

# Identifying and managing tuberculosis among hard-to-reach groups

Issued: March 2012

NICE public health guidance 37 guidance.nice.org.uk/ph37

NICE has accredited the process used by the Centre for Public Health Excellence at NICE to produce guidance. Accreditation is valid for 5 years from January 2010 and applies to guidance produced since April 2009 using the processes described in NICE's 'Methods for the development of NICE public health guidance' (2009). More information on accreditation can be viewed at www.nice.org.uk/ accreditation



# **Contents**

ntroduction: scope and purpose of this guidance	6
What is this guidance about?	6
Who is this guidance for?	7
Why is this guidance being produced?	7
How was this guidance developed?	7
What evidence is the guidance based on?	7
Status of this guidance	8
I Recommendations	9
Definitions	9
Who will benefit?	9
Who should take action?	10
Recommendation 1 Strategic oversight and commissioning of TB prevention and control activiti	ies 10
Recommendation 2 Local needs assessment	12
Recommendation 3 Cohort review	14
Recommendation 4 Commissioning multidisciplinary TB support for hard-to-reach groups	15
Recommendation 5 Raising and sustaining awareness of TB among health professionals and t working with hard-to-reach groups	
Recommendation 6 Raising and sustaining awareness of TB among hard-to-reach groups	18
Recommendation 7 Identifying active pulmonary TB among those using homeless or substance misuse services	e 19
Recommendation 8 Identifying and managing active TB in prisons or immigration removal cent organisational factors	
Recommendation 9 Identifying active TB in prisons or immigration removal centres	22
Recommendation 10 Managing active TB in prisons or immigration removal centres	22
Recommendation 11 Identifying and managing active and latent TB: vulnerable migrants	24
Recommendation 12 Identifying and managing latent TB: substance misusers and prison population	lations 25
Recommendation 13 Contact investigations	26

	Recommendation 14 Rapid-access TB services	. 27
	Recommendation 15 Enhanced case management	. 28
	Recommendation 16 Accommodation during treatment	. 31
2	Public health need and practice	. 33
	Social factors	. 33
	Homeless people, substance misusers and prisoners	. 33
	Vulnerable migrants	. 34
	Interventions	. 34
	Lack of – or incomplete – treatment	. 35
	Treatment costs	. 35
	Current approach	. 35
3	Considerations	. 37
	Definitions	. 37
	Overcoming barriers to diagnosis and treatment	. 37
	Staffing	. 41
	Evidence	. 41
	Cost effectiveness	. 42
	General	. 45
4	Implementation	. 48
5	Recommendations for research	. 49
6	Updating the recommendations	. 51
7	Related NICE guidance	. 52
	Glossary	
_	Case management	
	Case manager	
	Cohort review	

Directly observed therapy (DOT)	53
Enablers	53
Enhanced case management	54
Hard-to-reach children	54
High incidence	54
Homelessness	54
Immigration removal centre	55
Incident cases	55
Interferon-gamma release assays (IGRA) test	55
Latent TB	55
Lost to follow-up	55
Medical hold	55
Multidisciplinary TB team	56
Peers	56
Rapid access	56
Substance misuse	56
Triage	56
Vulnerable migrants	57
9 References	58
Appendix A Membership of the Programme Development Group (PDG), the NICE project team and external contractors	59
Programme Development Group	59
NICE project team	61
External contractors	62
Expert testimony	63
Appendix B Summary of the methods used to develop this guidance	65
Introduction	65

	Guidance development	. 65
	Key questions	. 66
	Reviewing the evidence	. 66
	Cost effectiveness	. 70
	Fieldwork	. 70
	How the PDG formulated the recommendations	. 71
Δ	ppendix C The evidence	. 73
	Evidence statements	. 75
	Additional evidence	. 86
	Cost-effectiveness evidence	. 87
	Fieldwork findings	. 88
Δ	ppendix D Gaps in the evidence	. 89
Δ	ppendix E Supporting documents	. 90
Δ	bout this guidance	. 92

# Introduction: scope and purpose of this guidance

# What is this guidance about?

This guidance aims to improve the way tuberculosis (TB) among hard-to-reach groups is identified and managed. It sets out how commissioners and services can achieve this. The recommendations cover:

- strategic oversight and commissioning of TB prevention and control activities
- local needs assessment
- · cohort review
- commissioning multidisciplinary TB support for hard-to-reach groups
- raising and sustaining awareness of TB among health professionals and those working with hard-to-reach groups
- raising and sustaining awareness of TB among hard-to-reach groups
- identifying active pulmonary TB among those using homeless or substance misuse services
- identifying and managing active TB in prisons or immigration removal centres: organisational factors
- identifying active TB in prisons or immigration removal centres
- managing active TB in prisons or immigration removal centres
- identifying and managing active and latent TB: vulnerable migrants
- identifying and managing latent TB: substance misusers and prison populations
- contact investigations
- rapid-access TB services
- enhanced case management
- accommodation during treatment.

# Who is this guidance for?

The guidance is for commissioners and providers of TB services and other statutory and voluntary organisations that work with hard-to-reach groups.

# Why is this guidance being produced?

The Department of Health (DH) asked the National Institute for Health and Clinical Excellence (NICE) to produce this guidance.

The guidance should be implemented alongside other guidance and regulations (for more details see sections on <u>implementation</u> and <u>related NICE guidance</u> respectively).

# How was this guidance developed?

The recommendations are based on the best available evidence. They were developed by the Programme Development Group (PDG).

Members of the PDG are listed in appendix A.

The guidance was developed using the NICE public health programme process. See <u>appendix B</u> for details.

Supporting documents used to prepare this document are listed in appendix E.

# What evidence is the guidance based on?

The evidence that the PDG considered included: three reviews of the evidence, economic modelling, the testimony of expert witnesses, stakeholder comments and fieldwork. Further detail on the evidence is given in the <u>considerations section</u> (3.25–3.39) and appendices  $\underline{B}$  and  $\underline{C}$ .

In some cases, the evidence was insufficient and the PDG has made recommendations for future research.

# Status of this guidance

The guidance complements but does not replace, other NICE guidance on tuberculosis (for further details, see <a href="section 7">section 7</a>).

### 1 Recommendations

The evidence statements underpinning the recommendations are listed in appendix C.

The Programme Development Group (PDG) considers that the recommended approaches are cost effective.

For the research recommendations and gaps in research, see <u>section 5</u> and <u>appendix D</u> respectively.

### **Definitions**

The term 'hard-to-reach groups' is used in this guidance to mean groups of adults, young people and children from any ethnic background, regardless of migration status. They are 'hard-to-reach' if their social circumstances, language, culture or lifestyle (or those of their parents or carers) make it difficult to:

- recognise the clinical onset of TB
- access diagnostic and treatment services
- self-administer treatment (or, in the case of children and young people, have treatment administered by a parent or carer)
- attend regular appointments for clinical follow-up.

Unless otherwise specified, the recommendations focus on active, rather than <u>latent TB</u>.

# Who will benefit?

The main groups considered in this guidance were:

- people who are homeless
- substance misusers
- prisoners

• vulnerable migrants.

In addition to preventing and treating TB among hard-to-reach groups, the recommendations will also benefit the wider community, by helping to reduce onward transmission of TB among the general population.

Please note: the diagnosis, management and treatment of TB among other individuals or groups is addressed in the <u>NICE clinical guideline on TB</u>. This includes some new entrants to the UK who are not otherwise considered vulnerable and the general population

### Who should take action?

Agencies, organisations (including commissioning bodies) and professionals are referred to in the recommendations using titles and terminologies anticipated in forthcoming legislation and policy. The terms used may change following publication of this guidance and will be updated once the relevant legislation has been finalised.

# Recommendation 1 Strategic oversight and commissioning of TB prevention and control activities

### Who should take action?

- NHS Commissioning Board.
- Public Health England.
- Bodies responsible for overseeing the commissioning of TB prevention and control, for example, clinical commissioning groups and local authorities.

- The NHS Commissioning Board, in partnership with Public Health England, should take responsibility for national oversight of TB prevention and control activities.
- Public Health England and commissioners could consider collaborative commissioning arrangements. These could, for example, cover a major metropolitan district (that is, an area larger than that served by a clinical commissioning group), taking into account:

- local TB incidence
- local at-risk populations and their movements across different geographical areas
- existing service configurations for organisations involved in TB prevention and control
- the need to share services, such as mobile X-ray facilities, across different geographical areas.
- Public Health England and commissioners should ensure TB prevention and control
  programmes are led by a director of public health or another nominated public health
  consultant. The lead should ensure a comprehensive prevention and control programme is
  commissioned to support the level of need (see <a href="recommendation 2">recommendation 2</a>).
- Public Health England and commissioners should ensure TB prevention and control programmes set up <u>multidisciplinary TB teams</u> to provide all TB services (see <u>recommendation 4</u>)
- Public Health England and commissioners should ensure the TB prevention and control
  programme is informed by relevant NICE guidance and developed in collaboration with
  relevant clinical services. It should also be informed by the standard minimum data set
  collected through local needs assessment and service audit (see <u>recommendation 2</u>).
- Public Health England and commissioners should ensure the TB prevention and control programme targets all ages, including children. In addition, it should cover all aspects of TB prevention and control as follows:
  - active case-finding (contact investigations and screening of high-risk groups)
  - awareness-raising activities
  - diagnostic and treatment services
  - standard and <u>enhanced case management</u> (including the provision of <u>directly</u> <u>observed therapy</u>)
  - finding those <u>lost to follow-up</u> and encouraging them back into treatment
  - identification and management of latent infection
  - immunisation

- incident and outbreak control
- <u>cohort review</u> (see <u>recommendation 3</u>)
- monitoring and evaluation
- the gathering of surveillance and outcome data.
- Public Health England and commissioners should ensure TB prevention and control
  programmes take account of the need to work with other programmes targeting hard-toreach groups (including those in the voluntary sector). Examples include programmes
  focused on: the health of asylum seekers and refugees, vulnerable children, <a href="https://homelessness.news.news.">homelessness</a>
  and housing, offenders and substance misusers.

### Recommendation 2 Local needs assessment

### Who should take action?

- Directors of public health and others who lead TB prevention and control programmes.
- Commissioners of TB prevention and control programmes.

- Directors of public health and others who lead TB prevention and control programmes should use cohort review (see <u>recommendation 3</u>) and other methods to collect data on the following, to inform local needs assessment:
  - Number of annual notified TB cases (see <u>Enhanced TB surveillance</u> on the Health Protection Agency website).
  - Size, composition (for example, age and ethnicity) and distribution of local at-risk groups<sup>[1]</sup>.
  - Indices of social deprivation.
  - Local statutory and non-statutory services working with these groups.
  - Organisation of local TB services, including the composition and capacity of the local multidisciplinary TB [2] and location of services.

- Numbers requiring **enhanced case management** (see <u>recommendation 15</u>).
- Numbers receiving directly observed therapy from the start, or at any point during, treatment (see <u>Enhanced TB surveillance</u> on the Health Protection Agency website).
- Evidence of recent transmission (for example, using DNA fingerprinting or surrogate markers such as number of cases in under 5s<sup>[3]</sup>).
- Completeness and yield of contact investigations. This includes: proportion of sputum-smear-positive cases with none, five or more contacts identified; proportion of identified contacts clinically assessed; and proportion of contacts with latent TB infection who successfully complete treatment. (See also recommendation 13.)
- Active case-finding initiatives.
- Treatment outcomes for everyone grouped according to social risk factors and by the use of directly observed therapy (including rates of loss to follow-up and treatment interruptions – see <u>Enhanced TB surveillance</u> on the Health Protection Agency website and <u>recommendation 13</u>).
- Local education and awareness-raising programmes for hard-to-reach groups and professionals working with them.
- Views and experience of TB patients and the services working with them.
- Directors of public health should provide TB prevention and control programme commissioners (see <u>recommendation 1</u>) with local needs assessment information on an annual basis.
- Directors of public health should ensure TB is part of the joint strategic needs assessment in areas of high need.
- Commissioners of TB prevention and control programmes should ensure services reflect the needs of their area, as identified by needs assessment.

### Recommendation 3 Cohort review

### Who should take action?

- Public health leads and allied professionals working for TB prevention and control programmes.
- Public Health England units (health protection units).
- MDTB teams, including case managers.

- TB prevention and control programme leads should initiate, audit and evaluate cohort reviews within their commissioning area. Quarterly cohort review meetings should take place in the area covered by the programme.
- TB case managers should present standardised information on each case, including: demographic information, status (clinical, laboratory, radiology), adherence to treatment and the results of contact investigations.
- TB case managers and key allied professionals from the TB prevention and control
  programme should attend cohort review meetings. Either a paediatrician with training and
  expertise in TB management, or a paediatric infectious disease specialist, should be present
  when cases of children with TB are presented.
- The chair of the cohort review should be neutral, that is, they should not work for any of the TB services included in the review. Examples of possible chairs include the director of public health, a specialist physician from a different geographical area, or a representative from the local Public Health England unit.
- Public Health England units, in conjunction with the TB prevention and control programme lead, should collate and then present cohort review data on TB treatment and the outcome of contact investigations at the review meetings. In addition, progress towards national, regional and local service targets should be presented.
- Those participating in a cohort review should review the results and evaluate local services.

- TB prevention and control programme leads should ensure outputs from the cohort review feed into the needs assessment for TB services. These leads should attend the cohort review at least once a year.
- TB case managers should feed back promptly to MDTB teams on issues identified as a result of cohort review. The chair of the cohort review should feed back to commissioners via needs assessment.

# Recommendation 4 Commissioning multidisciplinary TB support for hard-to-reach groups

### Who should take action?

Commissioners of TB prevention and control programmes.

