MED- 1612	Tuberculosis Disease – Medical Management Procedure
Version No.	1
Content Owner	Vikand Technology Solutions, LLC.

1. Purpose

To detail the requirements for the medical management of patients with suspected Tuberculosis disease (TB).

2. Responsibilities

2.1 Doctor

- Ensure the Medical Department staff is fully compliant with relevant jurisdictional medical aspects of the United States Centers for Disease Control and Prevention (CDC) (**http://www.cdc.gov/tb/publications/guidelines/**) the attached National Institute for Health and Clinical Excellence (NHS) clinical guidelines for the diagnosis, treatment and management of TB.
- Ensure full compliance with international and jurisdictional health reporting requirements.
- Ensure crew members are advised of procedures to follow for reporting symptoms of acute and chronic respiratory diseases.
- Participate as a member of the Outbreak Management Team
- Attachment: **TB Clinical Quick Reference Guide NHS**

2.2 Medical Staff

- On board surveillance of TB, disease management and record keeping.

3. Process

3.1 Clinical Case Definitions of Acute Respiratory Disease

- Suspected or confirmed communicable or potentially communicable pulmonary or laryngeal TB disease is confirmed through the following:
- Smear-positive sputum for Acid Fast Bacilli (AFB)
- Nucleic Acid Amplification (NAA) positive or culture positive for Mycobacterium TB from sputum, bronchio-alveolar lavage, gastric aspirate, lung tissue or other tissue of the respiratory tract such as the larynx or epiglottis.
- Chest radiograph, computed tomography scan, or clinical findings indicative of pulmonary TB sufficient to require treatment with anti-TB medications.
- Chest radiograph or respiratory symptoms improve while taking anti-TB medication**.**
- Respiratory symptoms indicative of pulmonary TB until a diagnostic evaluation is completed to rule out TB as a cause of symptoms

3.2 TB Surveillance

- All cases of TB, both suspected and confirmed, must be recorded with the TB Screening Form or entered into SeaCare (if available).

3.3 Tuberculin Skin Testing (TST)

- The Mantoux tuberculin skin test (TST) is used to detect LTBI, recent TB infection (as shown by conversion of the Mantoux from negative to positive) and as part of the diagnosis of TB disease.
- Mantoux TST is not recommended for individuals who have had a past Mantoux reaction of 15 mm or greater or in people who have had previous TB disease.
- Testing guidelines for determining a positive TST reaction are as follows:
    - An induration of 5 or more millimeters is considered positive in:
        - HIV-infected persons who report recent close contact with an individual with confirmed TB disease (with or without BCG-vaccination).
        - Individuals with fibrotic changes on chest radiograph consistent with prior TB.
        - Individuals with organ transplants
        - Individuals who are immunosuppressed (e.g., taking the equivalent of >15 mg/daily of prednisone for 1 month or longer, taking TNF antagonists).
    - An induration of 10 or more millimeters is considered positive in:
        - Crew who reside in high-prevalence countries, including persons born in Asia, Africa, the Caribbean, and Latin America.
        - Injection drug users
        - Children <4 years of age
        - Infants, children, and adolescents exposed to adults in high-risk categories.
    - Medical staff must follow the attached NHS Mantoux Test Guidelines when conducting a TST.
    - All ships should have at least 10 doses of PPD available at all times.
        - Attachment: **Mantoux Test Guidelines NHS**

3.4 Blood Test

- For patients with HIV and CD4 counts between 200-500 cells/mm 3.0, conduct an iGRA test alone or an IGRA test with a concurrent Mantoux test.

3.5 Close Contact Definition

- A close contact is defined as an individual who has had prolonged exposure to a guest or crew with suspected or confirmed communicable or potentially communicable TB.
- The probability of TB infection occurring depends not only on the intensity of the exposure (air volume and circulation), but also on the frequency and duration of the exposure. Prolonged exposures of at least 8 hours in continuous proximity are considered significant to establish close contact. For example, this includes cabin mates, sexual partners, and co-workers in immediate proximity to the index case at an adjacent workstation.
- Casual contacts and work mates who do not work in continuous close proximity to the index case are not considered close contacts.

- Guests/passengers who have at least 8 hours of close direct contact with an index case may also be considered close contacts.

