

Issue date: [March 2006](#)

# Tuberculosis

**Clinical diagnosis and management of  
tuberculosis, and measures for its  
prevention and control**

## **Clinical Guideline 33**

### **Tuberculosis: clinical diagnosis and management of tuberculosis, and measures for its prevention and control**

#### **Ordering information**

You can download the following documents from [www.nice.org.uk/CG033](http://www.nice.org.uk/CG033)

- The NICE guideline (this document) – all the recommendations.
- A quick reference guide, which has been distributed to healthcare professionals working in the NHS in England.
- Information for people who have tuberculosis or are being tested for it, their families and carers, and the public.
- The full guideline – all the recommendations, details of how they were developed, and summaries of the evidence on which they were based.

For printed copies of the quick reference guide or information for the public, phone the NHS Response Line on 0870 1555 455 and quote:

- N1008 (quick reference guide)
- N1009 (information for the public).

#### **This guidance is written in the following context**

This guidance represents the view of the Institute, which was arrived at after careful consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. The guidance does not, however, override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

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## **Introduction**

The incidence of tuberculosis (TB) is influenced by risk factors such as exposure to, and susceptibility to, TB and levels of deprivation (poverty, housing, nutrition and access to healthcare), and differs in different parts of England and Wales. Where scientific evidence supports it, this guideline makes recommendations on service organisation, as well as for individual teams of healthcare professionals. The guideline aims to focus NHS resources where they will combat the spread of TB, and some sections deal with high- and low-incidence areas separately.

The guideline is designed for use in the National Health Service in England and Wales. Readers in other countries, particularly where the incidence of TB is higher, should exercise caution before applying the recommendations.

## **Patient-centred care**

This guideline offers best practice advice on the care of people with, or at risk of contracting, TB.

Treatment and care should take into account patients' individual needs and preferences. People with, or at risk of contracting, TB should have the opportunity to make informed decisions about their care and treatment. If patients do not have the capacity to make decisions, healthcare professionals should follow the Department of Health guidelines – 'Reference guide to consent for examination or treatment' (2001) (available from [www.dh.gov.uk](http://www.dh.gov.uk)). From April 2007 healthcare professionals will need to follow a code of practice accompanying the Mental Capacity Act (a draft is available from [www.dca.gov.uk/menincap/mcbdraftcode.pdf](http://www.dca.gov.uk/menincap/mcbdraftcode.pdf)).

Good communication between healthcare professionals and patients is essential. It should be supported by the provision of evidence-based information offered in a form that is tailored to the needs of the individual patient. The treatment, care and information provided should be culturally appropriate and in a form that is accessible to people who have additional needs, such as people with physical, cognitive or sensory disabilities, and people who do not speak or read English.

Unless specifically excluded by the patient, carers and relatives should have the opportunity to be involved in decisions about the patient's care and treatment.

Carers and relatives should also be provided with the information and support they need.

## Key priorities for implementation

The following recommendations have been identified as priorities for implementation.

### Management of active TB

- A 6-month, four-drug initial regimen (6 months of isoniazid and rifampicin supplemented in the first 2 months with pyrazinamide and ethambutol) should be used to treat active respiratory TB<sup>1</sup> in:
  - adults not known to be HIV-positive
  - adults who are HIV-positive
  - children.

This regimen is referred to as 'standard recommended regimen' in this guideline.

- Patients with active meningeal TB should be offered:
    - a treatment regimen, initially lasting for 12 months, comprising isoniazid, pyrazinamide, rifampicin and a fourth drug (for example, ethambutol) for the first 2 months, followed by isoniazid and rifampicin for the rest of the treatment period
    - a glucocorticoid at the normal dose range
      - ◇ adults – equivalent to prednisolone 20–40 mg if on rifampicin, otherwise 10–20 mg
      - ◇ children – equivalent to prednisolone 1–2 mg/kg, maximum 40 mg
- with gradual withdrawal of the glucocorticoid considered, starting within 2–3 weeks of initiation.

### Improving adherence

- Use of directly observed therapy (DOT) is not usually necessary in the management of most cases of active TB. All patients should have a risk assessment for adherence to treatment, and DOT should be

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<sup>1</sup> TB affecting the lungs, pleural cavity, mediastinal lymph nodes or larynx.

considered for patients who have adverse factors on their risk assessment, in particular:

- street- or shelter-dwelling homeless people with active TB
  - patients with likely poor adherence, in particular those who have a history of non-adherence.
- The TB service should tell each person with TB who their named key worker is, and how to contact them. This key worker should facilitate education and involvement of the person with TB in achieving adherence.

### **New entrant screening**

- New entrants<sup>2</sup> should be identified for TB screening from the following information:
  - Port of Arrival reports
  - new registrations with primary care
  - entry to education (including universities)
  - links with statutory and voluntary groups working with new entrants.

### **BCG vaccination**

- Neonatal BCG vaccination for any baby at increased risk of TB should be discussed with the parents or legal guardian.
- Primary care organisations with a high incidence of TB<sup>3</sup> should consider vaccinating all neonates soon after birth.

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<sup>2</sup> New entrants are defined as people who have recently arrived in or returned to the UK from high-incidence countries, with an incidence of more than 40 per 100,000 per year, as listed by the Health Protection Agency (go to [www.hpa.org.uk](http://www.hpa.org.uk) and search for 'WHO country data TB').

<sup>3</sup> Incidence of more than 40 per 100,000, as listed by the Health Protection Agency (go to [www.hpa.org.uk](http://www.hpa.org.uk) and search for 'TB rate bands').

## Definitions used in this guideline

**Close contacts** These may include a boyfriend or girlfriend and frequent visitors to the home of the index case, in addition to household contacts

**Green Book** The 2006 edition of 'Immunisation against infectious disease', published by the Department of Health. Updated chapters are available online ([www.dh.gov.uk/PolicyAndGuidance/HealthAndSocialCareTopics/GreenBook/fs/en](http://www.dh.gov.uk/PolicyAndGuidance/HealthAndSocialCareTopics/GreenBook/fs/en)) and a printed version will be published during 2006

**High-incidence country** Country with more than 40 cases per 100,000 per year; these are listed by the Health Protection Agency – go to [www.hpa.org.uk](http://www.hpa.org.uk) and search for 'WHO country data TB'

**High-incidence primary care organisation** A primary care organisation with more than 40 cases per 100,000 per year; these are listed by the Health Protection Agency – go to [www.hpa.org.uk](http://www.hpa.org.uk) and search for 'TB rate bands'

**Household contacts** People sharing a bedroom, kitchen, bathroom or sitting room with the index case

**'Inform and advise' information** Advice on the risks and symptoms of TB, usually given in a standard letter

**New entrants** People who have recently arrived in or returned to the UK from high-incidence countries

**Respiratory TB** TB affecting the lungs, pleural cavity, mediastinal lymph nodes or larynx

**Standard recommended regimen** The '6-month, four-drug initial regimen' of 2 months of isoniazid, rifampicin, pyrazinamide and ethambutol, followed by 4 months of isoniazid and rifampicin

### **Drug regimen abbreviations for TB treatment**

Drug regimens are often abbreviated to the number of months a phase of treatment lasts, followed by letters for the drugs administered in that phase:

**H** is isoniazid, **R** rifampicin, **Z** pyrazinamide, **E** ethambutol, **S** streptomycin

#### **For example:**

**2HRZE/4HR** is the standard recommended regimen

**2HRE/7HR** is 2 months of isoniazid, rifampicin and ethambutol followed by 7 months of isoniazid and rifampicin

The following guidance is evidence based. Appendix A shows the grading scheme used for the recommendations: A, B, C, D or good practice point – D(GPP); recommendations on diagnostic tests are graded A(DS), B(DS), C(DS) or D(DS). A summary of the evidence on which the guidance is based is provided in the full guideline (see section 5).

## 1 Guidance

### 1.1 Diagnosis

#### 1.1.1 Diagnosing latent TB

Evidence is emerging on the performance of interferon-gamma tests. If this new evidence is significant, NICE will consider updating the guideline.

##### 1.1.1.1 To diagnose latent TB: **D**

- Mantoux testing should be performed in line with the Green Book<sup>4</sup>
- those with positive results (or in whom Mantoux testing may be less reliable) should then be considered for interferon-gamma immunological testing, if available.

If testing is inconclusive, the person should be referred to a TB specialist (see section 1.6 for management of latent TB).

#### 1.1.2 Diagnosing active TB

##### 1.1.2.1 To diagnose active respiratory TB:

- a posterior–anterior chest X-ray should be taken; chest X-ray appearances suggestive of TB should lead to further diagnostic investigation **C(DS)**
- multiple sputum samples (at least three, with one early morning sample) should be sent for TB microscopy and culture for

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<sup>4</sup> In this guideline the 'Green Book' is the 2006 edition of 'Immunisation against infectious disease', published by the Department of Health. Available from [www.dh.gov.uk/PolicyAndGuidance/HealthAndSocialCareTopics/GreenBook/fs/en](http://www.dh.gov.uk/PolicyAndGuidance/HealthAndSocialCareTopics/GreenBook/fs/en)); a printed version will be published during 2006. The Green Book contains details of people who may have suppressed responses to tuberculin skin testing.

suspected respiratory TB before starting treatment if possible or, failing that, within 7 days of starting **C(DS)**

- spontaneously produced sputum should be obtained if possible; otherwise induction of sputum or bronchoscopy and lavage should be used **B(DS)**
- in children unable to expectorate sputum, induction of sputum should be considered if it can be done safely, with gastric washings considered as third line **B(DS)**
- if there are clinical signs and symptoms consistent with a diagnosis of TB, treatment should be started without waiting for culture results (see section 1.2.1 for details) **D(GPP)**
- the standard recommended regimen should be continued in patients whose subsequent culture results are negative **D(GPP)**
- samples should be sent for TB culture from autopsy samples if respiratory TB is a possibility. **D(GPP)**

#### 1.1.2.2 To diagnose active non-respiratory TB:

- advantages and disadvantages of both biopsy and needle aspiration should be discussed with the patient, with the aim of obtaining adequate material for diagnosis **B(DS)**
- if non-respiratory TB is a possibility, part or all of any of the following samples should be placed in a dry pot (and not all placed in formalin) and sent for TB culture: **D(GPP)**
  - lymph node biopsy
  - pus aspirated from lymph nodes
  - pleural biopsy
  - any surgical sample sent for routine culture
  - any radiological sample sent for routine culture
  - histology sample
  - aspiration sample
  - autopsy sample
- microbiology staff should routinely perform TB culture on the above samples (even if it is not requested) **D(GPP)**

- the appropriate treatment regimen should be started without waiting for culture results if the histology and clinical picture are consistent with a diagnosis of TB (see sections 1.2 and 1.3) **C(DS)**
- all patients with non-respiratory TB should have a chest X-ray to exclude or confirm coexisting respiratory TB; in addition, tests as described in table 1 should be considered **D(GPP)**
- the appropriate drug regimen (see sections 1.2 and 1.3) should be continued even if subsequent culture results are negative. **D(GPP)**