### What action should they take?

Ensure MDTB teams:

- Have the skills and resources to manage those who are not from hard-to-reach groups. (One
  whole-time equivalent <u>case manager</u> is recommended per 40 <u>incident cases</u> requiring
  standard management.)
- Include at least one TB case manager with responsibility for planning and coordinating the care of hard-to-reach people. (One whole-time equivalent case manager is recommended per 20 incident cases requiring enhanced case management.)
- Include an appropriate range of clinical specialties including paediatrics, infection control and respiratory medicine.
- Have the skills and resources necessary to manage people with complex social and clinical needs (either directly or via an established route). This includes the ability to provide prompt access (or where necessary, referral) to skilled outreach and advocacy workers who can draw upon the services of allied practitioners. The aim is to address people's housing, asylum, immigration, welfare, substance dependency and other health and social care needs. (The allied practitioner support should include both a specified housing officer and a social worker.)

- Can provide rapid access TB clinics for hard-to-reach groups.
- Have the resources to provide a continuous service throughout the year.
- Can provide prompt access to a professional who has training and experience in the assessment and protection of children and vulnerable adults at risk of abuse or neglect.
- Have access to funds that can be used flexibly to improve adherence to treatment among hard-to-reach groups. For example, funds could be used to provide transport to clinics, to provide incentives for treatment, or for paying outreach workers or community services to support directly observed therapy. Funds may also be used to provide accommodation during treatment (see <u>recommendation 14</u>).
- Have the resources to provide ongoing TB awareness-raising activities for professional, community and voluntary (including advocacy) groups that work with hard-to-reach groups.

# Recommendation 5 Raising and sustaining awareness of TB among health professionals and those working with hard-to-reach groups

### Whose health will benefit?

- People from hard-to-reach groups with, or at risk of, TB.
- Close contacts of members of hard-to-reach groups who have TB.

### Who should take action?

- MDTB teams.
- Statutory, voluntary and community organisations (including advocacy organisations) that work with hard-to-reach groups or are involved in health promotion activities.
- Community champions and peers.

## What action should they take?

 MDTB teams should identify and support an ongoing TB education programme for local professionals in contact with hard-to-reach groups. This includes, for example, staff in

- accident and emergency departments, GPs, staff who support vulnerable migrants and those working in walk-in centres, hostels, <u>substance misuse</u> projects and prisons.
- MDTB teams should ensure the education programme increases other professionals' awareness of the possibility of TB disease and reduces the stigma associated with it. The programme should include detail on the:
  - Causes of TB, how it is transmitted and the signs and symptoms.
  - Lifestyle factors that may mask symptoms.
  - Local epidemiology, highlighting at-risk, hard-to-reach groups.
  - Principles of TB control: early diagnosis and active case-finding; how to support treatment (including directly observed therapy); drug resistance; awareness of drug interactions; and contact investigations following diagnosis of an active case.
  - Importance of adhering to treatment.
  - Fact that treatment is free for everyone.
  - Social and cultural barriers to accessing health services (for example, fear of stigma and staff attitudes).
  - Local referral pathways, including details of who to refer and how.
  - Role of allied professionals in awareness-raising, identifying cases and helping people complete treatment.
  - Misinformation which causes fear about TB, including concerns about housing people with the condition.
- Statutory, community and voluntary organisations and advocates working with hard-to-reach groups should disseminate information on TB education and awareness training to all frontline staff. (They should get information on this from the local MDTB team.)
- Where possible, statutory, community and voluntary organisations should ensure peers from hard-to-reach groups with experience of TB contribute to, or lead, awareness-raising activities. (Peers who lead such activities will need training and support.)

# Recommendation 6 Raising and sustaining awareness of TB among hard-to-reach groups

### Whose health will benefit?

- People from hard-to-reach groups with, or at risk of, TB.
- Close contacts of members of hard-to-reach groups who have TB.

### Who should take action?

- MDTB teams.
- Statutory, community and voluntary organisations (including advocacy organisations) that work with hard-to-reach groups or are involved in health promotion activities.
- Community champions and peers.

- MDTB teams should help professionals working in relevant statutory, community and voluntary organisations to raise awareness of TB among hard-to-reach groups. These professionals should be able to explain that treatment is free and confidential for everyone (irrespective of immigration status). They should also be able to provide people with details on:
  - How to recognise symptoms in adults and children.
  - How people get TB.
  - The benefits of diagnosis and treatment (including the fact that TB is treatable and curable).
  - Location and opening hours of testing services.
  - Referral pathways, including self-referral.
  - Where relevant, the potential interaction of TB medication with other drugs, for example, oral contraceptives and opioids (especially methadone) and HIV treatment.
  - TB/HIV co-infection.

- How to address the myths about TB infection and treatment (for example, to counter the belief that TB is hereditary).
- How to address the stigma associated with TB.
- The risk of vulnerable migrants from high-incidence countries developing active TB –
   even if they have already screened negative for it.
- MDTB teams and others working with hard-to-reach groups should use high quality material
  to raise awareness of TB. The material should be current, culturally and linguistically
  appropriate and available in a range of media formats (that is, not just in a written format).
   This material should be modified to meet the specific needs of the audience, if necessary.
- MDTB teams and others working with hard-to-reach groups should include information on TB with other health-related messages and existing health promotion programmes tailored to the target group.
- MDTB teams should work in partnership with voluntary organisations and 'community champions' to increase awareness of TB among hard-to-reach groups at risk of infection.
   Where possible, peers from these groups who have experience of TB should contribute to awareness-raising activities.

# Recommendation 7 Identifying active pulmonary TB among those using homeless or substance misuse services

### Whose health will benefit?

Homeless people or substance misusers with, or at risk of, TB.

### Who should take action?

- Commissioners of TB prevention and control programmes.
- Commissioners of services for homeless groups.
- Commissioners of substance misuse services.
- MDTB teams.

- Statutory, community and voluntary sector organisations working with homeless people or substance misusers.
- Mobile X-ray teams.

- In areas of identified need (see <u>recommendation 2</u>), including major urban centres with a high incidence of tuberculosis, commissioners should:
  - Ensure there is a programme of active case-finding using mobile digital radiography in places where homeless people and substance misusers congregate. (This includes: homeless day centres, rolling shelters, hostels and temporary shelters established as part of cold weather initiatives and venues housing needle and syringe programmes.)
  - Base the frequency of screening at any one location on population turnover.
  - Where local demand does not warrant a mobile X-ray team, consider commissioning mobile X-ray screening capacity from another area.
- MDTB teams should, in line with NICE's clinical guideline on tuberculosis<sup>[-]</sup>, consider using simple incentives, such as providing hot drinks and snacks, to encourage people to attend for screening.
- Commissioners of TB prevention and control programmes should consider offering homeless people and substance misusers other health interventions when they are screened for TB at a mobile X-ray unit. (Examples may include blood-borne virus [BBV] screening, dentistry and podiatry services.)
- MDTB teams should work closely with mobile X-ray teams and frontline staff in hostels and day centres to promote TB screening and to ensure appropriate onward referrals and followup.
- MDTB teams should consider using peer educators to promote the uptake of TB screening in hostels and day centres.
- MDTB teams should provide routine data to TB prevention and control programmes on: screening uptake, referrals and the number of active TB cases identified.

# Recommendation 8 Identifying and managing active TB in prisons or immigration removal centres: organisational factors

### Whose health will benefit?

Adults and children detained in a prison<sup>[s]</sup> or <u>immigration removal centre</u> and close contacts of those in these settings who have TB.

### Who should take action?

- Prison and immigration removal centre healthcare services.
- MDTB teams with a prison or immigration removal centre in their catchment area.
- UK Borders Agency and others who work in the criminal justice system.
- Public Health England units (health protection units).

- MDTB teams, prison and immigration removal centre healthcare services should have named TB liaison leads to ensure they can communicate effectively with each other.
- Prison and immigration removal centre healthcare services should develop a TB policy by working with the MDTB team and the local Public Health England unit.
- MDTB teams, in conjunction with prison and immigration removal centre healthcare services, should agree a care pathway for TB to ensure any suspected or confirmed cases are reported to, and managed by, the MDTB team.
- MDTB teams, in liaison with prison or immigration removal centre healthcare providers, should manage all cases of active TB. Investigations and follow-up should be undertaken within the prison or immigration removal centre, wherever practically possible.

# Recommendation 9 Identifying active TB in prisons or immigration removal centres

### Whose health will benefit?

Adults and children detained in a prison<sup>[5]</sup> or immigration removal centre and close contacts of those in these settings who have TB.

### Who should take action?

- Prison and immigration removal centre healthcare services.
- MDTB teams with a prison or immigration removal centre in their catchment area.
- UK Borders Agency and others who work in the criminal justice system.

### What action should they take?

- On arrival at the prison or immigration removal centre, healthcare professionals should ask all prisoners and detainees (including those being transferred from other establishments) if they are taking TB medication, to ensure continuity of treatment.
- Healthcare professionals in prisons and immigration removal centres should follow the recommendations for prison screening set out in <u>NICE's clinical guideline on tuberculosis</u> – but should ensure prisoners and detainees are screened within 48 hours of arrival.
- Prisons with Department of Health-funded static digital X-ray facilities for TB screening should X-ray all new prisoners and detainees (including those being transferred from other establishments) if they have not received a chest X-ray in the last 6 months. This should take place within 48 hours of arrival.

# Recommendation 10 Managing active TB in prisons or immigration removal centres

### Whose health will benefit?

Adults and children detained in a prison<sup>[5]</sup> or immigration removal centre and close contacts of those in these settings who have TB.

### Who should take action?

- Prison and immigration removal centre healthcare services.
- MDTB teams with a prison or immigration removal centre in their catchment area.
- UK Borders Agency and others who work in the criminal justice system.

- Everyone with X-ray changes indicative of active TB, and those with symptoms who are awaiting X-ray, should be isolated in an individual room or cell. Prisoners and detainees should be retained on <a href="mailto:medical hold">medical hold</a> until they have:
  - proven smear negative and had an X-ray that does not suggest active TB or
  - had a negative risk assessment for multi-drug resistant (MDR)-TB and completed 2 weeks of the standard treatment regimen.
- Prison and immigration removal centre health staff should report all suspected and confirmed TB cases to the local MDTB team within 1 working day.
- MDTB staff should visit every confirmed TB case in a prison or immigration removal centre in their locality within 5 working days.
- If a case of active TB is identified, the local Public Health England unit, in conjunction with the MDTB team, should plan a contact investigations exercise. They should also consider using mobile digital radiography to check for further cases.
- All prisoners and immigration removal centre detainees receiving treatment for active TB should have a named TB case manager. The case manager should be responsible for contingency planning for discharge from prison/detention.
- Prisons and immigration removal centres should ensure MDTB staff have access to prisoners and detainees who require treatment (for example, by being given security clearance).
- All prisoners receiving treatment for active TB should receive directly observed therapy[6].
- Prison health services should have contingency, liaison and handover arrangements to ensure continuity of care before any prisoner on TB treatment is transferred between prisons

or released<sup>[7]</sup>. In addition, other agencies working with prisoners or detainees should also be involved in this planning.

- Prison and immigration removal centre healthcare services should liaise with the named TB case manager (from the MDTB team) to ensure contingency plans for continuation of treatment are drawn up for prisoners and immigration removal centre detainees with TB.
- MDTB teams should ensure accommodation is available for the duration of TB treatment following the prisoner or detainee's release (see <a href="recommendation 16">recommendation 16</a>).
- MDTB teams should ensure directly observed therapy is arranged for prisoners or detainees being treated for TB following their release. This should be available close to where they will live in the community.

# Recommendation 11 Identifying and managing active and latent TB: vulnerable migrants

### Whose health will benefit?

Vulnerable migrants.

### Who should take action?

- NHS Commissioning Board.
- TB prevention and control programmes.
- Statutory (including primary care), community and voluntary services working with vulnerable migrant groups.

- The NHS Commissioning Board should ensure primary care services are fulfilling their obligation to register vulnerable migrants.
- Primary care services should support local, community-based and voluntary organisations that work with vulnerable migrants to ensure they:
  - Register with a primary care provider.

- Know how to use NHS services (emergency or primary care).
- Healthcare professionals, including primary care staff, responsible for screening new
  entrants should screen all vulnerable migrants who have not previously been checked, in
  line with <u>NICE guidance on tuberculosis</u> for new entrants. This is regardless of when they
  arrived in England. People born in countries with an incidence of more than 150 per 100,000
  per year should be made a priority for latent TB screening when they arrive here.
- TB prevention and control commissioners should ensure services take into account the barriers facing vulnerable migrants who may need treatment, and in particular, the stigma they may face. Other issues include the location of services (both geographically and in terms of opening times) and people's language and cultural needs, in terms of the format of advice and the type of information given.

# Recommendation 12 Identifying and managing latent TB: substance misusers and prison populations

### Whose health will benefit?

Substance misusers and prisoners at risk of latent TB infection.

### Who should take action?

- Commissioners of TB prevention and control programmes.
- MDTB teams.
- Prison health services.
- Substance misuse services.

- Commissioners of TB prevention and control programmes should ensure arrangements are in place to provide latent TB testing for substance misusers and prisoners.
- Substance misuse services should provide clients aged under 35 with access to an <a href="interferon-gamma release assays">interferon-gamma release assays</a> (IGRA) test for TB if they:
  - Live in a high incidence area[8].

