MYCOBACTERIUM TUBERCULOSIS (TB) PROCEDURE
INFECTION PREVENTION AND CONTROL MANAGEMENT WITHIN CARDIFF AND VALE UNIVERSITY HEALTH BOARD HOSPITALS.

Documents to read alongside this Procedure
- Infection Control Procedures on:
  - Isolation
  - Infectious Incidents and Outbreaks
  - Hand Decontamination

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1. SUMMARY

1.1 All forms of TB are notifiable- clinicians must report all suspected cases to the TB Clinical Nurse Specialist (TB CNS 02920335121) (7.1) who will notify the Consultant in Communicable Disease Control (CCDC 02920402478)

1.2 Unless there is a clear clinical or socioeconomic need, such as homelessness, people with TB at any site of disease should not routinely be admitted to hospital for diagnostic tests or care.

1.3 The Infection Prevention and Control Department (IPCD) should also be notified of any suspected or diagnosed case within a Health Board hospital. (7.2)

1.4 Adult patients requiring admission with suspected or diagnosed open pulmonary disease should be transferred to a single room ideally on a respiratory ward (UHW B7 or UHL West 6) or the infectious disease ward (A7) whenever possible.

1.5 Patients with smear positive pulmonary disease can be considered non-infectious after two weeks of treatment for drug-susceptible tuberculosis. (8.2.1).

1.6 Patients with suspected or confirmed Multiple Drug Resistant Tuberculosis (MDR-TB) must be transferred to the negative pressure room in the Infectious Disease Unit (ward A7, UHW). (8.4). FFP3 masks need to be used when entering this room. Please note fit testing is required before FFP3 masks are used. Please ensure that staff are trained in the use of these masks.

1.7 Healthcare workers caring for patients with confirmed TB do not need to use masks, gowns or barrier nursing techniques UNLESS MDR-TB is suspected OR aerosol generating procedures are being performed. (Appendix 4)

1.8 Smear negative pulmonary patients can be nursed on open ward unless there are immunocompromised patients present. (8.5)

1.9 Patients with non-pulmonary tuberculosis may be nursed on an open ward. (8.6)

1.10 Assessment of staff contacts of smear positive pulmonary tuberculosis patients will be carried out by the TB Nurse Specialist in-conjunction with the IPCD Department, local Public Health Officers (CCDC) and OH.
2. INTRODUCTION

2.1 In 2006, The National Institute for Health and Clinical Excellence (NICE) developed guidelines for TB, ‘Clinical diagnosis and management of tuberculosis, and measures for its prevention and control’. This guidance was updated in 2011.

2.2 Overall numbers, rates and geographical distribution UK & Wales:
In 2011 in the UK, a total of 8,963 cases of tuberculosis (TB) were reported, a rate of 14.4 cases per 100,000 population. TB notifications and rates increased until 2005, and have remained high but relatively stable since. As in previous years, London accounted for the highest proportion of cases in the UK (39%, 3511/8963) and the highest rate of disease (44.9 cases per 100,000; 95% CI 43.4-46.4). The main burden of disease remains concentrated in large urban areas (HPA TB Annual Report 2012).

In 2010, 154 cases of tuberculosis (TB) were reported to the enhanced TB surveillance system in Wales (5.1 per 100,000 population). This represents a 29% decrease in the number of cases reported in 2009 (218). The TB rates varied between Local Health Boards (LHBs) with the highest rate of 10.3 per 100,000 population in Cardiff and Vale LHB (ETS Annual Report for Wales 2010).

2.4 All forms of tuberculosis are notifiable; clinicians must report all suspected cases to the TB Nurse Specialist (02920335121) who will notify the Consultant in Communicable Disease Control (CCDC 02920 402478). Failure to notify in some circumstances could lead to action for medical negligence. This ensures appropriate advice is given, close contacts are identified to be screened and epidemiological data is collected (section 7).

3. AIMS

3.1 To provide appropriate advice to staff for the prevention and management of tuberculosis at all UHB hospitals based on current NICE guidance.

4. OBJECTIVES

4.1 To describe the actions required on the admission of a patient known or suspected to have tuberculosis.

4.2 To describe the actions required when a case develops in a UHB hospital.
4.3 To provide advice on the action required during an infectious incident or outbreak situation caused by tuberculosis (see also the UHB Infection Control Procedure for Infectious Incidents and Outbreaks).

