Clinical Guideline for Tuberculosis Management in a Hospital Setting

<table>
<thead>
<tr>
<th>Post holder responsible for Procedural Document</th>
<th>Judy Potter, Lead Nurse Infection Control</th>
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<tbody>
<tr>
<td>Author of Guideline</td>
<td>Mel Burden, Infection Prevention &amp; Control Nurse Specialist</td>
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<tr>
<td>Division/ Department responsible for Procedural Document</td>
<td>Specialist Services/ Infection Control</td>
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<tr>
<td>Contact details</td>
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<td>Date of original guideline</td>
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<td>Impact Assessment performed</td>
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Please specify standard/criterion numbers and tick ✓ other boxes as appropriate

### Monitoring Information

<table>
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<td>Maintain Operational Service Delivery</td>
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<tr>
<td>Integrated Community Pathways</td>
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<td>Develop Acute Services</td>
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<td>Delivery of Care Closer to Home</td>
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### CQC Fundamental Standards Regulations No:

12

### Other (please specify):

Note: This document has been assessed for any equality, diversity or human rights implications

Controlled document

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**Associated Trust Policies/ Procedural documents:**

Source Isolation Policy

**Key Words:**

Tuberculosis  
Multi-Drug Resistant TB  
Pulmonary  
Mycobacterium

**In consultation with and date:**

Infection Prevention & Control Team: 16th November 2015  
Consultant Microbiologists: 16th November 2015  
Respiratory Consultants: 16th November 2015  
Infection Control Operational Group: 8th February 2016

**Review Date**  
November 2018

**Contact for Review:**  
Lead Nurse

**Executive Lead Signature:**  
N/A
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1. Introduction

1.1 Tuberculosis (TB) remains a major international public health concern, even though the global incidence rate is reportedly declining. A total of 6,520 cases of TB were notified in England in 2014, a rate of 12.0 per 100,000 (PHE, 2015). As in previous years, almost three quarters of TB cases (73%) occurred among people born outside the UK with only 15% of these being recent migrants (diagnosed within two years of entering the UK). TB remains concentrated in the most deprived populations; in 2013, 70% of cases were resident in the 40% most deprived areas, nearly half (44%) of cases were not in employment and 10% had at least one social risk factor (history of alcohol or drug misuse, homelessness or imprisonment).

1.2 TB is caused by a bacterium called Mycobacterium tuberculosis. TB can affect any part of the body but is most common in the lungs and lymph glands.

1.3 All forms of active TB in the UK are statutory notifiable under the Health Protection (Notification) Regulations 2010, to the Consultant in Communicable Disease Control (CCDC) (PHE), either by the physician making the diagnosis or the laboratory if there is a positive investigation. Suspected TB cases should also be notified if commenced on anti-TB treatment as they can subsequently be de-notified if required i.e. if an alternative diagnosis is confirmed.

2. Purpose

2.1 The purpose of this guideline it to ensure that patients who may have tuberculosis are identified and managed correctly in order to:

- Ensure measures are taken to prevent transmission to healthcare workers (HCW), and other patients
- Direct optimal medical management including use where appropriate of antibiotics
- Alert relevant Public Health Agencies

3. Definitions

3.1 Open Cases of Pulmonary TB

3.1.1 TB disease most commonly affects the lungs; this is referred to as pulmonary TB.

3.1.2 Pulmonary TB producing sputum that is positive on direct microscopy smears (auramine phenol stain for Acid and Alcohol Fast Bacilli – AAFB) may transmit infection by droplet nuclei and should be regarded as highly infectious. Sputum microscopy is processed within one working day of reaching the designated laboratory with culture taking up to 12 weeks. Three sputum samples from three consecutive days are required for AAFB microscopy and culture with a specific request for AAFBs on medway or microbiology request form. Patients whose bronchial washings are positive on direct smear but negative on sputum smear are usually less infectious. However, if their sputum becomes positive following bronchoscopy, if they are in contact with immunocompromised patients or are suspected of having multi-drug resistant tuberculosis (MDRTB), they should be regarded as being infectious. Patients whose bronchial washings are positive on direct smear who cannot produce sputum for microscopy and culture are considered to be less infectious as they are presumed to have no productive cough. Patients with AAFB smear negative pulmonary tuberculosis are also not regarded as highly infectious. Patients with laryngeal TB should be managed as open cases.
3.2 Closed cases of Pulmonary TB