- Are likely to be involved with substance misuse or other support services on a regular basis (for example, for opioid substitution therapy). In such cases, support should be available for directly observed preventive therapy.
- All prisoners receiving treatment for latent TB should have a named TB case manager. The
  case manager should be responsible for contingency planning for discharge from prison/
  detention.
- In high incidence areas<sup>[s]</sup> (and at prisons which receive prisoners from high incidence areas), prison health services should offer IGRA testing for TB to inmates aged under 35 who are in regular contact with substance misuse or other support services, **provided** arrangements have been made for this support to continue after release. If the under-35s test positive, directly observed preventive treatment (DOPT) should be arranged alongside the existing support.
- Substance misuse services and prison health services should incorporate IGRA testing with screening for hepatitis B and C and HIV testing and refer prisoners and substance misusers with positive IGRA tests to local MDTB teams for further clinical investigations. The aim is to exclude active disease and assess their suitability for preventive treatment. For prisoners, these investigations should be undertaken within the prison wherever practically possible.
- Where practical, MDTB teams should start directly observed preventive therapy for prisoners with latent TB who, on release, will also receive support from other services.

# Recommendation 13 Contact investigations

### Whose health will benefit?

Contacts of people with active TB from hard-to-reach groups.

### Who should take action?

- MDTB teams.
- Public Health England units (health protection units).

### What action should they take?

- MDTB teams should follow NICE recommmendations on contact tracing (see <u>NICE</u> <u>guidance on tuberculosis</u>). They should also coordinate contact investigations at places where the person with TB spends significant amounts of time. Examples of the latter may include a pub, crack house or parks and community centres. The aim is to help identify people who have been living with them and people they frequently socialise with.
- MDTB teams dealing with someone from a hard-to-reach group should work alongside
  health and social care professionals known to them to help trace relevant contacts. They
  should also work in partnership with voluntary, community and statutory organisations to
  conduct outreach contact investigations.
- MDTB teams should, where available and appropriate, encourage peer educators to help with contact investigations when it involves hard-to-reach people who have complex social networks.
- Local Public Health England units should consider using digital mobile radiography for active
  case-finding in settings identified by social network analysis as places where people at risk
  congregate. They should also provide the necessary support so that MDTB teams can use
  strain-typing and social network analysis to ascertain where transmission is occurring in the
  community. (Examples of transmission sites may include pubs, crack houses, hostels and
  day centres.) They should focus on active case-finding in the settings identified.
- MDTB teams should investigate all those who have been in contact with <u>hard-to-reach</u> <u>children</u> who have pulmonary or non-pulmonary TB to identify the primary source of infection. If necessary, they should look beyond immediate close contacts to find the source.

# Recommendation 14 Rapid-access TB services

### Whose health will benefit?

- People from hard-to-reach groups with suspected TB.
- Close contacts of members of hard-to-reach groups with suspected TB.

### Who should take action?

MDTB teams.

• Statutory, community and voluntary organisations working with hard-to-reach groups.

### What action should they take?

- MDTB teams should establish relationships with statutory, community and voluntary
  organisations that work with hard-to-reach groups to develop appropriate TB referral
  pathways. They should ensure these organisations know how to refer people to local TB
  services.
- MDTB teams should accept referrals from healthcare providers and allied organisations
  working in the community with hard-to-reach groups. This includes voluntary and statutory
  organisations (for example, mobile X-ray teams or community organisations working with
  vulnerable migrants).
- MDTB teams should accept self-referrals to TB clinics by people from hard-to-reach groups.
- MDTB teams should use specialist TB nurses to <u>triage</u> referrals, so that <u>case management</u> starts promptly.
- MDTB teams should ensure people who have a smear-positive result are assessed within 24 hours. Others who are not smear-positive should be seen as soon as possible – and no later than 5 working days after a referral. Where necessary, outreach services should be used for assessment.
- Healthcare professionals from statutory organisations should refer people to TB clinics promptly. They should also ensure the results from first line diagnostic tests (including a sputum smear and chest X-ray) are available prior to the person seeing a physician. (Note: this should not delay the referral.)
- MDTB teams should use rapid diagnostics (for example, polymerase chain reaction [PCR]based methods) to minimise the time it takes to make a diagnosis and identify rifampicinresistant TB.

# Recommendation 15 Enhanced case management

### Whose health will benefit?

People from hard-to-reach groups with suspected or diagnosed TB (latent or active).

### Who should take action?

- MDTB teams, including case managers.
- Statutory, community and voluntary organisations working with hard-to-reach groups.
- People from hard-to-reach groups with suspected or diagnosed TB (latent or active).

- MDTB teams should, as soon as possible (and within 5 working days of a referral), allocate a named TB case manager to people who have TB and have been identified as hard-to-reach. They should also provide an individual care plan within the same timescale.
- TB case managers should undertake a risk assessment to identify whether the person should have directly observed therapy (DOT). DOT should be considered part of standard care, from the start of treatment, for all hard-to-reach children aged under 16. It should also be standard care for anyone who requests it and those who:
  - Do not (or have not in the past) adhered to treatment.
  - Have been treated previously for TB.
  - Have a history of homelessness, drug or alcohol misuse.
  - Are currently (or have previously been) in prison.
  - Have a major psychiatric, memory or cognitive disorder.
  - Are in denial of the TB diagnosis.
  - Have multi-drug resistant TB.
  - Are too ill to administer the treatment themselves.
- TB case managers should develop the care plan during a face-to-face discussion with the
  person. They should also involve representatives from other allied professionals and key
  workers from community organisations who work with the person. In addition, they should
  gain the person's consent to the plan and agree a review date.

- TB case managers should ensure the care plan identifies potential barriers to diagnosis and treatment (including fear of being stigmatised) and any support that may be required. It should also take account of cultural beliefs. The plan may include:
  - Demographic information (for example, age, nationality, place of birth, length of time in UK).
  - Current prescribing regimens.
  - Housing needs and living situation (see <u>recommendation 16</u>).
  - Substance use issues (drugs or alcohol).
  - Criminal justice issues.
  - The need for hepatitis B and C or HIV testing.
  - Other health issues (physical or mental).
  - Communication factors (for example, language and literacy level).
  - Ability to access treatment (mobility and transport needs).
  - Employment or entitlement to benefits.
  - Legal or immigration status (including risk of removal from, or relocation within, England).
  - Any 'enablers' or incentives to overcome the barriers to diagnosis or treatment.

### • The plan should:

- State who will be observing treatment and where (if the person is having directly observed therapy this should be provided at a location convenient to them).
- Include actions to take in the event of losing contact with someone who is being treated (for example, keeping details of people who might be able to help re-establish contact).
- Refer to, and be coordinated with, any other care plan already established for the person.

- Define the support needed to address any unmet health and social care needs (for example, support to gain housing or other benefits, or to help them access other health services).
- Explore appropriate ways that peers and voluntary organisations can provide support.
- Include an obligation on the person to commit to TB treatment.
- MDTB teams should aim to find people with active TB who are lost to follow-up, or who stop
  using services prior to completing diagnostic investigations. They should report all those lost
  to follow-up to local Public Health England units, GPs, the referring organisation or specialist
  outreach teams.

# Recommendation 16 Accommodation during treatment

### Whose health will benefit?

Homeless people diagnosed with pulmonary TB. (This includes those who are not sleeping rough but don't have access to housing or recourse to public funds.)

### Who should take action?

- MDTB teams.
- Commissioners of TB prevention and control programmes.
- Local authority housing departments.
- Providers of hostel accommodation.

- MDTB teams should assess the living circumstances of people with TB. They should work
  with allied agencies to ensure all those who are entitled to state-funded accommodation
  receive it as early as possible during the course of their treatment.
- All those listed above should work together to agree a process for providing accommodation
  for homeless people diagnosed with active pulmonary TB who are otherwise ineligible for
  state-funded accommodation. The process should detail the person's eligibility and ensure
  they are given accommodation for the duration of their TB treatment.

- Commissioners of TB prevention and control programmes should fund accommodation for homeless people diagnosed with active TB who are otherwise ineligible for state-funded accommodation. Health or public health resources should be used.
- MDTB teams should make people who would not otherwise be entitled to state-funded accommodation aware that they may lose this accommodation if they do not comply with treatment.
- MDTB teams should ensure plans are made to continue housing people once their TB treatment is completed.

<sup>&</sup>lt;sup>[1]</sup> Potential sources include: census data, the National Drug Treatment Monitoring Service, records of locally detained populations, records of homeless people in residential accommodation, the number of rough sleepers and the size of vulnerable migrant communities.

<sup>[2]</sup> See the results of local audit for details.

<sup>[9]</sup> See 'UK TB strain-typing database' and local incident and outbreak reports.

<sup>[4]</sup> See recommendation 1.8.8.1 in NICE clinical guideline 117 Tuberculosis.

Where the term 'prison' is used it applies to any of Her Majesty's prison establishments, including young offender institutions (YOIs).

<sup>&</sup>lt;sup>[e]</sup> This is an extract of recommendation 1.9.3.3 in 'Tuberculosis' NICE clinical guideline 117.

<sup>&</sup>lt;sup>[-]</sup> This is an extract of recommendations 1.9.3.4 and 1.9.3.5 in '<u>Tuberculosis</u>' NICE clinical guideline 117.

<sup>[8]</sup> Where TB notifications are greater than 40 per 100,000 people per annum.

# 2 Public health need and practice

In 2010, there were 8483 reported cases of tuberculosis (TB) in England – an incidence of 13.6 cases per 100,000 people. Seventy three per cent were among people born outside the UK (Health Protection Agency 2011). Most cases (39%) were reported in London which, as a result, has been a focus of TB control efforts.

### Social factors

TB incidence is influenced by a range of social factors in addition to exposure to the disease. Social factors include: poor nutrition, poor access to healthcare, homelessness, problem drug use and imprisonment (Lönnroth et al. 2009; Story et al. 2007).

These social factors are also associated with poor adherence to treatment, loss to follow-up, the development of drug resistance and transmission of the disease (Noyes and Popay 2007; Story et al. 2007; World Health Organization 2003). Where information is recorded, the national enhanced TB surveillance system found that 10% of TB cases had at least one of four risk factors (drug use, alcohol use, history of incarceration or homelessness) (Health Protection Agency 2011).

# Homeless people, substance misusers and prisoners

Although most people with TB in England were born outside the UK, the highest risk of disease is among those who are homeless people, problem drug users and prisoners.

A London-based study estimates the prevalence of TB at 354.3 per 100,000 among problem drug users, 208.4 per 100,000 among prisoners and 788.1 per 100,000 among those living in hostels (Story et al. 2007). These rates are considerably higher than those found among the migrant population in England (81.6/100,000) (Health Protection Agency 2011). Health Protection Agency data suggests that there are TB patients in all regions of England (not just London) who have these risk factors in common.

# Vulnerable migrants

Many migrants entering England with TB will not be 'hard-to-reach'. However, a proportion of migrants may be homeless, substance misusers or prisoners or subject to other specific social, cultural and economic pressures that make them particularly vulnerable. Unaccompanied minors, some refugees and some asylum seekers, for example may be particularly 'hard to reach'. Other factors that may impede the identification and management of TB in this group include:

- language and cultural issues
- lack of recourse to public funds
- concerns about immigration status.

### Interventions

Early identification and effective treatment of 'active' TB provides the best outcomes, reduces onward transmission and reduces the development of drug-resistant forms of the disease. The identification and management of latent TB infection and vaccination are also important.

Interventions that maximise the number of people who complete a full course of treatment (it takes at least 6 months) are likely to be particularly important for hard-to-reach groups. In a cohort of people with TB in London, problem drug users, homeless people and prisoners made up 17% of the cohort but accounted for 38% of poorly compliant people – and 44% of those who were lost to follow-up (Story et al. 2007). In addition, recent national surveillance data suggests that only 42%, of people with at least one social risk factor started treatment on directly observed therapy (Health Protection Agency 2011).

Typically, a 'passive case-finding' approach has been used – relying on symptomatic people to present themselves to health services. However, this may not be effective among hard-to-reach groups, whose social circumstances and lifestyle mean that they often find it difficult to access traditional health services. It also means their symptoms may go unnoticed.

Active case-finding involves seeking evidence of infection or disease in among people who might otherwise not present for care in a timely manner. It includes screening TB contacts through contact and 'outbreak' investigations. It also includes screening migrants (for example, at the preentry stage, at the port of arrival, in special clinics after arrival or in primary care). In addition, it

can involve screening of hard-to-reach groups (such as prisoners, homeless people and problem drug users).

# Lack of - or incomplete - treatment

Left untreated, one person with pulmonary TB may infect around 10–15 people every year (DH 2004). Evidence from strain-typing studies shows that homeless people are much more likely than other groups to transmit TB. For example, recent Health Protection Agency strain-typing data showed that most TB transmission in London was among hard-to-reach groups.

Recent data indicates that people with TB who have at least one of the social risk factors (that is, people with TB who are hard-to-reach) were less likely to complete treatment than those without any of the social risk factors (7.3% versus 4.2%). People who do not complete treatment are at risk of a relapse. They may also develop a drug-resistant form of the disease which is more difficult and slower to treat – and which can also be transmitted to other people. In 2010, for example, susceptibility test results indicated that 7.1% of culture-confirmed cases in the UK were resistant to at least one first-line drug at the start of treatment (Health Protection Agency 2011).

Recent figures suggest that drug-resistance levels are higher among hard-to-reach people with TB. Over 11% of people with a social risk factor were TB resistant to at least one drug, compared to only 6.9% of without any of the social risk factors (Health Protection Agency 2011).

# Treatment costs

The cost of treating 'normal' TB is around £5000. However the costs are much greater for more socially complex cases. This is due to the need for more frequent and longer hospitalisation episodes, higher treatment support costs and the higher cost of treating drug-resistant (including multidrug resistant) disease. It costs an estimated £50,000–£70,000 to treat the latter (DH 2009).