4.4 To provide advice on the communications necessary whenever a cluster of cases of tuberculosis develops amongst patients and/or staff.

5. SCOPE

5.1 Cardiff And Vale University Health Board accepts its responsibility under the Health and Safety at Work Act etc. 1974\(^5\) and the Control of Substances Hazardous to Health Regulations 2002\(^6\), to take all reasonable precautions to prevent exposure to tuberculosis in patients, staff and other persons working at or using its premises.

5.2 In order to prevent the possible spread of tuberculosis amongst patients and staff it is recognised that the UHB requires a procedural document to ensure effective management of infection. This is especially necessary in the case of an infectious incident/outbreak, as detailed in the UHB Infection Control Procedure for Infectious Incidents and Outbreaks.

6. ROLES AND RESPONSIBILITIES

6.1 Cardiff and Vale UHB Board is responsible for the approval of the Infection Control Procedure for *Mycobacterium tuberculosis* in UHB Hospitals 2013.

6.2 Individual directorates will be responsible for the implementation of the procedure document in clinical areas.

6.3 Distribution of the procedure will be through the UHB intranet site.

6.4 The Integrated TB service roles and contact details are shown in appendix 5.

7. NOTIFICATION OF TUBERCULOSIS

7.1.1 All forms of TB are notifiable - clinicians must report all suspected cases to the TB CNS (02920335121) who will notify the Consultant in Communicable Disease Control (CCDC 02920 402478). The TB nurse specialist in Cardiff and Vale UHB will then ensure the patient is officially notified on the Enhanced TB Surveillance System (ETS). This is used to monitor tuberculosis control and includes treatment outcome monitoring. Failure to
notify in some circumstances could lead to action for medical negligence.

7.1.2 The Infection Prevention and Control Department (IPCD) must also be informed. This will ensure that the appropriate infection control procedures are implemented at ward level.

7.1.3 The TB nurse specialist will be available to give advice and education to both the patient and staff, they will also ensure close household contacts are identified that may need TB screening.

7.1.4 Most staff will only require a ‘one-off’ reminder of TB signs and symptoms following a TB incident (infectious patient) on the ward. An assessment of staff close contacts will be made by the TB CNS in-conjunction with IPCD, the Occupational Health Department (OHD) and local Public Health Officers. The ward manager/nurse-in-charge will be given a letter and ward staff contact list to complete (Appendix 1a and 1b), which is then sent to occupational health department.

8. CONTROL MEASURES

8.1 The method of isolation/precautions used for patients with tuberculosis depends on the type of disease diagnosed see appendix 4 (CAV Infection Control). This includes a risk assessment for MDR-TB.

8.1.1 Unless there is a clear clinical or socioeconomic need, such as homelessness, people with TB at any site of disease should not routinely be admitted to hospital for diagnostic tests or care.

8.1.2 If admitted to hospital with suspected pulmonary TB, patients should be given a single room on a respiratory ward (West 6 UHL and B7 UHW) or a single room on A7 (UHW). This is imperative if the ward has known immunocompromised patients.

8.2 SUSPECTED OR CONFIRMED OPEN (SPUTUM SMEAR AFB POSITIVE) PULMONARY DISEASE

8.2.1 Patients admitted with suspected open pulmonary disease require isolation in a single room (as section 8.1.2).

8.2.2 Smear positive patients without risk factors for MDR-TB (Appendix 4) should be cared for in a single room, until:

- they have completed two weeks of standard treatment regimen or
- they are discharged from hospital (NICE 2006 & 2011)
8.2.2 If a patient on a general ward is diagnosed as having infectious tuberculosis after having been there for several days, the IPCD should be contacted to make an initial assessment of risk to other patients. If required a further risk assessment will be made jointly by the IPCD, TB CNS, TB Consultant and CCDC (TB Incident Team), this is to determine patient TB exposure risk and if patient TB screening is required. If patient contacts require TB screening this will be organised and completed by the TB Clinical Nurse Specialist’s.

8.2.3 Assessment of staff contacts of smear positive pulmonary tuberculosis patients will be carried out by the TB Nurse Specialist in-conjunction with the IPC Department, local Public Health Officers (CCDC) and OH.

