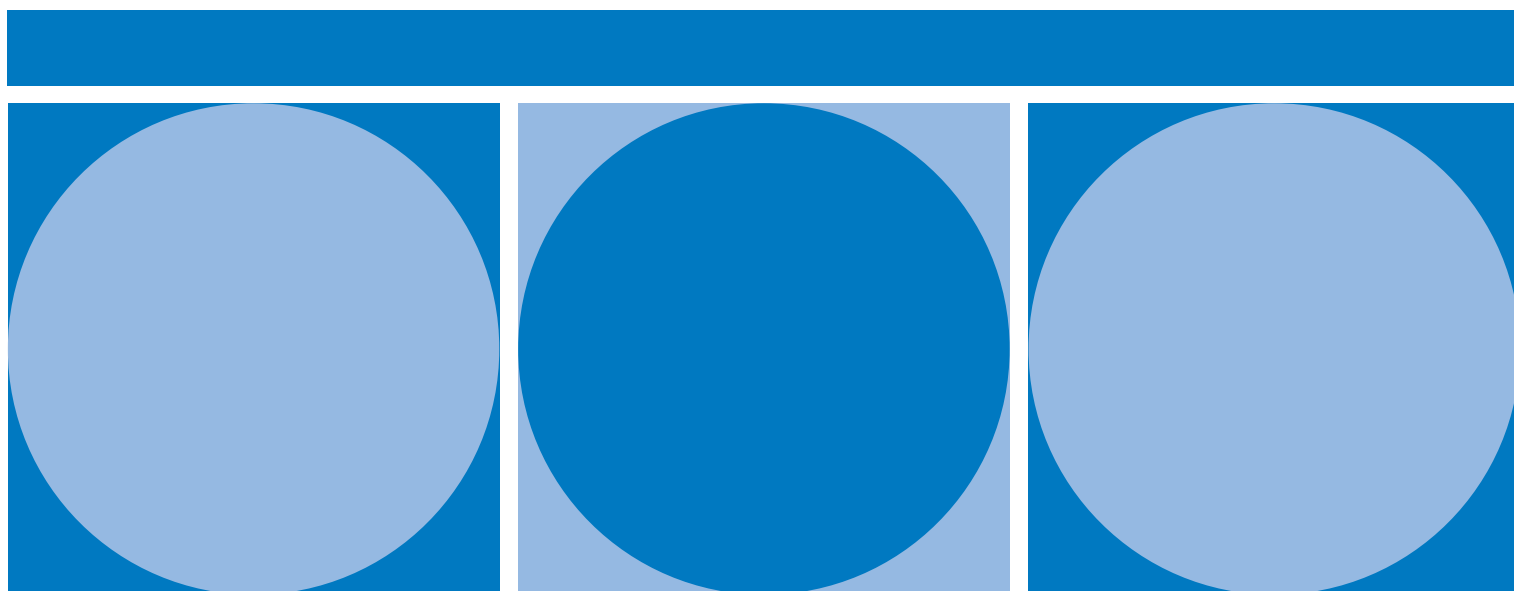


Tuberculosis prevention and treatment: a toolkit for planning, commissioning and delivering high-quality services in England



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June 2007

DH INFORMATION READER BOX

Policy HR/Workforce Management Planning Clinical	Estates Performance IM & T Finance Partnership working
Document purpose	Best Practice Guidance
Gateway reference	8020
Title	A TB toolkit for commissioners
Author	DH - TB Action Plan Team
Publication date	June 2007
Target audience	PCT CEs, SHA CEs, Medical Directors, Directors of PH, Directors of Nursing
Circulation list	Voluntary Organisations
Description	This document contains guidance for planning and delivering high quality services for the prevention and treatment of TB in England. There are two sections: Context, Framework and Toolkit and Principles of Best Practice. 5 annexes cover the following: PbR, a sample SLA, national advice networks, Gamma Interferon testing and a commissioning template.
Cross reference	TB Action Plan: Stopping TB in England
Superseded documents	N/A
Action required	For PCTs to use the framework and templates to provide appropriate TB services for their demography
Timing	N/A
Contact details	Ed Davis Dept of Health, TB Action Plan Team Wellington House Waterloo Road, London SE1 8UG 020 7972 1034
For recipient's use	

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Foreword

This toolkit has been developed by three expert working groups at the Department of Health – supported by the Health Protection Agency – with a remit to look at commissioning, service delivery and monitoring, and laboratory services.

It sets out to offer commissioners of tuberculosis (TB) services in England a framework for assessing their local needs and for planning and commissioning high-quality services in order to implement the TB action plan. It also contains models of best practice aimed at TB service providers, including laboratories and public health teams.

TB is a growing problem in England. The number of cases diagnosed continues to rise each year, with an increasing proportion of drug-resistant cases. Drug resistance is exacerbated by delays in diagnosis and by poor management – and, at £50,000 to £70,000 per case, it is also 10 times more expensive to treat than uncomplicated TB. Therefore, there is a strong financial case for the effective commissioning of TB services, in addition to the public health imperative to actively control the spread of the disease.

It is critical that primary care trusts (PCTs) engage with the current challenge if we are to contain the return of a disease over which we once had control. To this end, we strongly recommend that all PCTs plan for TB service provision. This applies just as much in low TB prevalence areas, since population shifts can rapidly change the prevalence of the disease in areas where it has historically remained low. And, given that there is an ongoing threat of reactivation of the latent form of the disease – especially in people who were born abroad – it is essential for commissioning teams to carry out regular reassessments of local needs and services and to act fast on what they find.

I hope that commissioners, together with service providers and other partners, will find this guidance valuable in examining the full range of TB services available, and will commission them as an integrated system of prevention and treatment, leading to improved control of this disease.

I would like to thank Professor Rod Griffiths, Dr Grace Smith and Dr John Moore-Gillon, who chaired the three expert TB working groups, without whose dedication this commissioning toolkit and models of good practice could not have been developed.



Sir Liam Donaldson, Chief Medical Officer

Executive summary

Aim of this document

The tuberculosis (TB) action plan, *Stopping tuberculosis in England*, published in October 2004 (www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4090417) urged stakeholders to make consistent and well-coordinated targeted efforts to regain control of the disease. In 2006, the National Institute for Health and Clinical Excellence (NICE) published clinical guidelines on the prevention and treatment of TB (<http://guidance.nice.org.uk/CG33>).

This document aims to help commissioners and TB service providers implement the action plan in line with the NICE guidelines.

Structure

This document comprises the following:

Section 1 Context, framework and toolkit

The audience for this section is primarily commissioners.

This section provides an overview of TB and goes on to make recommendations as to how primary care trusts (PCTs) can meet the challenge of bringing the disease back under control using the funding and resources currently available. The section also contains a framework that PCTs can use to assess their local needs, and to plan and commission high-quality services.

Section 2 Principles of best practice for TB service delivery

The audience for this section is primarily providers of TB clinical and microbiology services, and public health teams.

This section looks in more depth at what constitutes a good TB diagnostic and treatment service in both high- and low-incidence areas. It also looks at the various roles and responsibilities necessary to create an effective multidisciplinary team and the importance of raising awareness among clinical professionals and the public alike. Provision of enhanced case management (ECM) and the use of specialist TB centres is also addressed.

The toolkit then details recommended best practice for effective laboratory diagnosis of active TB, and current standards for surveillance.

Five annexes provide background reference material on:

- an example service level agreement (SLA);
- Payment by Results (PbR);
- a blank commissioning template;
- developing national advice networks; and
- interferon-gamma testing.

Section 1 key messages for commissioners

There is a strong economic case for effective management of TB. As well as a public health imperative, a lack of effective strategy and poor management of TB can be highly costly in the long term.

Poor management can lead to the emergence of drug-resistant cases which are much more expensive to treat.

To secure high-quality services, commissioners need to consider their local TB incidence and population demography, and potential changes to that demography, for example new demands as a result of population migration. Therefore, we recommend that all PCTs plan for TB services.

Every PCT should identify a named TB lead.

If the number of active cases within a PCT is likely to be low, commissioning TB services on a shared or amalgamated basis is a route to provide high-quality services.

TB is best diagnosed and managed by experienced specialists. While primary care clinicians may suspect a diagnosis of TB, a formal diagnosis – including treatment and care plans – is best made by specialist service providers.

Primary care does have an important role in providing support to the patient through the treatment period.

Section 2 key messages for providers

It is critical that TB (including suspected TB) is investigated and managed by individuals who have comprehensive experience of the condition and who have ready access to the multidisciplinary services and skills necessary for a favourable outcome.

Best practice suggests that all TB services identify a lead clinician with overall responsibility for the diagnosis and possible treatment of TB with whom PCTs can liaise.

In areas where there is a low incidence of TB, transferred or shared case management with more experienced centres or specialists needs to be considered.

A named key worker for each patient should be appointed.

High-incidence areas need to make provision for access to ECM.

TB service providers should aim to improve awareness of TB among the public, the professions and local authority agencies.

To provide reliable, high-quality TB diagnostic services, microbiology laboratories should be accredited and have sufficient throughput to maintain competency.

Reporting information should be in line with current national surveillance standards.

Section 1 Commissioning TB services: context, framework and toolkit

The disease context

TB – the picture today

In the last two years, TB cases in England have risen by 15%. Today, as many people are diagnosed with TB as with HIV, and around 350 people die each year from the disease. Furthermore, parts of the UK are now seeing more than 40 cases of TB per 100,000 population – which puts them on a par with some developing countries.

Late diagnosis and poor management risk spreading the infection. Moreover, poor management can lead to the emergence of drug-resistant cases, which are much more expensive to treat – typically £50,000–£70,000 per case.

Thus there is a strong economic case for effective management of the disease, according to best practice and against performance indicators.

An overview of TB

How the disease spreads

TB is caused by bacteria from the *Mycobacterium tuberculosis* complex. Infection is spread when bacteria, coughed up by an individual with TB affecting their lungs, are released into the air and inhaled by others.

In the past, infection could be acquired by drinking unpasteurised milk from cows, but this is a rare way of catching TB in the UK today.

While the initial site of TB infection is almost always in the lungs, bacteria can spread through the bloodstream and lymphatic system to affect any part of the body. Apart from the lungs, the most common sites for TB infection are:

- lymph glands in the neck and elsewhere;
- bones (especially the spine);
- abdomen;
- kidneys; and
- brain (known as TB meningitis).

The prognosis includes chronic weakening of the lungs, damage to other organs and death.

Different forms of TB

For public health planning and the commissioning of clinical services, it is vital to keep in mind the distinction between being **infected** with the TB bacterium and being ill **with active TB disease**. After being infected, the **majority** of people remain well. Only a small minority progress directly at that stage to become ill with the active disease, whether in the lungs or elsewhere. In others, the bacteria lie dormant, and these people with latent TB infection are at risk of these dormant bacteria reactivating and may become ill with TB months, years or even decades later.

Some strains of TB are resistant to two or more anti-TB drugs and this multi-drug-resistant TB (MDR TB) is associated with inappropriate or inadequate treatment – often a result of

non-completion of treatment. Uncomplicated TB requires a six-month course of drugs. The drug-resistant form of the disease is more difficult to treat and may require an even longer course of treatment.

TB and migrant populations

Data from 2005 indicate that 72% of TB cases in England were among people who were born abroad and, of these, over three-quarters developed the disease after they had been in the country for two years or longer. PCTs will want to consider how to achieve high awareness, among professions and the public, of the potential for reactivation of latent disease among migrant populations.

Summary

- TB infection mainly affects the lungs, but bacteria can spread through the bloodstream and lymphatic system to affect any part of the body.
- There are both active and dormant (or latent) forms of the disease. Some migrant populations are at particular risk of latent infection, which may progress to active disease in around 10% of infected individuals. At this point it becomes infectious, and therefore both a public health risk and a priority.
- Drug-resistant strains of TB are more difficult and expensive to treat.