# Current approach

NHS services have focused on early detection and diagnosis of people who present to them – and ensuring that people diagnosed with TB complete treatment. However, people at risk of TB from hard-to-reach groups often have difficulties accessing health services through the usual routes.

# Identifying and managing tuberculosis among hard-to-reach groups

NICE public health guidance

A service review and needs assessment was carried out in London recently (Hayward et al. 2010). It identified that the following were needed to deal with London's TB problems: central leadership and management, more accessible and responsive services, standardised clinical practice and policy, performance management and lead providers.

## 3 Considerations

The Programme Development Group (PDG) took account of a number of factors and issues when developing the recommendations.

## **Definitions**

- 3.1 The PDG felt that services should be viewed as 'hard to reach' not the people needing them. However, the term 'hard to reach' is commonly used to describe the groups targeted in this guidance and, to meet the remit of this guidance, the term was used.
- 3.2 The PDG focused on known hard-to-reach groups such as substance misusers, prisoners and vulnerable migrants. It acknowledged that others may be just as in need of the recommendations. It also acknowledged that the groups focused upon are not mutually exclusive and that there was likely be some overlap between them.
- 3.3 The PDG recognised that the term 'vulnerable migrants' covers a range of people and circumstances. The Group was also mindful that many of the social and cultural problems facing them would persist beyond the time when they may be classed as a new arrival to the country.
- 3.4 Even when people are in the prison system, they may still be hard-to-reach. Even if services locate and support them in prison, on release they are likely to become hard-to-reach again. Hence the recommendations on TB prevention and control on entry, throughout incarceration and on release from prison.
- There are different types of active TB. From a clinical perspective, all forms require treatment. From a public health perspective, smear-positive, pulmonary TB is the most important as it is responsible for most TB transmissions.

## Overcoming barriers to diagnosis and treatment

3.6 The PDG acknowledged that hard-to-reach groups face many barriers to accessing TB diagnosis and treatment services. These may include:

- lack of awareness of TB and the symptoms
- fear of TB and the consequences of infection
- lack of access to services
- health professionals who have an unhelpful or hostile attitude
- distrust of health professionals
- disjointed services
- delayed diagnosis
- the time it takes to complete treatment
- concerns about confidentiality
- concerns about stigma
- lifestyle, language or culture
- lack of support structure
- concerns around immigration status, including fear of being reported or deported.
- 3.7 Despite TB treatment being free, the PDG was aware that TB diagnosis and treatment could have financial implications for some people (for example, loss of earnings due to clinic attendance, or due to travel costs).
- 3.8 Lack of clarity over entitlement to, and eligibility for, NHS treatment for foreign nationals and failed asylum seekers can discourage these groups from seeking help for TB-like symptoms.
- 3.9 The PDG acknowledged that some people with pulmonary TB are prohibited from returning to hostel accommodation once diagnosed.
- 3.10 The PDG felt that it was important for professionals to adopt a proactive approach to helping people from hard-to-reach groups rather than leaving these groups to find their own way into TB services. However, it acknowledged

- that the way services are commissioned and conflicting priorities make such a cultural shift difficult to implement.
- 3.11 Making services as accessible as possible involves taking a range of factors into account. These include: people's language, literacy level, age, ethnicity and gender, as well as any disability, mental health or substance dependency-related problems. Location of clinics, transport to and from them, opening times and the provision of appropriate communication materials and prompts are all equally important.
- 3.12 Identifying people with TB from hard-to-reach groups involves links between social care, community and voluntary organisations and secondary and acute healthcare services.
- 3.13 Contact investigations for all types of TB help prevent transmission, particularly where it affects children. (TB among the latter indicates poor TB control and is a significant cause of preventable morbidity.) However, the PDG also acknowledged that some people may not want to disclose who they have been in contact with.
- 3.14 Trust is important when trying to identify and then treat people with TB. It involves maintaining the confidentiality of all interactions between an individual and health and social care practitioners.
- 3.15 Nurse-led clinics have a potential role in improving access to TB services for hard-to-reach groups.
- 3.16 Outreach services provided in convenient locations can be an important way to reach hard-to-reach groups.
- 3.17 Key features of successful TB services in New York and the Netherlands were: political will, leadership, commitment, an emphasis on tackling problems among hard-to-reach groups, and the commissioning of services at regional or city-wide levels. It was noted that the level of staff resources devoted to TB control in New York and the Netherlands was substantially greater per case than in England.

- 3.18 The PDG felt that people needed accommodation to ensure they completed their treatment. The Group also believed that the majority of people with TB would be eligible for state-funded accommodation if they were able to navigate the housing system. Given the results of the economic modelling and analysis, the PDG felt that providing accommodation was preferable to the existing alternatives (for example, bed blocking in hospitals or being lost to follow-up).
- The PDG was cognisant of the need for services to be accessible for hard-to-reach people and that includes provision at a time that's right for them. This was the basis for the Group's recommendation on rapid access: if someone from these groups has to wait for the next clinic space they are unlikely to turn up. The PDG acknowledged that current TB services are unlikely to have this type of facility. Nevertheless, it felt it important to ensure TB services can respond flexibly and proactively to referrals by, or on behalf of, hard-to-reach groups, rather than following the standard referral process.
- 3.20 The PDG was concerned about the fragmentation of TB services. The Group decided there was a need for 'national oversight' of TB prevention and control services supported by local TB programmes. It made this decision based on the following:
  - Hard-to-reach groups are often highly mobile and often cross the boundaries of different services.
  - Within one locality, there may not be a sufficient number of socially complex TB
    cases to merit the commissioning of specialised services. This means that local
    people may not receive the standard of care needed to improve outcomes and
    control the spread of disease.
  - A wide range of public health activities are involved (such as cohort reviews), beyond simply ensuring cases are treated effectively. These activities cross a range of organisational boundaries.
  - Experience from other countries with successful TB prevention and control programmes.

## **Staffing**

- 3.21 A range of statutory, community and voluntary professionals provide services for hard-to-reach groups.
- 3.22 Specialist TB nurses play a crucial role in ensuring TB services are effective.
- 3.23 The process involved in excluding TB as a diagnosis is very time-consuming and has an impact on the staffing levels needed for effective TB services.
- 3.24 Historically, recommended staffing ratios were 1:50 per TB case outside London and 1:40 per case in London. These figures were based on London having a higher, more socially complex caseload whereas, in fact, it is likely that the proportion of complex cases within hard-to-reach groups is similar in most cities (see 3.51). The PDG also considered current thinking and the ratios observed in other countries. For example, in New York, there is a standard 1:9 ratio of staff to patients. As a result, this guidance recommends the same staffing ratios for complex cases regardless of location.

## **Evidence**

- 3.25 In qualitative research, language and cultural barriers are often identified as factors affecting TB diagnosis and treatment. However, in quantitative studies, there was no evidence that 'migrant status' is an independent risk factor for poor compliance with TB treatment.
- 3.26 There was not enough evidence to make specific recommendations for hard-to-reach children (such as unaccompanied minors or looked-after children). However, the PDG felt it was important that paediatric commissioners and service providers take a role in implementing this guidance to ensure such children are not forgotten.
- 3.27 PDG members were aware that a significant proportion of looked-after children had a parent who was a substance misuser.

- 3.28 There is some evidence that the use of 'peers' or 'peer educators can be effective in outreach work or as part of enhanced case management.
- 3.29 Evidence showed that adherence to preventive treatment for latent TB infection is often very poor among hard-to-reach groups even when directly observed. No formal cost-effectiveness analyses were undertaken. However, the PDG felt that poor adherence, combined with the risks of adverse effects, could severely compromise the effectiveness and cost effectiveness of initiatives to identify and manage latent TB infection. Notable exceptions were directly observed preventive therapy (DOPT) in prison and DOPT given alongside regular opioid substitution therapy. (In these cases, very high adherence to treatment can be achieved.) As a result, the PDG felt it was reasonable to recommend interferon gamma release assay (IGRA) testing and DOPT for these two groups.

## Cost effectiveness

- 3.30 The PDG believed the quality of life of someone from a hard-to-reach group was as important as for anyone else. The consequent reduction in their quality of life, should they contract TB, is the same as for anyone else. This was taken into account in the economic analysis.
- 3.31 Active case-finding among the homeless population (using mobile X-ray screening) was found to be cost saving when background prevalence was above 550 per 100,000. (In the London base–case scenarios, background prevalence was 788 per 100,000 [Story et al. 2007].) In most realistic scenarios, except those where the prevalence of disease is lower than around 250 per 100,000, the estimated cost per QALY for the intervention was either cost saving or below £20,000. It only exceeded £30,000 per QALY at low TB prevalence rates. In prisons, interventions were relatively less cost effective, with the base–case scenario cost per QALY estimated at £22,000, due to the lower prevalence of TB among prisoners. In both population groups, when active case-finding was combined with measures to improve treatment completion rates, cost effectiveness increased.

- 3.32 The PDG was aware that the cost effectiveness of mobile X-ray screening will vary according to the prevalence of TB in any given area. It also noted that economies of scale and low population density may also be important. Recommendations for active case-finding among homeless groups are, therefore, targeted at metropolitan areas with a high incidence of TB and smaller towns and cities with multiple hostels for the homeless.
- 3.33 Cost-effectiveness analysis indicated how much it is worth spending to raise treatment completion rates from 55% to 75% among two separate populations: 10,000 homeless people and10,000 prisoners. It is based on the assumption that the NHS and other government bodies would be prepared to spend up to £20,000 to gain one QALY. The results suggest that it would be cost effective to spend an estimated £21,000 extra, per additional case successfully treated among homeless people, when the prevalence of TB among this group is 778 cases per 100,000. For a prison population with a prevalence of 208 cases per 100,000, it would be cost effective to spend an additional £35,000 per additional case of active TB successfully treated.
- 3.34 The cost effectiveness of mobile X-ray screening was more marginal in prisons compared with its use among homeless groups (due to the lower prevalence and lower transmission rates among prisoners). However, in prisons housing populations from high incidence areas and where the start-up costs had been largely funded by the DH, the PDG judged that it was cost effective. For other prisons, the PDG considered that existing NICE guidance on initial, symptom-based screening was adequate.
- 3.35 Whether interventions are cost effective, cost saving or not cost effective depends on the burden of TB in a particular population. In settings where a medium to high proportion of the population will be treated as a result of screening, then mobile X-ray and enhanced case management are likely to be cost effective and (in some cases) cost saving. If the prevalence of TB is low (100 per 100,000 population) then screening will be less cost effective. Likewise, the benefit of ensuring treatment is completed is greatest among groups where the prevalence of TB is highest. Thus commissioning decisions need to be informed by local epidemiology and local needs assessment.

- 3.36 The PDG was aware of a recent publication (Jit et al. 2011) which looked at the clinical and cost effectiveness of using a mobile X-ray service and enhanced case management, based on the London 'Find and treat' data. Although it was too late to include this evidence in the economic evidence review, the evaluation suggests that the mobile X-ray screening service was cost effective. It also suggests that it was likely to be cost effective in other high prevalence areas. In addition, the enhanced case management element of the 'Find and treat' service was shown to be cost effective.
- 3.37 The base–case scenarios in the cost-effectiveness analysis use operational and cost data derived from the London-based 'Find and treat' service. However, sensitivity analyses have allowed the PDG to consider how variations across the country will affect cost effectiveness. (For example, in terms of the size of hard-to-reach groups, economies of scale, the prevalence of TB and treatment completion rates.)
- 3.38 The economic model had a number of limitations and, as a result, the cost effectiveness of preventive activities will have been underestimated. For example, the model does not include the value of preventing the spread of non-pulmonary cases.
- 3.39 The PDG has been careful to ensure the resource investment required is realistic within the current financial climate.
- 3.40 Investment in more comprehensive multidisciplinary teams may not be cost effective in low incidence areas with few hard-to-reach people. To overcome this problem and to support people who are disadvantaged, the PDG has recommended commissioning models that cover larger geographical areas than those currently covered by one TB service.
- 3.41 Given that the infrastructure already exists for cohort review, the PDG felt that it would be cost effective to implement and was very likely to be cost saving.

#### General

- 3.42 The PDG recognised that TB is an important public health issue, both for the groups targeted and for the general population. Members also noted that many services and interventions to improve the identification and management of TB among hard-to-reach groups could also be used to tackle other diseases that disproportionately affect them. They felt that an alternative approach would have been to make recommendations on a range of common conditions for these groups.
- 3.43 The PDG considered at length the optimal configuration of TB services for both general and hard-to-reach populations. Common features for both included a multi-disciplinary approach, with the precise configuration of disciplines and resources determined by local need and assessment.
- 3.44 Given the current changes to the structure of the NHS, with responsibilities for public health moving into local authorities, the PDG struggled to identify exactly who should take action for each recommendation. However, it was known that the NHS Commissioning Board will be responsible for offender health and national screening services. Hence its inclusion in the recommendations on identifying TB among hard-to-reach groups.
- 3.45 The PDG was mindful that hard-to-reach groups in low incidence areas may be disadvantaged. In response, commissioning models covering a larger than usual geographical area have been recommended, along with the use of better resourced outreach teams.
- 3.46 The PDG made recommendations for populations where evidence was available. It may be that the interventions recommended for one group are transferable to other populations or circumstances (for example, in a disease-outbreak situation).
- 3.47 The PDG felt that it was important that vulnerable migrants being treated for TB are not moved during treatment (for example, deported or moved between cities in England). However, it was not within the remit of this guidance to make such a recommendation.

