NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

PUBLIC HEALTH DRAFT GUIDANCE

Identifying and managing tuberculosis among hard-to-reach groups

Introduction

The Department of Health (DH) asked the National Institute for Health and Clinical Excellence (NICE) to produce public health guidance on identifying and managing tuberculosis (TB) among hard-to-reach groups.

The guidance is for NHS and other policy makers, commissioners, managers and practitioners who have a direct or indirect role in, and responsibility for, identifying and managing TB. This includes those working in local authorities, the criminal justice system, drug and alcohol services and the wider public, private, voluntary and community sectors.

It may also be of interest to people from hard-to-reach groups, their families, people who have had TB and other members of the public.

The guidance complements but does not replace, NICE guidance on TB (for further details, see section 7).

The Programme Development Group (PDG) has considered the evidence reviews, cost effectiveness and expert testimony.

This document sets out the Group's preliminary recommendations. It does not include all sections that will appear in the final guidance. NICE is now inviting comments from stakeholders (listed on our website at: www.nice.org.uk).

Note that this document does not constitute NICE's formal guidance on identifying and managing TB among hard-to-reach groups. The recommendations made in section 1 are provisional and may change after consultation with stakeholders and fieldwork.

The stages NICE will follow after consultation (including fieldwork) are summarised below.

- The Group will meet again to consider the comments, reports and any additional evidence that has been submitted.
- After that meeting, the Group will produce a second draft of the guidance.
- The draft guidance will be signed off by the NICE Guidance Executive.

For further details, see 'The NICE public health guidance development process: An overview for stakeholders including public health practitioners, policy makers and the public (second edition, 2009)'. This document is available at www.nice.org.uk/phprocess

The key dates are:
Closing date for comments: 3 November 2011.
Next PDG meeting: 24 November 2011.

Members of the PDG are listed in appendix A and supporting documents used to prepare this document are listed in appendix E.

This guidance was developed using the NICE public health programme process.

Contents

1 Recommendations

When writing the recommendations, the Programme Development Group (PDG) (see appendix A) considered the evidence reviews, evidence of cost effectiveness, and expert testimony. Note: this document does not constitute NICE's formal guidance on this programme. The recommendations are preliminary and may change after consultation.

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

The PDG considers that the recommended measures are cost effective.

For the gaps in research, see appendix D.

The evidence reviews, supporting evidence statements and economic modelling report are available at www.nice.org.uk/guidance/PHG/Wave22/4

Please note: although the recommendations aim to help people from hard-to-reach groups, others may benefit as a result of reducing transmission of tuberculosis (TB) among the population as a whole.

Definitions

For the purposes of this guidance, hard-to-reach groups are defined as adults, young people and children, whose social circumstances 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.

The main groups considered were: prisoners, people who are homeless, substance misusers (problem drug and alcohol users) and subpopulations of

migrants who are hard to reach (for example, undocumented migrants and those with no recourse to public funds).

Where the term ‘people’ is used, it refers to everyone (of all ages, ethnic background and migration status) who belong to a hard-to-reach group.

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

Whose health will benefit?

People from hard-to-reach groups with, or at risk of, TB.

Who should take action?

- NHS Commissioning Board working in partnership with Public Health England.

What action should they take?

- Take joint responsibility for national oversight of TB control activities in partnership with subnational TB leads.

- Ensure TB programmes are commissioned by ‘subnational’ bodies which take responsibility for TB control in areas larger than those served by clinical commissioning groups. As an example, they could be responsible for cities (in major metropolitan areas) or in areas currently covered by strategic health authorities.

- Ensure subnational TB control programmes are led by by a director of public health or another nominated public health consultant. The lead should ensure a comprehensive control programme is commissioned to support the level of need (see recommendation 2).

- Ensure the subnational TB control programme is informed by relevant NICE guidance and the findings of the standard minimum data set collected through local needs assessments and service audits.

- Ensure the programmes include all aspects of TB prevention and control. This includes: active case-finding (contact-tracing and screening of high-risk groups); awareness-raising activities; standard and enhanced case management (including the provision of directly observed treatment); finding those lost to follow-up and getting them back into treatment; identification and management of latent infection; immunisation; cohort review (see recommendation 15); and the gathering of surveillance and outcome data.

- Ensure subnational TB control programmes take account of the need to work with other programmes targeting hard-to-reach groups. Examples include programmes focused on: the health of migrants, asylum seekers, refugees and offenders; homelessness and housing; children's services and drug and alcohol services.

Recommendation 2 Needs assessment

Whose health will benefit?

People from hard-to-reach groups with, or at risk of, TB.

Who should take action?

- Directors of public health.

- Public Health England.

What action should they take?

- Collect information on the following in relation to hard-to-reach groups, to inform the local needs assessment process:
    - Number of annual notified TB cases[1].
    - Size and distribution of local at-risk groups[2].

[1] Enhanced TB surveillance. See www.hpa.org.uk/web/HPAweb&Page&HPAwebAutoListName/Page/1294739536811

[2] 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, where relevant, the size of new migrant communities.

  - Indexes of social deprivation.
  - Local statutory and non-statutory services working with these groups.
  - Local TB service organisation.
  - Composition and capacity of local multidisciplinary TB team[3].
  - Numbers requiring enhanced case management and number receiving directly observed therapy (DOT) from the start, and at any point during, treatment[4].
  - Evidence of recent transmission[5].
  - Completeness and yield of contact tracing (see also recommendation 13).
  - Active case-finding initiatives.
  - Treatment completion rates among different at-risk groups including rates of loss to follow-up and treatment interruptions[6].
  - 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.