The policy context

The TB action plan does not include specific advice on models of commissioning or responsibility for TB diagnosis, treatment and control programmes. However, in the context of the leadership role of strategic health authorities (SHAs), the plan refers to ‘consideration of the need to commission specialist services and facilities (eg for MDR TB) at an appropriate level’. In addition, PCTs are to ‘commission the full range of TB services to agreed criteria’. No detail is given as to whether the ‘criteria’ are locally or nationally agreed, or whether all PCTs are to do this, or only those PCTs where local rates of TB are sufficiently high to warrant the commissioning of a full range of services. However, the plan does recommend that PCTs in high-incidence areas develop specific commissioning for TB services appropriate to their population needs. At the same time, it also recommends that **all** PCTs plan for the need for TB services so they can respond to an outbreak if required.

To this end, this toolkit contains a tiered commissioning model to enable commissioners to identify appropriate TB services for their demography. (See pages 16 to 23 for tables and templates.)

The cost of mismanagement

Effective management of TB, as with any infectious disease, is a public health imperative, regardless of the setting in which it occurs. Failure in any aspect of management can lead to rapidly escalating problems, with potentially serious consequences for the patients concerned and significant additional resource consequences for all the organisations with responsibilities in this area.

Given that treating drug-resistant TB can cost between £50,000 and £70,000 per patient (a non-drug-resistant case can cost less than £5,000), there are serious financial implications if the disease is not managed effectively. For example, an outbreak of a drug-resistant strain of TB in London is still not yet under control and there are now almost 300 linked cases seven years after it was first identified.

Effective commissioning for TB

Recent policy developments in healthcare (in particular *Commissioning a Patient-Led NHS*) offer an opportunity to consider how robust commissioning could improve the effectiveness of TB services.

Stakeholders in public health and clinicians active in the field of TB have long been convinced that the use of specific tools to commission TB services is essential if the NHS is to respond effectively to the projected rise in TB over the next decade.

Effective commissioning helps facilitate long-term planning and continuity in service development, including reconfiguration of services.

The enlargement of PCT populations in most areas does make it much more likely that TB will be given higher priority in areas with high rates of TB. This may result in more clarity on the real cost of managing TB appropriately and the financial cost of not doing so. Individual SHAs can review the priority given to TB by their PCTs, which will be dependent on the burden of disease.

There is at present a lack of clarity about how TB services are commissioned or procured. The approach adopted in developing this toolkit is underpinned by three core principles, as follows:

- Good public health measures are essential for effective TB control.
- The response to TB needs to be planned, **even in currently low-incidence areas**, so that in the event of an incident or outbreak or significant change in the population demography, local health service providers can respond effectively.
- Properly planned TB services will be required to achieve effective control of the epidemic and reverse disease trends in the UK. Effective control of TB will reap significant short- and long-term financial savings. PCTs/SHAs will have to respond to these challenges without additional central funding and will have to give TB appropriate priority, understanding that **TB treatment and appropriately organised services are very cost-effective interventions**.

The above approach depends on staff responsible for public health, clinical services and health protection being fully involved in the commissioning process. Conversely, because TB services require coordinated actions between hospitals, laboratories, primary care and other care services, commissioners are advised not to simply devolve all responsibility to their colleagues in their local health protection unit.

For this reason, a key recommendation of the framework is that each PCT, even in low-incidence areas, identifies a TB lead. The role of this person is described in more detail on page 14 of this document. In low-incidence areas, this may not need to be a full-time post and could involve collaboration across PCTs or networking with other commissioners, as necessary.

The keys to success include:

- good cooperation with and between local clinicians and health protection staff;
- good working practices according to recognised guidelines; and
- comprehensive assessment of patients (physical, psychosocial and financial).

A patient-centred approach to management is vital, particularly given the length of treatment. But, as with all infectious diseases, there is a balance to be struck between a patient-centred approach and the protection of other members of the community.

Commissioners will also want to consider how to develop sophisticated working relationships with partners in the local authority, the not-for-profit sector and voluntary organisations. This is essential if a whole-system/multi-agency response is to be made in order to address the problems of our most challenging patients.

Commissioners need to be aware that a diagnosis of TB is almost never confirmed in general practice and diagnosis and treatment of TB are best provided by specialist services.

To ensure timely identification of those who do have the disease and rapid exclusion of those who do not, commissioned services need to include the management of suspected TB.

An SLA should identify the requirements of the commissioner as regards the delivery of services. The commissioning toolkit will only be effective where a robust SLA is in place. An example of the services that might be commissioned is included at Annex 1.

Successful commissioning depends on the engagement of a wide range of stakeholders. Weakness in one area could jeopardise the ultimate success of the project.

The success of this toolkit is dependent on properly utilising the skills of providers to advise on good practice and to use the commissioning process to secure standards that will support the control of TB. Commissioning is not a magic formula that will solve all problems. Local economies can use this toolkit to plan service delivery and identify where locally their funding is best placed.

Summary

To secure high-quality services, commissioners need to consider:

- identifying a TB lead in each PCT, even in low-incidence areas;
- engaging with a wide range of stakeholders;
- their local TB incidence and prevalence and population demography, and attempt to anticipate likely present and future demand, for example new demand from population migration;
- that TB is best diagnosed and managed by experienced specialists. While primary care clinicians may suspect a diagnosis of TB, a formal diagnosis including treatment and care plans is best made by specialist service providers. Primary care does have an important role in providing support to the patient through the treatment period; and
- that if the number of active cases is likely to be low, commissioning TB services on a shared or amalgamated basis is a route to provide high-quality services.

Applying choice policy to TB

Choice policy currently requires that a patient electively referred from primary to specialist care is given a choice of at least four potential providers. The range of choice was extended from April 2006 and becomes wider still ('free choice') in 2008. In addition, the policy requires that the patient is able to make a mutually convenient appointment for consultation.

There are three main difficulties that arise in applying policy on choice to TB, as follows:

- TB is a public health problem, not merely a problem for the individual patient. If TB is not treated promptly, there is a risk that others may become infected.

- People with TB include a disproportionately large number of people with chaotic lifestyles (drug and alcohol problems, etc), who may find it difficult to initiate contact with health services.
- Identification of a new case of TB usually leads to a contact tracing exercise. Choose and Book may allow people who are contacts of a TB case to choose to be investigated at different places. This could hinder the development of a complete picture of the pattern of disease spread, and could compromise efforts to achieve the best public health outcome. Current best practice for treating contacts is that, other than in exceptional circumstances, they would all be managed under the direction of the same clinic.

Managing TB patients within choice/Choose and Book parameters

Public health imperatives dictate that all patients have access to secondary care diagnostic and treatment teams within two weeks and, where there is strong clinical suspicion on the part of the GP of active infectious TB, most services will aim to assess the patient within two days. **TB may therefore be excluded from the choice requirement on the grounds that it is a rapid access service.** In this way, a well-organised, integrated community TB service is able to justify exemption on the same grounds as maternity or mental health services. Consequently, it is not necessary for TB services to be provided within the Choose and Book framework. However, all efforts should be made to ensure that, where practical, patients have the opportunity to negotiate a mutually convenient appointment.

Choose and Book is a national IT system designed to manage access to care and to facilitate patient choice. Implemented by Connecting for Health, its role is to assist GPs and patients by providing information about the choice of services available, and enabling the patient to book an appointment in a convenient time at a convenient location.

Guidance on making local agreements that place TB services outside Choose and Book can be found at: www.dh.gov.uk/en/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/DH_4088353

Preserving inclusivity

It is important to note that it is not being suggested that hard-to-reach groups might be denied choice or a mutually convenient appointment simply because this is difficult to organise, as this would significantly undermine the principles of equity. Any compromise of the choice policy must be determined solely by wider public health interests, just as the Public Health (Control of Infectious Diseases) Act 1984 imposes limitations upon the principle of patient autonomy in those with diseases such as TB.

Ongoing review of Choose and Book compatibility

Choose and Book technology will gradually take over as the routine method by which GPs refer patients to other specialists. There may come a time when TB services will benefit from using this new technology to accept requests for assistance and the supporting clinical information from GPs. It is therefore recommended that providers review with commissioners on an annual basis as to whether elements of TB services could be included in Choose and Book.

Impact of Payment by Results

The aim of the Payment by Results (PbR) tariff is to:

- ensure that services are appropriately rewarded;
- create appropriate financial incentives; and
- support wider system reform.

Infectious disease services may pose particular challenges for commissioners and service providers, but identifying and discussing the issues before finalising SLAs could help all parties to agree a suitable approach. For example, PbR continues to evolve and develop, but the tariff is determined by diagnosis on discharge. TB and other infectious diseases may need to admit or examine many more suspected cases than are confirmed. Although PbR has flexibility within its rules for providers to seek extra funding from commissioners, commissioners operate within a cash limit and additional funding may only be possible in a limited number of cases. At the same time, commissioners need to be aware that TB services, particularly in low-incidence areas, may need to be provided sporadically. This is a significant issue and has yet to be addressed through PbR.

In 2007/08, the mandatory tariff will cover admitted patient care, outpatients and accident and emergency services. It applies to services provided by NHS trusts, foundation trusts and PCTs which are directly commissioned by PCTs and all forms of consortia, including specialised commissioners. Many services (and in application to TB services, radiology and pathology) are excluded from the scope of the PbR tariff, as well as all community services.

Further details about application of PbR can be found at: www.dh.gov.uk/en/Policyandguidance/Organisationpolicy/Financeandplanning/NHSFinancialReforms/index.htm

Many of the steps for TB treatment attract no PbR but may continue to be provided by locally negotiated agreements between commissioners and their service providers. Where tariffs do apply, providers need to be able to demonstrate to their commissioners how they are spending that money on TB services. (See Annex 2 for six worked examples of typical patient pathways and the PbR tariffs that they attract).

Summary

- It is not necessary to commission TB services within the choice policy framework – exclusions can be agreed locally.
- Many aspects of TB service provision attract no tariff, and consideration needs to be given to locally negotiated agreements.
- Where tariffs do apply, earmarked budgets for TB will encourage transparency about what is being provided.

Key components of an effective TB service – the framework

The TB lead

As indicated earlier, we have recommended that every PCT appoint a named TB lead who would be responsible for ensuring that the following steps are taken:

- coordinating development of the local plan for TB prevention and control;
- evaluating which elements of TB services need to be in place depending on local circumstances;
- developing partnerships with other organisations key to addressing present or future TB issues; and
- maintaining vigilance regarding potential outbreaks or rises in prevalence.

The TB lead could be a public health doctor or specialist or other manager. Most importantly, the TB lead would need to work closely with those commissioning TB services and would need to have the authority and influence to ensure services are commissioned against the local plan. (The role of the TB lead differs to that of the lead TB physician – see page 24 for more details.) Groups of collaborating PCTs might consider between them who is most suitable for the role of TB lead on behalf of the group.

A tiered model of commissioning

Some elements of TB services may be best suited to a 'scaled down' specialised commissioning approach. For example, case management requires a collaborative and team approach and cannot be provided by an individual or in isolation from other team members.

The commissioning toolkit on pages 16 to 23 makes use of a tiered model, where each element of the patient pathway is associated with one of three levels of organisation – primary (level one), secondary (level two) and tertiary (level three) – and indicates which might be best placed to commission each key element of a comprehensive TB service.

Each level indicates the infrastructure, training and support required to deliver its components. Any training required will be covered by existing structures such as undergraduate and basic professional training. It is recommended that all components included are present in the majority of services to which patients may self-refer, such as primary care services. These contacts will take place in the community.