- 3.48 The epidemiology of TB in England shows a disproportionate burden in London. However, the geographical variation in prevalence among hard-to-reach groups will probably be less marked. Indeed, although there is limited information on the prevalence of TB among these groups outside London, there is no reason to believe that the rates of infection and disease are substantially different.
- 3.49 The PDG felt it was unethical not to offer treatment to someone who is known to have active TB, regardless of their immigration status. It also felt that treatment was a means of protecting others from the disease.
- 3.50 The PDG noted that adherence to TB treatment may not be a problem for everyone who is hard-to-reach. However, there was strong evidence that homeless people, prisoners and substance misusers were all highly likely not to adhere to treatment. Others who may be difficult to treat once found include people held in immigration detention centres and looked-after children.
- 3.51 The PDG believed it was logical to recommend that substance misusers and ex-prisoners (both at high risk of TB) should be screened for latent TB infection when they contact services for other health problems. By the same token, where appropriate, it seems sensible to provide these service users with directly observed preventive therapy.
- 3.52 The PDG used 35 as the age cut-off point for identifying latent TB in substance misusers and prisoners, to align with the <u>clinical guideline on TB</u>.
- 3.53 The Group felt strongly that directly observed therapy for hard-to-reach groups should be viewed as just one component of enhanced case management. It acknowledged that even though it may not always be needed, it is always worth considering with these groups.
- 3.54 The PDG noted that interventions addressing the broader social determinants of health, including those that contribute to an individual or community becoming hard to reach, could have a significant impact on rates of TB infection.

3.55 The PDG felt there was no benefit in looking for latent infection among hard-to-reach groups, unless it was followed by effective chemoprophylaxis for people at high risk of developing active TB (where the risks outweigh the potential adverse effects of treatment). Members also acknowledged that isoniazid preventive therapy should only be used with isoniazid-sensitive strains. They noted that isoniazid-induced hepatoxicity is likely to be higher among those with viral hepatitis or alcohol-related liver disease – both of which are more common among hard-to-reach groups.

## 4 Implementation

NICE guidance can help:

- Commissioners and providers of NHS organisations, social care and children's services meet national priorities and the requirements of the DH's 'Operating framework for 2011/12'.
- National and local organisations improve quality and health outcomes and reduce health inequalities.
- Local authorities improve the health and wellbeing of people in their area.
- Local NHS organisations, local authorities and other local partners benefit from any identified cost savings, disinvestment opportunities or opportunities for re-directing resources.
- Provide a focus for integration and partnership working across social care, the NHS and public health organisations.

NICE has developed tools to help organisations put this guidance into practice. For details, see <u>our website</u>.

## 5 Recommendations for research

The Programme Development Group (PDG) recommends that the following research questions should be addressed. It notes that 'effectiveness' in this context relates not only to the size of the effect, but also to cost effectiveness and duration of effect. It also takes into account any harmful/negative side effects. These research recommendations should be read in conjunction with those contained in <u>Tuberculosis</u> NICE clinical guideline 117.

- 5.1 What factors aid or hinder the provision of TB screening services for hard-to-reach groups?
- 5.2 What factors help or prevent hard-to-reach groups from being screened for active TB:
  - when it involves different service providers (for example, healthcare professionals, community workers)
  - when it involves different settings and/or a different approach (for example, clinics, hospitals, detention centres, outreach, drop-in centres)?
- How effective and cost effective is TB testing (active and latent) for hard-toreach groups when included as part of a broader health check (for example, blood-borne virus [BBV] screening)?
- How effective and cost effective is routine testing for latent TB infection and subsequent, directly observed preventive therapy (DOPT) for hard-to-reach groups at risk of poor adherence?
- How effective and cost effective is peer support as part of an enhanced case management (ECM) approach to ensuring hard-to-reach groups with active TB complete treatment? In particular, does effectiveness and cost effectiveness vary:
  - according to the target population (that is, different hard-to-reach groups)
  - by setting (for example, outreach versus clinic)
  - by population (for example, age, gender, ethnicity)?

- 5.6 What demographic and socioeconomic factors aid or hinder treatment completion rates among hard-to-reach groups? (This includes, for example, housing, immigration status and recourse to public funds.)
- 5.7 What is the cost of treating hard-to-reach groups with active TB? (This includes enhanced case management, housing and hospital costs and the use of new technologies.)

More detail on the gaps in the evidence identified during development of this guidance is provided in  $\underline{appendix D}$ .

## **6 Updating the recommendations**

This guidance will be reviewed 3 years after publication to determine whether all or part of it should be updated. Information on the progress of any update will be posted at the <a href="NICE">NICE</a> website.

## 7 Related NICE guidance

Tuberculosis. NICE clinical guideline 117 (2011)

## 8 Glossary

## Case management

Case management involves follow-up of a suspected or confirmed TB case. It requires a collaborative, multidisciplinary approach and should start as soon as possible after a suspected case is discovered.

## Case manager

Standard and enhanced case management is overseen by a case manager who will usually be a specialist TB nurse or (in low-incidence areas) a nurse with responsibilities which include TB. Dependent upon the person's particular circumstances and needs, case management can also be provided by appropriately trained and supported non-clinical members of the TB multi-disciplinary team

## **Cohort review**

A systematic appraisal of the way every case of TB has been managed in a given locality in terms of treatment completion rates and contact investigations over a specified time period.

## Directly observed therapy (DOT)

A trained health professional, or responsible lay person supported by a trained health professional, provides the prescribed medication and observes the person swallowing every dose.

## **Enablers**

'Enablers' are methods of helping someone to overcome barriers to completing diagnostic investigations and TB treatment. Examples of barriers that may need to be overcome include: transport, housing, nutrition and immigration status.

#### 37

## Enhanced case management

Enhanced case management (ECM) is provided when someone has clinically or socially complex needs. It commences as soon as TB is suspected. As part of ECM, the need for directly observed treatment (DOT) is considered, in conjunction with a package of supportive care tailored to the person's needs.

## Hard-to-reach children

Groups of children identified as potentially hard-to-reach or treat include:

- unaccompanied minors
- those whose parents are hard-to-reach, including vulnerable migrants
- those whose parents are in prison or who abuse substances
- · those from traveller communities
- looked-after children.

## High incidence

A high incidence country or area has more than 40 cases of TB per 100,000 people per year. The Health Protection Agency lists high incidence countries and areas of the UK at <u>its website</u>.

## **Homelessness**

For the purposes of TB control, a broad and inclusive definition of homelessness has been adopted which incorporates overcrowded and substandard accommodation. It includes people:

- who share an enclosed air space with individuals at high risk of undetected active pulmonary tuberculosis (that is, those with a history of rough sleeping, hostel residence or substance misuse)
- · without the means to securely store prescribed medication
- without private space in which to self-administer TB treatment

• without secure accommodation in which to rest and recuperate in safety and dignity for the full duration of planned treatment.

## Immigration removal centre

Immigration removal centres are private or prison-run holding centres for migrants waiting to be accepted by, or deported from, the UK. Immigration removal centres are also known as immigration detention centres and pre-departure accommodation.

### Incident cases

The number of new cases of TB treated per year.

## Interferon-gamma release assays (IGRA) test

A blood test carried out after, at the same time as, or instead of the Mantoux test. If the result is positive, more tests are undertaken to see if the person has TB.

## Latent TB

Latent TB infection means someone is infected with mycobacteria of the *M. tuberculosis* complex, where the bacteria are alive but not currently causing active TB.

## Lost to follow-up

People are defined as 'lost to follow-up' if they:

- cannot be contacted within 10 working days of their first missed outpatient appointment (if they are on self-administered treatment)
- cannot be contacted within 10 working days of their first missed DOT appointment (if they are on daily or three times per week DOT).

## Medical hold

A process to ensure prisoners are not transferred until they are medically fit enough.

## Multidisciplinary TB team

A team of professionals with a mix of skills to meet the needs of someone with TB who also has complex physical and psychosocial issues (that is, someone who is hard-to-reach). The team will meet regularly to plan, implement and evaluate a care pathway. Specific members should be able to meet to deal with urgent issues. Team members will include a social worker, voluntary sector and local housing representatives, TB lead physician and nurse, a case manager, a peer supporter/advocate and a psychiatrist.

## **Peers**

Peers are members of the target population who may have experienced TB. They are often in a good position to help convey, with empathy, the need for screening or treatment. They may be recruited and supported to communicate health messages, assist with contact investigations or screening and to offer people support while they are being tested or treated.

## Rapid access

In the context of TB services, rapid access refers to timely support from a specialist team.

## Substance misuse

Substance misuse is defined as intoxication by – or regular excessive consumption of and/or dependence on – psychoactive substances, leading to social, psychological, physical or legal problems. It includes problematic use of both legal and illegal drugs.

## **Triage**

Triage is the process by which people are classified according to the type and urgency of their symptoms/condition/situation. The aim is to get someone in need to the right place at the right time to see an appropriately skilled person/team.

## Vulnerable migrants

Vulnerable migrants may include undocumented migrants and those with no recourse to public funds. Some refugees, asylum seekers and new entrants to the country may also fall into this category.

## 9 References

Department of Health (2004) Stopping tuberculosis in England: an action plan from the Chief Medical Officer. London: Department of Health

Department of Health (2009) <u>Supply of TB drugs to patients – changes to regulations and advice on implementation</u> [online]

Hayward J, Murray D, Iny I et al. (2010) <u>London TB service review and health needs assessment</u> [online]

Health Protection Agency (2011) Tuberculosis in the UK: 2011 report. London: Health Protection Agency

Jit M, Stagg HR, Aldridge RW et al. (2011) A dedicated outreach service to hard-to-reach tuberculosis patients in London: observational study and economic evaluation. BMJ 343: d5376

Lönnroth K, Jaramillo E, Williams BG et al. (2009) Drivers of tuberculosis epidemics: the role of risk factors and social determinants. Social Science and Medicine 68: 2240–6

Noyes J, Popay J (2007) Directly observed therapy and tuberculosis: how can a systematic review of qualitative research contribute to improving services? A qualitative meta-synthesis. Journal of Advanced Nursing 57: 227–43

Story A, Murad S, Roberts W et al. (2007) Tuberculosis in London: the importance of homelessness, problem drug use and prison. Thorax 62: 667–71

World Health Organization (2003) Adherence to long-term therapies: evidence for action. Geneva: World Health Organization

# Appendix A Membership of the Programme Development Group (PDG), the NICE project team and external contractors

## **Programme Development Group**

PDG membership is multidisciplinary. The Group comprises public health practitioners, clinicians, local authority officers, social care professionals, representatives of the public, academics and technical experts as follows.

#### Ibrahim Abubakar

Consultant/Section Head, Tuberculosis Section, Health Protection Agency for Infections

#### **Imtiaz Ahmed**

Consultant Chest Physician, Respiratory Department, Sandwell General Hospital

#### **Helen Bromley**

Specialty Registrar Public Health, Wirral University Teaching Hospital NHS Foundation Trust

#### **James Camp**

TB Outreach Worker, Bart's and the London NHS Trust

#### Fran Child

Consultant in Paediatric Respiratory Medicine, Department of Respiratory Paediatrics, Royal Manchester Children's Hospital

#### **Malcolm Cocksedge**

Senior TB Nurse Specialist, Bart's and The London NHS Trust

#### **Sue Collinson**

TB Case Worker, Department of Respiratory Medicine, Homerton University Hospital

#### **Katie Dee**

Assistant Director of Public Health, NHS North West

#### **Mark Edginton**

National Programme Manager, National Treatment Agency

#### Joe Hall

TB Social Worker, Find and Treat TB Project

#### **Andrew Hayward**

(Chair) UCL Centre for Infectious Disease Epidemiology Department of Infection and Population Health, Royal Free Campus

#### **Chiara Hendry**

Lead Nurse, KCA UK

#### **Alan Higgins**

Director of Public Health, Oldham

#### Mubarak Ismail

Community Member

#### Joanne Lord

Reader, Health Economics Research Group, Brunel University

#### **Mary Cate MacLennan**

Service Development Manager, Homeless Health

#### **Josie Mavromatis**

Community Member

#### David Olapoju

Community Member

#### **Elias Phiri**

Head of Awareness Programmes, TB Alert, Community Member

#### Fizza Qureshi

Community Member

#### S. Bertel Squire

Professor, Liverpool School of Tropical Medicine and Royal Liverpool and Broadgreen Hospital Trust

#### **Al Story**

Clinical Lead, Find and Treat TB Project

#### **Surinder Tamne**

TB Specialist Nurse, Respiratory and Systemic Infections, Health Protection Agency

#### **Anne Tunbridge**

Consultant in Infectious Diseases, Department of Infection and Tropical Medicine, Royal Hallamshire Hospital, Sheffield

#### **Susan Yates**

TB Research Nurse, Royal Free Hospital

## NICE project team

#### Mike Kelly

**CPHE** Director

#### **Catherine Swann**

Associate Director

#### **Kay Nolan**

Lead Analyst

#### **Una Canning**

Analyst

#### **Chris Carmona**

Analyst

#### **Andrew Hoy**

Analyst

#### Alastair Fischer/Kim Jeong

**Technical Adviser Health Economics** 

#### **Patricia Mountain**

**Project Manager** 

#### Palida Teelucknavan

Coordinator

#### **Sue Jelley**

Senior Editor

#### Alison Lake

Editor

## External contractors

#### **Evidence reviews**

Review 1 was carried out by Matrix Evidence. The principal authors were: Alison O'Mara, Isaac Marrero-Guillamon, Farah Jamal, Angela Lehmann, Chris Cooper, Theo Lorenc.

Review 2 was carried out by Matrix Evidence. The principal authors were: Farah Jamal, Angela Lehmann, Alexis Llewellyn, Isaac Marrero-Guillamon, Alison Martin, Alison O'Mara, Maria Rizzo, Chris Cooper, Alan Gomersall.