**Table 1 Suggested site-specific investigations in the diagnosis and assessment of non-respiratory TB**

Site	Imaging	Biopsy	Culture
Lymph node		<ul style="list-style-type: none"> <li>• Node</li> </ul>	<ul style="list-style-type: none"> <li>• Node or aspirate</li> </ul>
Bone/joint	<ul style="list-style-type: none"> <li>• Plain X-ray and computed tomography (CT)</li> <li>• Magnetic resonance imaging (MRI)</li> </ul>	<ul style="list-style-type: none"> <li>• Site of disease</li> </ul>	<ul style="list-style-type: none"> <li>• Biopsy or paraspinal abscess</li> <li>• Site or joint fluid</li> </ul>
Gastrointestinal	<ul style="list-style-type: none"> <li>• Ultrasound</li> <li>• CT abdomen</li> </ul>	<ul style="list-style-type: none"> <li>• Omentum</li> <li>• Bowel</li> </ul>	<ul style="list-style-type: none"> <li>• Biopsy</li> <li>• Ascites</li> </ul>
Genitourinary	<ul style="list-style-type: none"> <li>• Intravenous urography</li> <li>• Ultrasound</li> </ul>	<ul style="list-style-type: none"> <li>• Site of disease</li> </ul>	<ul style="list-style-type: none"> <li>• Early morning urine</li> <li>• Site of disease</li> <li>• Endometrial curettings</li> </ul>
Disseminated	<ul style="list-style-type: none"> <li>• High-resolution CT thorax</li> <li>• Ultrasound abdomen</li> </ul>	<ul style="list-style-type: none"> <li>• Lung</li> <li>• Liver</li> <li>• Bone marrow</li> </ul>	<ul style="list-style-type: none"> <li>• Bronchial wash</li> <li>• Liver</li> <li>• Bone marrow</li> <li>• Blood</li> </ul>
Central nervous system	<ul style="list-style-type: none"> <li>• CT brain</li> <li>• MRI</li> </ul>	<ul style="list-style-type: none"> <li>• Tuberculoma</li> </ul>	<ul style="list-style-type: none"> <li>• Cerebrospinal fluid</li> </ul>
Skin		<ul style="list-style-type: none"> <li>• Site of disease</li> </ul>	<ul style="list-style-type: none"> <li>• Site of disease</li> </ul>
Pericardium	<ul style="list-style-type: none"> <li>• Echocardiogram</li> </ul>	<ul style="list-style-type: none"> <li>• Pericardium</li> </ul>	<ul style="list-style-type: none"> <li>• Pericardial fluid</li> </ul>
Cold/liver abscess	<ul style="list-style-type: none"> <li>• Ultrasound</li> </ul>	<ul style="list-style-type: none"> <li>• Site of disease</li> </ul>	<ul style="list-style-type: none"> <li>• Site of disease</li> </ul>

- 1.1.2.3 Rapid diagnostic tests for *Mycobacterium tuberculosis* complex (*M tuberculosis*, *M bovis*, *M africanum*) on primary specimens should be used only if: **D(GPP)**
- rapid confirmation of a TB diagnosis in a sputum smear-positive person would alter their care, or
  - before conducting a large contact-tracing initiative.
- 1.1.2.4 Clinicians should still consider a diagnosis of non-respiratory TB if rapid diagnostic tests are negative, for example in pleural fluid, cerebrospinal fluid and urine. **B(DS)**
- 1.1.2.5 Clinical signs and other laboratory findings consistent with TB meningitis should lead to treatment (see section 1.3.1), even if a rapid diagnostic test is negative, because the potential consequences for the patient are severe. **D(GPP)**
- 1.1.2.6 Before conducting a large contact-tracing initiative (for example, in a school or hospital), the species of mycobacterium should be confirmed to be *M tuberculosis* complex by rapid diagnostic tests on microscopy- or culture-positive material. Clinical judgement should be used if tests are inconclusive or delayed. **D(GPP)**
- 1.1.2.7 If a risk assessment suggests a patient has multidrug-resistant (MDR) TB (see section 1.5.1): **D(GPP)**
- rapid diagnostic tests should be conducted for rifampicin resistance
  - infection control measures and treatment for MDR TB should be started as described in section 1.5, pending the result of the tests.
- 1.1.2.8 Rapid diagnostic tests for *M tuberculosis* complex identification should be conducted on biopsy material only if: **D(GPP)**
- all the sample has been inappropriately placed in formalin, and
  - acid-fast bacilli are visible on microscopy.

1.1.2.9 Clinical samples should ideally be sent for culture by automated liquid methods, bearing in mind that laboratories need a certain level of throughput to maintain quality control. **D(GPP)**

## **1.2 Management of respiratory TB**

Respiratory TB is defined as active TB that is affecting any of the following:

- lungs
- pleural cavity
- mediastinal lymph nodes
- larynx.

### **1.2.1 Drug treatment**

1.2.1.1 Once a diagnosis of active TB is made, the clinician responsible for care should refer the person with TB to a physician with training in, and experience of, the specialised care of people with TB. The TB service should include specialised nurses and health visitors. TB in children should be managed either by a paediatrician with experience and training in the treatment of TB, or by a general paediatrician with advice from a specialised physician. If these arrangements are not possible, advice should be sought from more specialised colleagues throughout the treatment period. **C**

1.2.1.2 A 6-month, four-drug initial regimen (6 months of isoniazid and rifampicin supplemented in the first 2 months with pyrazinamide and ethambutol) should be used to treat active respiratory TB in:

- adults not known to be HIV-positive **A**
- adults who are HIV-positive **B**
- children. **B**

This regimen is referred to as 'standard recommended regimen' in this guideline.

1.2.1.3 Fixed-dose combination tablets should be used as part of any TB treatment regimen. **C**

- 1.2.1.4 A thrice-weekly dosing regimen (using the dosages given in ‘British national formulary’ 50) should be considered for patients receiving directly observed therapy (DOT) (see section 1.4.2). **D(GPP)**
- 1.2.1.5 A twice-weekly dosing regimen should not be used for the treatment of active TB. **D(GPP)**

## 1.2.2 Infection control

The recommendations below deal with three levels of isolation for infection control in hospital settings:

- negative-pressure rooms, which have air pressure continuously or automatically measured, as defined by NHS Estates<sup>5</sup>
- single rooms that are not negative pressure but are vented to the outside of the building
- beds on a ward, for which no particular engineering standards are required.

- 1.2.2.1 All patients with TB should have risk assessments for drug resistance (see section 1.5) and for HIV. If risk factors for MDR TB are present, see section 1.5.3 for recommendations on infection control. **D(GPP)**
- 1.2.2.2 Unless there is a clear clinical or socioeconomic need, such as homelessness, people with TB at any site of disease should not be admitted to hospital for diagnostic tests or for care. **D(GPP)**
- 1.2.2.3 If admitted to hospital, patients with suspected respiratory TB should be given a single room. **D(GPP)**
- 1.2.2.4 Patients with respiratory TB should be separated from immunocompromised patients, either by admission to a single room on a separate ward, or to a negative-pressure room on the same ward. **D(GPP)**

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<sup>5</sup> NHS Estates (2005) *In patient accommodation: options for choice. Isolation facilities in acute settings HBN4 supplement 1*. London: The Stationery Office. Available from [www.dh.gov.uk](http://www.dh.gov.uk)

- 1.2.2.5 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 the source of infection. **D(GPP)**
- 1.2.2.6 Smear-positive TB patients without risk factors for MDR TB (see section 1.5.1) should be cared for in a single room, until: **D(GPP)**
- they have completed 2 weeks of the standard recommended regimen (see section 1.2.1), or
  - they are discharged from hospital.
- 1.2.2.7 Aerosol-generating procedures such as bronchoscopy, sputum induction or nebuliser treatment should be carried out in an appropriately engineered and ventilated area for: **D(GPP)**
- all patients on an HIV ward, regardless of whether a diagnosis of TB has been considered
  - all patients in whom TB is considered a possible diagnosis, in any setting.
- 1.2.2.8 Healthcare workers caring for people with TB should not use masks, gowns or barrier nursing techniques unless: **D(GPP)**
- MDR TB is suspected
  - aerosol-generating procedures are being performed.

When such equipment is used, the reason should be explained to the person with TB. The equipment should meet the standards of the Health and Safety Executive. See section 1.5.3 for further details of MDR TB infection control.

1.2.2.9 TB patients admitted to a setting where care is provided for HIV-positive or other immunocompromised patients should be considered infectious and should stay in a negative-pressure room until: **D(GPP)**

**For people who were sputum smear positive at admission:**

1. the patient has had at least 2 weeks of appropriate multiple drug therapy, and
2. if moving to accommodation (inpatient or home) with HIV-positive or immunocompromised patients, 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 definite clinical improvement on treatment, for example remaining afebrile for a week.

**For people who were sputum smear negative at admission**

(that is, three negative samples were taken on separate days; samples were spontaneously produced sputum if possible, or obtained by bronchoscopy or lavage if sputum samples were not possible): **all** of 1, 2, 3 and 5 above should apply.

1.2.2.10 Inpatients with smear-positive respiratory TB should be asked (with explanation) to wear a surgical mask whenever they leave their room until they have had 2 weeks' drug treatment. **D(GPP)**

### **1.3 Management of non-respiratory TB**

#### **1.3.1 Meningeal TB**

1.3.1.1 Patients with active meningeal TB should be offered:

- a treatment regimen, initially lasting for 12 months, comprising isoniazid, pyrazinamide, rifampicin and a fourth drug (for example, ethambutol) for the first 2 months, followed by

isoniazid and rifampicin for the rest of the treatment period **D(GPP)**

- a glucocorticoid at the normal dose range
  - adults – equivalent to prednisolone 20–40 mg if on rifampicin, otherwise 10–20 mg **A**
  - children – equivalent to prednisolone 1–2 mg/kg, maximum 40 mg **D(GPP)**

with gradual withdrawal of the glucocorticoid considered, starting within 2–3 weeks of initiation. **D(GPP)**

1.3.1.2 Clinicians prescribing treatment for active meningeal TB should consider as first choice:

- a daily dosing schedule **B**
- using combination tablets. **D**

### **1.3.2 Peripheral lymph node TB**

1.3.2.1 For patients with active peripheral lymph node tuberculosis, the first choice of treatment should:

- be the standard recommended regimen (see section 1.2.1 for further details) **B**
- use a daily dosing schedule **B**
- include combination tablets. **D**

1.3.2.2 Patients with active peripheral lymph node TB who have had an affected gland surgically removed should still be treated with the standard recommended regimen. **D(GPP)**

1.3.2.3 Drug treatment of peripheral lymph node TB should normally be stopped after 6 months, regardless of the appearance of new nodes, residual nodes or sinuses draining during treatment. **D(GPP)**

### 1.3.3 Bone and joint TB: drug treatment

1.3.3.1 The standard recommended regimen (see section 1.2.1 for details) should be planned and started in people with:

- active spinal TB **B**
- active TB at other bone and joint sites. **C**

1.3.3.2 Clinicians prescribing treatment for active bone and joint tuberculosis should consider as first choice:

- a daily dosing schedule **B**
- using combination tablets. **D**

1.3.3.3 A computed tomography (CT) or magnetic resonance (MR) scan should be performed on patients with active spinal TB who have neurological signs or symptoms. If there is direct spinal cord involvement (for example, a spinal cord tuberculoma), management should be as for meningeal TB (see section 1.3.1). **D(GPP)**

### 1.3.4 Bone and joint TB: routine therapeutic surgery

1.3.4.1 In patients with spinal TB, anterior spinal fusion should not be performed routinely. **B**

1.3.4.2 In patients with spinal TB, anterior spinal fusion should be considered if there is spinal instability or evidence of spinal cord compression. **D(GPP)**

### 1.3.5 Pericardial TB

1.3.5.1 For patients with active pericardial TB, the first choice of treatment should:

- be the standard recommended regimen (see section 1.2.1 for details) **B**
- use a daily dosing schedule **B**
- include combination tablets. **D**

1.3.5.2 In addition to anti-TB treatment, patients with active pericardial TB should be offered:

- for adults, a glucocorticoid equivalent to prednisolone at 60 mg/day **A**
- for children, a glucocorticoid equivalent to prednisolone 1mg/kg/day (maximum 40 mg/day)

with gradual withdrawal of the glucocorticoid considered, starting within 2–3 weeks of initiation. **D(GPP)**

### **1.3.6 Disseminated (including miliary) TB**

1.3.6.1 For patients with disseminated (including miliary) TB, the first choice of treatment should:

- be the standard recommended regimen (see section 1.2.1 for details) **B**
- use a daily dosing schedule **B**
- include combination tablets. **D**

1.3.6.2 Treatment of disseminated (including miliary) TB should be started even if initial liver function tests are abnormal. If the patient's liver function deteriorates significantly on drug treatment, advice on management options should be sought from clinicians with specialist experience of these circumstances. **D(GPP)**

1.3.6.3 Patients with disseminated (including miliary) TB should be tested for central nervous system (CNS) involvement by:

- brain scan (CT or MRI) and/or lumbar puncture for those with CNS signs or symptoms
- lumbar puncture for those without CNS signs and symptoms.