For example:

- **Level one services** could be provided by a range of service providers, which could include GPs and other community service providers, who may have a range of clinical responsibilities outside of TB.
- **Level two services** require specific extra training, support and infrastructure. Given that all national guidelines (British Thoracic Society, NICE, etc) recommend that TB patients be treated by doctors and nurses with specialist training and skills, these clinical staff will be providing most TB treatment, although nurse-led clinics staffed by clinical specialist TB nurses might take place in the community, for example at a health centre.
- **Level three services** require more specialist skills, facilities and more substantial infrastructure. This includes components that might require immediate hospital back up such as inpatient services and isolation beds.

Developing a comprehensive approach

Commissioning TB services needs to go beyond simply the treatment of active TB cases, as referenced by the full NICE guidelines and the TB action plan. A comprehensive TB service addresses:

- rapid access to specialist services if GPs suspect TB;
- prompt identification of non-TB patients;
- TB diagnostic services in hospitals (as opposed to primary care);
- case management of TB patients;
- ward visits to TB patients;
- tuberculin skin testing for ward patients;
- contact tracing of individuals exposed to TB;
- inpatient beds for TB patients requiring hospitalisation;
- negative pressure facilities;
- quality-assured and timely TB microbiology services;
- inpatient infection control services;
- provision and management of long-term isolation facilities;
- standardised outcome real-time monitoring;
- performance monitoring;
- advisory work/expert opinion/advice;
- staff training;
- multidisciplinary TB clinics;
- occupational health assessment of TB risk among healthcare workers;
- community infection control services;
- community home visiting;
- managed access to social care and support;
- hospital and community TB clinics responsive to patient need;
- outreach work;
- directly observed therapy (DOT);
- new entrant services;
- locally targeted health promotion and awareness raising;
- protection of public health;
- reactive outbreak case detection/monitoring;
- coherent service provision with the prison and custody sector;
- reference laboratories; and
- surveillance.

Summary

Successful commissioning is likely to be best provided by:

- every PCT (or group of collaborating PCTs) having a TB lead who is responsible for coordinating the development of the TB plan, and has the authority and influence to ensure that services are commissioned against the local plan;
- different elements of TB services being provided by the most appropriate level of service provider to suit local circumstances:
 - GPs and other community-owned service providers;
 - secondary care providers;
 - tertiary providers;
- ensuring that services cover all elements of TB – not just the treatment of active cases.

The toolkit

The following pages contain three tables designed to guide commissioners through the full range of activities required in order to create and deliver a comprehensive TB service.

Table 1 maps suggested commissioning responsibilities and says what needs to be done. Each PCT ought to be able to say, for each activity, where the activity is carried out and by whom, and in addition what information is reviewed, what happened last year and what is expected next year.

Table 2 provides a template of who might commission which function, who might provide which service and where the activities might be carried out. There are also two worked examples (**Tables 3A and 3B**). A blank template for PCTs' local use is in Annex 3.

Local circumstances will vary. PCTs range in size and population and the prevalence of TB can vary considerably. One size does not fit all, and each PCT can determine the appropriate level for their circumstances and assure themselves that all the activities are being carried out somewhere.

Table 4 covers possible performance measures.

Used together, it is hoped that these tables will provide a useful prompt for any PCT to plan and deliver a comprehensive TB service.

Table 1 – A map of suggested commissioning responsibilities

Organisation	GPs or groups of GPs	PCTs	PCT groups	Supra-regional
Possible population size ¹	50,000	1 million	5 to 8 million	8 million+
Planning	<ul style="list-style-type: none"> • Carry out needs assessment • Service improvement strategy • Commission services for practice population 	<ul style="list-style-type: none"> • Carry out needs assessment • Set up and operate governance arrangements • Local forward planning • Ensure that choice operates at an appropriate level • Partnership planning with local authority and other stakeholders • Maintain links with advisory bodies (eg Expert Patient Forum, TB Network) • Liaise and co-operate with health protection unit 	<ul style="list-style-type: none"> • Provide strategic direction and leadership • Anticipate future trends and develop appropriate policies • Ensure supply and capacity • Take action in case of failure 	
Finance and information management	<ul style="list-style-type: none"> • Manage care budget • Ensure that all referral decisions are consistent with financial parameters • Ensure that financial constraints are met 	<ul style="list-style-type: none"> • Set practice budgets • Ensure financial stability • Manage claims and disputes 	<ul style="list-style-type: none"> • Ensure that providers have sufficient capacity/competencies and financial stability • Ensure contestability • Performance manage PCTs 	<ul style="list-style-type: none"> • Information management • Ensure adequate financial data is available to manage risk locally • Claims management and/or reconciliation
Care pathway focus	<ul style="list-style-type: none"> • Commission care package for individual patient • Manage and support patient in choice of provider/booking 	<ul style="list-style-type: none"> • Ensure that local care pathways meet the needs of patients • Support Expert Patient schemes • Survey patient satisfaction • Ensure that the majority of complaints are managed at local level 	<ul style="list-style-type: none"> • Negotiate framework for quality access and price • Capacity planning and service mapping (with PCTs) • Liaise with advisory bodies (eg a network of TB leads, TB Alert) 	<ul style="list-style-type: none"> • Commission very low-demand/high-cost services (eg long-term isolation facilities) • Liaise with advisory bodies (eg NICE, British Lung Foundation, TB Alert, British Thoracic Society, Faculty of Public Health)

¹ London is an exception to the PCT population size as London has been permitted to maintain its PCT structure.

Table 2 – A template for who might commission which services at what level

How to use this template

Commissioners of services at each tier and for each organisation level need to consider the following questions:

- What is the prevalence of TB relative to my tier or organisational level?
- What is the best level at which each element of TB services is commissioned (taking into account existing services, demography, etc)?
- What are the NICE guidelines on TB services for each level and organisation level?

Commissioners can find surveillance data from the HPA to indicate local incidence of TB and local culture rate data for their area to assist the commissioning process. Data can be found at the HPA website: www.hpa.org.uk/infections/topics_az/tb/menu.htm

GPs or groups	Who might commission which service?			Who might provide which service?
	PCTs	PCT groups	Supra-regional/national	
<ul style="list-style-type: none"> • BCG • Health promotion (practice-based campaigns) • New entrant screening 	<ul style="list-style-type: none"> • BCG • Health promotion (local campaigns) • Screening services (contact tracing, case finding, including new entrant screening) • TB consultants and nurses (case management), community-based services 	<ul style="list-style-type: none"> • Health promotion (regional campaigns) • Screening services (contact tracing, case finding, including new entrant screening) • TB nursing (case management), community-based services 	<ul style="list-style-type: none"> • Health promotion (national campaigns) 	<p>Level one GPs and/or other community-owned service providers</p>

Table 2 – A template for who might commission which services at what level (continued)

GPs or groups of GPs	Who might commission which service?			Who might provide which service?
	PCTs	PCT groups	Supra-regional/national	
	<ul style="list-style-type: none"> • BCG • Inpatient bed days • Inpatient infection control services • Investigation of suspected cases of TB • Negative pressure isolation facilities (local hospital) • TB consultants and nurses (case management) • TB diagnostics (bronchoscopy, non-microbiology) • TB microbiology services 	<ul style="list-style-type: none"> • Negative pressure isolation facilities (regional treatment centre) • TB microbiology services (regional specialist centre) • TB nursing (case management) 	<ul style="list-style-type: none"> • Negative pressure isolation facilities (national treatment centre) 	<p>Level two Secondary care providers</p>
	<ul style="list-style-type: none"> • Advisory bodies • Negative pressure isolation facilities • Prison TB services • Surveillance 	<ul style="list-style-type: none"> • Advisory bodies • Negative pressure isolation facilities • Prison TB services • Surveillance 	<ul style="list-style-type: none"> • Advisory bodies • Negative pressure isolation facilities • Prison TB services (national treatment centre/prison) • Reference laboratory services • Screening services (port of entry services/mobile screening units) • Surveillance 	<p>Level three Tertiary providers</p>

Some services, such as BCG and health promotion, are shown in more than one column or row. This is because they may be commissioned for different populations and provided at different levels dependent upon the local preferred service configuration. There is no 'one size fits all'. For example, BCG services for neonates from high-risk groups may be provided by either primary or secondary care providers.

Table 3A – Example of a possible service configuration in a high-incidence PCT (TB rates 50 per 100,000 population)

GP practice populations	Geographical scope of service			Who might provide which service?
	PCT population (individual or multiple PCTs)	SHA population	Supra-regional/national population	
<ul style="list-style-type: none"> • BCG – through GP enhanced contract as part of a universal neonatal policy • New entrant screening – as part of new registrations check • X-ray facilities – GP walk-in X-ray service 	<ul style="list-style-type: none"> • Local health promotion campaigns 	<ul style="list-style-type: none"> • Regional health promotion campaigns 	<ul style="list-style-type: none"> • National health promotion campaigns 	<p>Level one GPs and/or other community-owned service providers</p>

Table 3A – Example of a possible service configuration in a high-incidence PCT (TB rates 50 per 100,000 population) (continued)

GP practice populations	Geographical scope of service			Who might provide which service?
	PCT population (individual or multiple PCTs)	SHA population	Supra-regional/national population	
<ul style="list-style-type: none"> X-ray facilities – at local teaching hospital 	<ul style="list-style-type: none"> Inpatient bed days – from local teaching hospital as part of TB service Inpatient infection control services – from local teaching hospital as part of TB service Negative pressure isolation facilities – from local teaching hospital as part of TB service TB consultants – from local teaching hospital as part of TB service TB diagnostics (bronchoscopy, non-microbiology) – from local teaching hospital as part of TB service TB nursing (case management) – from local teaching hospital as part of team of 2.5 nurses TB microbiology services – from local teaching hospital as part of TB service Screening services (contact tracing) – from local teaching hospital as part of TB service 			<p>Level two Secondary care providers</p>
		<ul style="list-style-type: none"> Advisory bodies – clinically managed network Surveillance – from the health protection unit 	<ul style="list-style-type: none"> Advisory bodies – TB Alert; NICE; British Thoracic Society Reference laboratory services – through the local mycobacterium reference unit Surveillance – from the HPA Centre for Infections providing national surveillance 	<p>Level three Tertiary providers</p>

Table 3B – Example of a possible service configuration in a low-incidence PCT (TB rates 4 per 100,000 population)

GP practice populations	Geographical scope of service			Who might provide which service?
	PCT population (individual or multiple PCTs)	SHA population	Supra-regional/national population	
<ul style="list-style-type: none"> • BCG – through GP enhanced contract as part of a universal neonatal policy • New entrant screening – as part of new registrations check 	<ul style="list-style-type: none"> • Local health promotion campaigns 	<ul style="list-style-type: none"> • Regional health promotion campaigns 	<ul style="list-style-type: none"> • National health promotion campaigns 	Level one GPs and/or other community-owned service providers
<ul style="list-style-type: none"> • TB diagnostics (bronchoscopy, non-microbiology) – from local teaching hospital as part of TB service • X-ray facilities – at local teaching hospital 	<ul style="list-style-type: none"> • Inpatient bed days – from local teaching hospital as part of TB service • Inpatient infection control services – from local teaching hospital as part of TB service • Negative pressure isolation facilities – from local teaching hospital as part of TB service 			Level two Secondary care providers
	<ul style="list-style-type: none"> • Inpatient bed days – from the teaching hospital in a neighbouring area • Screening services (contact tracing) – from local teaching hospital as part of TB service • TB consultants – from the teaching hospital in a neighbouring area • TB microbiology services – from the teaching hospital in a neighbouring area • TB nursing (case management) – from health protection unit 	<ul style="list-style-type: none"> • Advisory bodies – clinically managed network • Negative pressure isolation facilities (from regional treatment centre) – from the specialist infectious disease unit at the regional tertiary referral centre • Prison TB services – services are provided through the prison that services the local area mainly for remand • Surveillance – from the health protection unit 	<ul style="list-style-type: none"> • Advisory bodies – TB Alert; NICE; British Thoracic Society • Reference laboratory services – through the local mycobacterium reference unit • Screening services (port of entry services/mobile screening units) – as part of national service • Surveillance – from the HPA Centre for Infections providing national surveillance 	Level three Tertiary providers