- Provide the subnational TB control programme (see recommendation 1) with local needs assessment information on an annual basis.

- Ensure TB is an annex to the joint strategic needs assessment in areas of high need.

[3] Refer to local audit.
[4] Enhanced TB surveillance. See www.hpa.org.uk/web/HPAweb&Page&HPAwebAutoListName/Page/1294739536811.
[5] UK TB strain typing database. See www.hpa-bionum.org.uk/TBtyping/home.php and local incident and outbreak reports.
[6] Enhanced TB surveillance. See www.hpa.org.uk/web/HPAweb&Page&HPAwebAutoListName/Page/1294739536811 and recommendation 14.

Recommendation 3 Commissioning: multidisciplinary TB teams

Whose health will benefit?

People from hard-to-reach groups with, or at risk of, TB.

Who should take action?

Commissioners of subnational TB control programmes.

What action should they take?

Ensure the service specification for multidisciplinary TB teams covers:

- The resources needed to provide TB patients from hard-to-reach groups with access to enhanced case management (ECM). If ECM services cannot be made available locally, they should be provided by working in conjunction with a team that does have this capacity. Alternatively, a process should be in place to transfer them to a team offering ECM support (where practical for the patient).

- The resources needed to manage patients with complex social and clinical needs, including the need to work in partnership with other statutory and voluntary services (to address any unmet health and social care needs). One whole-time equivalent case manager is needed per 20 patients requiring enhanced case management.

- The resources needed to effectively manage other patients. (One whole-time equivalent case manager is needed per 40 notifications requiring standard case management.)

- Access to skilled outreach and advocacy workers who can draw upon the services of allied agencies to address patients' housing, addiction, welfare and other health and social care needs.

- Access to a specified housing officer and social worker.

- 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 pharmacists to support directly observed therapy. Funds may also be used to provide accommodation during treatment (see recommendation 15).

- The resources to provide ongoing TB awareness-raising activities for professional and voluntary (including advocacy) groups that work with hard-to-reach groups.

Recommendation 4 Raising awareness of TB among hard-to-reach groups

Whose health will benefit?

People from hard-to-reach groups with, or at risk of, TB.

Who should take action?

- Multidisciplinary TB teams.

- Statutory or voluntary organisations (including advocacy organisations, community champions and peers) that work with hard-to-reach groups.

What action should they take?

- Multidisciplinary TB teams should train relevant statutory and voluntary professionals to raise awareness of TB among hard-to-reach groups. They should provide them with details on:
    - how to recognise symptoms
    - how people get TB
    - the benefits of diagnosis and treatment (including the fact that TB is treatable – and treatment is free and confidential for everyone, irrespective of immigration status)
    - the location and opening hours of testing services

  - where relevant, the potential interaction of TB medication with other drugs (for example, oral contraceptives and opiates, especially methadone)
  - the risk of migrants from high incidence countries developing active TB – even if they have already screened negative for it.

- Multidisciplinary TB 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 written material). Modify this material to meet the specific needs of the audience, if necessary.

- Multidisciplinary TB 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.

- Multidisciplinary TB 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 5 Raising and sustaining awareness of TB among those working with hard-to-reach groups

Whose health will benefit?

People from hard-to-reach groups with, or at risk of, TB.

Who should take action?

- Multidisciplinary TB teams.

- Statutory or voluntary organisations (including advocacy organisations, community champions and peers) that work with hard-to-reach groups.

What action should they take?

- Multidisciplinary TB teams should identify and provide 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, asylum seeker support staff and those working in walk-in-centres, hostels, drug and alcohol projects and prisons.

- Multidisciplinary TB teams should ensure the education programme increases awareness of the possibility of TB disease and aims to reduce the stigma associated with it. The programme should include detail on:
    - the causes, how it is transmitted and the signs and symptoms
    - lifestyle factors that may mask symptoms
    - local epidemiology, highlighting at-risk, hard-to-reach groups
    - the 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 tracing following diagnosis of an active case)
    - 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
    - the role of allied professionals in awareness-raising, identifying cases and helping people complete treatment.

- Statutory 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 from the local multidisciplinary TB team.)

- Where possible, organisations should ensure peers from hard-to-reach groups with experience of TB contribute to awareness-raising activities.

Recommendation 6 Rapid-access TB services

Whose health will benefit?

People from hard-to-reach groups with suspected TB.

Who should take action?

Multidisciplinary TB teams.

What action should they take?

- Ensure TB services clearly publicise how those working with hard-to-reach groups can refer people to the service.
- Accept referrals from healthcare providers and allied agencies working in the community with hard-to-reach groups. This includes voluntary and statutory agencies.
- Use specialist TB nurses to ‘triage’ referrals, so that case management starts promptly (as soon as possible and no later than 5 working days after a referral). Ensure the results from first line diagnostic tests (including a chest X-ray and sputum smear) are available prior to the patient seeing a physician.

Recommendation 7 Finding latent TB among problem drug users and prison populations

Whose health will benefit?

Problem drug users and prisoners at risk of latent TB infection aged under 35.

Who should take action?

- Drug treatment services.
- Local TB services (including multidisciplinary TB teams).
- Prison healthcare services.

What action should they take?