3.2.1 This includes those who are sputum smear negative but culture positive. Unlike open pulmonary TB there is negligible risk of transmission as the inflammation is on the lungs’ periphery and not inside.

3.3 Extra Pulmonary TB

3.3.1 Extra pulmonary TB disease occurs in places other than the lungs, including the larynx, lymph nodes, the pleura, the brain, the kidneys, or the bones and joints. In HIV-infected persons, extra pulmonary TB disease is often accompanied by pulmonary TB. Persons with TB pleural effusions may have underlying pulmonary TB that is masked on chest radiograph because the effusion fluid compresses the lung. These patients should be considered infectious until pulmonary TB disease is excluded. Those with extra pulmonary TB disease are usually not infectious unless they have:

- Pulmonary disease in addition to extra pulmonary disease
- Extra pulmonary disease located in the oral cavity or the larynx
- Extra pulmonary disease that includes an open abscess or lesion in which the concentration of organisms is high, especially if drainage from the abscess or lesion is extensive, or if drainage fluid is aerosolised

3.4 Latent TB

3.4.1 Tubercle bacilli have a thick waxy coat, are slow growing and can survive in the body for many years in a dormant or inactive state. In this instance people are infected, but non-infectious and show no signs of TB disease, this is called latent TB. Those with Latent TB Infection (LTBI) have M. tuberculosis in their bodies, but do not have TB disease and cannot spread the infection to other people. A person with LTBI is not regarded as having a case of TB and therefore does not require isolation. LTBI may reactivate in later life; particularly if an individual's immune system has become weakened, for example by disease (e.g. HIV), certain medical treatments (e.g. cancer chemotherapy, corticosteroids) or in old age. In some people, the tubercle bacilli overcome the immune system and multiply, resulting in progression from LTBI to TB disease (see section 3.1).

3.5 Disseminated (including Miliary) TB

3.5.1 Miliary TB occurs when tubercle bacilli enter the bloodstream and disseminate to all parts of the body, where they grow and cause disease in multiple sites. This condition is rare but serious. Miliary TB may be detected in an individual organ including the brain; in several organs; or throughout the whole body. If large numbers of TB bacilli are detected in the lungs the patient may have open TB and would need isolation until confirmed otherwise. The need for isolation should be maintained until open TB has been excluded.

3.6 Non-Tuberculous Mycobacterium (NTM)

3.6.1 Other species of mycobacterium causing clinical disease have been identified are referred to by the collective name Non-Tuberculous mycobacteria (NTM). NTM infections can occur throughout the body. However, pulmonary infections, lymphadenitis, and skin and soft tissue infections are the most commonly described. The most common organisms associated with pulmonary disease are the Mycobacterium avium complex (MAC) and M. abscessus. NTM infections are of particular importance in patients who are awaiting or
have undergone lung transplantation and those with cystic fibrosis (please refer to Trust Infection Control Guidance for Patients with Cystic Fibrosis).

3.6.2 Although the exact route of NTM infection is not established with certainty, it is very likely that the organism is ingested, inhaled, or implanted. Infection control measures are based on the NTM species and potential patient groups at increased risk of infection, therefore please seek advice from the IPC Team.

4. Duties and responsibilities

4.1 The Chief Executive and Board of Directors are responsible for ensuring the provision of suitable and sufficient resources and facilities to enable effective management of a patient admitted with tuberculosis.

4.2 The Directors of Infection Prevention and Control (DsIPC) are responsible for:
Providing expert guidance and advice to the Infection Prevention and Control Team, clinical and managerial staff about measures needed to protect staff, patients and members of the public from infection.