Table 4 – Performance management competencies for TB commissioning

PCT commissioning standard	Performance measure	Reported to
<ul style="list-style-type: none"> • TB services are provided through an agreed service level agreement (SLA) 	<ul style="list-style-type: none"> • A discrete SLA is in place governing TB control and prevention services • Provider has fulfilled contractual obligations 	SHA
<ul style="list-style-type: none"> • The PCT has ensured that TB services appropriate to the local population are in place 	<ul style="list-style-type: none"> • A local specification for TB services has been agreed • A local needs and risk assessment has been performed against the commissioning framework • Universal neonatal BCG vaccination is applied in all areas where TB rates are >40:100,000 • Selective neonatal BCG vaccination is applied in all areas where TB rates are <40:100,000 • A system is in place to capture patient feedback • TB is given an appropriate place within the annual public health report and local delivery plan 	SHA
<ul style="list-style-type: none"> • The PCT has a strategy for TB control 	<ul style="list-style-type: none"> • Strategy in place 	SHA
<ul style="list-style-type: none"> • Services achieve the performance criteria identified in the TB action plan 	<ul style="list-style-type: none"> • Over the next three to five years, a reduction in the number of cases among people born in the UK • An increase in the proportion of cases that are completing treatment • A reduction in the number of new cases developing resistance while undergoing treatment • 65% of pulmonary TB has a laboratory culture for typing and confirmation of diagnosis • Suspected pulmonary TB cases to be seen by the TB service within one week of presentation to primary care • A clinical network is in place to ensure effective cross-boundary working 	SHA
<ul style="list-style-type: none"> • Performance to Healthcare Commission standards 	<ul style="list-style-type: none"> • The PCT has information about communicable diseases, including TB, within its annual public health report and make this information available to the local community • PCTs engage in active, locally targeted awareness-raising campaigns • The PCT is aware of the local prevalence of TB and have planned/commissioned services to address this • The PCT works with key partnership organisations, including local resilience forums, in the preparation and planning in order to respond effectively to an incident or serious outbreak situation that would put local TB services under pressure. This could include plans to draft in staff from other services, awareness events for GPs and community nurses, and links with a high incidence area that could offer advice and support in an emergency situation 	Healthcare Commission
<ul style="list-style-type: none"> • Public health issues 	<ul style="list-style-type: none"> • Surveillance standards are referenced on page 37 • Commissioners may wish to consider including a requirement that these are followed as part of the commissioning process 	SHA

Section 2 Providing TB services

Principles of best practice for TB service delivery

This section is aimed at clinicians, diagnostic microbiologists and public health teams. It supplements the NICE guidelines on TB (<http://guidance.nice.org.uk/CG33>), highlights points of particular importance and offers practical guidance on additional matters related to commissioning.

Overview

The overriding principle is that TB (including suspected TB) is investigated and managed by individuals who have regular and continuing experience of the condition, and who have ready access to the multidisciplinary services and skills necessary for a favourable outcome. The management of patients and the experience gained can be discussed and shared among peer groups. Good TB management practice also requires close working relationships between commissioners and service providers.

A good TB diagnostic service will comprise clinical assessments as well as laboratory and radiological testing for people suspected as having TB from any referral service including self-referral. Investigation of suspected TB is a crucial part of TB control. All three components of the diagnostic service must be present: clinical, radiological and laboratory testing.

- In high-incidence areas this would normally be part of a dedicated TB service that offers treatment and diagnosis, usually with a separate weekly or more frequent outpatient clinic.
- In lower incidence areas seeing few cases, the diagnostic service would normally be provided by a respiratory physician. If TB is confirmed, the patient is best managed by, or in conjunction with, a clinician (a respiratory physician or appropriately trained infectious disease physician) who sees at least 10 confirmed cases per year.
- In some low-incidence areas there may not be one clinician who sees this number alone, even though the total number seen in a particular hospital is 10 or more. If this is the case, then the alternatives are for all TB cases to be transferred to the care of the TB lead clinician (see below) or for management to be discussed on a multidisciplinary team basis, as with cancer cases. We further recommend that, in low-incidence areas, there is discussion of cases between hospitals on a multidisciplinary team basis, in order to pool experience and optimise management. This is discussed below.
- Tracing the contacts of infectious cases requires a robust and well-defined structure with close cooperation between the acute hospital service and the consultant in communicable disease control (CCDC) and local health protection unit.

Adopting a multidisciplinary approach

Successful prevention, control and treatment of TB requires a multidisciplinary approach. NICE guidelines and the TB action plan emphasise the roles of TB clinicians, specialist TB nurses or health visitors and health advocates and their liaison with other primary care, secondary care and local authority resources.

The appointment of a lead clinician

Best practice suggests that all TB services identify a lead clinician with overall responsibility for the diagnosis and possible treatment of TB, who is the point of contact for commissioners. This will normally be a respiratory physician but may be an infectious disease physician who can liaise with the local microbiologist. The responsibilities of this person extend to assisting in the identification

of other individuals who will take the lead for TB in their respective specialist fields (most particularly microbiology, radiology, surgical diagnostic procedures and pharmacy).

The lead clinician will also be responsible for organising intra-hospital and (in low-incidence areas) inter-hospital multidisciplinary team activities.

In accordance with NICE guidelines, the lead clinician is required to have close working relationships with, and ready access to, specialist nurses and adequate secretarial support.

The steps outlined above are recommended even in areas where the incidence of TB is very low. The lack of clearly defined responsibilities in low-incidence areas can lead to delay in diagnosis and treatment when cases do occur. Additionally, local population changes with an influx of residents from high-incidence areas may occur at short notice.

If any trust has no physician responsible for the management of 10 or more cases of TB per year, the model of good practice would be to ensure that treatment is undertaken and monitored in close collaboration with clinical peers with experience of treating TB. It is important that a lead clinician for TB is still appointed; this may be arranged as a time-limited post, rotating between physicians. In low-incidence areas, clinical TB peer groups can be formed locally with adjacent trusts to ensure a critical mass of combined experience, and such groups in turn seek advice when appropriate from other TB experts. The national MDR TB peer group (see Annex 4) and the Joint Tuberculosis Committee are developing and coordinating an 'advice network' for all aspects of TB management.

NICE set out guidelines for a TB service and it is recommended that the lead clinician follow those guidelines. In addition, commissioners may want to include the following specific responsibilities for the lead clinician in the service they commission:

- liaising with a named health protection unit CCDC to ensure that wider public health issues are specifically addressed, for example through active and comprehensive contact tracing;
- ensuring management of cases is carried out in conjunction and discussion with local peers and regional experts when local case numbers are low or the case is complex;
- ensuring shared management with paediatric colleagues for children with TB. Paediatric units with a caseload of fewer than 10 new cases of active TB per year are recommended not to treat a TB case without liaison with their adult TB colleagues, and the latter are recommended not to treat childhood TB without the involvement of the paediatric services. Rigid professional demarcations must not be allowed to stand in the way of high-quality care by experienced individuals of children with TB;
- ensuring shared management of TB with colleagues with specialist HIV expertise when a patient is found to be co-infected with HIV. Similarly, HIV clinicians are recommended not to treat HIV/AIDS patients who develop TB except in consultation with the lead TB clinician;
- arranging internal clinical audit and internal peer review of TB cases; and
- considering succession planning for TB experts approaching retirement age.

The appointment of a named key worker (or 'case manager')

All patients taking anti-TB treatment (including chemoprophylaxis) are recommended to have a named key worker. This will usually be a specialist TB nurse or (in low-incidence areas) a nurse with responsibilities which include TB. In a few cases, it could be another appropriate person dependent upon the patient's particular circumstances and needs. An example of this would be someone who already had a good working relationship with a substance-misusing client who has gone on to develop TB.

Central to the concept of the key worker is that it is an individual to whom both the treating clinician **and the patient** have ready access. It is recommended that all patients are given a card bearing the name of their case manager along with a direct telephone number or dedicated hospital extension number, with an answerphone/voicemail facility for out-of-hours messages.

The **named key worker** would take responsibility for:

- undertaking a risk assessment for all suspected cases of TB on first presentation, or as soon as practically possible, to identify those with complex needs. This would be done in discussion with the lead clinician. Such cases may require ECM from presentation to ensure completion of relevant clinical investigations;
- risk assessment prior to commencement of a planned course of anti-TB treatment to identify those cases that require ECM (including DOT) to promote treatment adherence;
- providing patient education;
- arranging screening and contact investigation in accordance with NICE guidelines in cooperation with the lead clinician and CCDC;
- deciding and agreeing on a care plan and coordinating care with allied providers where appropriate, with the aim of ensuring completion of the prescribed treatment regimen;
- ensuring treatment delivery including supervision of DOT and attendance for clinical assessment and follow-up care; and
- reporting on surveillance systems and reporting of treatment completion.

Note: where the named key worker is not **routinely** involved with TB (as in the example given above), then some of these responsibilities will devolve to other team members.

Providing TB services in high-incidence areas

Models of good practice for acute hospital trusts in high-incidence areas providing TB diagnosis and treatment services include the following:

- Patients with suspected or confirmed TB are best managed in TB-specific outpatient clinics attended by the multidisciplinary TB team, and not alongside other general respiratory outpatients.
- The lead clinician (see above) should have substantial TB experience, and a deputy who, although not necessarily having TB as their principal sub-specialty interest, is able to offer a high standard of management of all but the most complex cases.
- Specialist TB nurses directly employed by the acute trust is the preferred model and will normally offer the greatest chance of achieving best practice but, in some areas, other service models may already be in place and, if they are achieving high standards, should not be disrupted. Experience suggests that immediate access to the investigating and treating medical team improves communication and care. TB nurses would also have responsibility for domiciliary visiting of patients and contacts within their catchment area. Furthermore, flexibility is vital in terms of occasional cross-boundary working when necessitated by patients with complex problems, family groups and the provision of support/surge capacity for a large outbreak in a neighbouring area.
- Advocacy services should be freely available, preferably from an advocate who is an integral part of the TB team for at least the dominant ethnic/language group in the local TB population.
- There should be adequate isolation facilities for hospitalised patients with suspected or confirmed TB, including high-quality negative pressure isolation facilities.

- There should be evidence of clear and robust arrangements for urgent investigation, including clearly defined internal referral pathways for rapid biopsy of lymph nodes and other tissues.
- There should be evidence of clear pathways of communication between the lead clinician and CCDC on the one hand, and non-health agencies including housing and social services on the other.
- EMC should be provided, where necessary.

Providing TB services in low-incidence areas

The principle underpinning TB services in areas of low TB incidence is that the care of the individual patient presenting in that area must be delivered to the same standard as that which the patient would receive if diagnosed in an area where TB is more common. In assessing this objective, an overall view must be taken. An uncomplicated case of TB may gain little from referral to a distant clinic, and may lose much in terms of practical difficulties, personal expense and family support. By contrast, a case of multi-drug-resistant cerebral TB must be managed by a highly expert team.