- Where practical, drug treatment services should offer clients aged under 35 an interferon-gamma release assays (IGRA) test for TB alongside other blood-borne virus tests if they:
  - live in a high incidence area[7]
  - are on regular observed maintenance therapy such as methadone.

- In high incidence areas,[8] prison healthcare services should offer IGRA testing for TB to prisoners who are:
  - aged under 35 and will be in prison for at least 3-plus months or
  - aged under 35 and on regular observed maintenance therapy (such as methadone) with arrangements for this to continue after release (if they test positive, directly observed preventive treatment (DOPT) can be arranged alongside the other therapy.

- Wherever possible, incorporate IGRA testing with blood-borne virus screening.

- Refer prisoners and drug users with positive IGRA tests to local TB services 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 appropriate, initiate DOPT alongside methadone maintenance therapy or while in prison.

[7] Where TB notifications are greater than 40 per 100,000 people per annum.
[8] Where TB notifications are greater than 40 per 100,000 people per annum.

Recommendation 8 Finding active TB among homeless groups

Whose health will benefit?

Homeless people with, or at risk of, TB.

Who should take action?

- Commissioners of subnational TB control programmes.
- Commissioners of services for homeless groups.
- Multidisciplinary TB teams.
- Statutory and voluntary sector professionals working in hostels and day centres.
- Mobile X-ray teams.

What action should they take?

- In areas of identified need (see recommendation 2) for example, with a high incidence of TB[9] or substantial numbers of homeless people, local TB commissioners should:
    - Ensure there is a programme of active case-finding using mobile digital radiography in places where homeless people congregate. (This includes: homeless day centres, rolling shelters, hostels and temporary shelters established as part of cold weather initiatives.)
    - Base the frequency of screening at any one location on population turnover, to ensure homeless people have access to screening on a 6-monthly basis.
    - Where local demand does not warrant a mobile X-ray team, consider commissioning the use of mobile X-ray screening capacity from other areas.

[9] Where TB notifications are greater than 40 per 100,000 people per annum.

- In line with NICE's clinical guideline on tuberculosis[10], simple incentives to attend screening, such as hot drinks and snacks should be considered.

- Consider offering homeless people other relevant health interventions when they are screened for TB at a mobile X-ray unit.

- Local multidisciplinary TB 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 referral and follow-up.

- Mobile X-ray teams should consider using peer educators to promote the uptake of TB screening in hostels and day centres.

- Mobile X-ray teams should provide routine data to subnational TB control programmes on: screening uptake, referrals and the number of active TB cases identified.

Recommendation 9 Finding active TB among people in prison[11] or immigration removal centres

Whose health will benefit?

People detained in a prison or immigration removal centre (IRC).

Who should take action?

- Commissioners and providers of prison or IRC healthcare services.

- TB services with a prison or IRC in their catchment area.

- Local health protection units.

[10] See recommendation 1.8.8.1 in NICE clinical guideline 117 'Tuberculosis'. Available from www.nice.org.uk/guidance/CG117.

[11] Where the term 'prison' is used it applies to any of Her Majesty's prison establishments including young offender institutes (YOIs).

What action should they take?

- On arrival at the establishment, prison and IRC healthcare professionals should ask all 'receptions' (including 'transfers') if they are taking TB medication, to ensure continuity of treatment.

- Prisons which have Department of Health-funded static digital X-ray facilities for TB screening should X-ray all new 'receptions' (including transfers) who have not received a chest X-ray in the last 6 months. This should take place within 48 hours of arrival. The results should be reported within 24 hours. If active TB is suspected following the X-ray, three sputum samples (including one early morning sample) should be taken within a 24-hour period. This should be sent for AFB microscopy and culture[12].

- Healthcare professionals in all other prisons and IRCs should follow the recommendations for prison screening set out in NICE's clinical guideline[13] – but should ensure prisoners are screened within 48 hours of arrival.

- Prisoners should be screened for TB by a health questionnaire on each entry to the prison system. Then for those with signs and symptoms of active TB, a chest X-ray and three sputum samples taken in 24 hours for TB microscopy, including a morning sputum sample.[14.]

- 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 should be retained on medical hold 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.

[12] For more on TB diagnosis, see 'Tuberculosis' NICE clinical guideline 117. Available from www.nice.org.uk/guidance/CG117.
[13] See 'Tuberculosis' NICE clinical guideline 117. Available from www.nice.org.uk/guidance/CG117.
[14] This is an extract of recommendation 1.9.3.2 in 'Tuberculosis' NICE clinical guideline 117. Available from www.nice.org.uk/guidance/CG117.

- Prison health staff should report all suspected and confirmed TB cases to local multidisciplinary TB teams within one working day**.**

- Local TB service staff should visit every confirmed TB case in a prison or IRC in their locality within five working days.

- If a case of active TB is identified, the local health protection unit should plan a contact-tracing exercise and consider using mobile digital radiography to check for further cases.

Recommendation 10 Hard-to-reach migrants (or 'new entrants')

Whose health will benefit?

People born in countries with a TB prevalence of 40 per 100,000 people or greater who have moved to England within the last 5 years.

Who should take action?

- Subnational TB control programmes.

- Multidisciplinary TB teams.

- Primary care services.

- Health services working with new arrivals.

- Local voluntary and community services working with migrant groups.

- Accident and emergency services.

What action should they take?

- In line with previous NICE guidance, healthcare professionals, including primary care staff, responsible for screening new entrants should maintain a coordinated programme to:
    - detect active TB and start treatment
    - detect latent TB and start treatment

  - provide BCG vaccination to those in high-risk groups who are not infected and who are previously unvaccinated
  - provide relevant information to all new entrants[15].