8.2.4 Any visitors to a child with TB in hospital should be screened as part of contact tracing, and kept separate from other patients until they have been excluded as a source of infection. The TB CNS can arrange this screening.

8.2.5 Housekeepers cleaning the room are not at particular risk but should have had their BCG status established. Normal housekeeping procedures should be carried out, including terminal cleaning on discharge of the patient.

8.3.6 Patients with smear-positive pulmonary TB must wear a surgical mask whenever they leave their single room, and to go to other departments.

8.2.7 Healthcare workers caring for people with confirmed TB and where no other respiratory infections are suspected should not use masks, gowns or barrier nursing techniques UNLESS: MDR TB is suspected (Appendix 4) OR Aerosol-generating procedures are being performed (eg chest physiotherapy). Standard infection prevention and control procedures do still apply.

8.2.8 The door of the room should be kept closed at all times unless the clinical need of the patient dictates otherwise.

8.2.9 Crockery and cutlery can be treated as for any other patient and no extra precautions are required for linen etc. Infected material and other clinical waste should be disposed of into an infected “clinical waste” bag (HTM 07-01 Safe Management of Healthcare Waste 2006).

8.3 MULTIPLE DRUG RESISTANT TUBERCULOSIS (MDR-TB)

8.3.1 Patients with suspected or confirmed multiple drug resistant tuberculosis must be transferred to a negative pressure room on the Infectious Diseases Unit (Ward A7 UHW).

8.3.2 Staff and visitors entering the room of a confirmed or suspected case of MDR-TB should wear a specialised FFP3 mask (see appendix 4). Staff need to be fit tested to wear these masks (H+S requirement).
8.3.3 The patient should remain in isolation in a negative pressure room until assessed to be safe for discharge by a TB clinician.

8.3.4 Before the decision is made to discharge a patient with suspected or known MDR TB from hospital, secure arrangements for the supervision and administration of all anti-TB therapy should have been agreed with the patient, carers and TB Nurse Specialist.

8.3.5 The decision to discharge a patient with suspected or known MDR TB should be discussed and planned with the TB clinician and TB Nurse Specialists.

8.3.6 Crockery and cutlery can be treated as for any other patient and no extra precautions are required for linen etc. Infected material and other clinical waste should be disposed of into an infected “clinical waste” bag (HTM 07-01 Safe Management of Healthcare Waste 2006).

8.4 CONFIRMED (SPUTUM AFB SMEAR NEGATIVE) PULMONARY DISEASE

8.4.1 The patient may be nursed on the open ward unless there are immunocompromised patients (section 8.8) on the same ward in which case the patient should be placed in a side room. If aerosol-generating procedures are to be performed (e.g. bronchoscopy) the patient should be isolated during the procedure.

8.6 NON-PULMONARY TUBERCULOSIS

8.6.1 The patient may be nursed on the open ward

8.7 INFANTS BORN TO MOTHERS WITH INFECTIOUS TUBERCULOSIS

8.7.1 Infants born to mothers who have infectious TB should receive chemoprophylaxis for six weeks and then be TB (tuberculin) tested. Specialist advice should be sought from the TB CNS and TB Lead for Paediatrics before starting treatment. These will arrange the TB preventative treatment and TB testing.

8.8 TB PATIENTS ADMITTED TO A SETTING WHERE CARE IS PROVIDED FOR PEOPLE WHO ARE IMMUNOCOMPROMISED

TB patients should not be admitted to a setting where care is provided for people who are immunocompromised (e.g. Haematology/oncology wards, solid organ transplant wards). TB patients may be admitted to the infectious
disease ward (which may contain HIV+ patients) but only to a negative pressure room.

Patients should be considered Infectious and, if sputum smear-positive at admission, should stay in a negative pressure room (A7-UHW) until:

1. the patient has had at least two weeks of appropriate multiple drug therapy, and
2. if moving to accommodation (inpatient or home) with people who are immunocompromised, including those who are HIV-positive, the patient has had at least three negative microscopic smears on separate occasions over a 14 day period, and
3. the patient is showing tolerance to the prescribed treatment and an ability and agreement to adhere to treatment, and either
4. any cough has resolved completely, or
5. there is a definite clinical improvement on treatment, for example remaining afebrile for a week.

For people who are sputum smear negative at admission (that is, three negative samples were taken on separate days; samples were spontaneously produced sputum if possible or lavage if sputum samples were not possible): all of 1, 2, 3 and 5 above should apply.