Review 3 was carried out by Matrix Evidence. The principal authors were: Maria Rizzo, Alison Martin, Victoria Cliff-Matthews, Farah Jamal, Angela Lehmann, Alexis Llewellyn, Isaac Marrero-Guillamon, Alison O'Mara, Chris Cooper, Alan Gomersall.

Review 4 was carried out by Matrix Evidence. The principal authors were: Maria Rizzo, Alison Martin, Farah Jamal, Angela Lehmann, Alexis Llewellyn, Isaac Marrero-Guillamon, Alison O'Mara, Victoria Clift-Matthews, Chris Cooper, Alan Gomersall.

#### **Cost effectiveness**

The economic modelling was carried out by the Health Protection Agency. The principal authors were: Peter White, Mark Jit, Helen Stagg, Laura Pimpin, Yoon Choi, Tendai Mugwagwa.

#### **Fieldwork**

The fieldwork was carried out by Word of Mouth.

## Expert testimony

Expert paper 1(anonymous).

Expert paper 2 by Mubarak Ismail, Sheffield Hallam University.

Expert paper 3 by Anne Tunbridge, Royal Hallamshire Hospital, Sheffield.

Expert paper 4 by Surinder Tamne, Health Protection Agency.

Expert paper 5 by Jacqui White, Royal Free Hospital.

Expert paper 6 by Frank Arnold, Medical Justice.

Expert paper 7 by Rob van Hest, Municipal Public Health Service Rotterdam-Rijnmond.

Expert paper 8 by Sara Hemming, Royal Free Hospital.

Expert paper 9 by Stephen Davies, King Georges Hostel, London.

Expert paper 10 by Sue Yates, Royal Free Hospital.

Expert paper 11 by Sue Collinson, Homerton University Hospital.

Expert Paper 12 by Philip Monk, Health Protection Agency.

Expert paper 13 by Debbie Crisp, NHS Warwickshire.

Expert paper 14: by Oliver Blatchford, NHS Scotland.

Expert paper 15 by Alistair Story and Joe Hall, Find and Treat London.

Expert paper 16 by Claire Smith, Claire Smith Consultancy.

Expert paper 17 by Malcolm Cocksedge, Bart's and the London NHS Trust.

Expert paper 18 by Jacqueline Nation and Imtiaz Ahmed, Sandwell General Hospital.

Expert paper 19 by Nick Relph, London TB Commissioning Board.

Expert paper 20 by Fran Child, Royal Manchester Children's Hospital.

Expert paper 21 by Chris Griffiths, Barts and the London School of Medicine and Dentistry.

Expert paper 22 by Elias Phiri, TB Alert.

## Appendix B Summary of the methods used to develop this guidance

## Introduction

The reviews, primary research, commissioned reports and economic modelling report include full details of the methods used to select the evidence (including search strategies), assess its quality and summarise it.

The minutes of the Programme Development Group (PDG) meetings provide further detail about the Group's interpretation of the evidence and development of the recommendations.

All supporting documents are listed in <u>appendix E</u> and are available at the <u>NICE website</u>.

## Guidance development

The stages involved in developing public health programme guidance are:

- 1. Draft scope released for consultation
- 2. Stakeholder meeting about the draft scope
- 3. Stakeholder comments used to revise the scope
- 4. Final scope and responses to comments published on website
- 5. Evidence reviews and economic modelling undertaken and submitted to PDG
- 6. PDG produces draft recommendations
- 7. Draft guidance (and evidence) released for consultation and for field testing
- 8. PDG amends recommendations
- 9. Final guidance published on website

10. Responses to comments published on website

## Key questions

The key questions were established as part of the scope. They formed the starting point for the reviews of evidence and were used by the PDG to help develop the recommendations. The overarching questions were:

- 1. Which interventions are effective and cost effective at identifying and managing TB among hard-to-reach groups?
- 2. Which case management tools are most effective and cost effective at identifying those who may need support to complete treatment?
- 3. Which service models and organisational structures are most effective and cost effective at supporting TB diagnosis and treatment for hard-to-reach groups?
- 4. What factors help or hinder the uptake of TB diagnosis and treatment services by people from hard-to-reach groups. (An example could be the acceptability of different testing modalities.) How can the barriers be overcome?

These questions were made more specific for each review (see reviews for further details).

## Reviewing the evidence

#### Effectiveness reviews

Four reviews were conducted: three effectiveness (including cost effectiveness) reviews and one qualitative review (review 1).

## Identifying the evidence

The following databases were searched for all reviews in October 2010:

- ASSIA (Applied and Social Sciences Index and Abstracts)
- BL Direct (British Library)

- British Nursing Index
- CINAHL (Cumulative Index to Nursing and Allied Health Literature)
- CRD (Centre for Reviews and Dissemination): DARE, HTA, NHS EED (Database of Abstracts of Reviews of Effectiveness, Health Technology Assessment, NHS Economic Evaluations Database)
- CDSR (Cochrane Database of Systematic Reviews)
- Community Abstracts
- Current Contents Connect
- EconLIT
- EMBASE
- ERIC (Educational Resources Information Centre)
- HMIC (Health Management Information Consortium)
- MEDLINE
- MEDLINE In-Process
- PsycINFO
- Sociological Abstracts
- Social Services Abstracts
- SPP (Social Policy and Practice)
- WoS (and conference proceedings) (Web of Science).

The following websites and databases were searched manually for relevant literature:

- Advocacy to Control TB Internationally
- Association of Public Health Observatories
- British Infection Association

- British Thoracic Society
- Centers for Disease Control and Prevention
- Community Abstracts via Oxmill
- Google Scholar
- Health Protection Agency
- National Research Register archive site
- NICE, including the former Health Development Agency and NHS Evidence
- Stop TB Partnership
- TB Alert
- UK Clinical Research Network
- UK Coalition to Stop TB
- World Health Organization
- World Health Organization Global Health Atlas

#### Selection criteria

Inclusion and exclusion criteria for each review varied and details can be found at the <u>NICE</u> <u>website</u>. However, in general, studies were included if they:

- covered TB services of any kind
- were conducted in an Organisation for Economic Cooperation and Development (OECD) country
- were published in 1990 or later in English
- included data on any hard-to-reach group (that is, any group that was less likely than normal to access healthcare services).

Additional criteria were added for each review as follows:

- Studies were included in review 1 if they presented perceptions of, or attitudes towards, TB services (both qualitative and quantitative views data were included).
- Studies were included in review 2 if they presented quantitative empirical data on identifying TB cases.
- Studies were included in review 3 if they presented quantitative empirical data on managing TB cases.
- Studies were included in review 4 if they presented quantitative empirical data on the design of services to identify or manage TB.

#### **Quality appraisal**

Included papers were assessed for methodological rigour and quality using the NICE methodology checklist, as set out in the NICE technical manual 'Methods for the development of NICE public health guidance' (see appendix E). Each study was graded (++, +, -) to reflect the risk of potential bias arising from its design and execution.

## Study quality

- ++ All or most of the checklist criteria have been fulfilled. Where they have not been fulfilled, the conclusions are very unlikely to alter.
- + Some of the checklist criteria have been fulfilled. Those criteria that have not been fulfilled or not adequately described are unlikely to alter the conclusions.
- Few or no checklist criteria have been fulfilled. The conclusions of the study are likely or very likely to alter.

The evidence was also assessed for its applicability to the areas (populations, settings, interventions) covered by the scope of the guidance. Each evidence statement concludes with a statement of applicability (directly applicable, partially applicable, not applicable).

## Summarising the evidence and making evidence statements

The review data was summarised in evidence tables (see full reviews).

The findings from the reviews were synthesised and used as the basis for a number of evidence statements relating to each key question. The evidence statements were prepared by the external contractors (see <a href="mailto:appendix A">appendix A</a>). The statements reflect their judgement of the strength (quality, quantity and consistency) of evidence and its applicability to the populations and settings in the scope.

## Cost effectiveness

There was a review of economic evaluations and an economic modelling exercise.

#### Review of economic evaluations

A range of databases was searched for economic evidence as part of the effectiveness reviews (see above). As a result, several economic evaluations were included in the four reviews.

#### **Economic modelling**

An economic model was constructed to incorporate data from the reviews of effectiveness and cost effectiveness. The results are reported in: 'Economic analysis of identifying and managing TB among hard-to-reach groups'.

The model assessed the cost effectiveness of using either a mobile chest X-ray or enhanced case management – or both – to identify TB among homeless people and prison populations and to manage treatment.

## **Fieldwork**

Fieldwork was carried out to evaluate how relevant and useful NICE's recommendations are for practitioners and how feasible it would be to put them into practice. It was conducted with commissioners and practitioners who are involved in TB services and services for hard-to-reach groups. They included people working in the NHS, local authorities and voluntary sector organisations.

The fieldwork comprised:

- Two focus groups carried out in Manchester and London by Word of Mouth. They involved a range of professionals including commissioners of TB services, TB nurses and drugs service workers.
- Seven individual interviews carried out via telephone by Word of Mouth.
- An online survey.

The fieldwork was commissioned to ensure there was ample geographical coverage. The main issues arising are set out in appendix C under fieldwork findings.

## How the PDG formulated the recommendations

At its meetings in 2010 and 2011, the Programme Development Group (PDG) considered the evidence, expert reports and cost effectiveness to determine:

- whether there was sufficient evidence (in terms of strength and applicability) to form a judgement
- where relevant, whether (on balance) the evidence demonstrates that the intervention or programme/activity can be effective or is inconclusive
- where relevant, the typical size of effect (where there is one)
- whether the evidence is applicable to the target groups and context covered by the guidance.

The PDG developed draft recommendations through informal consensus, based on the following criteria:

- Strength (type, quality, quantity and consistency) of the evidence.
- The applicability of the evidence to the populations/settings referred to in the scope.
- Effect size and potential impact on the target population's health.
- Impact on inequalities in health between different groups of the population.
- Equality and diversity legislation.

- Ethical issues and social value judgements.
- Cost effectiveness (for the NHS and other public sector organisations).
- Balance of harms and benefits.
- Ease of implementation and any anticipated changes in practice.

The PDG noted that effectiveness of interventions to identify and manage TB can vary according to the context. For example the background prevalence of TB in a locality.

Where possible, recommendations were linked to an evidence statement(s) (see <a href="appendix C">appendix C</a> for details). Where a recommendation was inferred from the evidence, this was indicated by the reference 'IDE' (inference derived from the evidence).

The draft guidance, including the recommendations, was released for consultation in September 2011. At its meeting in November 2011, the PDG amended the guidance in light of comments from stakeholders and experts and the fieldwork. The guidance was signed off by the NICE Guidance Executive in February 2012.

## Appendix C The evidence

This appendix lists the evidence statements from four reviews provided by external contractors (see <a href="mailto:appendix A">appendix A</a> and <a href="mailto:appendix E">appendix E</a>) and links them to the relevant recommendations. (See <a href="mailto:appendix B">appendix B</a> for the key to quality assessments.)

Appendix C also lists 10 expert papers and their links to the recommendations and sets out a brief summary of findings from the economic analysis and the fieldwork.

The four evidence reviews are:

- Review 1: 'Tuberculosis evidence review 1: Review of barriers and facilitators'
- Review 2: 'Evidence review on the effectiveness and cost effectiveness of interventions aimed at identifying people with tuberculosis and/or raising awareness of tuberculosis among hard-to-reach groups'
- Review 3: 'Evidence review on the effectiveness and cost effectiveness of interventions aimed at managing tuberculosis in hard-to-reach groups'
- Review 4: 'Evidence review on the effectiveness and cost effectiveness of service models or structures to manage tuberculosis in hard-to-reach groups'

The evidence statements are short summaries of evidence, in a review, report or paper (provided by an expert in the topic area). Each statement has a short code indicating which document the evidence has come from. The letter(s) in the code refer to the type of document the statement is from, and the numbers refer to the document number, and the number of the evidence statement in the document.

Evidence statement Q1.2 indicates that the linked statement is numbered 1.2 in review 1.

Evidence statement I3.9 indicates that the linked statement is numbered 3.9 in review 2.

Evidence statement M1.2 indicates that the linked statement is numbered 1.2 in review 3.

Evidence statement S4.2 indicates that the linked statement is numbered 4.2 in review 4. EP1 indicates that evidence in expert paper 1 is linked to the recommendation.

The reviews, expert reports, economic analysis and fieldwork report are available <u>online</u>. Where a recommendation is not directly taken from the evidence statements, but is inferred from the evidence, this is indicated by IDE (inference derived from the evidence).

Where the Programme Development Group (PDG) has considered other evidence, it is linked to the appropriate recommendation below. It is also listed in the additional evidence section of this appendix.

Recommendation 1: EP7; IDE

Recommendation 2: IDE

Recommendation 3: EP5

**Recommendation 4**: evidence statements Q7.2, I15.1, I15.2, I15.4, M6.1, M6.4, M13.0, M13.1; EP11; IDE

Recommendation 5: evidence statements Q3.3, Q3.4, Q3.7, Q6.2; EP2, EP4, EP21

**Recommendation 6**: evidence statements Q1.1, Q1.2, Q1.3, Q1.4, Q1.5, Q1.6, Q1.7, Q1.8, Q1.9, Q1.10, Q2.2, Q2.3, Q3.5, Q3.8, Q3.11; EP1

Recommendation 7: evidence statements I13.1, I15.1, I15.3, I15.4; EP9

Recommendation 8: EP10; IDE

Recommendation 9: evidence statements I6.1, I6.2, EP10, IDE

Recommendation 10: EP10; IDE

Recommendation 11: evidence statements Q3.3, Q3.5, Q7.3, I1.1; EP 2, EP3

Recommendation 12: evidence statements S4.0, S4.1; IDE

Recommendation 13: evidence statement I8.1; IDE

Recommendation 14: evidence statement Q3.7; EP1, EP17, EP18; IDE

**Recommendation 15**: evidence statements Q7.2, Q7.3, I13.1, M2.0, M6.0, M7.0, M7.1, M11.2, M13.0, M13.1, S5.0; IDE

Recommendation 16: evidence statement M16.0; EP11; IDE

## Evidence statements

Please note that the wording of some evidence statements has been altered slightly from those in the evidence reviews to make them more consistent with each other and NICE's standard house style.