- New entrant screening for TB should be incorporated within larger health screening programmes for new entrants and linked to local services[16].

- Assessment for, and management of TB in new entrants should consist of the following:
  - Risk assessment for HIV, including HIV prevalence rates in the country of origin, which is then taken into account for Mantoux testing and BCG vaccination.
  - Assessment for active TB if interferon-gamma test is positive; which would include a chest X-ray.
  - Treatment for latent TB infection for people aged 35 years or younger in whom active TB has been excluded, with a positive Mantoux test inconsistent with their BCG history, and a positive interferon-gamma test.
  - Consideration of BCG vaccination for unvaccinated people who are Mantoux negative.
  - 'Inform and advise' information for people who do not have active TB and are not being offered BCG or treatment for latent TB infection[17].

- New entrants should be identified for TB screening from the following information:
  - Port of Arrival reports
  - new registrations with primary care
  - entry to education (including universities)

[15] This is an extract from recommendation 1.8.7.1 in 'Tuberculosis' NICE clinical guideline 117. Available from www.nice.org.uk/guidance/CG117.
[16] This is an extract from recommendation 1.8.7.2 in 'Tuberculosis' NICE clinical guideline 117. Available from www.nice.org.uk/guidance/CG117.
[17] This is an extract from recommendation 1.8.7.3 in 'Tuberculosis' NICE clinical guideline 117. Available from www.nice.org.uk/guidance/CG117.

  - links with statutory and voluntary groups working with new entrants[18].

- Any healthcare professional working with new entrants to England should encourage them to register with a GP[19].

- Primary care services should encourage local, community-based organisations that work with hard-to-reach new migrants to encourage those groups to:
  - register with a primary care provider
  - use NHS services (emergency or primary care).

- All of the above actions should be applied to people from high incidence countries who have been in England for up to 5 years and have not previously been screened.

Recommendation 11 Managing TB in prisons[20] and immigration removal centres

Whose health will benefit?

People diagnosed with latent or active TB who have been detained in prison or an immigration removal centre (IRC).

Who should take action?

- Subnational TB control programmes.

- Commissioners and providers of prison or IRC health services.

- TB services with a prison or IRC in their catchment area.

[18] This is an extract from recommendation 1.8.7.4 in 'Tuberculosis' NICE clinical guideline 117. Available from www.nice.org.uk/guidance/CG117.
[19] This is an extract from recommendation 1.8.7.5 in 'Tuberculosis' NICE clinical guideline 117. Available from www.nice.org.uk/guidance/CG117
[20] Where the term 'prison' is used it applies to any of Her Majesty's Prison Establishments including all young offender institutes (YOIs).

What action should they take?

- Prison and IRC healthcare services should develop a TB policy by working with the local TB service and the local health protection unit.
- Prison and IRC healthcare services should ensure they have a named lead for TB.
- Local TB services should ensure there is a named lead for any prison and IRC that falls within their locality.
- Local TB services, in conjunction with prison and IRC healthcare services, should agree a care pathway for TB to ensure any suspected or confirmed cases are reported to the local TB service.
- All cases of active TB should be managed by the local TB service in liaison with prison or IRC healthcare providers. Investigations and follow-up should be undertaken within the prison, wherever practically possible.
- Prisons and IRCs should ensure local TB service staff have access to detainees who require treatment (for example, by being given security clearance).
- All prisoners and IRC detainees receiving treatment for active or latent TB should have a named TB case manager.
- All prisoners receiving treatment for active or latent TB should receive directly observed therapy (DOT)[21].
- Prison medical services should have liaison and handover arrangements to ensure continuity of care before any prisoner on TB treatment is transferred between prisons[22].

[21] This is an extract of recommendation 1.9.3.3 in 'Tuberculosis' NICE clinical guideline 117. Available from www.nice.org.uk/guidance/CG117
[22] This is an extract of recommendation 1.9.3.4 in 'Tuberculosis' NICE clinical guideline 117. Available from www.nice.org.uk/guidance/CG117

- If a prisoner is being treated for active or latent TB, the prison medical services should draw up as early as possible a contingency plan for early discharge, which could happen directly from a court appearance. This plan should include firm arrangements for clinical follow-up and treatment monitoring in the intended district of residence, and should take into account that there may not be a fixed residence arranged for the prisoner after release. The prisoner should be given contact details for a named key worker, who will visit and monitor the prisoner after release and liaise between services involved[23].

- Contingency plans for prisoners and IRC detainees with TB should be drawn up in liaison with the named TB case manager.

- The case manager should ensure accommodation is available for the duration of TB treatment following the prisoner or detainee's release (see recommendation 15).

- Multidisciplinary TB 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 12 Enhanced case management

Whose health will benefit?

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

Who should take action?

- Multidisciplinary TB teams.

- Professionals and community organisations working with hard-to-reach groups on other issues.

[23] This is an extract of recommendation 1.9.3.5 in 'Tuberculosis' NICE clinical guideline 117. Available from www.nice.org.uk/guidance/CG117

What action should they take?

- Multidisciplinary TB teams should, as soon as possible (and within 5 working days of a referral), allocate a named TB case worker 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 children aged under 16, people who request it and those who:
    - do not (or have not in the past) adhere/d 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 patient. They should also involve representatives from other professional teams and key workers from community organisations. Finally, they should gain the patient's consent to the plan and agree a review date.