9. TRANSFER OF PATIENTS

9.1 As with all Infection Control matters, the Nurse-in-charge of the ward has the responsibility to ensure that the necessary information regarding an infectious patient is passed on to a senior member of the receiving ward/department, prior to transfer.

9.2 WITHIN THE HOSPITAL

9.2.1 Patients with sputum that is AFB smear negative pulmonary and non-pulmonary tuberculosis do not present a problem for the receiving ward. When transfers of this type take place the receiving ward must be informed of the patient’s current status prior to transfer.

9.2.2 AFB smear positive pulmonary tuberculosis patients should be transferred, whenever possible, to the Infectious Diseases Unit (Ward A7 UHW) and should only be discharged from this unit to another ward in the hospital when the consultant-in-charge of the patient is satisfied that they are no longer infectious.
9.2.3 Immediate clinical need may occasionally necessitate patient movement outside the Infectious Diseases Unit. If this is necessary then patients should wear a surgical mask during transfer. Further advice is available from the IPCD.

9.3 VISITS TO OTHER DEPARTMENTS AND SURGICAL OPERATIONS

9.3.1 Visits of smear-negative pulmonary and non-pulmonary tuberculosis cases to other departments should be kept to a minimum. When there is a need arrangements must be made with the senior staff of the department concerned prior to transfer. Patients should be seen at the end of the working session and should spend the minimum time in the department.

9.3.2 Patients with smear-positive pulmonary tuberculosis must not visit other departments, unless there is an overriding clinical need. If they do need to visit another department, the patient should wear a surgical mask when outside the isolation room.

9.4 TRANSFER TO OTHER HOSPITALS

9.4.1 Smear positive pulmonary tuberculosis patients should only be transferred to other units / hospitals / Health Boards / Trusts following full communication of the patient’s infectious status and acceptance by the receiving units / hospitals / Health Boards / Trusts that they are aware of the diagnosis and have appropriate facilities for the patient. Prior arrangements will have to be made with the ambulance service for transfer of an infectious patient. No transfer should take place unless all parties, especially in the case of MDR-TB, have agreed these arrangements. For smear-negative or non-pulmonary tuberculosis transfer can take place much more readily; but the receiving ward must be notified of the patient’s status prior to transfer.

9.5 AMBULANCE TRANSPORTATION

9.5.1 The ambulance service must be notified prior to transfer of any patient with suspected or confirmed open pulmonary tuberculosis, especially MDR-TB. Further information for the ambulance service can be obtained from the Consultant in Communicable Disease Control (CCDC 029 20 402478).

10. HEALTH CARE PERSONNEL

10.1 PRE-EMPLOYMENT

10.1.1 Employees new to the NHS who will be working with patients or clinical specimens should not start work until they have completed a TB screen or health check, or documentary evidence is provided of such screening in the last 12 months.
10.1.3 Employees new to the NHS who will have contact with patients should not start work if they have signs & symptoms of TB.

10.1.4 Health checks for employees new to the NHS who will have contact with patients or clinical materials should include:

- assessment of personal or family history of TB

- symptoms and signs enquiry/questionnaire

- documentary evidence of TB testing and/or BCG scar check by an Occupational Health professional, not relying on the applicant’s personal assessment

- Mantoux result within the last 5 years if available

10.2 TB SCREENING & BCG VACCINATION

10.2.1 New employees from the UK or countries with low TB incidence:

10.2.2 Offer a Mantoux test to new NHS employees who will be in contact with patients or clinical materials if the employees:

- Are not new entrants from high-incidence countries and
- Have not had BCG vaccination (for example they are without scar, other documentation or reliable history)

10.2.3 If Mantoux test is negative, refer to the Green Book for BCG immunisation guidance. An individual risk assessment for HIV infection needs to be made before BCG vaccination is given

10.2.4 If the Mantoux test is positive, offer an Interferon-gamma test and inform the TB Service. If interferon gamma positive, the person should be referred to the TB service for clinical assessment for diagnosis and possible treatment of latent infection or active disease

10.3 New employees from countries of high TB Incidence or have had contact with patients in settings with a high TB prevalence:

Should have an interferon-gamma test.