If evidence of CNS involvement is detected, treatment should be the same as for meningeal TB (see section 1.3.1). **D(GPP)**

### 1.3.7 Other sites of infection

1.3.7.1 For patients with:

- active genitourinary TB, or
- active TB of any site other than:
  - respiratory system
  - CNS (typically meninges)
  - peripheral lymph nodes
  - bones and joints
  - pericardium
  - disseminated (including miliary) disease

the first choice of treatment should:

- be the standard recommended regimen (see section 1.2.1 for details) **B**
- use a daily dosing schedule **B**
- include combination tablets. **D**

## 1.4 *Monitoring, adherence and treatment completion*

### 1.4.1 Treatment completion and follow-up

1.4.1.1 Follow-up clinic visits should not be conducted routinely after treatment completion. **D**

1.4.1.2 Patients should be told to watch for symptoms of relapse and how to contact the TB service rapidly through primary care or a TB clinic. Key workers should ensure that patients at increased risk of relapse are particularly well informed about symptoms. **D(GPP)**

1.4.1.3 Patients who have had drug-resistant TB should be considered for follow-up for 12 months after completing treatment. Patients who have had MDR TB should be considered for prolonged follow-up. **D(GPP)**

## 1.4.2 Improving adherence: directly observed therapy

1.4.2.1 Use of directly observed therapy (DOT) is not usually necessary in the management of most cases of active TB. **A**

All patients should have a risk assessment for adherence to treatment, and DOT should be considered for patients who have adverse factors on their risk assessment, in particular:

- street- or shelter-dwelling homeless people with active TB **B**
- patients with likely poor adherence, in particular those who have a history of non-adherence. **D(GPP)**

1.4.2.2 Clinicians who are planning to start a patient on a course of DOT should consider ways to mitigate the environmental, financial and psychosocial factors that may reduce adherence, including stability of accommodation, prescription charges and transport. The setting, observer and frequency of treatment should be arranged to be most practicable for the person with TB. The person with TB and his or her assigned key worker should be involved in deciding these arrangements. DOT should also be supported by frequent contact with the key worker (see 1.4.3.2). **D(GPP)**

## 1.4.3 Other strategies to improve adherence

1.4.3.1 To promote adherence, patients should be involved in treatment decisions at the outset of treatment for active or latent TB. The importance of adherence should be emphasised during discussion with the patient when agreeing the regimen. **D(GPP)**

1.4.3.2 The TB service should tell each person with TB who their named key worker is, and how to contact them. This key worker should facilitate education and involvement of the person with TB in achieving adherence. **D(GPP)**

1.4.3.3 TB services should consider the following interventions to improve adherence to treatment for active or latent TB if a patient defaults:

- reminder letters in appropriate languages **B**
- health education counselling **B**
- patient-centred interview and health education booklet **B**
- home visits **D(GPP)**
- patient diary **D(GPP)**
- random urine tests and other monitoring (for example, pill counts) **D(GPP)**
- information about help with paying for prescriptions **D(GPP)**
- help or advice about where and how to get social security benefits, housing and social services. **D(GPP)**

1.4.3.4 Pharmacies should make liquid preparations of anti-TB drugs readily available to TB patients who may need them – for example, children and people with swallowing difficulties. **D(GPP)**

1.4.3.5 TB services should assess local language and other communication needs and, if there is a demonstrated need, provide patient information accordingly<sup>6</sup>. **D(GPP)**

## **1.5 Risk assessment and infection control in drug-resistant TB**

### **1.5.1 Risk factors**

1.5.1.1 A risk assessment for drug resistance should be made for each patient with TB, based on the risk factors listed below: **C**

1. history of prior TB drug treatment; prior TB treatment failure
2. contact with a known case of drug-resistant TB
3. birth in a foreign country, particularly high-incidence countries<sup>7</sup>
4. HIV infection
5. residence in London

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<sup>6</sup> Patient information should be drawn from national high-quality resources if available; for examples, see [www.hpa.org.uk](http://www.hpa.org.uk). Information on TB will be added to the National Knowledge Service website ([www.nks.nhs.uk](http://www.nks.nhs.uk)) over the coming months.

<sup>7</sup> Countries with more than 40 cases per 100,000 per year, as listed by the Health Protection Agency (go to [www.hpa.org.uk](http://www.hpa.org.uk) and search for 'WHO country data TB').

6. age profile, with highest rates between ages 25 and 44
7. male gender.

1.5.1.2 The TB service should consider the risk assessment for drug resistance and, if the risk is regarded as significant, urgent molecular tests for rifampicin resistance should be performed on smear-positive material or on positive cultures when they become available (see section 1.1.2). **D(GPP)**

1.5.1.3 Response to treatment should be closely monitored in patients at increased risk of drug resistance. If there is no clinical improvement, or if cultures remain positive after the 4th month of treatment ('treatment failure'), drug resistance should be suspected and treatment reviewed with a clinician experienced in the treatment of MDR TB. **D(GPP)**

(See section 1.2.1 for details of the standard recommended regimen.)

## 1.5.2 Referral

1.5.2.1 The options for organising care for people with MDR TB should be discussed with clinicians who specialise in this. The views of the patient should be sought and taken into account, and shared care should be considered. **D(GPP)**

## 1.5.3 Infection control

1.5.3.1 Patients with suspected or known infectious MDR TB who are admitted to hospital should be admitted to a negative-pressure room. If none is available locally, the patient should be transferred to a hospital that has these facilities and a clinician experienced in managing complex drug-resistant cases. Care should be carried out in the negative-pressure room until the patient is found to be non-infectious or non-resistant, and ideally until cultures are negative. **D(GPP)**

- 1.5.3.2 Staff and visitors should wear FFP3 masks<sup>8</sup> during contact with a patient with suspected or known MDR TB while the patient is considered infectious. **D(GPP)**
- 1.5.3.3 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 and carers. **D(GPP)**
- 1.5.3.4 The decision to discharge a patient with suspected or known MDR TB should be discussed with the infection control team, the local microbiologist, the local TB service, and the consultant in communicable disease control. **D(GPP)**
- 1.5.3.5 Negative-pressure rooms used for infection control in MDR TB should meet the standards of the Interdepartmental Working Group on Tuberculosis<sup>9</sup>, and should be clearly identified for staff, for example by a standard sign. Such labelling should be kept up to date. **D(GPP)**

For a summary of recommendations on infection control, see the algorithm on isolation decisions for patients with suspected respiratory TB (appendix E).

#### **1.5.4 Treatment of non-MDR drug-resistant TB**

- 1.5.4.1 Patients with drug resistant TB, other than MDR, should be under the care of a specialist physician with appropriate experience in managing such cases. First-choice drug treatment is set out in table 2.

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<sup>8</sup> European standard EN149:2001; masks should meet the standards in 'Respiratory protective equipment at work: a practical guide HSG53' published by the Health and Safety Executive (2005). Available from [www.hsebooks.com/Books](http://www.hsebooks.com/Books)

<sup>9</sup> The Interdepartmental Working Group on Tuberculosis (1998) *The prevention and control of tuberculosis in the United Kingdom: UK guidance on the prevention and control of transmission of 1. HIV-related tuberculosis 2. drug-resistant, including multiple drug-resistant, tuberculosis*. London: Department of Health. Available from [www.dh.gov.uk](http://www.dh.gov.uk)

**Table 2 Recommended regimens for non-MDR drug-resistant TB**

Drug resistance	Initial phase	Continuation phase
S	2RHZE	4RH
H known before treatment	2RZSE	7RE
found after starting treatment	2RZE	10RE
Z	2RHE	7RH
E	2RHZ	4RH
R (only if confirmed isolated resistance)	2HZE	16HE
S+H	2RZE	10RE
Other	individualised	
See page 10 for details of abbreviations		

## 1.6 Management of latent TB

### 1.6.1 Treatment of latent TB infection

1.6.1.1 Treatment of latent TB infection should be considered for people in the following groups, once active TB has been excluded by chest X-ray and examination. **D(GPP)**

- People identified through screening who are:
  - younger than 36 years (because of increasing risk of hepatotoxicity with age)
  - any age with HIV
  - any age and a healthcare worker
 and are either:
  - Mantoux positive (6 mm or greater), and without prior BCG vaccination, or
  - strongly Mantoux positive (15 mm or greater), interferon-gamma positive, and with prior BCG vaccination.
  
- Children aged 1–15 years identified through opportunistic screening to be:
  - strongly Mantoux positive (15 mm or greater), and
  - interferon-gamma positive (if this test has been performed), and
  - without prior BCG vaccination.

- People with evidence of TB scars on chest X-ray, and without a history of adequate treatment.
- 1.6.1.2 People with HIV who are in close contact<sup>10</sup> with people with sputum smear-positive respiratory TB should have active disease excluded and then be given treatment for latent TB infection. Mantoux testing may be unreliable in people with HIV. **D(GPP)**
- 1.6.1.3 Treatment for latent TB infection should not be started in close contacts of people with sputum smear-positive MDR TB who are strongly Mantoux positive (15 mm or greater), as no regimen is of proven benefit, and only a small proportion of people infected will develop the disease. Long-term monitoring should be undertaken for active disease. **D(GPP)**
- 1.6.1.4 People who have agreed to receive treatment for latent TB infection should be started on one of the following regimens: **C**
- either 6 months of isoniazid (6H) or 3 months of rifampicin and isoniazid (3RH) for people aged 16–35 not known to have HIV **A**
  - either 6 months of isoniazid (6H) or 3 months of rifampicin and isoniazid (3RH) for people older than 35 in whom treatment for latent TB infection is recommended (see 1.6.1.1), and who are not known to have HIV **D(GPP)**
  - 6 months of isoniazid (6H) for people of any age who have HIV **A**
  - 6 months of rifampicin (6R) for contacts, aged 35 or younger, of people with isoniazid-resistant TB. **D(GPP)**

People eligible for treatment of latent TB infection, but who decline to take this treatment, should be given ‘Inform and advise’ information about TB and have chest X-rays at 3 and 12 months later. **D(GPP)**

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<sup>10</sup> Close contacts may include a boyfriend or girlfriend and frequent visitors to the home of the index case, in addition to household contacts.

- 1.6.1.5 Neonates who have been in close contact with people with sputum smear-positive TB who have not received at least 2 weeks' anti-tuberculosis drug treatment should be treated as follows. **D(GPP)**
- The baby should be started on isoniazid 5 mg/kg for 3 months and then a Mantoux test performed after 3 months' treatment.
  - If the Mantoux test is positive (6 mm or greater) the baby should be assessed for active TB (see section 1.1.2). If this assessment is negative, then isoniazid should be continued for a total of 6 months.
  - If the test is negative (less than 6 mm), then isoniazid should be stopped and a BCG vaccination performed (see section 1.7).

See section 1.8 for recommendations on assessment if the index case has other types of TB.

- 1.6.1.6 Children older than 4 weeks but younger than 2 years who have not had BCG vaccination and are in close contact with people with sputum smear-positive TB should be treated as follows. **D(GPP)**
- The child should be started on isoniazid 5 mg/kg and a Mantoux test performed.
  - If the Mantoux test is positive (6 mm or greater), the child should be assessed for active TB (see section 1.1.2). If active TB is ruled out, full treatment for latent TB infection should be given (see 1.6.1.8).
  - If the test is negative (less than 6 mm), then isoniazid should be continued and the Mantoux test repeated after 6 weeks.
  - If the repeat test is negative, isoniazid may be stopped and BCG vaccination performed (see section 1.7).
  - If the repeat test is positive (6 mm or greater), an interferon-gamma test should be conducted, if available. If this is positive, full treatment for latent TB infection should be given. If the test is not available, the child should be started on treatment for latent TB infection after a positive repeat Mantoux test result.

Contact tracing for children younger than 2 years when the index case is sputum smear-positive is summarised in an algorithm (appendix E). See section 1.8 for recommendations on assessment if the index case has other types of TB.