- TB case managers should aim to find patients 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 health protection units or specialist street outreach teams.

- Case managers should ensure the care plan identifies potential barriers to diagnosis and treatment and any support that may be required. It may include:

  - demographic information (for example, age, nationality, length of time in UK, primary language)
  - housing needs and living situation
  - substance use issues (drugs or alcohol)
  - criminal justice issues
  - other health issues
  - 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
  - any 'enablers' or incentives to overcome the barriers to diagnosis or treatment.

- The plan should:
  - state who will be delivering treatment and where (if the patient is having directly observed therapy this should be provided at a location convenient to them)
  - include measures to take in the event of loss to follow-up (including 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 patient
  - 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 the patient access other health services).

Recommendation 13 Contact investigations

Whose health will benefit?

Contacts of TB index cases from hard-to-reach groups.

Who should take action?

- Multidisciplinary TB teams including case managers.
- Local health protection units.

What action should they take?

- TB case managers should conduct contact-tracing at the index case's place of residence when the index case comes from a hard-to-reach group or is a child. The aim is to help identify people who have been living with them and people they frequently socialise with.
- TB case managers with patients from hard-to-reach groups should work alongside health and social care professionals known to the client to help trace relevant contacts.
- Where available and appropriate, encourage peer educators to help with contact-tracing when it involves hard-to-reach patients who have complex social networks.
- Local health protection units should provide the necessary support so that multidisciplinary TB 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.
- Local health protection 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.
- Check everyone (adults and children) who has had close contact with a child under 16 who has been diagnosed with TB.

Recommendation 14 Cohort review

Whose health will benefit?

Local populations at risk of TB and the wider community.

Who should take action?

- Public health leads and allied professionals from the subnational TB control programme.
- Local multidisciplinary TB teams, including case managers.

What action should they take?

- Subnational TB 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 subnational 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 subnational TB control programme should attend cohort review meetings. A paediatrician should be present when cases of children with TB are being 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 health protection unit.
- Local public health teams should collate and 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.

- The public health lead for subnational TB control programmes 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.

Recommendation 15 Accommodation during treatment

Whose health will benefit?

Homeless people diagnosed with active TB.

Who should take action?

- Multidisciplinary TB teams including TB case managers.

- Commissioners of the subnational TB control programme.

- Local authority housing departments.

- Providers of hostel accommodation.

What action should they take?

- TB case managers should assess TB patients' living circumstances and work with allied agencies to ensure all those who are entitled to state-funded accommodation receive it.

- All those listed above should work together to agree a process for providing accommodation for homeless people diagnosed with active TB who are otherwise ineligible for state-funded accommodation. The process should detail a TB patient's eligibility and ensure they are given accommodation for the duration of their TB treatment.

- Commissioners of subnational TB 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

2 Public health need and practice

In 2009, there were 9040 reported cases of tuberculosis (TB) in England – an incidence of 15 cases per 100,000 people. Seventy five per cent were among people born outside the UK (Health Protection Agency 2010).

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 9% of TB cases had at least one of four risk factors (drug use, alcohol use, history of incarceration or homelessness). A quarter of people with one of these risk factors had all four (Health Protection Agency 2010).

Homeless people, prisoners and problem drug users

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

(Note: a higher proportion of foreign-born patients have non-pulmonary disease that is not infectious and therefore does not pose a public health risk [Health Protection Agency 2010]. In addition, in London, patients with TB who were not born in the UK have been shown to have higher rates of adherence to treatment – and lower rates of loss to follow-up – than UK-born cases [Story et al. 2007].)

In London, the prevalence of TB was estimated 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.

Interventions

Early identification and effective treatment of ‘active’ TB provides the best patient 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 TB patients in London, problem drug users, homeless people and prisoners made up 17% of the cohort but accounted for 38% of poorly compliant patients – and 44% of those who were lost to follow-up [Story et al 2007]. In addition, recent national surveillance data suggests that only 31%, of people with at least one social risk factor started treatment on directly observed therapy (Health Protection Agency 2010).

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 patients who might otherwise not present for care in a timely manner. It includes screening TB contacts through contact-tracing and ‘outbreak investigations’. It also includes screening migrants (for example, at the pre-entry 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.

Patients 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 2009, for example, susceptibility test results indicated that 7.8% of culture-confirmed cases in the UK were resistant to at least one first-line drug at the start of treatment (Health Protection Agency 2010).

Recent figures suggest that drug-resistance levels are higher among hard-to-reach people with TB. For example, up to 14.3% of people who were homeless, 16.4% of problem drug users and 17.8% of prisoners were resistant to isoniazid (Health Protection Agency 2010).

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

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 populations such as problem drug users, prisoners and certain categories of new migrants (for example, those with no recourse to public funds and undocumented migrants). It acknowledged that others may not have been specifically considered.

3.3 In this guidance (as with NICE clinical guideline 117) 'new arrivals' are defined as people who have relocated to England in the last 5 years. (Only 21% of non-UK born TB cases notified to the Health Protection Agency [HPA] in 2009 were diagnosed within 2 years of entering the UK.) However, the PDG was mindful that not all new arrivals are hard to reach. It was also mindful that many of the problems that can make new arrivals hard to reach may persist beyond 5 years.

3.4 People who have been in prison can be defined as hard to reach once released.

3.5 There are different types of active TB. From a clinical perspective, all forms require treatment. From a public health perspective active, pulmonary TB is the most important as this can be transmitted to other people.

