Tuberculosis Summary Needs Assessment: Leicester, Leicestershire and Rutland

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Produced by the TB Strategy Board

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JSNA programme

NHS
Leicester City
Clinical Commissioning Group

Leicester
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1 Executive Summary

- During the 1990s cases of TB began to rise and TB re-emerged as a public health problem. This was predominantly as a result of increased immigration of people from countries where TB is common, but also due to the ageing of the established migrant population whose undiagnosed latent TB developed into active disease.

- Two TB related conditions exist; latent TB infection (LTBI) and TB disease. People with LTBI are infected with M. Tuberculosis but do not have any symptoms of disease. Without treatment, an estimated 10% of infected people will develop TB disease. The vast majority of TB cases develop the disease after previously acquired latent infection.

- Some ethnic minority population groups have much higher incidence of TB than others due to previous residence, and frequent travel to countries with higher prevalence of TB. Irrespective of ethnicity, TB is more prevalent in socially deprived communities.

- Comprehensive TB management delivered by well organised and integrated services is a very cost effective intervention. Late diagnosis and poor management increase the risk of the disease spreading and can lead to the emergence of drug resistant cases. A multi drug resistant case typically costs £50,000 - £70,000 to treat, compared to £5,000 for a case of non drug resistant TB.

- A range of national policy and guidance documents exist to support commissioners and providers to plan and deliver integrated services for the early detection, and treatment of latent and active TB. These include the NHS and Public Health Outcomes Frameworks which have specific indicators relating to TB.

- Leicester City CCG is the lead commissioner for TB services on behalf of all CCGs across Leicester, Leicestershire and Rutland. It is not possible to determine the total value of resources invested in TB services.

- Leicester City has the highest incidence rate of TB in the East Midlands at 56/100,000 in 2012. The incidence rate in Leicestershire County and Rutland is very low at 5/100,000.

- Leicester TB services have achieved a consistent reduction in the overall number of active cases of TB. Between 2005 and 2012 the number of active cases fell by 30%.

- While case numbers in Leicestershire and Rutland are low, there are significantly higher proportions of infectious pulmonary cases in this cohort which poses a substantial risk of local outbreaks.

- Between 10% and 20% of active TB cases in Leicester City have black African ethnicity and are predominantly recent arrivals from sub-Saharan Africa (Zimbabwe and Somalia).

- Independent of gender, active TB is significantly more common in young adults aged 16-45. The vast majority of newly diagnosed young adult cases are non-UK born.

- Current service provision across Leicester, Leicestershire and Rutland is highly integrated and effective. A specialist TB nursing service coordinates the range of services that work in partnership to deliver a comprehensive TB service which includes a Rapid Access Service for the early diagnosis and treatment of infectious TB.

- The success of the service is reflected in the reducing incidence of active TB cases. The service has also been audited against, and shown to be compliant with, national guidelines in all but the provision of new entrant screening.

- Patient surveys show consistently high levels of patient satisfaction with the Specialist Nursing Service and Rapid Access Service.

- The services in Leicester, Leicestershire and Rutland have been overseen by the TB Strategy Board since 2002. This structure ensures care pathways and management protocols are monitored and maintained. However, following the implementation of the Health and Social Care Act 2012 and the resultant changes in commissioning responsibility, the Board does not currently have any commissioner representation.
- Overall the TB service in Leicester provides a high quality, comprehensive and well integrated service with partners working successfully to treat and reduce the incidence of active disease. However, there remains a significant gap in the provision of a screening service for new entrants from countries with a high prevalence of TB, and the TB nursing service no longer meets recommendations in relation to the ratio of WTE specialist nurses to cases.

2 Introduction

2.1 Purpose of this needs assessment

The purpose of this needs assessment is to support the commissioning process to ensure the optimum use of resources in securing the provision of high quality, comprehensive and effective services for the prevention and treatment of TB across Leicester, Leicestershire and Rutland (LLR). It will facilitate this by:

- describing the nature and extent of TB disease and latent TB infection across Leicester, Leicestershire and Rutland
- describing current commissioning arrangements and service provision for people with suspected or confirmed TB disease, and for those at high risk of developing TB in Leicester, Leicestershire and Rutland
- detailing current national standards, and guidelines
- formulating recommendations for commissioners.

2.2 What is Tuberculosis?

Tuberculosis (TB) is a communicable disease, which is caused by bacteria from the *Mycobacterium tuberculosis* complex (M. *tuberculosis*, M. *bovis* or M. *africanum*). TB usually affects the lungs, but can affect other parts of the body such as the lymph nodes (glands), kidneys, gut, bones and rarely the brain [1].