- 1.6.1.7 BCG-vaccinated children older than 4 weeks but younger than 2 years, in close contact with people with sputum smear-positive respiratory TB, should be treated as follows. **D(GPP)**
- The child should have a Mantoux test. If this is positive (15 mm or greater), the child should be assessed for active TB (see section 1.1.2). If active TB is excluded, then treatment for latent TB infection should be given (see 1.6.1.8).
  - If the result of the test is as expected for prior BCG (less than 15 mm), it should be repeated after 6 weeks.
  - If the repeat test is also less than 15 mm, no further action is needed.
  - If the repeat test becomes more strongly positive (15 mm or greater and an increase of 5 mm or more over the previous test), an interferon-gamma test should be conducted, if available. If this is positive, the child should be assessed for active TB (see section 1.1.2). If the interferon-gamma test is not available, the child should be assessed for active TB after a positive repeat Mantoux test result. If active TB is excluded, treatment for latent TB infection should be given.
- 1.6.1.8 For children requiring treatment for latent TB infection, a regimen of either 3 months of rifampicin and isoniazid (3RH) or 6 months of isoniazid (6H) should be planned and started, unless the child is known to be HIV-positive, in which case 6H should be given (see 1.6.1.4). **D(GPP)**
- 1.6.1.9 Healthcare workers should be aware that certain groups of people with latent TB are at increased risk of going on to develop active TB, including people who: **D(GPP)**
- are HIV-positive

- are injecting drug users
- have had solid organ transplantation
- have a haematological malignancy
- have had a jejunoileal bypass
- have chronic renal failure or receive haemodialysis
- have had a gastrectomy
- are receiving anti-TNF-alpha treatment
- have silicosis.

Patients in these groups should be advised of the risks and symptoms of TB, on the basis of an individual risk assessment, usually in a standard letter of the type referred to as 'Inform and advise' information.

## **1.7 BCG vaccination**

1.7.1.1 When BCG is being recommended, the benefits and risks of vaccination and remaining unvaccinated should be discussed with the person (or, if a child, with the parents), so that they can make an informed decision. This discussion should be tailored to the person, be in an appropriate language, and take into account cultural sensitivities and stigma. **D(GPP)**

1.7.1.2 People identified for BCG vaccination through occupational health, contact tracing or new entrant screening who are also considered to be at increased risk of being HIV positive, should be offered HIV testing before BCG vaccination.<sup>11</sup> **D(GPP)**

### **1.7.2 BCG vaccination for neonates**

1.7.2.1 Neonatal BCG vaccination for any baby at increased risk of TB should be discussed with the parents or legal guardian.

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<sup>11</sup> See the British HIV Association guideline for details of further action in HIV-positive patients. Available from [www.bhiva.org](http://www.bhiva.org)

1.7.2.2 Primary care organisations with a high incidence of TB<sup>12</sup> should consider vaccinating all neonates soon after birth. **D(GPP)**

1.7.2.3 In areas with a low incidence of TB, primary care organisations should offer BCG vaccination to selected neonates who: **D(GPP)**

- were born in an area with a high incidence of TB, or
- have one or more parents or grandparents who were born in a high-incidence country, or
- have a family history of TB in the past 5 years.

### 1.7.3 BCG vaccination for infants and older children

1.7.3.1 Routine BCG vaccination is not recommended for children aged 10–14.

- Healthcare professionals should opportunistically identify unvaccinated children older than 4 weeks and younger than 16 years at increased risk of TB (see section 1.6.1) who would have qualified for neonatal BCG and provide Mantoux testing and BCG (if Mantoux negative). **C**
- This opportunistic vaccination should be in line with the Chief Medical Officer's advice on vaccinating this age group following the end of the school-based programme<sup>13</sup>. **D(GPP)**

1.7.3.2 Mantoux testing should not be done routinely before BCG vaccination in children younger than 6 years unless they have a history of residence or prolonged stay (more than 1 month) in a country with a high incidence of TB<sup>14</sup>. **D(GPP)**

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<sup>12</sup> More than 40 cases per 100,000 per year, as listed by the Health Protection Agency (go to [www.hpa.org.uk](http://www.hpa.org.uk) and search for 'TB rate bands').

<sup>13</sup> Available from [www.dh.gov.uk/assetRoot/04/11/81/35/04118135.pdf](http://www.dh.gov.uk/assetRoot/04/11/81/35/04118135.pdf)

<sup>14</sup> More than 40 cases per 100,000 per year, as listed by the Health Protection Agency (go to [www.hpa.org.uk](http://www.hpa.org.uk) and search for 'TB WHO country data').

## 1.7.4 BCG vaccination for new entrants from high-incidence areas

1.7.4.1 BCG vaccination should be offered to Mantoux-negative new entrants<sup>15</sup> who:

- are from high-incidence countries **B**, and
- are previously unvaccinated (that is, without adequate documentation or a characteristic scar) **B**, and
- are aged:
  - younger than 16 years, **D(GPP)** or
  - 16 to 35 years<sup>16</sup> from sub-Saharan Africa or a country with a TB incidence of 500 per 100,000. **D(GPP)**

## 1.7.5 BCG vaccination for healthcare workers

1.7.5.1 BCG vaccination should be offered to healthcare workers, irrespective of age<sup>17</sup>, who: **D(GPP)**

- are previously unvaccinated (that is, without adequate documentation or a characteristic scar), and
- will have contact with patients or clinical materials, and
- are Mantoux (or interferon-gamma) negative.

See sections 1.9.1 and 1.9.2 for details of occupational health screening.

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<sup>15</sup> People who have recently arrived in or returned to the UK from high-incidence countries.

<sup>16</sup> The November 1995 draft of the Green Book recommends BCG for new entrants only up to the age of 16. However in this guideline BCG is recommended for those aged up to 35 who come from the countries with the very highest rates of TB because there is some evidence of cost-effectiveness (see full guideline).

<sup>17</sup> As outlined in the Green Book, there is not sufficient age-specific evidence to make recommendations on BCG vaccination for people older than 35 (see full guideline for details). However, in this guideline BCG vaccination is recommended for healthcare workers of all ages because of the increased risk to them – and consequently the patients they care for – if they remain unvaccinated.

## **1.7.6 BCG vaccination for contacts of people with active TB**

- 1.7.6.1 BCG vaccination should be offered to Mantoux-negative contacts of people with respiratory TB (see section 1.8.1 for details of contact tracing) if they are previously unvaccinated (that is, without adequate documentation or a characteristic scar) and are: **D(GPP)**
- aged 35 or younger
  - aged 36 and older and a healthcare or laboratory worker who has contact with patients or clinical materials (see section 1.7.5).

## **1.7.7 BCG vaccination for other groups**

- 1.7.7.1 BCG vaccination should be offered to previously unvaccinated, Mantoux-negative people younger than 35 in the following groups at increased risk of exposure to TB, in accordance with the Green Book: **D(GPP)**
- veterinary and other staff such as abattoir workers who handle animal species known to be susceptible to TB, such as simians
  - prison staff working directly with prisoners
  - staff of care homes for elderly people
  - staff of hostels for homeless people and facilities accommodating refugees and asylum seekers
  - people going to live or work with local people for more than 1 month in a high-incidence country.

See section 1.7.5 for advice on healthcare workers.

## **1.8 Active case finding**

### **1.8.1 Contact tracing: human to human transmission**

- 1.8.1.1 Once a person has been diagnosed with active TB, the diagnosing physician should inform relevant colleagues so that the need for contact tracing can be assessed without delay. Contact tracing should not be delayed until notification. **D(GPP)**

1.8.1.2 Screening should be offered to the household contacts of any person with active TB, irrespective of the site of infection. Household contacts are defined as those who share a bedroom, kitchen, bathroom or sitting room with the index case. Screening should comprise: **D(GPP)**

- standard testing for latent TB (see section 1.1.1) for those aged 35 or younger, and consideration of BCG or treatment for latent TB infection once active TB has been ruled out
- interferon-gamma test 6 weeks after the Mantoux test, and consideration of BCG or treatment for latent TB infection once active TB has been ruled out, for those who:
  - are previously unvaccinated and
  - are household contacts of a person with sputum-smear positive TB and
  - are Mantoux negative (less than 6 mm)
- chest X-ray (if there are no contraindications) for those older than 35, possibly leading to further investigation for active TB.

The recommendations on asymptomatic household and other close contacts of people with active TB are summarised in an algorithm (appendix E).

1.8.1.3 For people with sputum smear-positive TB, other close contacts should be assessed. These may include boyfriends or girlfriends and frequent visitors to the home of the index case. Occasionally, a workplace associate may be judged to have had contact equivalent to that of household contacts, and should be assessed in the same way. **D(GPP)**

See section 1.6 for contact tracing for children younger than 2 years who are close contacts of people with sputum smear-positive TB.

1.8.1.4 Casual contacts of people with TB, who will include the great majority of workplace contacts, should not normally be assessed. **C**

1.8.1.5 The need for tracing casual contacts of people with TB should be assessed if: **D(GPP)**

- the index case is judged to be particularly infectious (for example, evidenced by transmission to close contacts), or
- any casual contacts are known to possess features that put them at special risk of infection (see section 1.6.1).

1.8.1.6 'Inform and advise' information should be offered to all contacts of people with smear-positive TB. **D(GPP)**

## **1.8.2 Contact tracing: cattle to human transmission**

1.8.2.1 'Inform and advise' information should be given to people in contact with TB-diseased animals. Diagnostic tests for latent TB should be considered only for children younger than 16 who have not had BCG vaccination and have regularly drunk unpasteurised milk from animals with TB udder lesions. **D(GPP)**

## **1.8.3 Contact tracing: cases on aircraft**

1.8.3.1 Following diagnosis of TB in an aircraft traveller, contact tracing of fellow passengers should not routinely be undertaken. **D(GPP)**

1.8.3.2 The notifying clinician should inform the relevant consultant in communicable disease control (CCDC) if:

- less than 3 months has elapsed since the flight and the flight was longer than 8 hours **D(GPP)**, and
- the index case is sputum smear-positive **D(GPP)**, and either
  - the index case has MDR TB **C**, or
  - the index case coughed frequently during the flight. **D(GPP)**

The CCDC should provide the airline with 'Inform and advise' information to send to passengers seated in the same part<sup>18</sup> of the aircraft as the index case. **D(GPP)**

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<sup>18</sup> Published evidence does not allow for a precise definition, but such contact tracing on aircraft has often included only people within three rows on either side of the index case.

- 1.8.3.3 If the TB index case is an aircraft crew member, contact tracing of passengers should not routinely take place. **D(GPP)**
- 1.8.3.4 If the TB index case is an aircraft crew member, contact tracing of other members of staff is appropriate, in accordance with the usual principles for screening workplace colleagues (see section 1.8.1). **B**

#### **1.8.4 Contact tracing: cases in schools**

- 1.8.4.1 Following diagnosis of TB in a school pupil or member of staff, the consultant in communicable disease control should be prepared to explain the prevention and control procedures to staff, parents and the press. Advice on managing these incidents and their public relations is available from the Health Protection Unit. **D(GPP)**
- 1.8.4.2 If a school pupil is diagnosed with sputum smear-positive TB, the rest of his or her class (if there is a single class group), or the rest of the year group who share classes, should be assessed as part of contact tracing. **B**
- 1.8.4.3 If a teacher has sputum smear-positive TB, the pupils in his or her classes during the preceding 3 months should be assessed as part of contact tracing. **C**
- 1.8.4.4 Clinicians conducting contact tracing in a school should consider extending it to include children and teachers involved in extracurricular activities, and non-teaching staff, on the basis of: **D(GPP)**
- the degree of infectivity of the index case
  - the length of time the index case was in contact with others
  - whether contacts are unusually susceptible to infection
  - the proximity of contact.
- 1.8.4.5 Secondary cases of sputum smear-positive TB should be treated as index cases for contact tracing. **See 1.8.4.1–4 for class of recommendation**

1.8.4.6 If the index case of a school pupil's TB infection is not found, and the child is not in a high-risk group for TB, contact tracing and screening (by either symptom enquiry or chest X-ray) should be considered for all relevant members of staff at the school. **D(GPP)**

### **1.8.5 Contact tracing: community childcare**

1.8.5.1 When an adult who works in childcare (including people who provide childcare informally) is diagnosed with sputum smear-positive TB, management is as for contact tracing (see section 1.8.1). **D(GPP)**

### **1.8.6 Contact tracing: cases in hospital inpatients**

1.8.6.1 Following diagnosis of TB in a hospital inpatient, a risk assessment should be undertaken. This should take into account:

- the degree of infectivity of the index case
- the length of time before the infectious patient was isolated
- whether other patients are unusually susceptible to infection
- the proximity of contact.