4.3 The nursing staff in the clinical area / ward in which a patient who may have tuberculosis is recognised, are responsible for ensuring that appropriate actions with regards to the implementation of source isolation and/or other infection control interventions are implemented.

4.4 The clinician responsible for care is responsible for referring the person with diagnosed TB to a physician with training in, and experience of, the specialised care of people with TB for treatment and follow up i.e. respiratory physician.

4.5 The respiratory physicians are responsible for the medical management of patients diagnosed with tuberculosis or the supervision of the medical management of patients with tuberculosis and are the only medical staff who should prescribe anti-tuberculous treatment so anyone with a diagnosis of TB must be referred for treatment and follow up.

4.6 The Respiratory Nurse Specialist is responsible for the follow up of any contacts with significant exposure

4.7 The Infection Prevention & Control Team are responsible for advising on infection control measures, especially on the correct use and, where necessary, use of personal protective equipment, including FFP3 masks.

4.8 The Infection Control Doctor and Consultant Microbiologists are responsible for providing advice on the diagnosis of tuberculosis and use of antibiotics. Where appropriate they will liaise with specialist reference diagnostic laboratories.

4.9 The Occupational Health Physician is responsible for ensuring that process are in place to screen an vaccinate new employees who may be required to have contact with patients with tuberculosis in accordance with the Immunisation and Screening Policy.

4.10 Patient Flow Manager and Site Management Team are responsible for organising patient movements to negative pressure isolation rooms on the isolation ward (Torridge ward) if this is assessed as necessary.
4.11 **Isolation Ward (Torridge Ward) staff** are responsible for ensuring that patients are managed in an appropriate negative pressure isolation room if this is assessed as necessary.

4.12 All staff required to have contact with patients are responsible for ensuring that they are compliant with the Staff Screening and Immunisation policy.

5. **Reporting**

5.1 All TB cases are reported via the on-line Enhanced Tuberculosis Surveillance (ETS) by the respiratory nurse specialising in TB. A report is then created which is signed by the Physician making the diagnosis and subsequently sent to the CCDC (PHE). A copy is also placed in the patient's medical notes. All patients with TB must be under the care of a respiratory or infectious diseases physician with treatment supervised by them.

6. **Treatment**

6.1 Once a diagnosis of TB is made, the clinician responsible for care should refer the patient with TB to a physician with training in, and experience of, the specialised care of people with TB, as per the [British Thoracic Society Guidelines](#) (2011).

6.2 The only people in the hospital who should prescribe anti-tuberculous treatment are respiratory physicians; therefore anyone with a diagnosis of TB must be referred for treatment and follow up. There is always a respiratory physician on call for advice or clinical review; close liaison with a TB nurse specialist is essential. This is to ensure appropriate dosing and regimens, while minimising the risk of serious drug reactions and ensuring appropriate follow up with those with TB and NTM infection.

7. **Patient Risk Groups**

7.1 Anyone exposed to TB bacteria can become infected but people at particular risk are those that are less able to fight infection. These include:

- Household and frequent contacts of infectious cases
- Those who have lived in, travelled to or receive visitors from places where there is a high incidence of TB
- Those who live in ethnic minority communities originating from places where there is a high incidence of
- Those with immune systems weakened by HIV infection
- The very young and the elderly, as their immune systems are less robust
- Those with chronic poor health and nutrition because of lifestyle problems such as homelessness, drug abuse or alcoholism
- Those who are in or have been in prison
- Those living in poor or crowded housing conditions, including those living in hostels
- Other conditions that suppress immunity such as renal failure and chemotherapy
- Those with diabetes as this increases the likelihood of reactivation of TB
8. Transmission

8.1 Tubercle bacilli are transmitted in the air when they are expelled in very small droplets from an infectious person with pulmonary or laryngeal TB. Activities that can generate infectious aerosols include coughing and sneezing and are defined in section 5.2 of this policy. As these droplets evaporate, minute airborne particles consisting of viable tubercle bacilli remain and continue to drift in normal air currents for prolonged periods. These are known as “droplet nuclei” and are tiny enough when inhaled to escape removal by the ciliated epithelium in the upper respiratory passages. The risk of infection diminishes as the distance from the source patient increases due to dilution of infectious droplet nuclei in the air. The risk of infection from TB from other sites is minimal, but may follow accidental inoculation.