- If negative, offer BCG vaccination as 10.2.2. & 10.2.3
- Is positive the person should be referred to the TB service for clinical assessment for diagnosis and possible treatment of latent infection or active disease.
If a prospective or current healthcare worker who is Mantoux negative (less than 6mm), declines BCG vaccination, the risks should be explained and the oral explanation supplemented by written advice. If the person still declines BCG vaccination, he or she should not work where there is a risk of exposure to TB.

10.4 Healthcare workers who are immunocompromised:

Healthcare workers who are immunocompromised should be screened in the same way as other people who are immunocompromised:

For people with HIV, if CD4 counts less than 200 cells/m$^3$, offer an interferon-gamma test and a concurrent Mantoux test. If either test positive refer to the TB service, who will:

- Perform a clinical assessment to exclude active TB and
- Consider treating latent TB infection

For people with HIV and CD4 counts of 200 - 500 cells/mm$^3$ offer an interferon-gamma test alone or an interferon-gamma test with a concurrent Mantoux test. If either tests positive refer to the TB service, which will:

- Perform a clinical assessment to exclude active TB and
- Consider treating latent TB infection

10.5 Clinical students, agency and locum staff:

Those that have contact with patients or clinical materials should be screened for TB to the same standard as new employees in healthcare environments as recommended before. Documentary evidence of screening to this standard should be sought from locum agencies and contractors who carry out their own screening.

10.6 STAFF CLOSE CONTACT SCREENING

Reminders of symptoms of TB, and the need for prompt reporting of such symptoms, should be included with annual reminders about occupational health for staff who:

- Are in regular contact with TB patients or clinical materials, or
- Have worked in a high-risk clinical setting for four weeks or longer.

10.6.1 Assessment of staff contacts of smear positive pulmonary tuberculosis patients (open TB):

An assessment of staff close contacts will be made by the TB CNS in -
10.6.2 Close contacts are defined as members of staff who carry out:

- mouth-to-mouth resuscitation
- prolonged care of a high dependency patient
- repeated chest physiotherapy

One-off reminders should be given to these identified staff after a TB Incident on their ward.

Casual contacts (not identified on list) should only be assessed if they are unusually susceptible (immunosuppressed) or have no history of BCG vaccination.

10.6.1 Assessment of staff contacts of smear negative pulmonary or non-pulmonary tuberculosis patients (open TB):

In these cases no action is necessary.

11. RESOURCES

11.1 The necessary resources for the management, training, risk assessments, monitoring and auditing for tuberculosis are already in place and the implementation of this procedure will not entail additional expenditure.

12. TRAINING

12.1 Mandatory Infection and Prevention and Control training updated every two years.

12.2 Further departmental based training is available by contacting the TB Clinical Nurse Specialists

13. IMPLEMENTATION

13.1 The document will be available on the UHB intranet site and the Infection Prevention and Control clinical portal site. Individual directorates will be
responsible for the implementation of the procedure document in clinical areas.

14. FURTHER INFORMATION

14.1 Guidance on the management of Tuberculosis was published by NICE in 2011. This guidance is still current and has been used in the preparation of this procedure which also takes into account local circumstances within the UHB.

15. EQUALITY

15.1 This procedure has had an equality impact assessment and has shown there has been no adverse effect or discrimination made on any particular individual or group.

16. AUDIT

16.1 Audit of compliance with the procedural document will be carried out by the Infection Prevention and Control Department as part of their procedure audit programme.

17. REVIEW

17.1 This procedure will be reviewed every three years or sooner if the national guidelines are updated.

18. REFERENCES

Appendix 1a

TB CONTROL SERVICE & OCCUPATIONAL HEALTH SERVICE

CARDIFF AND VALE UNIVERSITY HEALTH BOARD

List of Staff Contacts (all disciplines) of:

NAME OF PATIENT:  
WARD, HOSPITAL:  
DATES OF ADMISSION:  

To be completed and returned to Occupational Health Department within seven days. If no contacts are identified, Ward Manager to sign below.