Contact tracing and testing should be carried out only for patients for whom the risk is regarded as significant. **D(GPP)**

1.8.6.2 Patients should be regarded as at risk of infection if they spent more than 8 hours in the same bay as an inpatient with sputum smear-positive TB who had a cough. The risk should be documented in the contact's clinical notes, for the attention of the contact's consultant. The contact should be given 'Inform and advise' information, and their GP should be informed. **D(GPP)**

1.8.6.3 If patients were exposed to a patient with sputum smear-positive TB for long enough to be equivalent to household contacts (as determined by the risk assessment), or an exposed patient is known to be particularly susceptible to infection, they should be managed as equivalent to household contacts (see section 1.8.1). **D(GPP)**

1.8.6.4 If an inpatient with sputum smear-positive TB is found to have MDR TB, or if exposed patients are HIV-positive, contact tracing should be in line with The Interdepartmental Working Group on Tuberculosis guidelines<sup>19</sup>. **D(GPP)**

1.8.6.5 In cases of doubt when planning contact tracing after diagnosing sputum smear-positive TB in an inpatient, further advice should be sought from the regional or national Health Protection Agency and/or people experienced in the field. **D(GPP)**

### 1.8.7 New entrants

1.8.7.1 Healthcare professionals, including primary care staff, responsible for screening new entrants should maintain a coordinated programme to:

- detect active TB and start treatment **B**
- detect latent TB and start treatment **B**
- provide BCG vaccination to those in high-risk groups who are not infected and who are previously unvaccinated **D(GPP)**
- provide relevant information to all new entrants. **D(GPP)**

1.8.7.2 New entrant screening for tuberculosis should be incorporated within larger health screening programmes for new entrants, linked to local services. **D(GPP)**

1.8.7.3 Assessment for, and management of, TB in new entrants should consist of the following. **D(GPP)**

- A chest X-ray for those who have not had one recently taken, unless they are younger than 11 or are possibly pregnant.
- Clinical assessment for those with an abnormal chest X-ray.
- Risk assessment for HIV, including HIV prevalence rates in the country of origin, which is then taken into account for Mantoux testing and BCG vaccination.

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<sup>19</sup> The Interdepartmental Working Group on Tuberculosis (1998) *The prevention and control of tuberculosis in the United Kingdom: UK guidance on the prevention and control of transmission of 1. HIV-related tuberculosis 2. drug-resistant, including multiple drug-resistant, tuberculosis*. London: Department of Health. Available from [www.dh.gov.uk](http://www.dh.gov.uk)

- A Mantoux test for people with normal recent chest X-ray who are:
  - younger than 16, or
  - aged 16–35, from sub-Saharan Africa or a country with a TB incidence greater than 500 per 100,000.
- A Mantoux test for
  - children younger than 11 years
  - pregnant women.
- Interferon-gamma test (if available) if Mantoux test is positive (6 mm or greater) in someone who has not had BCG vaccination, or strongly positive (15 mm or greater) in someone who has been vaccinated.
- Assessment for active TB if interferon-gamma test is positive; interpret chest X-ray first if it is not contraindicated.
- Treatment for latent TB infection for people aged 35 or younger in whom active TB has been excluded, with a positive Mantoux test inconsistent with their BCG history, and a positive interferon-gamma test (if this test was available), and who are:
  - younger than 16, or
  - aged 16–35, from sub-Saharan Africa or a country with a TB incidence greater than 500 per 100,000.
- Consideration of BCG for unvaccinated people who are Mantoux negative (see section 1.7.4).
- ‘Inform and advise’ information for people who do not have active TB and are not being offered BCG or treatment for latent TB infection.

See the algorithm on new entrant screening in appendix E for a summary.

1.8.7.4 New entrants should be identified for TB screening from the following information:

- Port of Arrival reports **D(GPP)**
- new registrations with primary care **B**
- entry to education (including universities) **D(GPP)**
- links with statutory and voluntary groups working with new entrants. **D(GPP)**

1.8.7.5 Any healthcare professional working with new entrants should encourage them to register with a GP. **D(GPP)**

### **1.8.8 Street homeless**

1.8.8.1 Active case finding should be carried out among street homeless people (including those using direct access hostels for the homeless) by chest X-ray screening on an opportunistic and/or symptomatic basis. Simple incentives for attending, such as hot drinks and snacks, should be considered. **D(GPP)**

1.8.8.2 Healthcare professionals working with people with TB should reinforce and update education about TB, and referral pathways, to primary care colleagues, social workers and voluntary workers who work with homeless people. **D(GPP)**

## **1.9 Preventing infection in specific settings**

### **1.9.1 Healthcare environments: new NHS employees**

1.9.1.1 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 having taken place within the preceding 12 months. **D(GPP)**

1.9.1.2 Employees new to the NHS who will not have contact with patients or clinical specimens should not start work if they have signs or symptoms of TB. **D(GPP)**

- 1.9.1.3 Health checks for employees new to the NHS who will have contact with patients or clinical materials should include: **D(GPP)**
- assessment of personal or family history of TB
  - symptom and signs enquiry, possibly by questionnaire
  - documentary evidence of TB skin testing (or interferon-gamma 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.
- 1.9.1.4 If an employee new to the NHS has no (or inconclusive) evidence of prior BCG vaccination, a Mantoux or interferon-gamma test (see section 1.1.1) should be performed. **D(GPP)**
- 1.9.1.5 Employees who will be working with patients or clinical specimens and who are Mantoux negative (less than 6 mm) should have an individual risk assessment for HIV infection before BCG vaccination is given. **D(GPP)**
- 1.9.1.6 Employees new to the NHS should be offered BCG vaccination, whatever their age, if they will have contact with patients and/or clinical specimens, are Mantoux negative (less than 6 mm) and have not been previously vaccinated. **D(GPP)**
- 1.9.1.7 Employees of any age who are new to the NHS and are from countries of high TB incidence, or who have had contact with patients in settings with a high TB prevalence should have a Mantoux test. If negative (less than 6 mm), recommendations 1.9.1.4 and 1.9.1.5 should be followed. If positive (6 mm or greater), the person should be referred for clinical assessment for diagnosis and possible treatment of latent infection or active disease. **D(GPP)**
- 1.9.1.8 If a new employee from the UK or other low-incidence setting, without prior BCG vaccination, has a positive Mantoux or interferon-gamma test, they should have a medical assessment and a chest X-ray. They should be referred to a TB clinic for consideration of TB

treatment if the chest X-ray is abnormal, or for consideration of treatment of latent TB infection if the chest X-ray is normal. **D(GPP)**

1.9.1.9 If a prospective or current healthcare worker who is Mantoux negative (less than 6 mm) 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. The employer will need to consider each case individually, taking account of employment and health and safety obligations. **D(GPP)**

1.9.1.10 Clinical students, agency and locum staff and contract ancillary workers who have contact with patients or clinical materials should be screened for TB to the same standard as new employees in healthcare environments, according to the recommendations set out above. Documentary evidence of screening to this standard should be sought from locum agencies and contractors who carry out their own screening. **D(GPP)**

1.9.1.11 NHS trusts arranging care for NHS patients in non-NHS settings should ensure that healthcare workers who have contact with patients or clinical materials in these settings have been screened for TB to the same standard as new employees in healthcare environments (see recommendations 1.9.1.1–8). **D(GPP)**

See the algorithm on screening new NHS employees (appendix E) for a summary.

## **1.9.2 Healthcare environments: occupational health**

These recommendations set the standard for NHS organisations and therefore should apply in any setting in England and Wales where NHS patients are treated.

- 1.9.2.1 Reminders of the symptoms of TB, and the need for prompt reporting of such symptoms, should be included with annual reminders about occupational health for staff who: **D(GPP)**
- are in regular contact with TB patients or clinical materials, or
  - have worked in a high-risk clinical setting for 4 weeks or longer.

One-off reminders should be given after a TB incident on a ward.

- 1.9.2.2 If no documentary evidence of prior screening is available, staff in contact with patients or clinical material who are transferring jobs within the NHS should be screened as for new employees (see section 1.9.1). **D(GPP)**

- 1.9.2.3 The risk of TB for a new healthcare worker who knows he or she is HIV-positive at the time of recruitment should be assessed as part of the occupational health checks. **D(GPP)**

- 1.9.2.4 The employer, through the occupational health department, should be aware of the settings with increased risk of exposure to TB, and that these pose increased risks to HIV-positive healthcare workers. **D(GPP)**

- 1.9.2.5 Healthcare workers who are found to be HIV-positive during employment should have medical and occupational assessments of TB risk, and may need to modify their work to reduce exposure. **D(GPP)**

### **1.9.3 Prisons and remand centres**

- 1.9.3.1 Healthcare workers providing care for prisoners and remand centre detainees should be aware of the signs and symptoms of active TB. TB services should ensure that awareness of these signs and symptoms is also promoted among prisoners and prison staff. **D(GPP)**

- 1.9.3.2 Prisoners should be screened for TB by:
- a health questionnaire on each entry to the prison system **D(GPP)**, then
  - for those with signs and symptoms of active TB, a chest X-ray **C**, and three sputum samples taken in 24 hours for TB microscopy, including a morning sputum sample (see section 1.1.2). **D(GPP)**
- 1.9.3.3 All prisoners receiving treatment for active or latent TB should receive DOT. **D(GPP)**
- 1.9.3.4 Prison medical services should have liaison and handover arrangements to ensure continuity of care before any prisoner on TB treatment is transferred between prisons. **D(GPP)**
- 1.9.3.5 If a prisoner is being treated for active or latent TB, the prison medical services should draw up as early as possible a contingency plan for early discharge, which could happen directly from a court appearance. This plan should include firm arrangements for clinical follow-up and treatment monitoring in the intended district of residence, and should take into account that there may not be a fixed residence arranged for the prisoner after release. The prisoner should be given contact details for a named key worker, who will visit and monitor the prisoner after release and liaise between services involved. **D(GPP)**
- 1.9.3.6 Prison service staff and others who have regular contact with prisoners (for example, probation officers and education and social workers) should have pre- and on-employment screening at the same level as for healthcare workers with patient contact (see sections 1.9.1 and 1.9.2). **D(GPP)**

## 2 Notes on the scope of the guidance

All NICE guidelines are developed in accordance with a scope document that defines what the guideline will and will not cover. The scope of this guideline

was established, after a period of consultation, at the start of the guideline development process; it is available from [www.nice.org.uk/CG033](http://www.nice.org.uk/CG033)

This guideline sets out best practice guidance for the diagnosis, treatment, prevention and control of TB in the NHS in England and Wales. It covers latent TB infection and active TB of the following sites:

- respiratory (lung, bronchus, pleura, thoracic lymph nodes)
- meningeal
- pericardial
- bone and joint
- peripheral lymph nodes
- genitourinary
- disseminated (including miliary).

The guideline does not extend to comorbidities such as HIV, drug dependencies, diabetes, hepatic disease, renal disease, or mental illness, nor does it give guidance on highly specialised and individualised activities such as treatment of multidrug-resistant (MDR) TB. It does not include special guidance for patients who are pregnant, planning pregnancy or unconscious, or for older people in long-term care. It considers only the *M tuberculosis* complex of bacteria, and therefore does not provide guidance on other mycobacterial infections.

### **3 Implementation in the NHS**

The Healthcare Commission will assess the performance of NHS organisations in meeting core and developmental standards set by the Department of Health in 'Standards for better health' issued in July 2004.

Implementation of clinical guidelines forms part of the developmental standard D2. Core standard C5 says that national agreed guidance should be taken into account when NHS organisations are planning and delivering care.

This guideline is supported by the following implementation tools available on our website ([www.nice.org.uk/CG033](http://www.nice.org.uk/CG033)).

- A slide set – key messages for local discussion.