9. Infection Control Precautions for Open TB (where MDRTB is not suspected or confirmed)

9.1 Isolation

9.1.1 Known or suspected cases of sputum smear positive TB must be admitted to a single room with en-suite facilities as soon as possible. Ideally patients with AAFB positive sputum should be nursed in negative pressure isolation rooms, such as those on Torridge ward. However, the availability of negative pressure single rooms is limited and therefore patients are likely to be nursed in side rooms on any ward (excluding Yeo and Yarty), under the care of a respiratory physician. Doors must be kept closed with appropriate isolation signage in place.

9.1.2 Known or suspected paediatric cases within the RD&E hospital must be isolated in a side room on Bramble Green ward. It is essential that the doors to the side rooms and the lobby are kept closed (except when persons need to enter or leave the rooms). When there is a child with known or suspected open pulmonary TB in one of these side rooms, the other side room should be left vacant. Immunocompromised children, or those with particular respiratory risk i.e. cystic fibrosis, must not be cared for in the adjoining side rooms.

9.2 Personal Protective Equipment (PPE)

9.2.1 Patients should receive training and supplies to ensure that they cough into tissues or cover their mouths when tissues are not available. The risk of staff acquiring infection is low and a single use disposable Filtering Face Piece (FFP3) mask along with gloves and aprons are not required for routine care such as administration of medication, clinical observations, medical ward rounds, venepuncture and cannulation.

9.2.2 FFP3 masks are the only FFP class acceptable to the Health & Safety Executive (HSE) for use against aerosols in healthcare in the UK. They should be worn only if performing aerosol generating procedures (AGP). These include:

- Induction of sputum
- Cardio-pulmonary Resuscitation (CPR)
- Intubation, extubation and suctioning
- Bronchoscopy
- Dental procedures
- High frequency oscillating ventilation
- Non Invasive Ventilation – BIPAP and CPAP
• Surgery and post mortems involving high speed devices

9.2.3 FFP3 masks should be applied and removed as per manufacturer’s instructions. Before using an FFP3 it must be verified that each user has a mask suitable for their face shape and that they can put it on such that it leaves no gaps between the mask and their face for air to pass through unfiltered. This process is known as fit testing. It is a HSE legal requirement that those required to use FFP3 masks are fit tested by a competent person, that the results are satisfactory and those results are recorded and available for inspection. If fit testing is required please contact the Infection Prevention and Control Team (IPCT). FFP3 masks are disposable, single use items and following use must be disposed of as clinical waste.

9.2.4 Inpatients with smear positive pulmonary TB should be asked (with explanation) to wear a surgical face mask whenever they leave their room to attend another department within the Trust where patient activity occurs until they have had two weeks of appropriate drug therapy. (Please discuss with IPCT if clarification is required).

9.2.5 In summary:
• FFP3 masks required for AGP only
• Gloves and aprons are not routinely required for direct contact and cleaning (limited to standard precautions only)

9.3 Duration of Isolation

9.3.1 If hospital care is required patients with open pulmonary TB must be isolated until discharge or until all of the following have been achieved:
• two weeks of effective drug therapy
• tolerance of the prescribed treatment
• ability and agreement to adhere to the prescribed treatment
• signs of clinical improvement

9.3.2 If patients are transferring to areas where they may come into contact with HIV positive or immunocompromised patients they must have at least three negative sputum microscopy smears taken on separate occasions over a minimum of 14 days in addition to above.