However, infection with TB bacteria may not always lead to TB disease. As a result two TB related conditions exist; latent TB infection (LTBI) and TB disease. People with latent TB are infected with M. Tuberculosis but do not have any symptoms of disease. Without treatment, an estimated 10% of infected people will develop TB disease at some time in their lives. About half of those people who develop TB will do so within the first two years of infection. For people whose immune systems are weak, especially those with HIV infection, the risk of developing TB disease is considerably higher than for people with normal immune systems. TB disease occurs when the TB bacteria overcome the defences of the immune system and begin to multiply, resulting in the progression from latent TB infection to TB disease. Some people develop TB disease soon after infection, while others develop TB disease later when their immune system becomes weakened [2].

Some ethnic minority population groups have much higher incidence of TB than others due to previous residence and also frequent travel to countries with higher prevalence of TB. Irrespective of ethnicity, TB is more prevalent in socially deprived communities and groups [3].

2.3 Spread of TB

TB is most commonly spread by inhalation of infected droplets containing mycobacteria. The bacteria get into the air when a person who has TB disease of the lungs coughs or sneezes. To be at risk of acquiring the infection prolonged and close contact with someone who has TB of the lungs is needed. However, not all people with TB in the lungs are equally infectious to other people. People with TB disease are most infectious when the bacteria are expelled with their sputum [1]. Left untreated or with delayed diagnosis, a person with infectious TB of the lungs will infect an average of 10–15 people a year [4].

The vast majority of active TB cases develop the disease after previously acquired latent infection. It is estimated that 2 billion people worldwide harbour the latent form of the disease. It is estimated that only 10% of latently infected individuals will develop active TB in their life time but the progression rate is highly variable and dependent on the individual immune status and other factors. The time period between acquisition of the micro-organism and developing active disease is also highly variable ranging from weeks to several decades.

2.4 Risk factors for TB

Anyone can catch TB but certain groups or individuals are at increased risk of acquiring the infection and progressing to active TB disease. These include:

- close contacts of infectious cases
- those who have lived in, travel to or receive visitors from places where TB is still very common
- those who live in ethnic minority communities originating from places where TB is very common
- those with immune systems weakened by HIV infection or other medical problems
- the very young and the elderly, as their immune systems are less robust
- those with chronic poor health and nutrition because of lifestyle problems such as homelessness, drug abuse or alcoholism
- those living in poor or crowded housing conditions, including those living in hostels [3].

Although most people with TB in England were born outside the UK, the highest risk of developing disease is among people who are homeless, problem drug users and prisoners [5]. These social factors are also associated with poor adherence to treatment and loss to follow up resulting in the development of drug resistance and onward transmission of the disease [6] [7] [8].

2.5 Resurgence of TB

During the 1960s and 1970s the impact of TB in England was largely controlled through a range of measures including effective drug treatment, immunisation, early detection through mass x-ray programmes and public health programmes to detect and treat infection in close contacts of people with TB [4]. During the 1990s cases began to rise and TB re-emerged as a public health problem. This was predominantly as a result of increased immigration of people from countries where TB is very common, but also due to the ageing of the established migrant population whose unrecognised latent TB developed into disease [4].

2.6 Benefits of effective commissioning

Effective management of TB is a public health imperative and the lack of an effective commissioning strategy can be costly in the long term. Failure in any aspect of TB management can lead to rapidly escalating problems with potentially serious consequences for the patients concerned and the wider public. This may have significant additional resource consequences for all the organisations with responsibilities for TB and/or public health.

Comprehensive TB management delivered by well organised and integrated services is a very cost effective intervention. Late diagnosis of incident cases and incomplete and poorly monitored management not only increase the risk of the disease spreading and affecting more individuals, but can also lead to the emergence of multi drug resistant cases which typically cost £50,000 - £70,000 per case to treat. Managing a non drug resistant case diagnosed in a timely fashion on the other hand can cost less than £5,000 [9]. In populations with high levels of migrants in particular there is, therefore, a clear financial incentive to ensure TB services across the county are effective in detecting disease early, treating cases curatively, and preventing disease not only in contacts at risk of disease but also in recently arrived young immigrants from TB high prevalence countries.

High proportions of TB cases are preventable and almost all people with TB can be cured [3].

2.7 National drivers

2.7.1 CMO Action plan

In 2004 the Chief Medical Officer published a TB Action Plan [4] identifying TB as a new threat needing "concerted action to deal with it". The action plan sets out three long term goals:

- reduce the risk of people being newly infected with TB in England
- provide high quality treatment and care for people with TB
- maintain low levels of drug resistance, particularly multidrug resistant (MDR) TB.

Following the Action Plan, the Department of Health TB Action Plan Team produced a toolkit for planning, commissioning and delivering TB services in England [9]. The purpose of the toolkit is to support commissioners and TB service providers in implementing the CMO Action Plan in line with current NICE guidance.