- Costing tools:
  - a national costing report, which estimates the overall resource impact associated with implementation
  - a local costing template; a simple spreadsheet that can be used to estimate the local cost of implementation.
- Implementation advice – practical suggestions on how to address potential barriers to implementation.

Suggested audit criteria based on the key priorities for implementation are listed in appendix D of this document (see page 60), and can be used to audit practice locally.

## **4 Research recommendations**

The Guideline Development Group has made the following recommendations for research, on the basis of its review of the evidence. The Group regards these recommendations as the most important research areas to improve NICE guidance and patient care in the future. The Guideline Development Group's full set of research recommendations is detailed in the full guideline (see Section 5).

### **4.1 Interferon-gamma tests**

A diagnostic and qualitative study is needed to assess whether interferon-gamma tests are acceptable to patients and are more effective than tuberculin skin tests for:

- predicting subsequent development of active TB, or
- diagnosing or ruling out current active TB

when undertaking TB screening in:

- new entrants from high TB prevalence countries
- healthcare workers
- children in high-risk areas who missed neonatal BCG
- contacts of people with sputum smear-positive TB
- HIV positive patients.

This study should compare the strategies of Mantoux test only, Mantoux test then interferon gamma test if positive, and interferon gamma test only.

### **Why this is important**

These are new diagnostic tests and there is not yet evidence to show increased effectiveness in predicting subsequent development of active TB, which could enable better targeting of preventive treatment. Also, the acceptability of the tests to various screening groups has not been investigated.

## ***4.2 Directly observed therapy***

A cluster randomised controlled trial of directly observed therapy (DOT) compared with self-administered treatment for latent and/or active TB should be conducted in a UK population. This should be targeted at homeless people, and those with a history of non-adherence, alcoholism, drug abuse, or mental illness.

### **Why this is important**

There is currently no evidence from controlled studies on the use of DOT in the UK. If a UK programme of DOT is found to promote adherence to treatment in these populations, then patients would be less likely to experience future relapse, drug resistance or transmit TB to other patients.

## ***4.3 New entrant screening and treatment for latent TB infection***

A study is needed of people found by new entrant screening (as set out in section 1.8.7) to be Mantoux positive and interferon-gamma positive, to establish better estimates of the cost-effectiveness of screening and treatment for latent TB infection in this population. This could identify factors predisposing people to developing active TB so that more effective targeted treatment programmes can be developed for latent TB infection.

### **Why it is important**

The current guideline recommendations are based on a health economic model, which attempts to target effort on those people at highest risk. This

would be more useful if more accurate cost-effectiveness estimates were evaluated for the current UK scenario.

#### **4.4 Protective effects of BCG**

A case-control study is needed, comparing people who developed active or latent TB with those who did not, and comparing the proportions of people in each group who had been vaccinated and the time since vaccination. The aim will be to derive improved estimates of protective efficacy and duration of protection of the BCG vaccine.

##### **Why it is important**

There is little up-to-date evidence on the duration of BCG protection in England and Wales across various age ranges and population groups. This information would aid the development of future BCG vaccination policies in these groups.

#### **4.5 Quality of life**

A study is needed to ascertain quality-of-life score estimates from those with TB (both active disease and latent infection), including adverse treatment effects, using an appropriate quality-of-life instrument. This will improve economic decision-making throughout TB care.

##### **Why it is important**

Patients' views on their quality of life would be more accurately reflected in future work. There are currently no quality-of-life estimates in the guideline models based on data drawn directly from patients. Cost effectiveness estimates in the form of QALYs would increase the accuracy of health economic models.

#### **4.6 Contact tracing in household contacts and homeless people**

Research is needed to determine whether contact tracing is more effective (in terms of identifying cases of latent infection and active disease) among household contacts than among street homeless contacts of patients with

confirmed TB disease (including those using direct-access hostels for the homeless).

### **Why it is important**

Evidence from one non-analytic study suggests that contact tracing identifies fewer cases of TB in the homeless than in contacts who were housed. Depending on the outcome, the research findings could have implications for modifying conventional contact tracing so that it is tailored to the needs of the homeless population.

## ***4.7 Incentives for attending new entrant screening***

Research is needed to determine whether Port of Arrival scheme referrals with incentives for attending screening identify more cases of latent TB infection and active TB disease in new entrants than Port of Arrival scheme referrals with no incentives.

### **Why it is important**

Currently there is no evidence from controlled studies in this area. If incentives were found to improve attendance for TB screening among this population, then this method would be a more effective way of reaching and treating this patient group.

## ***4.8 Incentives for homeless people attending chest X-ray screening***

Research is needed to determine whether incentives for attending chest X-ray screening achieve better coverage in the homeless population, or identify more cases of latent TB infection and active TB disease, than no incentives.

### **Why it is important**

Currently there is no evidence from controlled studies in this area. If incentives were found by the research evidence to improve attendance for chest X-ray screening among this population, then this method would be a more effective way of reaching and treating this patient group.

## **5 Other versions of this guideline**

The National Institute for Clinical Excellence commissioned the development of this guidance from the National Collaborating Centre for Chronic Conditions. The Centre established a Guideline Development Group, which reviewed the evidence and developed the recommendations. The members of the Guideline Development Group are listed in appendix B. Information about the independent Guideline Review Panel is given in appendix C.

The booklet 'The guideline development process: an overview for stakeholders, the public and the NHS' has more information about the Institute's guideline development process. It is available from the Institute's website and copies can also be ordered by telephoning 0870 1555 455 (quote reference N0472).

### **5.1 Full guideline**

The full guideline, 'Tuberculosis: National clinical guideline for diagnosis, management, prevention and control', is published by the Royal College of Physicians of London; it is available from [www.rcplondon.ac.uk/pubs/](http://www.rcplondon.ac.uk/pubs/), the NICE website ([www.nice.org.uk/CG033fullguideline](http://www.nice.org.uk/CG033fullguideline)) and the website of the National Library for Health ([www.nlh.nhs.uk](http://www.nlh.nhs.uk)).

### **5.2 Quick reference guide**

A quick reference guide for health professionals is also available from the NICE website ([www.nice.org/CG033quickrefguide](http://www.nice.org/CG033quickrefguide)) or from the NHS Response Line (telephone 0870 1555 455; quote reference number N1008).

### **5.3 Information for the public**

A version of this guideline for people who have tuberculosis or are being tested for it, their families and carers, and the public, is available from the NICE website ([www.nice.org.uk/CG033publicinfo](http://www.nice.org.uk/CG033publicinfo)) or from the NHS Response Line (0870 1555 455); quote reference number N1009.

## **6 Related NICE guidance**

There is no related NICE guidance.

## **7 Review date**

The process of reviewing the evidence is expected to begin 4 years after the date of issue of this guideline. Reviewing may begin before this if significant evidence that affects the guideline recommendations is identified. The updated guideline will be available within 2 years of the start of the review process.

## **Appendix A: Grading scheme**

The classification of recommendations and the levels of evidence for intervention studies used in this guideline are adapted from the Scottish Intercollegiate Guidelines Network ('SIGN 50: a guideline developers' handbook'), and summarised in the tables on page 54). The classification of recommendations and levels of evidence for the accuracy of diagnostic tests are adapted from 'The Oxford Centre for Evidence-Based Medicine levels of evidence' (2001) and the 'Centre for Reviews and Dissemination report No. 4' (2001). They are summarised in the tables on page 55 and are being used on a pilot basis.

## Classification of recommendations on interventions

Recommendation grade	Evidence
A	<ul style="list-style-type: none"> <li>• At least one meta-analysis, systematic review, or randomised controlled trial (RCT) that is rated as 1<sup>++</sup>, and is directly applicable to the target population, <b>or</b></li> <li>• A systematic review of RCTs or a body of evidence that consists principally of studies rated as 1<sup>+</sup>, is directly applicable to the target population and demonstrates overall consistency of results, <b>or</b></li> <li>• Evidence drawn from a NICE technology appraisal</li> </ul>
B	<ul style="list-style-type: none"> <li>• A body of evidence that includes studies rated as 2<sup>++</sup>, is directly applicable to the target population and demonstrates overall consistency of results, <b>or</b></li> <li>• Extrapolated evidence from studies rated as 1<sup>++</sup> or 1<sup>+</sup></li> </ul>
C	<ul style="list-style-type: none"> <li>• A body of evidence that includes studies rated as 2<sup>+</sup>, is directly applicable to the target population and demonstrates overall consistency of results, <b>or</b></li> <li>• Extrapolated evidence from studies rated as 2<sup>++</sup></li> </ul>
D	<ul style="list-style-type: none"> <li>• Evidence level 3 or 4, <b>or</b></li> <li>• Extrapolated evidence from studies rated as 2<sup>+</sup>, <b>or</b></li> <li>• Formal consensus</li> </ul>
D(GPP)	<ul style="list-style-type: none"> <li>• A good practice point (GPP) is a recommendation for best practice based on the experience of the Guideline Development Group</li> <li>• Extrapolated from level 2 clinical evidence, supplemented with health-economic modelling</li> </ul>

## Levels of evidence for intervention studies

Level of evidence	Type of evidence
1 <sup>++</sup>	<ul style="list-style-type: none"> <li>• High-quality meta-analyses, systematic reviews of RCTs, or RCTs with a very low risk of bias</li> </ul>
1 <sup>+</sup>	<ul style="list-style-type: none"> <li>• Well-conducted meta-analyses, systematic reviews of RCTs, or RCTs with a low risk of bias</li> </ul>
1 <sup>-</sup>	<ul style="list-style-type: none"> <li>• Meta-analyses, systematic reviews of RCTs, or RCTs with a high risk of bias</li> </ul>
2 <sup>++</sup>	<ul style="list-style-type: none"> <li>• High-quality systematic reviews of case-control or cohort studies</li> <li>• High-quality case-control or cohort studies with a very low risk of confounding, bias or chance and a high probability that the relationship is causal</li> </ul>
2 <sup>+</sup>	<ul style="list-style-type: none"> <li>• Well-conducted case-control or cohort studies with a low risk of confounding, bias or chance and a moderate probability that the relationship is causal</li> </ul>
2 <sup>-</sup>	<ul style="list-style-type: none"> <li>• Case-control or cohort studies with a high risk of confounding, bias, or chance and a significant risk that the relationship is not causal</li> </ul>
3	<ul style="list-style-type: none"> <li>• Non-analytical studies (for example, case reports, case series)</li> </ul>
4	<ul style="list-style-type: none"> <li>• Expert opinion, formal consensus</li> </ul>

## Classification of recommendations on diagnostic tests

Grade	Evidence
A(DS)	• Studies with level of evidence Ia or Ib
B(DS)	• Studies with level of evidence II
C(DS)	• Studies with level of evidence III
D(DS)	• Studies with level of evidence IV

DS, diagnostic studies.