## **Evidence statement Q1.1**

Strong evidence from nine studies suggests that hard-to-reach participants commonly view smoking as a risk factor for or cause of TB. These views were reported by studies with:

- a range of hard-to-reach participants (for example, immigrants, prisoners) in the UK (one [++])
- homeless participants in the USA (two [+])
- mixed immigrant groups in the UK (one [+])
- mixed immigrant groups in Canada (one [++])
- Somali immigrants in the UK (one [++])
- Somali and Ethiopian immigrants in Norway (one [+])
- Asian immigrants (Chinese, Vietnamese) in the UK (one [-]) and the USA (one [-]).

#### **Evidence statement Q1.2**

Moderate evidence from five studies reported that participants frequently thought poverty was a condition associated with contracting TB. These views were reported by studies of:

- homeless participants in the USA (one [+])
- mixed immigrant groups in the UK (one [+])
- Somali immigrants in the UK (one [++])

 Somali and Ethiopian immigrants in Norway (one [+]) and Vietnamese immigrants in the USA (one [+]).

#### **Evidence statement Q1.3**

Weak evidence from six studies suggests that hard-to-reach participants may consider food or diet-related factors (such as poor diet or unripe/unwashed fruit) to increase the risk of TB. These views were reported by studies of:

- homeless participants in the USA (two [+])
- mixed immigrant groups in the UK (one [+])
- African immigrants in the UK (one [-]) and in Norway (one [+])
- Asian immigrants in the UK (one [-]).

### **Evidence statement Q1.4**

Weak evidence from four studies suggests that hard-to-reach participants may believe that susceptibility to TB is higher when a person has another illness, such as:

- AIDS (homeless people in the USA; one [+])
- low immunity (Asian immigrants in the UK: one [-])
- asthma (Somali immigrants in the UK: one [++])
- pneumonia (African immigrants in the UK: one [++]). In the case of Somali immigrants in the UK, some participants thought that complications in asthma led to TB.

Other factors believed to affect susceptibility have less basis in fact, and yet cannot be claimed to be entirely incorrect, such as lack of self-care, sexual contact, and a hereditary transmission (since mother to infant transmission may occur).

#### Evidence statement Q1.5

Moderate evidence from seven studies suggests that hard-to-reach participants commonly view lack of self-care ('not looking after yourself') or a health imbalance as risk factors for TB. These views were reported by studies with:

- a range of hard-to-reach participants in the UK (one [++])
- homeless participants in the USA (one [+])
- mixed immigrant groups in the UK (one [+])
- mixed immigrant groups in Canada (one [++])
- Somali immigrants in the UK (one [++])
- Somali and Ethiopian immigrants in Norway (one [+])
- Filipino immigrants in the USA (one [++]).

#### **Evidence statement Q1.6**

Moderate evidence from five studies suggests that hard-to-reach participants commonly attribute hereditary causes to TB infection. These views were reported by studies with a range of hard-to-reach and homeless participants in the UK (one [-]); mixed immigrant groups in Canada (one [++]) and New Zealand (one [-]); and African immigrants in the UK (two [++]).

## **Evidence statement Q1.7**

Weak evidence from two studies suggests that hard-to-reach participants may believe that TB could be transmitted through sexual contact. These views were reported by studies with a range of hard-to-reach participants in the UK (one [-]) and mixed immigrant groups in the UK (one [+]).

#### Evidence statement Q1.8

Weak evidence from two studies suggests that hard-to-reach participants may believe that stress is a cause of TB. These views were reported by studies of Somali immigrants in the UK (one [++]) and Vietnamese immigrants in the USA (one [+]).

### **Evidence statement Q1.9**

Strong evidence from eight studies suggests that hard-to-reach participants commonly view environmental conditions (such as a 'dirty' or 'wet' environment, or weather-related conditions) as a cause of TB. These views were reported by studies with:

• a range of hard-to-reach participants in the UK (one [++])

- homeless participants in the USA (one [+])
- mixed immigrant groups in Canada (one [++])
- Somali immigrants in the UK (one [++] and one [-])
- Asian immigrants (Chinese, Vietnamese, and Filipino) in the UK (two [-] and one [++]).

### **Evidence statement Q1.10**

Moderate evidence from five studies suggests that hard-to-reach participants sometimes consider the sharing of objects such as cigarettes, cutlery, and glasses as a likely transmission mechanism. These views were reported by studies with a range of hard-to-reach participants in the UK (one [-]); homeless people in the USA (two [+]); mixed immigrant groups in the UK (one [+]); and African immigrants in the UK (one [++]). Applicability: five of the 13 studies reviewed here were conducted in the UK, and the rest reported populations of relevance to the UK (for example, Somali and Vietnamese immigrants). We have no reason to believe that the views held by the samples here would not be transferable to populations in the UK.

## **Evidence statement Q2.2**

Weak evidence from two studies indicates that some hard-to-reach groups are unfamiliar with non-symptomatic or latent TB. Some Somali and Ethiopian participants in Norway thought that a lack of symptoms meant that they were healthy (one [+]) and one study explicitly reported no knowledge of latent TB in their sample of various vulnerable groups in London (one [-]).

#### **Evidence statement Q2.3**

Strong evidence from seven studies suggests that participants are aware of the fatality of TB but did not always know whether it was curable. Fatality was discussed by:

- Somali participants in the UK (one [++])
- African immigrants in the UK (one [++])
- various vulnerable groups in the UK (one [-])
- homeless people in the US (one [+]).

Chinese immigrants in the US viewed TB as a curable disease (one [-]), but a lack of understanding about curability was evidenced by African immigrants in the UK (one ++) and homeless people in the USA (one [+]).

#### **Evidence statement Q3.3**

Moderate evidence from two UK studies (both [++]) found that culturally sensitive and appropriate care increased access and adherence to treatment. One sample of African immigrants in the UK found that counselling from healthcare providers, personalised care from specialist nurses, and advice from well-informed peers could improve adherence to treatment. Many women and men from Muslim communities also noted the ability to access gender-compatible services as a facilitator to service access.

#### **Evidence statement Q3.4**

Inconsistent evidence from four studies suggests that some participants viewed the standard of care as low. Common themes included feelings of staff being neglectful (HIV patients in respiratory isolation in the USA: one [+]; drug users USA: one [+]) or disrespectful (USA) (one [+]). However, one UK (++) study on Somali immigrants in Sheffield reported that patients were generally happy with their TB services.

#### Evidence statement Q3.5

Strong evidence from three studies indicated a lack of information or awareness about service availability or access for vulnerable groups in London (one [++]), Somali immigrants in London (one [++]), or Chinese immigrants in New York (one [-]).

#### **Evidence statement Q3.7**

Strong evidence from five studies suggests that hard-to-reach groups (mostly African immigrants) have a lack of confidence in or are concerned about misdiagnoses or delayed diagnosis by healthcare professionals. Groups that mentioned these concerns included:

- Somalis in Sheffield (one [++])
- various vulnerable groups including HIV patients in London (one [-])
- African immigrants in London (two [++])

• Somali and Ethiopian immigrants in Norway (one [+]).

#### **Evidence statement Q3.8**

Strong evidence from five studies suggests that various hard-to-reach groups felt that fear of death from TB was a barrier to wanting to be screened. This was mentioned by:

- various vulnerable groups in London (one [++])
- Somali immigrants in Sheffield (one [++])
- Filipino immigrants in Hawaii and California (one [++])
- homeless people in San Francisco (one [+])
- homeless people in the North-Eastern US (one [+]).

#### **Evidence statement Q3.11**

Strong evidence from three studies shows that language barriers between service users and service providers are a concern for many hard-to-reach immigrant populations. This was evident for Somalis in Sheffield (one [++]); migrant Africans in London (one [++]); and various refugee and minority ethnic groups in New Zealand (one [-]).

#### **Evidence statement Q6.2**

Weak evidence from two studies in UK and New Zealand (both [-]) noted differences between hard-to-reach groups. Differences related to preferences for traditional versus modern medicines and confidence in GPs or the healthcare system. Somalis in the UK had little confidence in GPs, preferring to go to accident and emergency, while Somalis in New Zealand had high confidence in GPs. Chinese people in the UK visited their GPs, but when they failed to improve they used Chinese practitioners who were seen to have more effective treatment, while Chinese immigrants in New Zealand had a preference for traditional medications. Maori and Pacific Islanders in New Zealand also had a preference for traditional medications and. People with HIV and prisoners in the UK had little faith in healthcare services, and people with HIV preferred to self-medicate than go to the GP.

Applicability: the low quality of the two studies reporting cross-group comparisons reduces confidence in the research findings.

#### **Evidence statement Q7.2**

Moderate evidence from three UK studies (one [-] and two [++]) suggested that the complex social and clinical interactions surrounding a patient with TB can be a challenge to participation and adherence, and that outreach TB link workers or social care workers can facilitate coordination of services.

### **Evidence statement Q7.3**

Strong evidence from four UK studies (all [++]) suggested that healthcare workers find it challenging to meet the complex care needs of hard-to-reach groups with TB, especially where there are cultural and language barriers that make it difficult to interpret symptoms and explain about the disease and its treatment.

#### **Evidence statement I1.1**

Moderate evidence from three retrospective cohort studies (two from Switzerland and one from The Netherlands) (all [+]) suggests that active screening is associated with a reduction in the severity or infectivity of identified cases, with a lower proportion of cases who were symptomatic or smear or culture-positive. However the studies did not adjust for baseline differences between cohorts of new entrants being actively screened and other groups of passively-screened foreign-born residents who were usually workers, students or tourists, or undocumented migrants.

Applicability: none of the studies identified in this section were from the UK, the rest originating from a range of European and North American countries with different immigration policies and screening strategies for new entrants, and which are targeted by new entrants from different countries with different demographies and prevalence of TB and other infections such as HIV. This limits the applicability of the findings in this section to the UK. However, the findings are reasonably consistent across countries, and we found no evidence of a national difference in effectiveness of different strategies.

#### Evidence statement I6.1

Weak evidence from one USA before-and-after study (-) found that the yield for identifying active TB was comparable when using chest X-rays (0.056%) and TST (0.069%) among prisoners, however this was not compared using a statistical test and as such the findings are limited. In addition, the study did not compare for baseline differences between the groups.

## **Evidence statement 16.2**

Weak evidence from one UK retrospective cohort (-) suggests that screening with a mobile X-ray unit should be offered to all prisoners regardless of symptoms of TB, since limiting screening to those with symptoms would have missed a substantial number of cases. The conclusions drawn from this study are limited as it looked retrospectively at collected data to calculate how many cases would have been missed if screening had been limited in such a way.

#### **Evidence statement 17.1**

Weak evidence from one USA cost-comparison study (+) suggests that the cost per case of active TB would be lowest if the screening of prisoners was conducted by chest X-ray (\$9600) compared with TST (\$32,100) and using a symptom questionnaire (\$54,100). The findings are limited as the study did not directly compare the costs of screening in, for example, an incremental cost-effectiveness ratio (ICER). In addition the study did not take into account the start-up costs of implementing screening with chest X-ray.

#### **Evidence statement 18.1**

Moderate evidence from one case-control study (++, UK) suggests that using mobile X-ray units (MXU) to screen for TB reduced diagnostic delay among hard-to-reach groups in the UK (including the homeless, drug users and prisoners) compared with passive case detection (adjusted hazard ratio for delay = 0.35, 95% confidence interval [CI] 0.21 to 0.59, p less than 0.0001). People identified as having TB by MXU screening were less likely to be symptomatic on diagnosis compared with those identified by passive case-detection (adjusted odds ratio [OR] 0.35, 95% CI 0.15 to 0.81, p less than 0.001).

#### **Evidence statement I13.1**

Moderate evidence from two randomised controlled trials (RCTs) (both [++], USA) suggest that using peers from the same hard-to-reach group as part of the screening programme can improve screening outcomes for drug users and the homeless. One study found that problem drug users with peers as case managers were more likely to identify contacts than those without such case managers (p = 0.03). However, it is not known how much of this difference was due to the staff being former drug misusers or due to the extra case management received. One study found that the homeless with a peer health adviser were more likely to complete screening than those given usual care (p = 0.004).

## **Evidence statement I5.1**

Strong evidence from five studies, two USA RCTs (both [++]) and three before-and-after studies (two USA and one Canada) (two [+]and one [++]) shows that drug misusers who are provided with small monetary incentives are statistically more likely to complete screening compared with no incentives (p = 0.004, [+]; p < 0.001, [+]).

#### **Evidence statement I15.2**

Strong evidence from two USA RCTs (both [++]) found that providing drug misusers with a brief educational programme alone is unlikely to increase the proportion who complete screening compared with no incentives or education (p = 0.786 and p = 0.547).

#### **Evidence statement I15.3**

Moderate evidence from two USA studies, one RCT (++) and one before-and-after study (+) suggests that drug misusers who were provided with monetary incentives and a brief educational programme were statistically more likely to complete screening compared with providing no monetary incentives or education (p = 0.001 [++]; p = 0.001 [++].