Even in low-incidence areas, most acute hospital trusts will achieve a caseload close to that discussed previously. The advantages of management close to home means that care for uncomplicated TB cases is best offered by a respiratory physician based in their local hospital. In low-incidence areas, the principle of clinical TB peer group review is an important one, and those commissioning TB services from such areas are advised to seek evidence of these arrangements.

The lead clinician and the named key worker/case manager have similar responsibilities in high- and lower-incidence areas, and it is recommended that PCTs commissioning TB services in low-incidence areas also specify these. The models by which these responsibilities are fulfilled will differ in different low-incidence areas, in particular:

- some trusts will employ a specialist nurse(s) with responsibilities additional to those for TB (eg asthma, chronic obstructive pulmonary disease);
- in other areas, neighbouring trusts may cooperate and share a nurse(s) with exclusively TB responsibilities and expertise;
- nurse(s) covering several trusts may be employed by the health protection unit. Whatever the local model, two principles need to be adhered to: nurses must have adequate training and continuing experience; and they must have close working relationships with the treating clinicians. For more information on nurse service models, see the NICE guidelines, Section 4.1; and
- the timely provision in lower-incidence areas of laboratory and other (non-clinical) diagnostic services of an appropriate standard must be considered.

Enhanced case management

ECM is essential to meet the needs of complex and challenging patients. It will be needed in some cases in both high- and low-incidence areas – along with peer review of treatment between adjacent trusts and further afield if required.

ECM is coordinated by a named case manager working alongside a multidisciplinary TB team able to provide expert clinical and psychosocial care and to engage effectively with the client group. In addition to the standard expertise within a multidisciplinary TB team, ECM also draws upon:

- skilled ancillary and clerical staff and clinic receptionists;
- skilled outreach workers; and
- health advocates/skilled interpreters.

Use of specialist TB centres

It is recommended that ECM is available to acute units providing TB services in high-incidence areas.

Commissioners need to be aware that some patients may require enhanced **clinical** management not available at some provider trusts, even in high-incidence areas, and use of the clinical peer group system and the advice network coordinated by the Joint Tuberculosis Committee is advised. Examples include patients with central nervous system TB, with bone (especially spinal) TB, TB in patients with renal failure, and those with complex drug reactions or drug resistance patterns, but this list is not exclusive. These patients are best managed directly by, or sometimes in close conjunction with, a **specialist TB centre**.

In addition to all the physical and case management facilities of any TB service in a high-incidence area, a specialist TB centre must offer very broad multidisciplinary expertise. It is anticipated that there will normally be services for:

- neurology and neurosurgery;
- spinal surgery;
- renal dialysis;
- an HIV team; and
- high-quality facilities for the medium-term isolation of complex infectious MDR TB.

A specialist TB centre will accept referrals of complex clinical cases on a regional basis and occasionally from beyond, as well as accepting self-referrals from walk-in clinics.

It is recommended that commissioning bodies recognise the high cost of engaging such patients, and in doing so keep in mind the high mortality and potentially the very high rates of long-term disability and thus dependency of such cases if they are sub-optimally managed.

Increasing TB awareness and education

It is recommended that service providers aim to improve awareness of TB among the public, the professions and local authority agencies. Experience suggests that targeted campaigns tailored to the local population work better than national campaigns. Examples include:

- keeping local GPs informed about local TB services and reminding them of the importance of screening new entrants on arrival and on an ongoing basis;
- keeping GPs aware of prompt referral systems;
- resourcing TB services adequately so that they are not only involved in teaching clinical colleagues, but also in raising awareness of TB, particularly among high-risk groups; and
- informing clinicians of peer group networks and encouraging them to seek advice on treatment where appropriate.

Summary

For effective delivery of TB services, it is recommended that:

- all TB services identify a lead clinician with overall responsibility for diagnosis and treatment of TB, as a point of contact with commissioners;
- all patients should be allocated a named case worker;
- TB should be treated by specialists who have regular and continuing experience of treating the disease;
- transferred or shared case management with more experienced centres or specialists is considered in areas with low numbers of patients;
- NICE guidelines should be followed; and
- high-incidence areas provide, or have access to, ECM.

Standards and criteria for effective laboratory diagnosis of (active) *Mycobacterium tuberculosis* infection

This section is intended for microbiologists and histopathologists working to diagnose active TB via the use of appropriate laboratory tests.

PCTs might find this section useful for background reference when considering appointing laboratory providers as part of effective local TB commissioning.

Introduction

This section of the toolkit recommends methodologies and criteria to ensure the rapid, accurate diagnosis of active TB. With the needs and expectations of patients and their clinicians in mind, it also addresses:

- supporting the early confirmation of appropriate treatment;
- instigating suitable measures to reduce transmission; and
- providing timely evidence to help identify and investigate possible outbreaks.

Many microbiology laboratories only perform certain investigations because confirmation of identity, antimicrobial susceptibility testing and molecular typing can only be done at a few specialist centres. However, best practice requires all laboratories to meet the appropriate criteria for the procedure(s) they undertake. Time guidelines are indicated on the basis of microbiology services being provided six days each week, with local arrangements for public holidays to minimise delays.

The criteria discussed in this section are designed to complement the information and recommendations published in other national guidance documents. It is recommended that they are read in conjunction with the guidelines on tuberculosis issued in March 2006 by NICE and the National Standard Method (Bacteriology Standard Operating Procedure (BSOP) 40) for the microbiological investigation of specimens of *Mycobacterium* species issued by the Standards and Evaluations Unit of the HPA. See links listed below.

NICE guidelines on tuberculosis

<http://guidance.nice.org.uk/CG33/quickrefguide/pdf/English>

<http://guidance.nice.org.uk/CG33/guidance/pdf/English>

www.nice.org.uk

The National Standard Method (BSOP 40)

www.hpa-standardmethods.org.uk/documents/bsop/pdf/bsop40.pdf

www.evaluations-standards.org.uk

Samples that may be examined

Types of sample

Laboratories undertaking mycobacterial work should be prepared for the examination of a wide variety of specimen types, including:

- sputum or other respiratory samples;
- cerebrospinal fluid, spinal/paraspinal/intracerebral material;
- gastric washings;
- lymph node or other tissue samples or tissue fluids;

- blood or bone marrow (taken into mycobacterial culture medium);
- bone; and
- urine.

Number of samples

For sputum, three fresh, purulent samples (ideally 5ml or greater) from the lower respiratory tract should be collected at intervals of 8–24 hours, including at least one early morning sample. Most other specimen types will be single samples except for gastric washings and urine. For patients with sputum initially positive for *M. tuberculosis* complex (MTBC), repeat sputum specimens (if available) should be sent monthly until at least one is reported as culture-negative for MTBC.

Documentation

Full personal identification and clinical details are provided with the samples. This is required to comply with local specimen labelling policies and minimum data set requirements in accordance with trust policy and Clinical Pathology Accreditation standards.

Transfer to the laboratory

Ideally, specimens need to be received in the laboratory within one working day (48 hours maximum) of collection. This is necessary to prevent increased overgrowth by commensal flora and the possible deterioration of mycobacterial cell walls, which may not impact on viability but can lead to the failure to retain stain and risk a false negative smear test. For the same reason, laboratories that do not perform any mycobacteriological investigations on site are required to transfer specimens to their processing laboratory within one working day.

For information on the transport of potentially infected clinical samples, see ‘Transport of samples and cultures’ on page 33.

Initial investigations

Microscopy – auramine fluorescent staining

It is recommended that at least a six-day service is provided for smear examination on appropriate samples during the normal working day. Out-of-hours smear testing for *M. tuberculosis* may compromise quality guidelines. Risk assessment of the patient with suspected TB needs to assume the patient is infectious.

For optimum clinical and public health management, microscopy should be performed and the result issued within one working day of receipt of the specimen by the processing laboratory. Any new positive results need to be telephoned through as soon as possible to a member of the clinical team responsible for the patient’s care.

It is also recommended that the lead TB nurse, lead clinician for TB and the CCDC are also informed within one working day, in line with locally agreed arrangements to ensure that:

- the person with confirmed TB is told in a timely fashion by someone with appropriate expertise; and
- suitable public measures can be instigated.

Laboratories accredited for this work will have an internal quality control (IQC) programme in place and show satisfactory performance in an external quality assurance (EQA) proficiency scheme. To achieve this, laboratory staff need to maintain proficiency in interpretation of smears through continuing professional development (CPD) and peer review (for example, by an interpretative quality assurance programme).

Molecular tests for MTBC may be used in appropriate circumstances; see 'Molecular fingerprinting/typing' on page 34.

Culture, isolation and identification

To meet internationally accepted criteria, the culture, isolation and identification in 90% of cases need to be completed within 21 days of the source laboratory receiving a specimen. (Although most non-tuberculous species will grow in this time, some are slower, eg *M. malmoense*, *M. xenopi*. Definitive identification of some of these species may also be more protracted.)

Culture

In order to meet the 21-day criteria for speed and sensitivity:*

- Automated liquid culture needs to be done on all samples being processed for mycobacterial culture (by arrangement with other laboratories if necessary).
- This is required to be set up within one working day of receipt of the specimen (six-day service).
- Conventional solid culture also needs to be set up on at least one sample of each suitable specimen type received for mycobacterial investigation (see BSOP 40). This is required for some MTBC isolates and other *Mycobacterium* species that do not grow well in liquid culture.

Positive cultures

Acid-fast bacilli isolates (liquid or solid culture) for identification and susceptibility testing go to the appropriate regional centre for mycobacteriology (RCM) within one working day of the culture becoming positive. However, if the mycobacterial growth indicator tube (MGIT), BD culture system is used, consideration may be given (in conjunction with the RCM) to incubating cultures for a further 48 hours before despatch to achieve suitable biomass. To maintain the quality of the sample, and for safety reasons, the culture needs to reach the regional centre within one working day of despatch (for information on transport, see page 33). At least one acid-fast bacilli isolate from each new patient needs to be identified to complex/species level, and suitable susceptibility tests performed if identified as MTBC. Repeat AFB isolates from the same patient need to be identified and susceptibility tests performed if cultured from a specimen taken three months or more after a previously referred MTBC isolate.

Identification

To facilitate timely initiation of clinical treatment and public health measures:

- A nucleic acid amplification test (NAAT) or a hybridisation gene probe for MTBC needs to be done within one working day of a culture being shown to be positive or within one working day of receipt of a positive culture by the RCM.
- As necessary, other hybridisation probes and phenotypic identification tests will be done in the RCM.

Reporting

Similarly the RCM needs to report receipt of the isolate and initial identification results to the source laboratory within one working day. The source laboratory then needs to inform a member of the clinical team responsible for the patient's care, and ensure that the lead TB nurse, the lead clinician for TB and the CCDC are informed of new positive culture results and identification results from the RCM. This should also be done within one working day of the results being received, in line with locally agreed arrangements.

* Health Technology Assessment 2007, Volume 11 No. 3 concludes: 'fully automated liquid culture methods were superior to culture on solid media, in terms of their speed and precision'.

Laboratory facilities and expertise

- Safety: all culture work in primary diagnostic laboratories and RCMs needs to be done in a containment level 3 facility which has Health and Safety Executive approval for the purpose; has a contingency plan for containment in the case of accidental dispersal; and has a continuity plan for service support in the event of containment level 3 facility closure.
- To maintain reliable services of appropriate quality, those commissioning TB diagnostic services are strongly advised to use laboratories accredited for mycobacteriology culture, with an IQC programme in place, and which show satisfactory performance in an EQA proficiency scheme for every level of service provided, ie microscopy, culture, identification and susceptibility testing. In addition, the laboratory needs to maintain sufficient throughput to sustain competence levels.
- Consultant medical microbiologists/clinical scientists and biomedical scientists in laboratories providing *M. tuberculosis* culture are required to maintain their expertise and competence in laboratory testing – and also in the provision of advice on diagnosis, management and infection control aspects of TB through an appropriate programme of CPD.