2.7.2 NICE Guidelines

In 2011 NICE published a revision to its 2006 Guideline. The original document was updated to include evidence from recent research, particularly in relation to the use of gamma interferon based blood testing (IGRA) in the diagnosis of latent TB. The revised guideline makes recommendations covering diagnosis of primary cases of TB, identifying secondary cases, treating active disease, preventing further transmission and preventing active TB through control and treatment of latent infection. It provides standards based on the best available evidence and examples of good practice. Such standards have been used to assess local services and inform the recommendations in this Needs Assessment.

The incidence of TB among new migrants and people with a history of drug use, alcohol use, homelessness and prisoners is much higher than in the general population. Members of these groups may often face challenges in engaging with services over a sustained period, posing a specific risk of developing drug resistant TB and transmitting the disease more widely.

Whilst it is acknowledged that not all new migrants will be hard to reach, some may face specific social, cultural and economic pressures that may inhibit the ability to identify and manage TB in this group.

As a result, in 2012 NICE published guidance aimed at ensuring services are appropriately configured and resourced to identify and mange TB among these specific groups.

This guidance was accompanied by a Self Assessment Tool to support local commissioners and services in identifying how services could be improved to ensure they are able to meet the needs of these vulnerable groups.

Further detail of all national guidance is provided in section 4.

2.7.3 Outcomes Frameworks

The Department of Health has published three outcomes frameworks for the NHS, Public Health and Social Care. These frameworks are intended to set the direction and provide the focus for action and improvement across the health and care system by setting out high level domains in which the DH would like to see improvement. Each of the domains is supported by a range of indicators to allow monitoring of progress and processes for monitoring that reflect the differing accountability mechanisms that exist across the system [10]. Table 1 shows the outcome indicators that are relevant to this needs assessment.

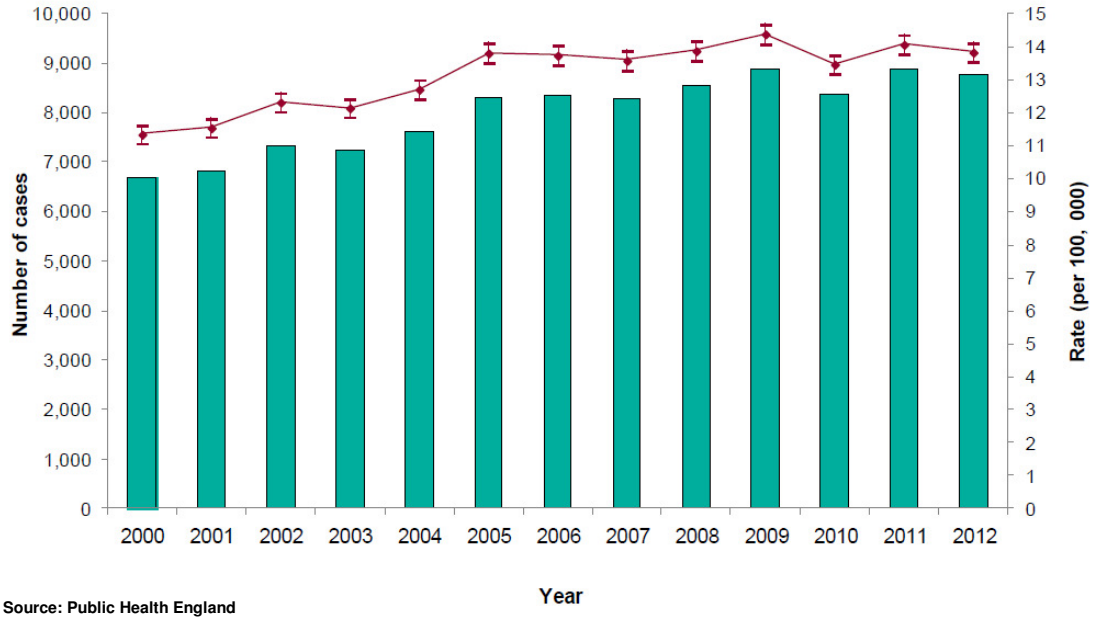
Outcomes Framework	Domain	Indicator
NHS [11]	1 Preventing people from dying prematurely	1ai Potential Years of Life Lost from causes amenable to healthcare (TB mentioned specifically in list of conditions amenable to healthcare)
	4 Ensuring that people have a positive experience of care	4b Patient Experience of hospital care
		4.1 Patient experience of outpatient care
		4.9 People's experience of integrated care (placeholder)
Public Health [12]	3 Health Protection	Treatment completion for tuberculosis
		Inter agency plans for responding to public health incidents
	4 Healthcare public health and preventing premature mortality	Mortality from causes considered preventable
		Mortality from communicable diseases