#### Evidence statement I15.4

Moderate evidence from two studies, one USA RCT (++) and one UK before-and-after study (+), suggests that providing monetary incentives increases the uptake of screening (from 23% with no incentive to 62% with a £1.50 incentive and 45% with a £3.00 incentives [+]; and from 53% with no incentive to 84% for \$5.00 incentives, p less than .001 [++]). Although the quality of the studies varied, both studies supported the same findings.

#### **Evidence statement M2.0**

Weak evidence from one USA RCT (+) found that statistically more intravenous drug users were likely to complete treatment if they received peer support (57%) compared with treatment as usual (49%; p less than 0.001), when adherence was measured using electronic bottle caps. However, there was no significant difference when adherence was measured by self-report. All participants received a \$10 incentive to adhere to the research protocol, so these adherence rates might not be replicable in settings where such an incentive is not available.

#### **Evidence statement M6.0**

Moderate evidence from one USA RCT (++) found that there was a statistically significant benefit of adding case-management which included an education intervention (8 sessions over 24 weeks) to directly observed preventive therapy (DOPT) to manage latent TB infection in the homeless compared with providing DOPT alone (AOR = 3.01, 95% CI 2.15 to 4.20).

#### **Evidence statement MS6.1**

Weak evidence from one USA RCT (+) found that adding twice-weekly \$5 cash incentives to attend DOPT appointments resulted in statistically greater adherence to treatment completion in the homeless (44%) compared with providing DOPT provided by a peer without incentives (19%; p = 0.02) but that incentives were not significantly more effective than treatment as usual (26%; p 0.11). The clinical significance of these differences is unclear. The generalisability of the study to hard-to-reach groups may be limited as it included participants who lived in apartments and only included those who returned for their TST results within one week.

#### **Evidence statement M6.4**

Moderate evidence from one USA RCT (++) found that drug users with latent TB infection were statistically more likely to complete treatment when provided with incentives (regardless of whether outreach was also provided), compared with DOPT plus outreach without incentives (AOR = 45.5, 95% CI 9.7 to 214.6; p less than 0.0001). However, the confidence intervals are wide, reducing the precision of the results.

#### **Evidence statement M7.0**

Weak evidence from one USA RCT (+) in intravenous drug users found a statistically significant increase in adherence to treatment completion when a service model approach or social care support was used (59.5%, 95% CI 43.6 to 75.3) compared with treatment as usual (13.1%, CI 3.0% to 23.7%; p less than 0.0001) but no difference compared with DOPT plus methadone maintenance without additional social care support (p values not reported). The study was limited due to baseline differences between groups and the generalisability of the findings was limited because different daily doses of isoniazid were prescribed.

#### Evidence statement M7.1

Weak evidence from one USA before-and-after study (+) found a statistically significant increase in treatment completion rates in favour of service model approach or social care support compared with treatment as usual (p less than 0.001) in mixed hard-to-reach groups with latent TB infection (service model approach or social care support = 70.3%, 102/145 vs. treatment as usual = 47.9%). The study was mainly limited by baseline differences between groups and there may have been treatment contamination across the two time periods.

#### **Evidence statement M11.2**

Weak evidence from one Spanish before-and-after study (-) suggests that adherence among prisoners who were smear-positive increased significantly over time, both before and after DOT was introduced, rising from 95 per 100 in 1993 to 100 per 100 in 2000 for those who received DOT, and from 60 per 100 in 1987 to 76 per 100 in 1992 for those who received treatment as usual. There was also no information reported on the sample characteristics.

#### **Evidence statement M13.0**

Moderate evidence from one USA before-and-after study (+) found that there was a statistically significant benefit of adding incentives to DOT on treatment completion compared with DOT alone (OR = 5.73, 95% CI 2.25 to 14.84) in a population that included over 50% of drug users. The study was limited because DOT was compared with a retrospective cohort of patients.

#### Evidence statement M13.1

Moderate evidence from one Spanish before-and-after study (+) found that there was a statistically significant benefit of adding incentives to DOT on treatment completion compared with self-administered therapy (RR = 3.07, 95% CI 2.13 to 4.41) in mixed hard-to-reach groups. The study was limited because DOT was compared with a retrospective cohort of patients and there were significant differences between the cohorts in the two time periods.

#### **Evidence statement M16.0**

Moderate evidence from three USA studies (all [+]) found that the main characteristic that was shown to be predictive of treatment completion was residing in stable housing before receiving treatment for TB in the homeless and in prisoners. Therefore, participants who live on the streets

37

or in a shelter have poorer adherence to treatment for TB and may need additional support to maintain their adherence with treatment.

#### **Evidence statement S4.0**

Moderate evidence from one USA RCT (++) found that treatment completion for managing latent TB infection among drug users was 52.8% when it was conducted in an outreach setting at a site convenient for the participant compared with 60% when it was conducted onsite in a drug services facility. These differences were not statistically compared, limiting the study findings, but suggest that there was no added benefit in adherence to treatment when it was delivered in an outreach setting.

#### **Evidence statement S4.1**

Moderate evidence from one USA RCT (+) found that the proportion of intravenous drug users who enrolled and complied with medical treatment (including treatment for TB) was 92% for those treated onsite at a methadone clinic compared with 32% for those treated offsite at a medical centre (p less than 0.001). The proportion of drug users with positive PPT tests who received a chest X-ray was 75% for those who received medical treatment onsite compared with 24.4% for those treated offsite. The number of patients with positive PPD tests who received chemoprophylaxis was 12.5% for people treated onsite compared with 7.1% for those treated offsite. Statistical significance was not calculated for either of these differences.

#### **Evidence statement S5.0**

Moderate evidence from one USA RCT (++) found that the probability of completing treatment was statistically greater when peers delivered enhanced case management to drug users compared with limited case management delivered by a healthcare worker (RR = 2.68, 95% CI 1.24 to 5.82; p = 0.01). The conclusions drawn from these findings were limited because the peer-led intervention also had enhanced case management. It is therefore not known how much of the positive treatment outcomes were due to the healthcare worker who delivered the service or the intensity of case management.

## Additional evidence

Expert paper 1: 'Service user perspectives'.

- Expert paper 2: 'Socio-cultural factors influencing an understanding of tuberculosis within the Somali community in Sheffield'.
- Expert paper 3: 'Screening international migrants for infection'.
- Expert paper 4: 'Primary care tuberculosis survey 2010'.
- Expert paper 5: 'Cohort review in practice'.
- Expert paper 7: 'Tuberculosis control, specifically among hard to reach groups in Rotterdam'.
- Expert paper 9: 'Health MOT in a hostel'.
- Expert paper 10 'TB in a London prison'
- Expert paper 11: 'The importance of housing homeless people with tuberculosis'.
- Expert paper 17: 'Nurse led triage'.
- Expert paper 18: 'Nurse led service Birmingham'.
- Expert paper 21: 'Screening for tuberculosis and HIV in primary care'.

## Cost-effectiveness evidence

The economic analysis looked at the cost effectiveness of using mobile X-ray screening and enhanced case management – combined and separately – to identify and manage TB among homeless and prison populations. This was compared with current practice. The analysis also estimated the number of cases of pulmonary TB that would be averted due to earlier detection.

The results indicate that the interventions are most cost effective among populations with the highest prevalence of TB. Likewise, the benefit of ensuring treatment is completed is greater among those at high risk of transmitting TB (that is, among groups where TB prevalence is highest).

The recommendations for vulnerable migrants are largely based on existing NICE guidance (clinical guideline 117).

Estimates of cost per quality-adjusted life years (QALY) are presented for mobile X-ray screening. They are expressed as a threshold analysis (not as a cost per QALY) for enhanced

case management and for mobile X-ray screening combined with enhanced case management. Sensitivity analyses were performed on key parameters, including prevalence of disease.

The economic analysis indicated how much it is worth spending to raise treatment completion rates from 55% to 75% among two separate populations: 10,000 homeless people and10,000 prisoners. It is based on the assumption that the NHS and other government bodies would be prepared to spend up to £20,000 to gain one QALY. The results suggest that it would be cost effective to spend an estimated £21,000 extra per additional case found among homeless people, when the prevalence of TB among this group is 778 cases per 100,000. For a prison population with a prevalence of 208 cases per 100,000, it would be cost effective to spend an additional £35,000 per additional case of active TB found.

The economic model adopted a conservative approach to estimate the cost-effectiveness of mobile X-ray screening and enhanced case management over a 20 year period. The benefits of interventions that extend lives more than 20 years is ignored, as is any potential reduction in cases of TB more than 20 years into the future. In addition, the model assumed there was no benefit in preventing latent infection that did not progress to active pulmonary disease. For these reasons, it is likely that the interventions described in the model will be more cost effective than estimated.

## Fieldwork findings

Fieldwork aimed to test the relevance, usefulness and feasibility of putting the recommendations into practice. The PDG considered the findings when developing the final recommendations. For details, go to the fieldwork section in <a href="mailto:appendix B">appendix B</a> and 'Fieldwork report: identifying and managing TB among hard to reach groups'.

Fieldwork participants who work in TB services or with hard-to-reach groups were overwhelmingly positive about the recommendations and their potential to help identify and manage TB. Many stated that the guidance was an endorsement for prioritising TB prevention and control. It was viewed as a timely document because of concerns about increasing levels of TB.

Participants felt that the recommendations on planning and funding TB services presented an ideal scenario. As such, they did have some reservations about the likelihood of them being implemented in the current economic climate.

# **Appendix D Gaps in the evidence**

The Programme Development Group (PDG) identified a number of gaps in the evidence related to the programmes under examination based on an assessment of the evidence stakeholder and expert comment and fieldwork. These gaps are set out below.

- 1. A comparison of the relative effectiveness of different interventions to ensure treatment is completed among hard-to-reach groups in England. (Source review 3)
- 2. A comparison of the relative effectiveness of different service models used in England to identify and manage TB among hard-to-reach groups. (Source review 4)
- 3. Data on the cost-effectiveness of interventions to manage TB among hard-to-reach groups in England. (Source review 3)
- 4. Evidence on how to improve passive case-finding of TB among hard-to-reach groups. (Source review 2)
- 5. Effective interventions to identify and manage TB among people who are homeless. (Source reviews 2 and 3)

The Group made five recommendations for research into areas that it believes will be a priority for developing future guidance. These are listed in <u>section 5</u>.

#### 37

# **Appendix E Supporting documents**

Supporting documents include the following:

- Evidence reviews:
  - Review 1: 'Tuberculosis evidence review 1: Review of barriers and facilitators'
  - Review 2: 'Evidence review on the effectiveness and cost-effectiveness of interventions aimed at identifying people with tuberculosis and/or raising awareness of tuberculosis among hard-to-reach groups'
  - Review 3: 'Evidence review on the effectiveness and cost effectiveness of interventions aimed at managing tuberculosis in hard-to-reach groups'
  - Review 4: 'Evidence review on the effectiveness and cost effectiveness of service models or structures to manage tuberculosis in hard-to-reach groups'.
- Economic modelling: 'Economic analysis of identifying and managing TB among hard-toreach groups'.
- Expert papers:
  - Expert paper 1: 'Service user perspectives'
  - Expert paper 2: 'Socio-cultural factors influencing an understanding of tuberculosis within the Somali community in Sheffield'
  - Expert paper 3: 'Screening international migrants for infection'
  - Expert paper 4: 'Primary care tuberculosis survey 2010'
  - Expert paper 5: 'Cohort review in practice'
  - Expert paper 6: 'Hard to reach patients with, or at risk of, tuberculosis in immigration detention'
  - Expert paper 7: 'Tuberculosis control, specifically among hard to reach groups in Rotterdam'
  - Expert paper 8: 'Tuberculosis case management lessons from New York City (NYC)'

- Expert paper 9: 'Health MOT in a hostel'
- Expert paper 10: 'Managing a tuberculosis service in prison'
- Expert paper 11: 'The importance of housing homeless people with tuberculosis'
- Expert paper 12: 'Leicester model'
- Expert paper 13: 'Strategies for managing tuberculosis in the chaotic community of rural Warwickshire'
- Expert paper 14: 'Tuberculosis in Scotland'
- Expert paper 15: 'London Find & Treat'
- Expert paper 16: 'Brief overview of prisons'
- Expert paper 17: 'Nurse led triage'
- Expert paper 18: 'Nurse led service Birmingham'
- Expert paper 19: 'Model of care London tuberculosis plan'
- Expert paper 20: 'What about the children?'
- Expert paper 21: 'Screening for tuberculosis and HIV in primary care'
- Expert paper 22: 'The truth about tuberculosis awareness and advocacy programme'
- Fieldwork report: 'Fieldwork report: identifying and managing TB among hard to reach groups'

## About this guidance

NICE public health guidance makes recommendations on the promotion of good health and the prevention of ill health.

This guidance was developed using the NICE <u>public health programme</u> guidance process.

The recommendations from this guidance have been incorporated into a <u>NICE pathway</u>. Tools to help you put the guidance into practice and information about the evidence it is based on are also available.

## Changes after publication

June 2014: Minor maintenance

### Your responsibility

This guidance represents the views of the Institute and was arrived at after careful consideration of the evidence available. Those working in the NHS, local authorities, the wider public, voluntary and community sectors and the private sector should take it into account when carrying out their professional, managerial or voluntary duties.

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

### Copyright

© National Institute for Health and Clinical Excellence 2012. All rights reserved. NICE copyright material can be downloaded for private research and study, and may be reproduced for educational and not-for-profit purposes. No reproduction by or for commercial organisations, or for commercial purposes, is allowed without the written permission of NICE.

#### **Contact NICE**

National Institute for Health and Clinical Excellence

Level 1A, City Tower, Piccadilly Plaza, Manchester M1 4BT

www.nice.org.uk

nice@nice.org.uk

0845 033 7780