Barriers to services

3.6 Despite the NHS being free at the point of use, 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 and prescription costs).

3.7 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.

3.8 Lack of clarity over entitlement to 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 patients with pulmonary TB are prohibited from returning to hostel accommodation once diagnosed.

3.10 The PDG felt that it is 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.

Success factors

3.11 Specialist TB nurses play a crucial role in ensuring TB services are effective.

3.12 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 addiction-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.

3.13 Identifying people from hard-to-reach groups with TB involves linking up with social care and voluntary organisations as well as secondary and acute healthcare services.

3.14 Contact tracing is important to prevent transmission of all types of TB, particularly where it affects children. (TB among the latter indicates poor TB control and is a significant cause of preventable morbidity.) The PDG also acknowledged that some people may not want to disclose the people they have been in contact with.

3.15 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.

3.16 Nurse-led clinics have a potential role in improving access to TB services for hard-to-reach groups.

3.17 The PDG recognised the importance of outreach services provided in convenient locations for hard-to-reach groups.

3.18 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.

3.19 ‘Peers’ or ‘peer educators’ are sometimes used for outreach or enhanced case management and there is some evidence of their effectiveness.

3.20 The PDG noted that investment in more comprehensive multidisciplinary teams may not be cost effective in low incidence areas with few hard-to-reach patients. To overcome this problem – and to support patients who are disadvantaged, it has recommended commissioning models that cover larger geographical areas than those currently covered by one TB service.

3.21 The PDG decided there was a need for ‘national oversight’ of TB control services supported by ‘subnational’ TB control programmes and local action. It made this decision based on the following:

- Hard-to-reach groups are often highly mobile and therefore, often cross the boundaries of locally commissioned services.
- Within one locality, there may not be sufficient numbers of socially complex TB cases to merit the commissioning of specialised services. This means that local patients may not receive the standard of care needed to improve outcomes and control the spread of disease.
- TB control involves a wide range of public health activities, beyond simply ensuring cases are treated effectively (such as cohort reviews). These activities cross a range of organisational boundaries.
- Experience from other countries that have successful TB control programmes.

Staffing

3.22 A wide variety of statutory and voluntary professionals provide services for hard-to-reach groups.

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 3.7 above). As a result, this guidance recommends the same staffing ratios for dealing with complex cases both within and outside London.

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 evidence that adherence to preventive treatment for latent infection is often very poor among hard-to-reach groups – even when directly observed preventive treatment is used. Although no formal cost-effectiveness analyses were undertaken, 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 preventative therapy (DOPT) in prison and DOPT given alongside regular methadone maintenance (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 (lGRA) testing and DOPT for these two groups.

Cost effectiveness

3.27 The PDG believed the quality of life of someone from a hard-to-reach group was as important as for anyone else – and the consequent reduction in their quality of life should they contract TB, is the same.

3.28 Active case-finding among the homeless population 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 very 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.

3.29 The PDG was aware that the cost effectiveness of active case-finding 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.

3.30 The cost effectiveness of using radiographic 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 serving populations from high incidence areas – and where the start-up costs for radiographic screening had already been largely covered through DH funding, the PDG judged that radiographic screening would be cost effective. For other prisons, the PDG considered that existing NICE guidance on initial, symptom-based screening was adequate.

3.31 The economic analysis supports the recommendations made in the guidance and the PDG has been careful to ensure the resource investment required is realistic within the current financial climate.

3.32 The PDG was aware that the economic model had a number of limitations and that, 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.

3.33 The base-case scenarios used for the economic modelling 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, in terms of the size of hard-to-reach groups, economies of scale and the prevalence of TB, will affect cost effectiveness.

General

3.34 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.

3.35 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.

3.36 The PDG felt it was unethical not to treat 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.

3.37 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 problem drug users 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.

3.38 The PDG believed that the identification and treatment of 'active' TB was a priority, as this is the communicable form of the infection (see 3.5 above). Members noted that treating latent infection can reduce the risk of someone developing the active form of the disease. It also noted the possible side effects, including liver damage. The latter is more likely among those hard-to-reach groups where there are high rates of alcohol or drug-related liver damage – and a high prevalence of viral hepatitis.

3.39 The PDG felt that it may not be cost effective to use a case-finding approach for latent TB.

3.40 New technologies, such as the use of line probe assays for diagnosis, could have an impact on how quickly people enter the treatment pathway.

3.41 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. Additionally, the committee felt there may be opportunities for combining TB interventions with other health promotion activities.

3.42 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 preventative therapy should only be used with isoniazid-sensitive strains. In addition, the PDG 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:

- NHS organisations, social care and children's services meet the requirements of the DH's revised 'Operating framework for 2010/11'.
- National and local organisations improve quality and health outcomes and reduce health inequalities.
- Local authorities fulfil their remit to promote the wellbeing of communities.
- 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 multi-sector partnerships for health, such as the integration of health and social care and health improvement.

NICE will develop tools to help organisations put this guidance into practice. Details will be available on our website after the guidance has been issued (www.nice.org.uk/guidance/PHxx).

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 'Tuberculosis' NICE clinical guideline 117.

5.1 How effective and cost effective is routine testing and treatment for latent TB infection and the subsequent directly observed preventative therapy (DOPT) for hard-to-reach groups (as defined in this guidance) at risk of poor adherence? What are the risks of treating latent TB infection, including any adverse drug interactions and the development of drug resistance?