10. Suspected or Confirmed Multi Drug Resistant TB (MDRTB) and Extensively Drug Resistant TB (XDRTB)

10.1 MDRTB is caused by organisms resistant to the most effective anti-TB drugs, isoniazid and rifampicin. These drugs are considered first-line drugs and are used to treat most persons with TB disease.

10.2 XDRTB is a relatively rare type of drug-resistant TB and is resistant to isoniazid and rifampicin, plus any fluoroquinolone and at least one of three injectable second-line drugs.

10.3 A risk assessment for drug resistance should be made for each patient with TB, based on the following risk factors:
• History of previous TB drug treatment
• Failure to respond clinically to treatment with standard anti-tuberculosis therapy or remain culture positive after 4th month of treatment
● Contact with a known case of MDRTB
● HIV infection
● Birth or residence in a foreign country, particularly high incidence countries.
● Residence in London or other UK areas with more than 40 cases per 100,000 per year

11. Infection Control Precautions for Suspected or Confirmed MDRTB and XDRTB

11.1 Isolation

11.1.1 All patients, including children, with suspected or confirmed MDRTB must be admitted to a lobbied negative pressure ventilation room on Torridge ward at the Royal Devon & Exeter Hospital, with continuous pressure monitoring (magnehelic gauge). The pressure differentials must be monitored and recorded once a day by the nursing staff. If the gauge is registering neutral or positive pressure, with the doors and windows closed, this must be reported to the estates department for urgent investigation.

Whilst awaiting transfer to Torridge ward, patients should be admitted to single rooms with en-suite facilities. Wards should be avoided where there are immunocompromised, respiratory or HIV positive patients.

11.2 Personal Protective Equipment (PPE)

11.2.1 FFP3 respirator masks must be worn by all staff and visitors during all patient contact whilst the patient is considered infectious

11.2.2 In summary:

● FFP3 face masks required for ALL patient contact & on entry to the side room
● Gloves and aprons are not routinely required for direct contact and cleaning (limited to standard precautions only)

11.3 Duration of isolation

11.3 If patients have MDRTB, precautions must only be discontinued after consultation with both the respiratory and infection control teams.

12. TB and Staff

12.1 All staff should be aware of their tuberculin status. BCG vaccination will be offered to healthcare workers, irrespective of age, who fulfil all the following criteria:

● Previously unvaccinated (that is, without adequate documentation or a characteristic scar)
● Will have contact with patients or clinical materials.
● Are negative on Mantoux or Interferon Gamma Release Assay (e.g. Quantiferon) test negative.

12.2 All staff in contact with patients with open pulmonary TB should be aware of the following principles:

● The importance of BCG immunisation as a basic protection
• The need to report to Occupational Health or senior ward staff if they are unusually susceptible e.g. a transplant recipient taking immunosuppressive therapy, HIV positive.
• The extremely low risk of occupationally acquired tuberculosis where appropriate precautions are taken.
• The need to report any symptoms suggestive of tuberculosis to the Occupational Health Department.

12.3 Staff in contact with open pulmonary TB do not normally need follow up. A decision on this will be made by the Occupational Health Department in conjunction with a Consultant Microbiologist or Consultant Respiratory Physician.

13. Follow up of patients exposed to TB

13.1 The Infection Control Team will liaise with the Respiratory Nurse Specialists. Lists of patients in contact with a smear positive pulmonary case will be compiled. The contacts should be recorded in the patient’s notes and for each contact an assessment should be made of the degree of contact. In discussion with the Consultant in Respiratory Medicine, a decision will be made as to the level of follow up that is appropriate for each patient. This will depend on the infectiousness of the source, the susceptibility of the patient and the nature of contact. When appropriate the patients GP, and if necessary other healthcare providers should be informed.

14. Terminal Cleaning

14.1 Terminal cleaning of the patient’s room is required on discharge. Please see terminal cleaning policy.

15. Pathology Specimens

15.1 Specimen containers and request forms for sputum and other potentially infectious material e.g. vomit, pus or tissue must be labelled with danger of infection stickers, and clinical details must indicate TB.

