to the UDRAI was developed by the Physicians Council to obtain additional information regarding MTB risk factors. It is attached to this Bulletin if your establishment would like to use it for this purpose, but is not mandatory. Establishments may utilize their current process to obtain the additional information described in this Bulletin.

If you have questions, please contact **[standards@aatb.org](mailto:standards@aatb.org)** (**<mailto:standards@aatb.org>**).

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