5.2 How effective and cost effective is peer support as part of an enhanced case management approach to members of hard-to-reach groups with TB in the UK? Does effectiveness and cost effectiveness vary according to the target population (that is, different hard-to- reach groups), setting (for example, outreach versus a clinic) or population factors (for example, age, gender or ethnicity)?

5.3 What factors aid or hinder the uptake of TB testing from the perspective of hard-to-reach populations. In addition, what aids or hinders its provision from the perspective of different service providers (for example, healthcare professionals versus community workers) and in different settings (for example, clinics, drop-in centres, hospitals and detention centres)? What ways of working or interventions can help overcome or exploit these factors?

5.4 Is it more effective and cost effective to offer TB testing as part of a broader health check (for example with blood-borne virus screening) for people from hard-to-reach groups? What factors influence the suitability and acceptability of different 'bundles' of tests and advice? For example, does effectiveness vary by clinical setting (such as a community or hospital-based clinic); by population factors (such as age, faith, race/ethnicity or type of hard-to-reach group); or by other characteristics such as lifestyle?

5.5 How do treatment completion rates vary in different hard-to-reach groups? Which demographic and socioeconomic factors impact on treatment completion (for example, housing, location, immigration status or recourse to public funds)?

5.6 What is the cost of treating people with active TB who have different and socially complex backgrounds? How does this differ according to the different social factors involved? What methods should be employed to calculate the cost of service provision for hard-to-reach groups?

More detail on the gaps in the evidence identified during development of this guidance is provided in appendix D.

6 Updating the recommendations

This section will be completed in the final document.

7 Related NICE guidance

Tuberculosis. NICE clinical guideline 117 (2011). Available from www.nice.org.uk/guidance/CG117

8 Glossary

Case management

Case management involves follow-up of a suspected or confirmed TB case. It requires a collaborative, multidisciplinary approach. Case management should commence as soon as possible after a suspected case has been discovered to ensure a timely diagnostic conclusion.

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 patient 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.

Enhanced case management

Enhanced case management commences as soon as TB is suspected. It includes directly observed treatment (DOT) in conjunction with a package of supportive care tailored to the patient's needs. It is provided when a patient has clinically or socially complex needs.

Incentives

Incentives are ‘small rewards’ that encourage patients with both suspected and confirmed TB to attend for community TB screening, out-patient follow-up and directly observed therapy appointments.

Index case

The first case of TB in a family or another defined group to come to the attention of the medical investigator.

Interferon-gamma test

A blood test sometimes done after, at the same time or instead of the Mantoux test. If the result is positive, more tests should be undertaken to see if the person has TB.

Lost to follow-up

Patients 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).

Mantoux test

A small amount of protein from dead TB bacteria is injected under the skin (you cannot catch the disease from this test). The area is checked a few days later. If the skin around the injection is raised (and also, sometimes reddened), the result is positive and more tests will be needed. If there is no skin reaction the result is negative, which means the person is unlikely to have TB.

Multidisciplinary TB team

A group of health, social care and administrative professionals and peer educators or advocates from the NHS, local authority and the voluntary

sector. The team works closely together to coordinate patient care and public health activities.

New arrival

Someone who has arrived in England in the last 5 years. They may be a migrant, asylum seeker, refugee or unaccompanied minor.

Outbreak Investigation

An epidemiological investigation into the occurrence of disease in a population to identify transmission sources and prevent additional cases.

Peers

Members of the target population who may have experience of TB. They may be recruited to help communicate health messages or may offer support to individuals during diagnosis and treatment

Source case

The person with infectious TB disease who transmits it to someone else.

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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, teachers, social care professionals, representatives of the public, academics and technical experts as follows.

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Evidence reviews

Review 1: 'Tuberculosis evidence review 1: Review of barriers and facilitators' 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: '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' 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: 'Evidence review on the effectiveness and cost effectiveness of interventions aimed at managing tuberculosis in hard-to-reach groups' 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: 'Evidence review on the effectiveness and cost effectiveness of service models or structures to manage tuberculosis in hard-to-reach groups' 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 ’Economic analysis of identifying and managing TB among hard-to-reach groups’ was carried out by the Health Protection Agency. The principal authors were: Peter White, Mark Jit, Helen Stagg, Laura Pimpin, Yoon Choi, Tendai Mugwagwa.

Expert testimony

Expert paper 1: ‘Service user perspectives’ anonymous.

Expert paper 2: ‘Socio-cultural factors influencing an understanding of tuberculosis within the Somali community in Sheffield’ by Mubarak Ismail, Sheffield Hallam University.

Expert paper 3: ‘Screening international migrants for infection’ by Anne Tunbridge, Royal Hallamshire Hospital, Sheffield.

Expert paper 4: ‘Primary care tuberculosis survey 2010’ by Surinder Tamne, Health Protection Agency.

Expert paper 5: ‘Cohort review in practice’ by Jaqui White, Royal Free Hospital.

Expert paper 6: ‘Hard to reach patients with, or at risk of, tuberculosis in immigration detention’ by Frank Arnold, Medical Justice.

Expert paper 7: ‘Tuberculosis control, specifically among hard to reach groups in Rotterdam’ by Rob van Hest, Municipal Public Health Service Rotterdam-Rijnmond.

Expert paper 8: ‘Tuberculosis case management – lessons from New York City (NYC)’ by Sara Hemming, Royal Free Hospital.