## Levels of evidence for studies of the accuracy of diagnostic tests

Levels of evidence	Type of evidence
Ia	<ul style="list-style-type: none"> <li>• Systematic review (with no or minor variations in the directions and degrees of results between studies) of level-1 studies, which are studies that use: <ul style="list-style-type: none"> <li>– a blind comparison of the test with a validated reference standard (gold standard)</li> <li>– a sample of patients that reflects the population to whom the test would apply</li> </ul> </li> </ul>
Ib	<ul style="list-style-type: none"> <li>• Level-1 studies</li> </ul>
II	<ul style="list-style-type: none"> <li>• Level-2 studies, which are studies that have only one of the following: <ul style="list-style-type: none"> <li>– the population is narrow (the sample does not reflect the population to whom the test would apply)</li> <li>– a poor reference standard is used (defined as that where the ‘test’ is included in the ‘reference’, or where the ‘testing’ affects the ‘reference’)</li> <li>– the comparison between the test and reference standard is not blind</li> <li>– the study is a case–control study</li> </ul> </li> <li>• Systematic reviews of level-2 studies</li> </ul>
III	<ul style="list-style-type: none"> <li>• Level-3 studies, which are studies that have at least two of the features listed for level-2 studies</li> <li>• Systematic reviews of level-3 studies</li> </ul>
IV	<ul style="list-style-type: none"> <li>• Expert committee reports, opinions and/or clinical experience without explicit critical appraisal; or based on physiology, bench research or ‘first principles’</li> </ul>

## **Appendix B: The Guideline Development Group**

### **Ms Sue Appleby**

Specialist Nurse in Health Protection, Dorset and Somerset Health Protection Unit

### **Dr Gerry Bryant**

Director of Public Health, Derbyshire Dales and South Derbyshire Primary Care Trust

### **Dr Ian Campbell**

Consultant Physician, Cardiff and Vale NHS Trust

### **Mr Michael Carter**

Patient and carer representative, London

### **Mr Malcolm Cocksedge**

Senior Clinical Nurse Specialist, Barts and The London NHS Trust

### **Ms Sue Dart**

TB Nurse Manager, Haringey Teaching Primary Care Trust

### **Professor Peter Davies**

Consultant Physician, Cardiothoracic Centre Liverpool NHS Trust

### **Mrs Bernadette Ford**

Information Scientist, National Collaborating Centre for Chronic Conditions, London

### **Mr Rob Grant**

Senior Project Manager, National Collaborating Centre for Chronic Conditions, London

### **Mr Ashley Green**

Patient and Carer Representative, London

**Professor Chris Griffiths**

Professor of Primary Care, Queen Mary's School of Medicine and Dentistry,  
University of London

**Professor Andy Hall**

Professor of Epidemiology, London School of Hygiene and Tropical Medicine,  
University of London; Representative of the Joint Committee on Vaccination  
and Immunisation, Department of Health

**Dr Andrew Hayward**

Senior Lecturer in Infectious Disease Epidemiology, Royal Free and  
University College Medical School, University of London

**Dr John Hayward (Public Health Advisor, Chair of the Clinical Sub-Group  
of the GDG)**

Director of Public Health, Newham Primary Care Trust, London; General  
Practitioner, London

**Dr Bernard Higgins**

Director, National Collaborating Centre for Chronic Conditions; Consultant  
Respiratory Physician, Newcastle upon Tyne Hospitals NHS Trust

**Dr John Innes**

Consultant Physician, Birmingham Heartlands and Solihull (Teaching) NHS  
Trust

**Dr Jane Jones**

Consultant Epidemiologist, Centre for Infections, Health Protection Agency,  
London

**Dr Ian Lockhart**

Health Services Research Fellow in Guideline Development, National  
Collaborating Centre for Chronic Conditions, London

**Dr Joanne Lord**

Health Economics Advisor, National Institute for Health and Clinical  
Excellence

**Dr John Magee**

Director, Health Protection Agency Newcastle Regional Laboratory

**Dr Jonathan Mant (Chair of the Prevention and Control Sub-Group of the GDG)**

Senior Lecturer in Primary Care, University of Birmingham Medical School

**Dr John Moore-Gillon**

Consultant Physician, Barts and The London NHS Trust

**Ms Helen Murshali**

Patient and Carer Representative, London

**Ms Ndid Okonta**

Patient and Carer Representative, London

**Professor Peter Ormerod (Clinical Advisor)**

Professor of Medicine and Consultant Physician in Respiratory and General Medicine, East Lancashire Hospitals NHS Trust

**Dr Delane Shingadia**

Senior Lecturer in Paediatric Infectious Diseases, Barts and The London Medical and Dental School

**Ms Caroline Trevithick**

Lead Infection Control Nurse, University Hospitals of Leicester NHS Trust

**Ms Susan Varney**

Health Services Research Fellow in Guideline Development, National Collaborating Centre for Chronic Conditions, London

**Dr Irving Wells**

Consultant Radiologist, Plymouth Hospitals NHS Trust

**Dr Martin Wiselka**

Consultant Physician and Honorary Senior Lecturer in Infectious Diseases, University Hospitals of Leicester NHS Trust

## **Appendix C: The Guideline Review Panel**

The Guideline Review Panel is an independent panel that oversees the development of the guideline and takes responsibility for monitoring its quality. The Panel includes experts on guideline methodology, health professionals and people with experience of the issues affecting patients and carers. The members of the Guideline Review Panel were as follows.

### **Dr Peter Rutherford (Chair)**

Senior Lecturer in Nephrology, University of Wales College of Medicine

### **Dame Helena Shovelton**

Chief Executive, British Lung Foundation

### **Dr Rob Higgins**

Consultant in Renal and General Medicine, University Hospitals Coventry and Warwickshire NHS Trust, Coventry

### **Mrs Fiona Wise**

Chief Executive, Ealing Hospital NHS Trust

### **Dr John Young**

Medical Director, Merck Sharp & Dohme (MSD)

## Appendix D: Technical detail on the criteria for audit

### **Data collection**

Data for criteria 1, 2 and 4 can be collected from patient notes or prescribing software. Given the small number of patients receiving directly observed therapy (DOT), retrospective data collection across a year will be needed to provide an accurate proportion.

Criterion 3 will be useful only for local or national comparative audit and discussion; it is not possible to determine a target. These data probably need to be collected from patients during a clinic visit (at a consistent point in their treatment for comparability), which also provides an opportunity to collect qualitative data on interaction with, or understanding of the roles of, key workers.

Data for criterion 5 can be collected in primary care trusts, where the sources of names (such as records from ports of arrival, GP registration, educational institutions) are all compiled at one point, and where it is possible to remove duplicated names.

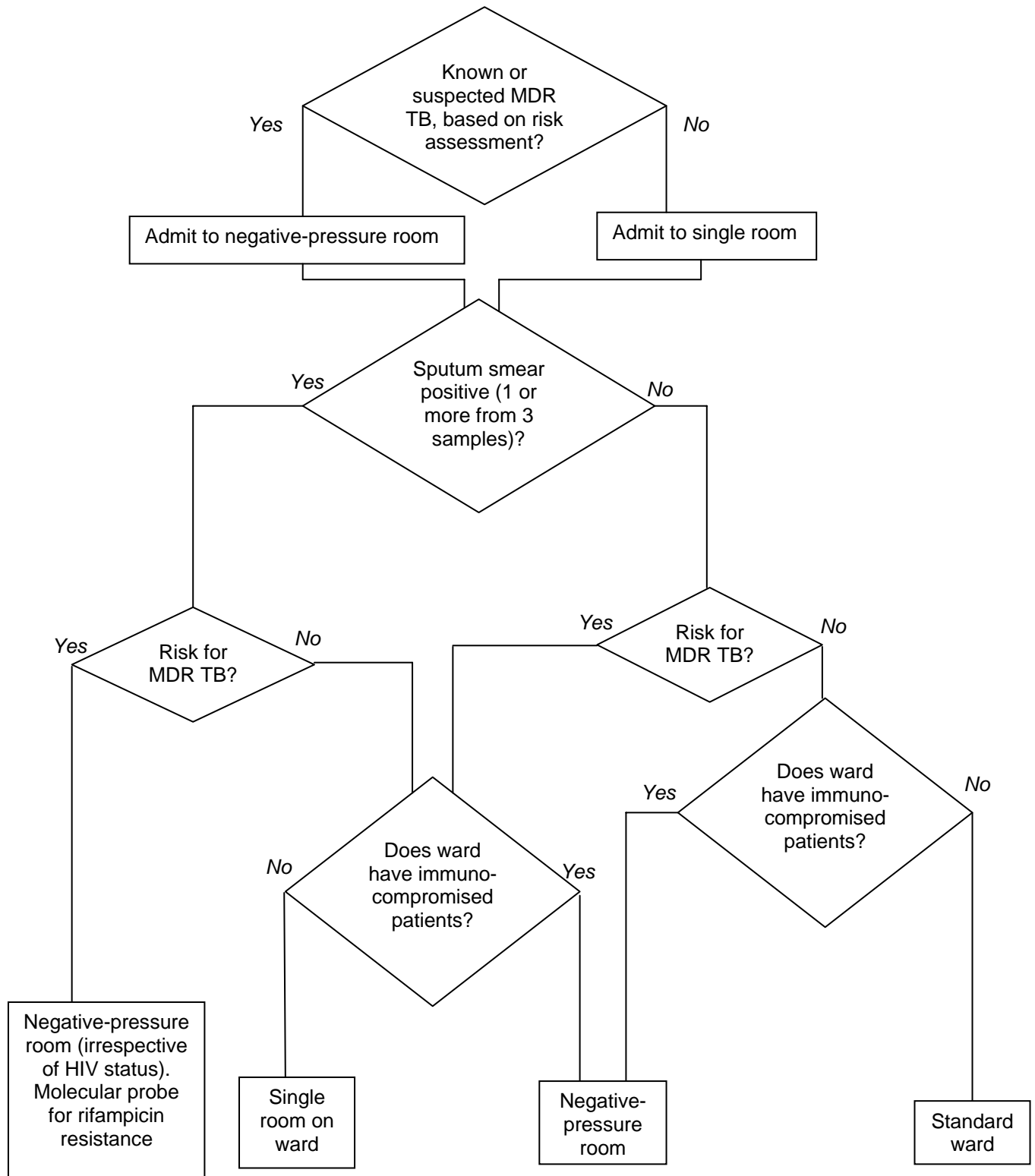
Criterion 6 should be assessed retrospectively on a population-wide basis by the primary care trust.

<b>Criterion</b>	<b>Exception</b>	<b>Definition of terms</b>
1. a) Process measure: percentage of patients with active TB receiving rifampicin, isoniazid, pyrazinamide and ethambutol (or other fourth drug) for the first 2 months of treatment  b) Outcome measure: percentage cure and completion rate	Contraindications, meningeal TB, CNS involvement, drug resistance	