Details of laboratory procedures for processing individual specimen types are given in the National Standard Method (BSOP 40), available at:

www.hpa-standardmethods.org.uk/documents/bsop/pdf/bsop40.pdf

Transport of samples and cultures

Patient samples

Patient samples need to be transported by a system conforming to the requirements for potentially infected samples (and routine for general bacteriology samples).

Positive cultures

Under current international transport regulations, these are category A cultures. However, an exemption clause allows them to be transported as category B material for clinical and diagnostic purposes if transported by road or rail. These cultures are assigned to UN 3373 (diagnostic or clinical specimens) and need to bear the marking 'diagnostic specimens' or 'clinical specimens', and be packed to packing instructions P650. Substances packed and marked in accordance with packing instructions P650 are not subject to any other requirements in the regulations – thus there is no requirement for additional transportation documentation. Such specimens should not be transported via Royal Mail because any mail may be transported by air, which carries additional requirements.

Susceptibility testing

Results

To fulfil internationally accepted criteria, the results of susceptibility tests to primary therapeutic agents are required to be made available within 30 days of the **initial** receipt in the source laboratory of a clinical sample from which MTBC is isolated for at least 95% of specimens.

For each new patient case, the primary agents to be tested are isoniazid, rifampicin, pyrazinamide and ethambutol with test results ideally available within 14 days of receipt of the isolates by the RCM and reported to the source laboratory within one working day. If a new isolate of MTBC is found to be resistant to isoniazid or rifampicin, it is recommended that this information is telephoned by the RCM to the source laboratory.

To enable appropriate clinical and public health action, the source laboratory needs to inform a member of the clinical team responsible for the patient's care within one working day of the results being received, in line with locally agreed arrangements. Similarly, the source laboratory should also inform the lead TB nurse, the lead clinician for TB and the CCDC of the results.

Molecular detection

Molecular detection of resistance gene markers for rifampicin is useful in identifying possible MDR TB (see NICE guidance – <http://guidance.nice.org.uk/CG33>). It is recommended that the specimen or isolate should be sent within one working day of the test being agreed between the source laboratory and the RCM or another testing laboratory, and that those results (including the confirmation of the presence of MTBC) are available within three working days of receipt of the specimen or isolate at the testing laboratory. It is recommended that susceptibility testing is done in an RCM with appropriate accreditation, IQC and EQA in place.

Resistant isolates

If a previously unknown MTBC isolate is shown to be resistant to rifampicin or two other primary agents, further tests need to be performed to guide appropriate treatment. Agents tested would usually include a fluoroquinolone, amikacin, capreomycin, streptomycin, ethionamide, cycloserine, para-amino salicylic acid and a macrolide.

Ideally, these 'second' or 'third' line results are reported to the source laboratory within 30 days of the resistance to the primary agents being identified.

The RCMs will provide the facility for testing other (including novel) agents as appropriate.

The laboratory requirements are set out in 'Laboratory facilities and expertise' on page 33.

Molecular fingerprinting/typing

Many public health specialists and clinicians agree that, for optimal public health management of TB in the community, all new isolates of MTBC should undergo 15-loci mycobacterial interspersed repetitive units – variable number tandem repeats (MIRU-VNTR) typing and the results entered in the national database within 21 days of receipt of the isolate at the RCM for at least 95% of isolates. Other molecular techniques may be used for particular investigations as appropriate. The most appropriate facilities for these tests are at an RCM, and it is recommended that:

- the results are reported to the source laboratory within one working day of the test being done; and
- the source laboratory ensures that that local arrangements are in place to inform the clinical team, the lead TB nurse, the lead clinician for TB and the CCDC of the results within one working day of them being received.

Reporting to the HPA surveillance system

To enable comprehensive public health surveillance and monitoring, the laboratory that first isolates *M. tuberculosis* from a sample should report this to the HPA as part of CoSURV reporting to the Communicable Diseases Report (CDR). The RCM will also report to the CDR all positive cases within one working day of confirming the positive results.

The RCM will report culture details including susceptibility results to the Mycobacterial Surveillance Network (MycobNet) within one working day of the report being sent to the source laboratory.

Direct nucleic acid amplification tests for detection of *M. tuberculosis*

This is not part of the routine investigation of samples for *M. tuberculosis* but may be considered where there is a high suspicion of infection and a definitive diagnosis of *M. tuberculosis* is deemed urgent in clinical terms or for health protection purposes (see NICE guidance – <http://guidance.nice.org.uk/CG33>). This test could be arranged between the requesting clinician and a suitably experienced local medical microbiologist, clinical or biomedical scientist who will liaise with the RCM or other laboratory providing the service. Good practice would be availability of the result within three working days of receipt of the sample by the testing site laboratory.

Immunodiagnostic tests

Debate continues on the use of interferon-gamma tests and the NICE guidelines contain recommendations on their use. Further information on the microbiological aspects is provided in Annex 5.

There is currently no evidence that interferon-gamma tests are cost-effective in diagnosis of active TB but may be useful in diagnosis of latent TB.

The HPA is developing further advice on use of interferon-gamma tests in the form of frequently asked questions. They are expected to be published later in 2007.

Histopathology of lymph nodes and other tissue samples taken at biopsy or autopsy

This summary guidance should be read in conjunction with current histopathology and autopsy guidance.

Tissue biopsies

It is recommended that:

- results are reported within three working days (or four, if extended fixation is indicated on safety grounds) of receiving the sample when TB is suspected clinically, or as soon as detected when discovered unexpectedly and the pathologist considers it clinicopathologically urgent;
- when biopsy samples of tissue clinicoradiologically suspected to be TB are taken, including samples analysed by perioperative frozen section, arrangements are in place for part of it to be sent to microbiology for culture. This may be the clinician's or the pathologist's responsibility, according to local protocols;
- once the clinical team responsible for the patient's care has been given the diagnosis of TB, locally agreed arrangements ensure that the lead TB nurse, the lead clinician for TB and the CCDC are informed of the results as soon as is feasible;
- cytopathology laboratories receiving material for diagnosis of *M. tuberculosis* infection liaise with their microbiology laboratory, as described for biopsy samples (second bullet, above); and
- histopathology and cytopathology samples of fresh TB tissue are handled according to standard safety conditions until they are fixed and non-infectious (ie in a ventilated cabinet).

Autopsy tissues

It is recommended that:

- if *M. tuberculosis* infection is suspected before or during autopsy:
 - the autopsy is performed according to infection containment protocol;
 - fresh samples of potentially infected tissues should be sent for microbiological investigation; and
- when a diagnosis of TB is made through autopsy alone, the histopathologist reports the case to the local microbiology laboratory, which can inform the CCDC.

General considerations

Histopathologically, the diagnosis of TB is a continuum ranging from certain mycobacterial infection (ie acid-fast bacillus positive, in the appropriate cellular context) consistent with TB, to granulomas and/or necrosis, without evident acid-fast bacilli – consistent with TB, but also with other infectious and non-infectious conditions.

It is recommended that in reporting suspected TB samples, the pathologist conveys the degree of confidence in such a diagnosis, in order to aid clinical management, including consideration of empirical therapy. This is correlated with available microbiology results.

A polymerase chain reaction (PCR) of formalin-fixed, paraffin-embedded material is not reliable for diagnosing infection with *M. tuberculosis* (ie not sensitive or specific enough), and there are currently no CE-marked commercial kits available.

Audit trail

To fulfil accreditation requirements, all laboratories involved in the provision of diagnostic services for TB need to be able to show that they fulfil the criteria listed above for timeliness and completeness of reporting and quality assurance in reports for commissioners, SHA performance managers, the Healthcare Commission and Clinical Pathology Accreditation (CPA UK Ltd).

Standards for surveillance

This section is intended primarily for local public health teams and clarifies the current national surveillance standards for TB, It will also be useful to those who monitor the performance of TB services.

A programme by the HPA to review these standards is currently under way. This section will be updated once the review is complete.

Introduction

The aim of national surveillance is to provide information on cases of TB at local, regional and national level, which is timely, relevant, complete and accurate, to enable appropriate action. The information supports commissioning to ensure that services are tailored to local needs as the epidemiology of TB varies considerably across the country. It also allows disease trends and treatment outcomes to be monitored.

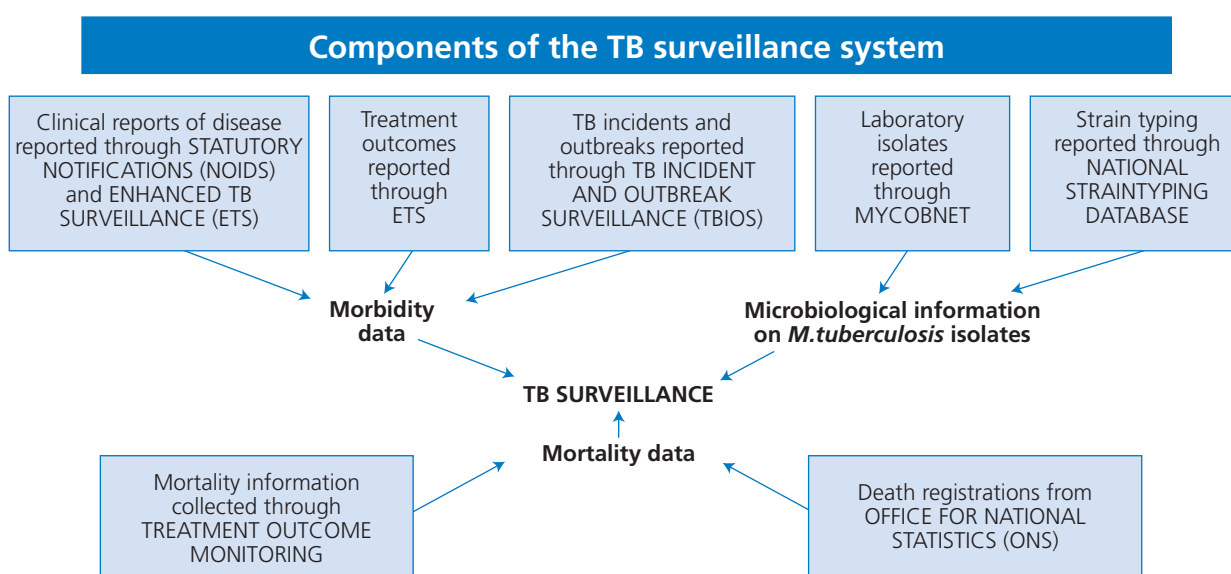
The HPA is currently revising the national surveillance system for TB and is developing a web-based system which will meet the requirements of the TB action plan and of its NHS partners. The new system will provide quarterly reports to contributing clinicians and local public health staff. These planned changes in the surveillance system and the potential for changes in the epidemiology of TB mean that any standards for surveillance need to be robust and flexible. The standards specified in this document apply to the current national surveillance arrangements. These standards will be reviewed and revised once the new surveillance system is in place.

The nature and organisation of TB surveillance varies in different parts of the country. The standards outlined in this document do not, therefore, include any specification on structure.

This document does not include the level of detail required for audit at each level of service delivery.

Current surveillance systems

TB surveillance is currently based on information from a number of different sources. The figure below outlines the various components of the current surveillance system.



Standards

Reporting new cases by clinical teams/local TB services (case definitions are given in the appendix on page 39)

- All cases should be reported by the clinical team to the local health protection unit.
- At least 95% of cases should be reported within two weeks of diagnosis or decision to treat with a full course of anti-TB drugs.
- At least 95% of reported cases should include complete data for the key variables (see appendix on page 40 for the key variables).
- At least 95% of all originally notified cases of TB that are subsequently denotified, should be reported within two weeks of the date of the non-TB diagnosis.