3.6 Close Contact Tracing

- All contacts that meet the definition of close contact with the index case must be recorded on the Contact Tracing Log or SeaCare (if available).
- Isolated extra-pulmonary TB and LTBI are not communicable. Initiate a close contact investigation for index patients with confirmed or suspected pulmonary, laryngeal, or pleural TB in the following circumstances:
    - The patient has an AFB smear or culture positive sputum and has cavitation associated with TB. Where sputum samples have not been collected, positive results from other respiratory specimens (e.g., gastric aspirates or broncho-alveolar lavage) may be interpreted in the same way as AFB.
    - AFB are not detected by microscopy of three sputum smears, a contact investigation is still recommended if the chest radiograph indicates the presence of cavitation in the lung.
    - An individual with AFB smear positive TB is considered to have been contagious during the 3 month period prior to onset of symptoms or smear positive testing, whichever is earliest.
- Contact investigations should not be initiated for index patients who have suspected TB disease but who have minimal findings in support of a diagnosis of pulmonary TB, including suspected cases with:
    - A negative CXR
    - If AFB is smear or culture positive, however an approved NAA test (Amplified Mycobacterium tuberculosis Direct Test [MTD], GenProbe, Amplicor Mycobacterium tuberculosis Test) for Mycobacterium tuberculosis is negative.
- Guidelines for contact investigations can be found at: (**http://www.cdc.gov/mmwr/pdf/rr/rr5415.pdf**)

3.7 Testing Close Contacts

- Identify close contacts within 3 days of diagnosing a suspected or confirmed index case of TB.
- Perform a Mantoux TST in contacts with previously negative TST results.
- Perform an IGRA test in crew whose Mantoux testing shows positive results.
- Test all contacts for HIV using the rapid test or a shoreside testing facility where a rapid test is unavailable.
- When a contact's exposure to the index TB patient has occurred within <8-10 weeks, repeat testing 8-10 weeks after the most recent exposure.

3.8 Isolation

- Isolate all suspected or confirmed cases of communicable TB (pulmonary, pleural and laryngeal TB) in the Medical Center, to a single ward, in order to prevent transmission of disease to others. Attempt to assign the patient to a ward furthest from other patients. Keep the door to the ward closed.

- Advise the patient of the importance of covering his/her nose and mouth when coughing or sneezing.
- Fit the patient with respiratory protective equipment (e.g., surgical mask) when transferred outside of the isolation room. For example, when transferred through public spaces, taken to X-ray, and when disembarked. Do not use an N-95 mask, as surgical masks prevent respiratory secretions from entering the environment.
- Advise disembarking crew members to wear a surgical mask when in public, and to remain isolated (in a hotel room, or at home) until evaluated by a communicable disease specialist for assessment and treatment.
- PPE, including N-95 mask, gloves and apron, should be worn at all times by medical staff when interacting with communicable TB cases.
- Practice frequent hand washing, particularly between patient interactions. Alcohol hand gels are also effective but should not replace hand washing.
- Wash and replace uniforms as soon as practical after interaction with a TB patient.
- Advise all workers to wear N-95 masks that are in enclosed spaces with the infected patient, such as transport, security, and escort personnel.
- Screen Medical Staff with significant exposure to respiratory secretions.

3.9 Latent Tuberculosis Infection (LTBI)

- LTBI is an infection with Mycobacterium tuberculosis bacteria, as evidenced by a significant reaction to a Mantoux tuberculin skin test or positive interferon gamma release assay (IGRA).
- A person with LTBI is non-communicable.
- LTBI occurs between 4-12 weeks after exposure, and this can be confirmed by a demonstrable primary lesion or conversion of the tuberculin skin test but may not be communicable. The majority of patients who ultimately develop communicable TB will do so within the first five years after LTBI.

3.10 LTBI Treatment

- Unless there is a documented TST greater than 5mm, or evidence of prior treatment for LTBI, treat asymptomatic patients for LTBI, if there are no physical findings of TB disease and:
    - Positive TST (>10mm) or IGRA
    - Normal chest radiograph
    - A smear and culture negative respiratory specimen result
- The treatment regimen for LTBI includes a short-course therapy with rifampin plus isoniazid. The short course combination therapy can be used in patients who are HIV+ if they are healthy and not on anti-retroviral therapy.
- The three month regimen includes rifampin 900mg 3 times per week plus INH 900mg 1 time per week for 3 months (12 doses).
- Perform baseline liver enzymes and CBC prior to treatment. Monitor liver enzymes regularly in those with regular alcohol use, HIV+, and patients with underlying liver disease.
- Check for drug interactions before initiating therapy.

- Perform a pregnancy test in female patients. Combination therapy should not be used for pregnant women.
- Directly observe therapy weekly in the Medical Center.
- Discontinue INH-RPT if a serum aminotransferase is >5 times the upper limit of normal.
- Additional information on LTBI treatment can be referenced at: https://www.cdc.gov/mmwr/volumes/67/wr/mm6725a5.htm?s_cid=mm6725a5_w

3.11 Notification and Reporting

- Notify Shoreside leadership and Vikand by email of all confirmed or suspected cases of TB disease.
- In discussion with Vikand, further land-based clinical evaluation and treatment may be requested.
- Reporting of TB cases externally and to Health Authorities is dependent on the type of TB diagnosed, as well as the ship's itinerary.

4. Records

4.1 The following records must be maintained in accordance with Company record retention policy:

- TB Screening Form
- TB Contact Tracing Log