16. Archiving Arrangements

16.1 The original of this guideline will remain with the author, who is the Lead Nurse/ Director for Infection Prevention and Control (DIPC). An electronic copy will be maintained on the Trust intranet, Tuberculosis management in hospital. Archived electronic copies will be stored on the Trust's "archived policies" shared drive, and will be held indefinitely. A paper copy (where one exists) will be retained for 10 years.

17. Process for Monitoring Compliance with and Effectiveness of the Guideline

17.1 To monitor compliance with this guideline, the auditable standards will be monitored as follows:

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<tr>
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<td>All in-patients, including children, with</td>
<td>Case records</td>
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</table>
2. All patients with a diagnosis of tuberculosis will be referred to a physician with training in, and experience of, the specialised care of people with TB. | Case records

17.2 Frequency
On a case by case basis as part of routine review of infectious patients. Any concerns will be discussed by the IPCT at routine meetings and if relevant reported to ICOG. Significant incidents will be included in the DIPC annual report.

17.3 Undertaken by
Infection Control Nurses

17.4 Dissemination of Results
At the Infection Control Operational Group which is held quarterly and at the Infection Control and Decontamination Assurance Group and the relevant Divisional Governance Groups if there is failure to comply with the guidance.

17.5 Recommendations/ Action Plans
Implementation of the recommendations and action plans will be monitored by the Infection Control and Decontamination Assurance Group, which meets quarterly. Any barriers to implementation will be risk-assessed and added to the risk register. Any changes in practice needed will be highlighted to Trust staff via the Governance Managers’ cascade system.

18. References


APPENDIX 1: EQUALITY IMPACT ASSESSMENT TOOL

Name of document | Tuberculosis Management in a Hospital Setting
---|---
Division/Directorate and service area | Trust Wide
Name, job title and contact details of person completing the assessment | Judy Potter, Lead Nurse/Director Infection Prevention and Control
Date completed: | 1st February 2016

The purpose of this tool is to:

- **Identify** the equality issues related to a policy, procedure or strategy
- **Summarise the work done** during the development of the document to reduce negative impacts or to maximise benefit
- **Highlight unresolved issues** with the policy/procedure/strategy which cannot be removed but which will be monitored, and set out how this will be done.

1. **What is the main purpose of this document?**
   To provide a framework for treatment and management of patients with measles.

2. **Who does it mainly affect?**
   Carers ☐  Staff ✓  Patients ✓  Other (please specify)

3. **Who might the policy have a ‘differential’ effect on, considering the “protected characteristics” below?** (By differential we mean, for example that a policy may have a noticeably more positive or negative impact on a particular group e.g. it may be more beneficial for women than for men)

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4. Apart from those with protected characteristics, which other groups in society might this document be particularly relevant to (e.g. those affected by homelessness, bariatric patients, end of life patients, those with carers etc.)?

All patient groups but particularly those listed in section 3 of the guideline.

5. Do you think the document meets our human rights obligations? ✓

Feel free to expand on any human rights considerations in question 6 below.

A quick guide to human rights:

- **Fairness** – how have you made sure it treats everyone justly?
- **Respect** – how have you made sure it respects everyone as a person?
- **Equality** – how does it give everyone an equal chance to get whatever it is offering?
- **Dignity** – have you made sure it treats everyone with dignity?
- **Autonomy** – Does it enable people to make decisions for themselves?

6. Looking back at questions 3, 4 and 5, can you summarise what has been done during the production of this document and your consultation process to support our equality / human rights / inclusion commitments?

- There were no concerns that may be relevant to equality or human rights identified during the creation of this guideline
- The Infection Control Operational Group, Infection Control & Decontamination Assurance Group, Occupational Health and the Policy Expert Panel were involved in this review.
7. If you have noted any ‘missed opportunities’, or perhaps noted that there remains some concern about a potentially negative impact please note this below and how this will be monitored/addressed.

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<td>Group that will be responsible for ensuring this carried out:</td>
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