Collection and forwarding of information on reported cases by HPA Local and Regional Services

- All cases reported by clinical teams/local TB services to HPA Local and Regional Services (LaRS) should be forwarded to HPA Centre for Infections (CfI) within three months of the date of diagnosis or decision to treat.

Treatment outcome (see appendix on page 39 for categories)

- Outcome of treatment should be reported on at least 95% of all cases reported as incident cases by the clinical team to the local health protection unit within three months of the one-year anniversary of the date of diagnosis or start of treatment.
- The outcome of treatment in all cases reported by clinical teams should be forwarded by HPA LaRS to HPA CfI within four months of the one-year anniversary of the date of diagnosis or start of treatment.

Microbiology results

- Mycobacteriology reference laboratories should report the results of species identity and drug susceptibility on all isolates, within one working day of the result being available, to the source primary diagnostic laboratory.
- Mycobacteriology reference laboratories should, simultaneously, report the results of species identity and drug susceptibility on all isolates, within one working day of the result being available, to MycobNet.
- The primary diagnostic laboratory should report the results of all new sputum smears positive for mycobacteria to the clinical team and local health protection unit (according to local arrangements) within one working day of the results being available.
- The primary diagnostic laboratory should report the results of all new positive mycobacterial cultures (identified as MTBC complex by the reference laboratory) to the clinical team and local health protection unit (according to local arrangements) within one working day of the results being available.

Molecular strain typing

- The mycobacteriology reference laboratories should report the results of molecular strain typing on all isolates, within one week of the result being available, to the national strain typing database (as well as the source primary diagnostic laboratory).

Feedback and reports

- HPA local, regional and national surveillance units/centres have a responsibility to produce timely reports to be distributed locally to inform appropriate action. Surveillance data collected within a given calendar year must be reported back within the subsequent year.
- Quarterly reports using provisional data should be produced within six months of the quarter in which a case is reported.
- Annual reports of finalised data should be available before the end of the following calendar year.
- Information should be provided by the HPA to commissioners, acute trusts, PCTs and the Department of Health to support commissioning and planning of TB services in a timely manner.

Audit trail

- All health protection units and the national surveillance centre should be able to show that they are achieving the standards outlined in this document for all cases reported within the geographical areas for which they are responsible.
- NHS trusts and SHAs should monitor compliance with the standards outlined through local TB networks in collaboration with the HPA.

Appendix

Case definition

Confirmed cases: These are culture confirmed cases, due to MTBC infection (including *M. tuberculosis*, *M. bovis* and *M. africanum*).

Other than culture confirmed cases: In the absence of culture confirmation, a case that meets the following criteria:

- a clinician's judgement that the patient's clinical and/or radiological signs and/or histological signs are compatible with TB; and
- a clinician's decision to treat the patient with a full course of anti-TB treatment.

Persons receiving preventive chemoprophylaxis should not be reported.

Outcome of treatment following World Health Organization and European recommendations

Treatment completed

A patient is defined as having completed treatment if the case:

- was reported;
- completed a full course of treatment; and
- was officially discharged by the attending physician.

Cured

A case is categorised as 'cured' if he/she had completed a full course of anti-TB chemotherapy within 12 months of starting treatment, diagnosis or notification, and had a documented negative culture conversion during treatment in sputum-culture-positive patients. The outcome 'cured' only applies to sputum-culture-positive pulmonary TB cases.

Death

The outcome 'death' is used for patients who died before or during treatment, and includes cases diagnosed post mortem. Four subcategories are used to provide information on the nature of the link between death and TB:

- TB caused death;
- TB contributed to death;
- TB was incidental to death (TB was not related to death); and
- relationship between TB and death unknown.

Still on treatment

This category is used for patients still on treatment one year after starting treatment.

Subcategories are used to provide reasons for still being on treatment:

- still on initially planned treatment (regimen longer than initial 12 months planned);
- treatment interrupted (non-completion of initially planned treatment regimen for 12 months or less); and
- treatment changed as a result of intolerance or side effects, initial drug resistance, development of new drug resistance, failure to culture convert or poor clinical response to treatment.

Treatment stopped

This outcome category is used for patients who do not complete treatment for reasons other than death or still being on treatment.

Transferred out

The patient is classified as 'transferred out' if responsibility for his/her care was transferred to another clinical team.

Lost to follow-up

The patient is classified in this category if he/she was lost to follow-up before the end of treatment.

Unknown

When no treatment details (including outcome) are available (eg lost patient notes) or when treatment is not completed for unknown reasons, the patient is classified as having an unknown outcome.

Key variables

The key variables are as follows:

- name;
- date of birth;
- sex;
- ethnic group;
- born/not born in the UK;
- postcode (with option for 'no fixed abode');
- date of notification;
- previous TB treatment;
- site of disease (pulmonary/extra-pulmonary); and
- sputum smear status (only needs to be completed for pulmonary cases).

Annex 1: An example of a service level agreement for organisation and delivery of TB services across the XYZ cluster

1 Population to be served

The TB service will provide care to residents of X, Y and Z and patients attending St Elsewhere Hospitals NHS Trust sites.

2 Collaboration

The TB service will be expected to work in close collaboration with:

- X PCT;
- Y PCT;
- Z PCT;
- St Elsewhere Hospitals NHS Trust;
- the HPA; and
- the TB network (clinical or commissioning).

3 Service to be provided

The TB service will provide:

- investigation of suspected but unconfirmed TB;
- case management of TB patients;
- contact tracing of individuals exposed to TB;
- ward visits to TB patients;
- tuberculin skin testing for ward patients;
- community home visiting;
- multidisciplinary TB clinics;
- nurse-led hospital and community TB clinics;
- outreach work;
- reactive outbreak screening; and
- DOT.

St Elsewhere Hospitals NHS Trust will provide:

- inpatient beds for TB patients requiring hospitalisation;
- negative pressure facilities;
- TB diagnostic services (radiology, microbiology, histopathology and cytopathology); and
- inpatient infection control services.

The PCTs will provide:

- BCG vaccination services;
- new entrant screening strategy;
- health promotion (in combination with the TB network); and
- community infection control services.

The health protection unit will provide:

- disease surveillance;
- outbreak and incident management; and
- support in planning.

The TB network will provide:

- peer review;
- performance data;
- audit support; and
- support in planning.

The SHA will provide:

- performance management; and
- support in planning.

4 Monitoring

The TB service will be monitored against national and TB network standards and this will be reported on a quarterly basis by the TB network.

5 Serious untoward incidents

Serious untoward incidents are the responsibility of the PCT or acute trust in which they occur. Local arrangements should be in place to deal with these issues. Incidents relating to staff should be reported to the lead (host) organisation.

6 Links to mainstream commissioning

To ensure investment plans are plugged into the mainstream business planning and commissioning functions of the PCTs, a representative from each of the stakeholders, the director of commissioning and contracting at the lead organisation and the TB network will need to jointly supervise commissioning of TB services. The TB service leads' work programme will be jointly agreed between the directors and fed into the local co-commissioning groups.

7 Finance

The cost of providing TB services and patient care, clinical governance and audit is detailed in a separate paper. (Example not provided.)

Signed:

Name:

Title:

On behalf of X PCT

Signed:

Name:

Title:

On behalf of Y PCT

Signed:

Name:

Title:

On behalf of Z PCT

Signed:

Name:

Title:

On behalf of St Elsewhere Hospitals NHS Trust

Date:

Annex 2: Payment by Results and typical TB patient pathways

Further details about application of PbR can be found on the DH website (at www.dh.gov.uk/en/Policyandguidance/Organisationpolicy/Financeandplanning/NHSFinancialReforms/index.htm).

Six different examples of possible TB patient pathways are included here, showing which stages attract a PbR tariff and which stages do not. Where tariffs do apply, providers should be transparent about how that money is spent on TB services.

Commissioners of TB services need to be aware of which steps in the treatment of a patient with TB need to be funded by local agreement.

Example patient pathways:

- 1 Patient with active pulmonary TB
- 2 Poorly compliant patient with active pulmonary TB
- 3 Patient with active MDR pulmonary TB
- 4 Patient with active lymph node TB
- 5 Paediatric patient with active lymph node TB
- 6 Patient requiring chemoprophylaxis (eg contact tracing)

Pathway and payments for patients with active pulmonary TB

PbR £

Local £

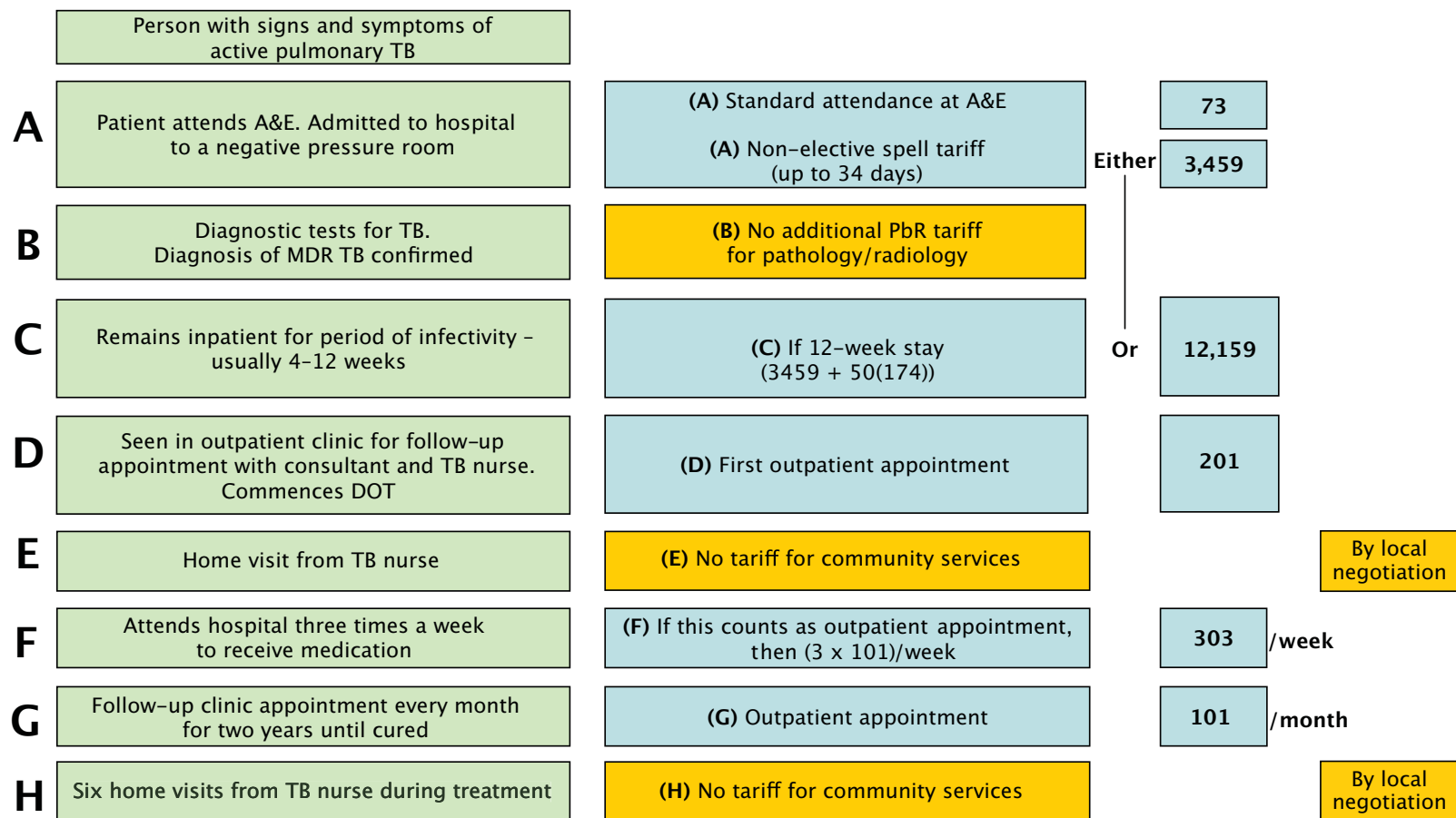
	Person (assume adult) with signs and symptoms of active pulmonary TB			
A	Patient attends GP. Referred to hospital. Admitted to hospital to a negative pressure room	(A) First outpatient appointment (thoracic medicine 340) Non-elective spell tariff (up to 34 days)	201	Isolation facility local flexibility
			3,459	
B	Diagnostic tests for TB. Diagnosis of fully sensitive pulmonary TB confirmed	(B) Pathology and radiography included within relevant outpatient or admitted patient tariff		
C	Seen in outpatient clinic for follow-up appointment with consultant and TB nurse	(C) Second outpatient appointment	101	
D	Home visit from TB nurse	(D) No tariff for community services		By local negotiation
E	Follow-up clinic appointment at 2, 3, 4, 5 and 6 months	(E) Follow-up appointments 5 x 101	505	
F	Two home visits during treatment from TB nurse	(F) No tariff for community services		By local negotiation