Expert paper 9: ‘Health MOT in a hostel’ by Stephen Davies, St Georges Hostel, London.

Expert paper 10: ‘Managing a tuberculosis service in prison’ by Sue Yates, Royal Free Hospital.

Expert paper 11: ‘The importance of housing homeless people with tuberculosis’ by Sue Collinson, Homerton University Hospital.

Expert Paper 12: ‘Leicester model’ by Philip Monk, Health Protection Agency.

Expert paper 13: ‘Strategies for managing tuberculosis in the chaotic community of rural Warwickshire’ by Debbie Crisp, NHS Warwickshire.

Expert paper 14: ‘Tuberculosis in Scotland’ by Oliver Blatchford, NHS Scotland.

Expert paper 15: ‘London Find & Treat’ by Alistair Story and Joe Hall, Find and Treat London.

Expert paper 16: ‘Brief overview of prisons’ by Claire Smith, Claire Smith Consultancy.

Expert paper 17: ‘Nurse led triage’ by Malcolm Cocksedge, Bart’s and the London NHS Trust.

Expert paper 18: ‘Nurse led service – Birmingham’ by Jacqueline Nation and Imtiaz Ahmed, Sandwell General Hospital.

Expert paper 19: ‘Model of care – London tuberculosis plan’ by Nick Relph, NHS Hounslow.

Expert paper 20: ‘What about the children?’ by Fran Child, Royal Manchester Children’s Hospital.

Expert paper 21: ‘Screening for tuberculosis and HIV in primary care’ by Chris Griffiths, Barts and the London School of Medicine.

Expert paper 22: ‘The truth about tuberculosis awareness and advocacy programme’ 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 appendix E and are available at www.nice.org.uk/guidance/PHG/Wave22/4

Guidance development

The stages involved in developing public health programme guidance are outlined in the box below.

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 (www.action.org)
- Association of Public Health Observatories (www.apho.org.uk)
- British Infection Association (www.britishinfection.org)
- British Thoracic Society (www.brit-thoracic.org.uk)
- Centers for Disease Control and Prevention (www.cdc.gov)
- Community Abstracts via Oxmill (www.oxmill.com)
- Google Scholar (http://scholar.google.co.uk/)
- Health Protection Agency (www.hpa.org.uk)
- National Research Register archive site (www.nihr.ac.uk/Pages/NRRArchive.aspx)
- NICE, including the former Health Development Agency and NHS Evidence (www.nice.org.uk)

- Stop TB Partnership (www.stoptb.org)
- TB Alert (www.tbalert.org)
- UK Clinical Research Network (www.crncc.nihr.ac.uk)
- UK Coalition to Stop TB (www.stoptbuk.org)
- World Health Organization (www.who.int)
- World Health Organization Global Health Atlas (www.who.int/globalatlas)

Selection criteria

Inclusion and exclusion criteria for each review varied and details can be found at www.nice.org.uk/guidance/PHG/Wave22/4 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 appendix 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'. They are available on NICE's website at: http://guidance.nice.org.uk/PHG/Wave22/4

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

This section will be completed in the final document.

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 appendix C for details). Where a recommendation was inferred from the evidence, this was indicated by the reference 'IDE' (inference derived from the evidence).

Appendix C The evidence

This appendix lists the evidence statements from four reviews provided by Matrix Evidence (see appendix A) and links them to the relevant recommendations. (See appendix B for the key to quality assessments.) The evidence statements are presented here without references – these can be found in the full reviews (see appendix E for details).

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

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'

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 are available at http://guidance.nice.org.uk/PHG/Wave22/4 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: IDE

Recommendation 2: IDE

Recommendation 3: evidence statements I15.1, I15.2, I15.4, M6.1, M6.4, M13.0, M13.1; IDE

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

Recommendation 6: EP17, EP18; IDE

Recommendation 7: evidence statements S4.0, S4.1; IDE

Recommendation 8: evidence statements I15.1, I15.3, I15.4; EP9

Recommendation 9: evidence statements I6.1, I6.2, I7.1; IDE

Recommendation 10: evidence statement I1.1; EP3

Recommendation 11: EP10; IDE

Recommendation 12: 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 13: evidence statement I8.1; IDE

Recommendation 14: EP5

Recommendation 15: 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 I6.2

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 I7.1

IWeak 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 I8.1

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 less than 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 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 9: ‘Health MOT in a hostel’.
- 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

Overall, active case-finding and enhanced case management were found to be cost effective.

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. It also estimated the number of cases of pulmonary TB that would be averted due to earlier detection.

The recommendations for hard-to-reach migrants are largely based on existing NICE guidance (clinical guideline 117). As such, these have already been deemed cost effective.

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 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).

All modelling is subject to limitations. In this model, the time horizon is 20 years. This ignores the benefits of interventions that extend lives more than 20 years. It also ignores any potential reduction in future cases of TB more than 20 years into the future. In addition, the analysis assumed there was no benefit to 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.

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. 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)

Appendix E Supporting documents

Supporting documents are available at www.nice.org.uk/guidance/PHG/Wave22/4. These 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-to-reach 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’.

For information on how NICE public health guidance is developed, see:

- ‘Methods for development of NICE public health guidance (second edition, 2009)’ available from www.nice.org.uk/phmethods
- ‘The NICE public health guidance development process: An overview for stakeholders including public health practitioners, policy makers and the public (second edition, 2009)’ available from www.nice.org.uk/phprocess