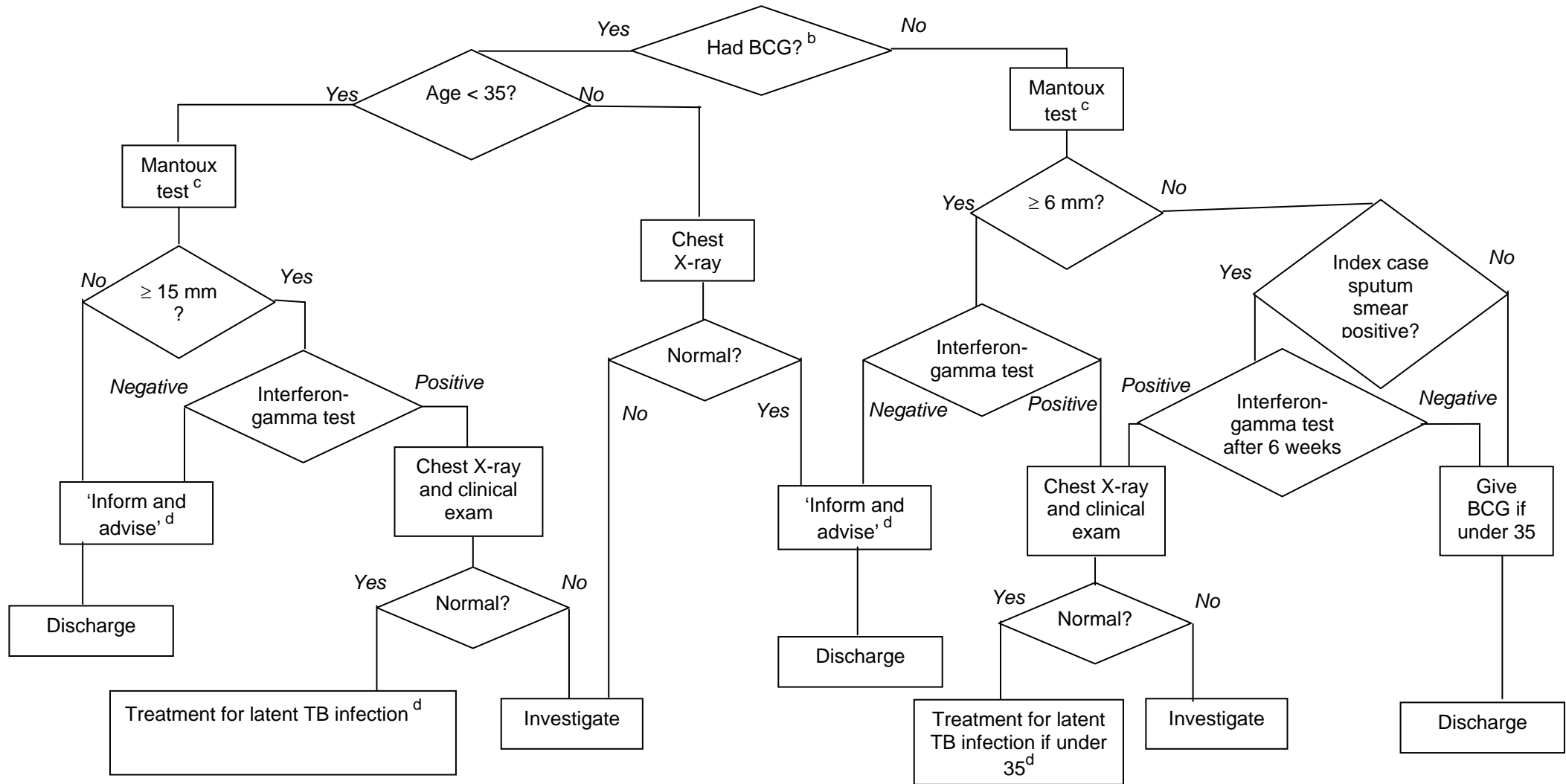
Criterion	Exception	Definition of terms
2. Process measure: percentage of patients with active TB who are treated with DOT		'Patients on DOT' are any patients who have been prescribed anti-TB drugs as directly observed therapy (regardless of observer) for part or all of their treatment.
3. Process measure: percentage of TB patients in possession of current correct key worker's details	Hospital inpatients	Key worker will have been named as specified in recommendations.
4. a) Process measure: percentage of patients with meningeal TB receiving rifampicin, isoniazid, pyrazinamide and ethambutol (or other fourth drug) for the first 2 months of treatment b) Process measure: percentage receiving/having received glucocorticoids c) Outcome measure: percentage cure and completion rate (12 months)	Contraindications, drug resistance	b) Any patient who received glucocorticoids for at least 2 weeks.
5. a) Process measure: percentage of new entrants referred or recorded who are contacted for screening b) Process measure: percentage of new entrants contacted for screening who complete the screening c) Process measure: percentage of new entrants contacted for screening who are referred to secondary care TB teams	A. Any people sought but not found B. Loss to follow-up, including not returning for Mantoux test to be read, chest X-ray to be taken, treatment for latent TB infection to be started, etc.	b) Any person who completes the screening process according to the algorithm is counted.
6. a) Process measure: percentage of neonates vaccinated with BCG b) Process measure: percentage of eligible neonates vaccinated with BCG	Informed refusal, HIV	

## Appendix E: The algorithms

### *Isolation decisions for patients with suspected respiratory TB*



**Testing and treating asymptomatic household and other close contacts of all cases of active TB<sup>a</sup>**



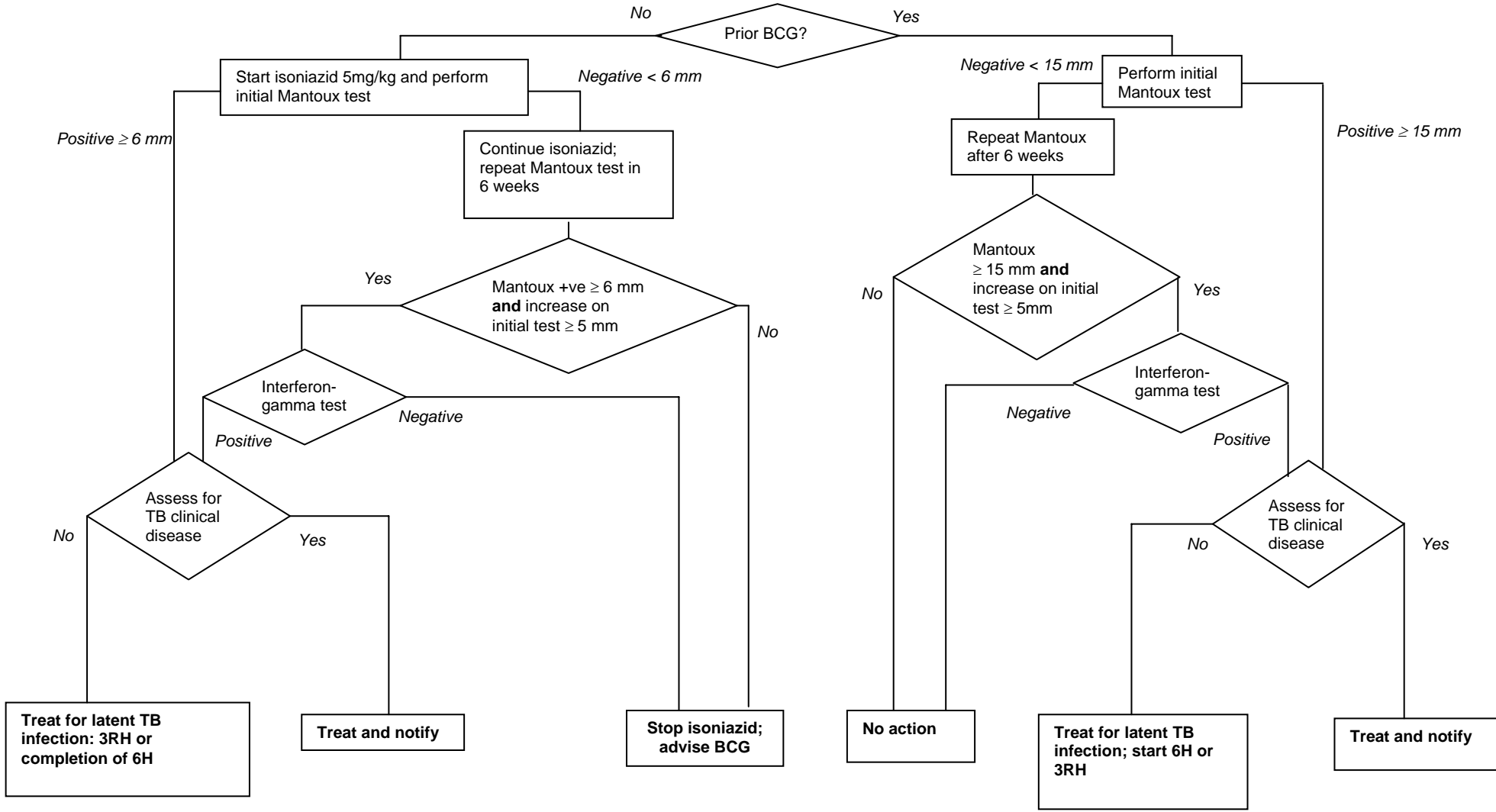
<sup>a</sup> For children aged between 4 weeks and 2 years old who are contacts of people with sputum smear-positive TB, use the algorithm on page 64.

<sup>b</sup> Previous BCG vaccination cannot be accepted as evidence of immunity in HIV-infected patients.

<sup>c</sup> A negative test in immunocompromised people does not exclude TB infection.

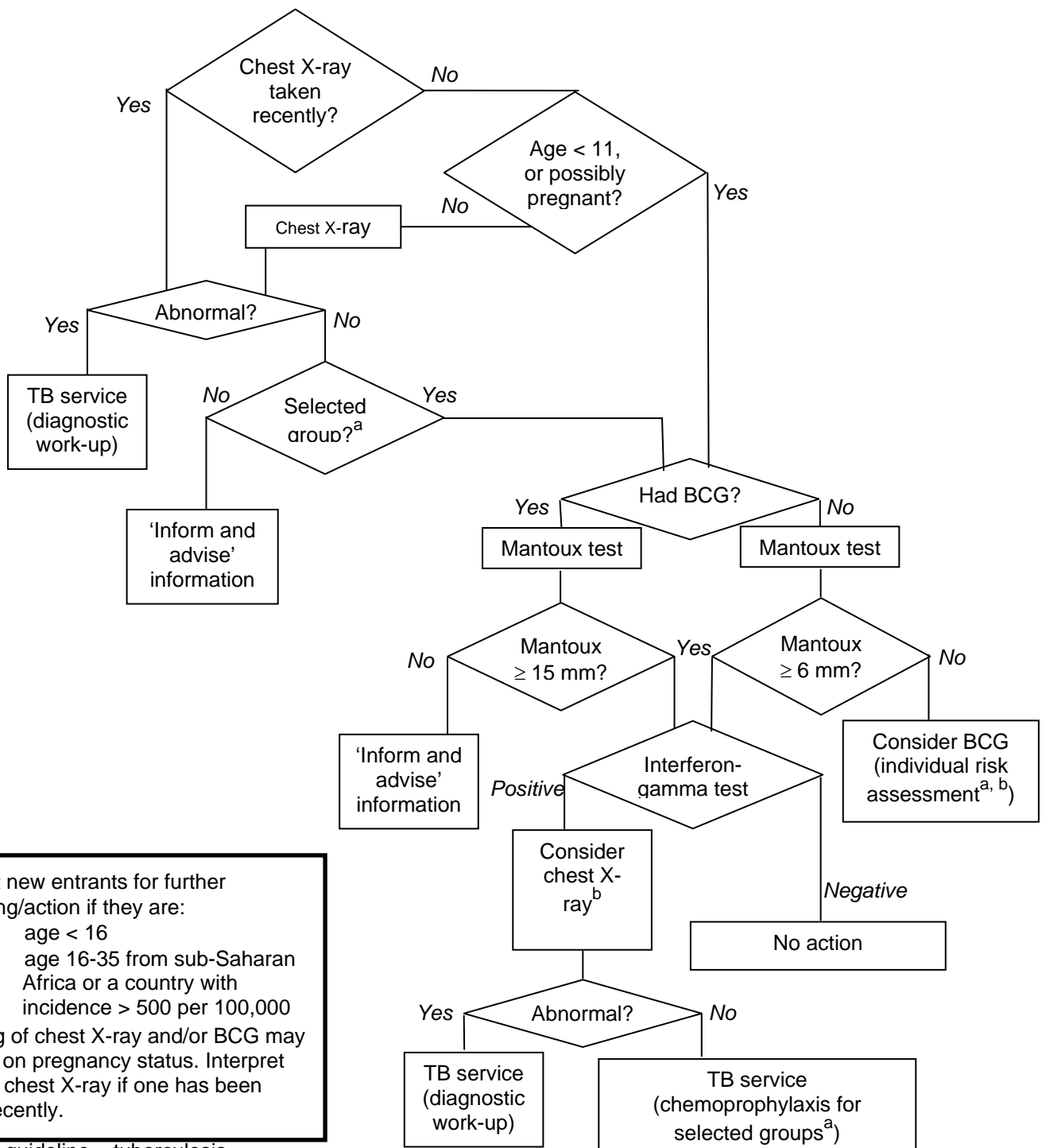
<sup>d</sup> People advised to have treatment for latent TB infection, but who decline, should have ‘Inform and advise’ information reinforced and chest X-ray follow-up at 3 and 12 months.

**Testing and treating asymptomatic children older than 4 weeks but younger than 2 years who are contacts of people with sputum smear-positive TB**



## New entrant screening

This algorithm sets out the actions for screening new entrants (or people returning after a prolonged stay) to England or Wales from a country with a high incidence of TB (as defined by the Health Protection Agency; go to [www.hpa.org.uk](http://www.hpa.org.uk) and search for 'WHO country data TB'). It does **not** apply to people who are known to be HIV-positive, who should be referred to an HIV team. People coming to the UK to work in healthcare who will have contact with patients or clinical material should be screened in line with the algorithm on new NHS employees (on page 66). This algorithm applies to dedicated new entrant screening services, and therefore does not detail the systems for detecting new entrants, nor the clinic activities that follow. Service providers with a different service model may need to adapt this to their individual processes.



# Screening new NHS employees

<sup>a</sup> New entrants are people arriving in or returning to the UK from a high-incidence country (more than 40 cases per 100,000 per year, as listed by the Health Protection Agency; go to [www.hpa.org.uk](http://www.hpa.org.uk) and search for 'WHO country data TB')