Pathway and payments for poorly compliant patients with active pulmonary TB			PbR £	Local £
	Person with signs and symptoms of active pulmonary TB			
A	Patient attends A&E. Admitted to hospital to a negative pressure room	(A) Standard attendance at A&E	73	
		(A) Non-elective spell tariff (up to 34 days)	3,459	
B	Diagnostic tests for TB. Diagnosis of TB confirmed	(B) Diagnostic tests included within relevant outpatient or admitted patient tariff		
C	Patient fails to attend follow-up clinic	(C) No tariff, but may incur other costs to TB services to follow up patient		By local negotiation
D	Home visit from TB nurse	(D) No tariff		By local negotiation
E	Seen in outpatient clinic for follow-up appointment with consultant and TB nurse. Commence directly observed therapy (DOT)	(E) First outpatient appointment	201	
F	Patient fails to attend for DOT	(F) No tariff, but may incur other costs to TB services to follow up patient		By local negotiation
G	Home visit from TB nurse	(G) No tariff		By local negotiation
H	Readmitted to hospital with worsening symptoms	(H) Short stay emergency tariff	692	
I	Patient fails to attend follow-up clinic	(I) No tariff, but may incur other costs to TB services to follow up patient		By local negotiation
J	Home visit from TB nurse	(J) No tariff		By local negotiation
K	Patient started on DOT in the community by TB nurse	(K) No tariff		By local negotiation
L	Patient fails therapy and is lost to follow-up	(L) No tariff, but may incur costs to TB services to try to trace patient		By local negotiation

Pathway and payments for patients with active MDR pulmonary TB

PbR £

Local £



Pathway and payments for patients with active lymph node TB			PbR £	Local £
	Persons with signs and symptoms of lymph node TB			
A	Patient referred to consultant. Diagnostic tests for TB	(A) First outpatient referral (thoracic medicine)	201	
B	Diagnostic tests for TB. Diagnosis confirmed	(B) No additional PbR tariff for diagnostics (pathology/radiology)		
C	Home visit from TB nurse	(C) No tariff for community services		By local negotiation
D	Follow-up appointment at 2, 3, 4, 5 and 6 months	(D) Follow-up appointments 5 x 101	505	
E	Two home visits from TB nurse during treatment	(E) No tariff for community services		By local negotiation

Pathway and payments for paediatric patients with active lymph node TB

PbR £ **Local £**

	Child with lymph node TB identified by TB nurse during contact tracing			
A	Seen in paediatric outpatient clinic for follow-up. Appointment with consultant and TB nurse	(A) First outpatient appointment (paediatrics)	217	
B	Diagnostic tests for TB. Diagnosis confirmed	(B) No additional tariff for pathology		
C	Home visit from TB nurse	(C) No tariff		By local negotiation
D	Follow-up appointment at 2, 3, 4, 5 and 6 months	(D) Follow-up appointments 5 x 114 (paediatrics)	570	
E	Repeated phone support from TB nurse during care	(E) No tariff		By local negotiation

Pathway and payments for patients requiring chemoprophylaxis		PbR £	Local £
	Patient with latent TB infection identified by TB nurse during contact tracing	No tariff for contact tracing	By local negotiation
A	Seen in outpatient clinic for follow-up appointment with consultant and TB nurse	(A) First outpatient appointment	201
B	Follow-up clinic appointment at 2 and 3 months	(B) Follow-up appointments 2 x 101	202
C	Repeated phone support from TB nurse during care	(C) No tariff	By local negotiation

Annex 3: Table 2 – blank template for local use

GPs or groups	Who might commission which service?			Who might provide which service?
	PCTs	PCT groups	Supra-regional/national	
				Level one GPs and/or other community-owned service providers
				Level two Secondary care providers
				Level three Tertiary providers

Annex 4: Developing a national advice network

Many individuals involved in the management of TB have developed informal pathways by which they seek advice on the management of TB cases that fall outside their regular experience. Research by the Joint Tuberculosis Committee coordinated by the British Thoracic Society demonstrates, however, that a substantial proportion of clinicians have no clear idea where to turn to for such advice.

It is intended that a national advice network be developed, offering help with the management of TB. This should not be prescriptive and should not displace those pathways that individuals may already have developed. Rather, it shows those who need it where to look for advice.

Some cases of TB will inevitably require highly skilled management, both to ensure a satisfactory outcome for the patient concerned and for the protection of public health. Multi-drug-resistant TB (MDR TB) is a prime example. For this reason, MDR TB has been chosen as the pilot for the development of an advice network. Notification of cases to the group is not mandatory, but it is anticipated that it will become the norm.

Highly experienced clinicians should not work in isolation and should be aware of the benefits to be gained from discussing and pooling experience. Further, the organised collection of data on relatively rare aspects of TB (such as in MDR TB) will facilitate research and the development of better management in the future.

The Multi-drug-resistant (MDR) TB group

Models of good practice for service delivery recommend that MDR TB cases be discussed with this group and that advice is sought on a regular basis on their continuing management.

MDR TB is rare – there are currently only 50 to 60 new cases diagnosed per year in the UK. Management is complex and expensive, and involves consideration of wider issues. For example, the imperative for infection control may necessitate prolonged isolation, with severe psychological implications. Patients with complex and challenging needs in the first place (substance misuse, mental illness, chaotic lifestyle or previous poor adherence to medication) are disproportionately represented among MDR TB patients.

Few clinicians, nurses, microbiologists or consultants in communicable disease control will have significant experience of MDR TB, yet from time to time they may be faced with the problems of such a case. The national MDR TB group is a virtual team of experts with experience in the management of the condition. Coordinated by the Joint Tuberculosis Committee of the British Thoracic Society, it includes:

- respiratory, infectious disease, HIV and paediatric consultant physicians;
- consultant microbiologists;
- consultants in communicable disease control; and
- TB and infection control specialist nurses.

The group has a remit to:

- offer timely advice on all aspects of the management of MDR TB cases, including transfer to appropriate treatment facilities where these are not available locally;
- collect and disseminate information on the management and outcomes of all MDR TB cases in the UK, with the aim of sharing experience within and outside the group and improving the future management of such cases; and
- ensure that further individuals are gaining expertise in the management of MDR TB, thus achieving appropriate succession planning as current experienced doctors and nurses approach retirement.

Annex 5: Interferon-gamma tests for diagnosis of TB – an evaluation

Background

Two detailed guidelines, one from the Centers for Disease Control and Prevention, USA and the other from the UK National Institute for Health and Clinical Excellence, have been produced on the appropriate use of novel cellular interferon-gamma assays (CIGAs) for the diagnosis of latent TB infection (LTBI) and active TB. In considering these guidelines, two commercial systems – the T-SPOT (Oxford Immunotec, UK) and QuantiFERON Gold (Cellestis, Australia) – were considered.

Active TB

- CIGAs are of value in diagnosing active TB (but should **not** replace appropriate microbiological and molecular investigation). CIGAs have no benefit in the diagnosis of known pulmonary TB cases with bacteriological/molecular confirmation.
- Studies have shown variable sensitivity but the assays are at least as sensitive as tuberculin skin tests (TSTs) (sensitivity of CIGAs is high (75–97%)). Sensitivity may be slightly reduced by disease as TST is reduced by anergy in severe disease.
- Specificity for active TB is very low. CIGAs do not cross-react with BCG but cross-react with a small number of non-tuberculous mycobacteria. Interpretation may be difficult in individuals who have recently arrived from a country with a high TB prevalence (who may be latently infected with TB) presenting with symptoms and signs consistent with TB.
- CIGAs would have the greatest potential benefit in the diagnosis of TB in difficult-to-diagnose cases such as those in children and those in the immune compromised, such as HIV-positive individuals, and of extra-pulmonary TB, especially TB meningitis. There is evidence for the use of CIGAs to diagnose active TB in children and in HIV-positive individuals but little for extra-pulmonary TB at this time.
- Overall, both tests perform similarly, but the T-SPOT may be more sensitive in HIV-positive and severely immune compromised individuals and has fewer indeterminate results; however, this may be due to the current cut-offs used for these tests (see 'Looking ahead' below). Conversely, the QuantiFERON assay is easier to perform, has a higher throughput and is less time-sensitive.

Looking ahead

Further work is needed to validate the use of these tests in active TB, including:

- more carefully designed head-to-head studies, particularly for difficult-to-diagnose groups (children, HIV-positive and other immuno-compromised individuals and in those with TB meningitis);
- careful analysis of cut-offs used in both assays and consideration of different cut-offs for different patient groups; and
- the replication of tests in repeated or sequential examinations of patients.

Laboratories should seek access to these tests when clinicians consider the results would be helpful. There is insufficient evidence at present to set guidelines for laboratory provision, but any laboratory providing the tests should be accredited and have an internal quality control programme in place. An external quality assurance scheme is not yet available. Generally, it would be expected that a clinician should receive a result within two weeks of submitting a sample for these tests.

Acronyms

AFB	Acid-fast bacilli
BCG	Bacillus Calmette-Guérin vaccine
BLF	British Lung Foundation
BSOP	Bacteriology Standard Operating Procedure
BTS	British Thoracic Society
CCDC	Consultant in communicable diseases control
CDR	Communicable Diseases Report
Cfi	Centre for Infections (Health Protection Agency)
CIGA	Cellular interferon-gamma assay
CoSURV	Communicable disease surveillance system application
CPA	Clinical Pathology Accreditation
CPD	Continuing professional development
CSF	Cerebrospinal fluid
EQA	External quality assurance
HPA	Health Protection Agency
HSE	Health and Safety Executive
IQC	Internal quality control
LaRS	Local and Regional Services (Health Protection Agency)
MDR TB	Multi-drug-resistant tuberculosis
MGIT	Mycobacterial growth indicator tube
MIRU-VNTR	Mycobacterial interspersed repetitive units – variable number tandem repeats
MTBC	<i>M. tuberculosis</i> complex
MycobNet	Mycobacterial Surveillance Network
NAAT	Nucleic acid amplification test
NICE	National Institute for Health and Clinical Excellence

Tuberculosis prevention and treatment

PAS	Para-amino salicylic acid
PbR	Payment by Results
RCM	Regional centre for mycobacteriology
PCR	Polymerase chain reaction
SHA	Strategic health authority
TST	Tuberculin skin test