<table>
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<th>SURNAME</th>
<th>FORENAME</th>
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<th>STAFF GRADE</th>
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Mycobacterium tuberculosis (TB) Infection Control Procedure in University Health Board hospitals.
NO CLOSE CONTACTS IDENTIFIED. Signed ____________________________ Ward Manager
Tuberculosis Control Unit
TB Nurse Specialists
TB Control Service, PCSC (Primary Care Services Centre), Cardiff Royal Infirmary, CF24 0SZ

Confidential

Date:

Dear Sister/Charge Nurse – Ward:

Re:

Ward: From: To:

The person named above has been diagnosed as suffering from smear positive (open) pulmonary tuberculosis. In order to assist with the screening and monitoring of staff that have cared for this patient, would you please complete a list of the names of all staff working on the ward/unit that were in close regular contact on the attached form.

CLOSE REGULAR CONTACT IS DEFINED AS ANY STAFF MEMBER INVOLVED IN:-

1. PROVIDING PERSONAL CARE FOR A HIGH DEPENDENCY PATIENT
2. ADMINISTERING ACTIVE AND RECURRENT CHEST PHYSIOTHERAPY
3. PERFORMING MOUTH-TO-MOUTH RESUSCITATION

The completed form should be returned to the Occupation Health Department of your health board.
Most staff will only require a reminder of TB signs and symptoms from the Occupational Health department.
All other staff in contact with this patient may be reassured that they are not at risk. Staff who are unsure if they are protected against TB should contact the Occupational Health Department for further advice.

If you require any further detail regarding this matter, please contact us on the above telephone number.

Yours sincerely

Liz Weeks

Liz Weeks & Sally Jones
Clinical Nurse Specialists in Tuberculosis
Follow instructions for contact isolation
Please ask nursing staff for a Mask or Visor
Appendix 3

Integrated TB Service

Lead TB Clinician
Tel: 02920 715024

Infectious Diseases (ID)
TB Clinicians
Tel: 02920 742184

ID Spr
Bleep 5402

Paediatric Consultant
(ID Interest)
Tel: 02920 742273

TB Clinical Nurse Specialists
(Lead nurse)
Office 02920 335125
Mob: 07980 736560
Office: 02920 335124
Mob: 07980 736561

TB Office
Referrals & appointments
Office & Answerphone 02920 335121
Fax: 02920 335126

Consultant Communicable Disease Control (CCDC)
Office 02920 402478

Infection Prevention and Control Team

IP+C Doctor 02921 41772
Senior Nurse IP&C 02920 746618
CNS for IP&C 02920 746523
02920 743596
02920 748734
ACNS for IP&C

02920 716261
02920 746095

Administrator for IP&C

02920 746703
TUBERCULOSIS INFECTION CONTROL MEASURES IN IN-PATIENTS
Cardiff and Vale UHB – October 2011

Management of suspected TB cases
Most patients with suspected or proven TB do not need to be admitted. Discuss with SpR/consultant respiratory or ID. Environmental mycobacteria are not uncommon in those with chronic chest disease and are non-infectious.

Consider TB
- high risk ethnic group
- cough > 3 weeks
- fever > 3 weeks
- night sweats
- weight loss

CXR
With early review

Radiological features of pulmonary TB
Upper zone patchy infiltrates and cavities (Lymphadenopathy and Pleural effusion are features of TB but in the absence of infiltrates/cavities are not usually AFB+ in sputum)

Pulmonary TB unlikely
Assess need for admission
Pulmonary TB likely

Segregate in side room. 3 sputa for AFB and TB culture

Pulmonary TB unlikely

General ward bed (not a ward with Immunocompromised Patients)

3 AFB neg

Smear +, MDR Low risk
Masks (FFP3) not necessary unless:
- Chest physiotherapy
- Sputum induction
- Bronchoscopy
- Patient to use surgical Mask for transfers

Smear +, MDR High risk
Contact Respiratory/ID SpR/cons
Negative pressure room
FFP3 Masks/contact Precautions as per NICE Guideline section 9.3.1

High risk countries for MDRTB
Any former soviet block country. (rates in new cases up to 28%, retreatment cases up to 60%) 1

MDR TB risk assessment
- From high risk country
- previous TB therapy
- Contact with drug resistant TB case

Multiple drug resistance (MDR) assessment.
Defined as rifampicin and Isoniazid resistance (may be resistance to other drugs as well). All patients with suspected or proven smear+ TB should be assessed for MDR.

Contact TB nurse specialist
For all patients discharged to
Arrange review/FU

1. WHO Multidrug and extensively drug resistant TB 2010 report on global surveillance and response
2. NICE Tuberculosis guidance 2011