Table 1 Outcomes Framework indicators relevant to TB service provision

3 Epidemiology

3.1 UK epidemiology

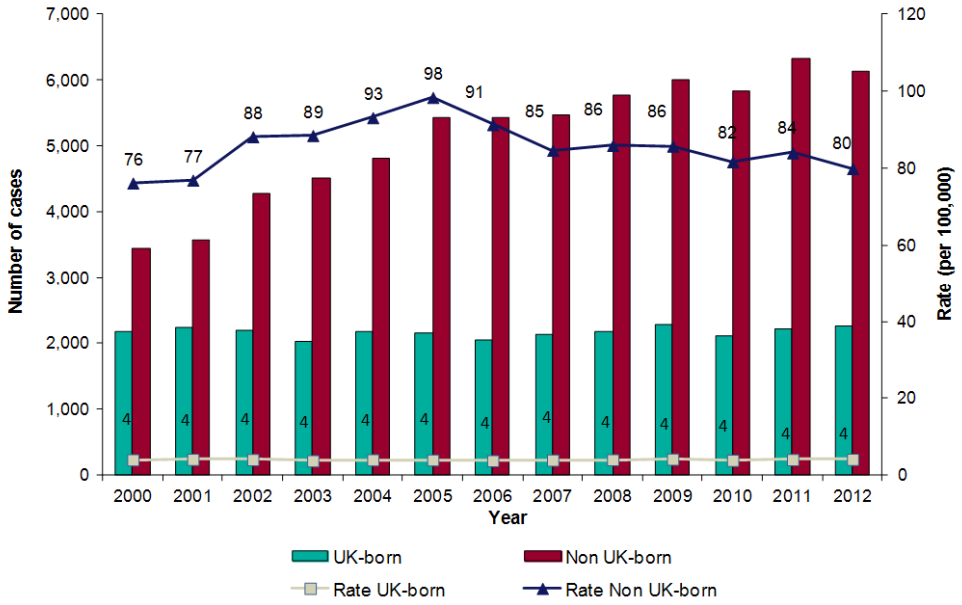
In 2012 in the UK, a total of 8,751 cases of TB were reported, a rate of 13.9 cases per 100,000 population (Figure 1). TB notifications and rates increased until 2005, and have remained high but relatively stable since.



Source: Public Health England

Figure 1 Tuberculosis case reports, rates and annual percentage change, UK 2000-2012

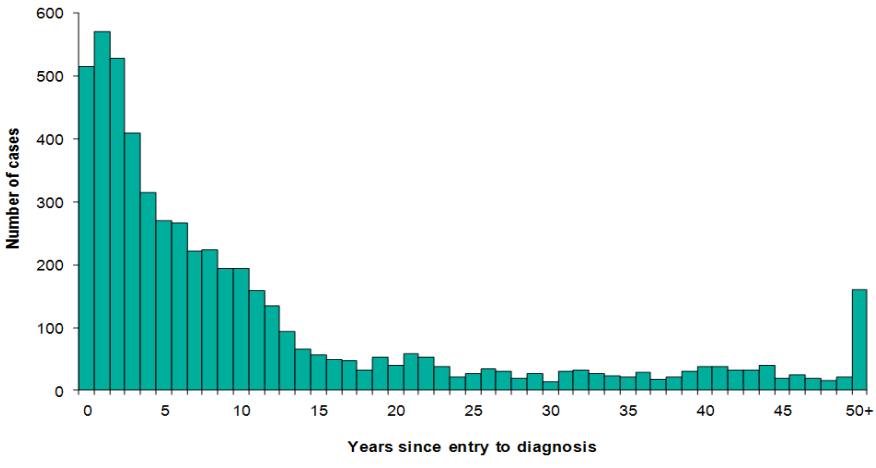
The majority of TB cases in the UK (73%) occurred in migrants from countries with high levels of TB (figure 2)



Source: Enhanced Tuberculosis Surveillance (ETS), Enhanced Surveillance of Mycobacterial Infections (ESMI), Office for National Statistics (ONS)
Data as at July 2013
Prepared by: TB Section, Centre for Infectious Disease Surveillance and Control, Public Health England

Figure 2 Tuberculosis case reports and rates by place of birth, UK 2000-2012

Almost half of non-UK born cases developed TB within 5 years after arrival (Figure 3). 30 % of non UK-born cases were diagnosed within two years of arrival.



Source: Enhanced Tuberculosis Surveillance (ETS), Enhanced Surveillance of Mycobacterial Infections (ESMI)
Data as at July 2013

Figure 3 Non UK born tuberculosis case reports by time since entry to the UK to tuberculosis diagnosis, UK 2012

Across the UK there has for many years been a concentration of cases in large urban cities (Figure 4).Leicester, Leicestershire and Rutland are no exception to this rule with more than 10 fold higher incidence rates in Leicester City than in the county.

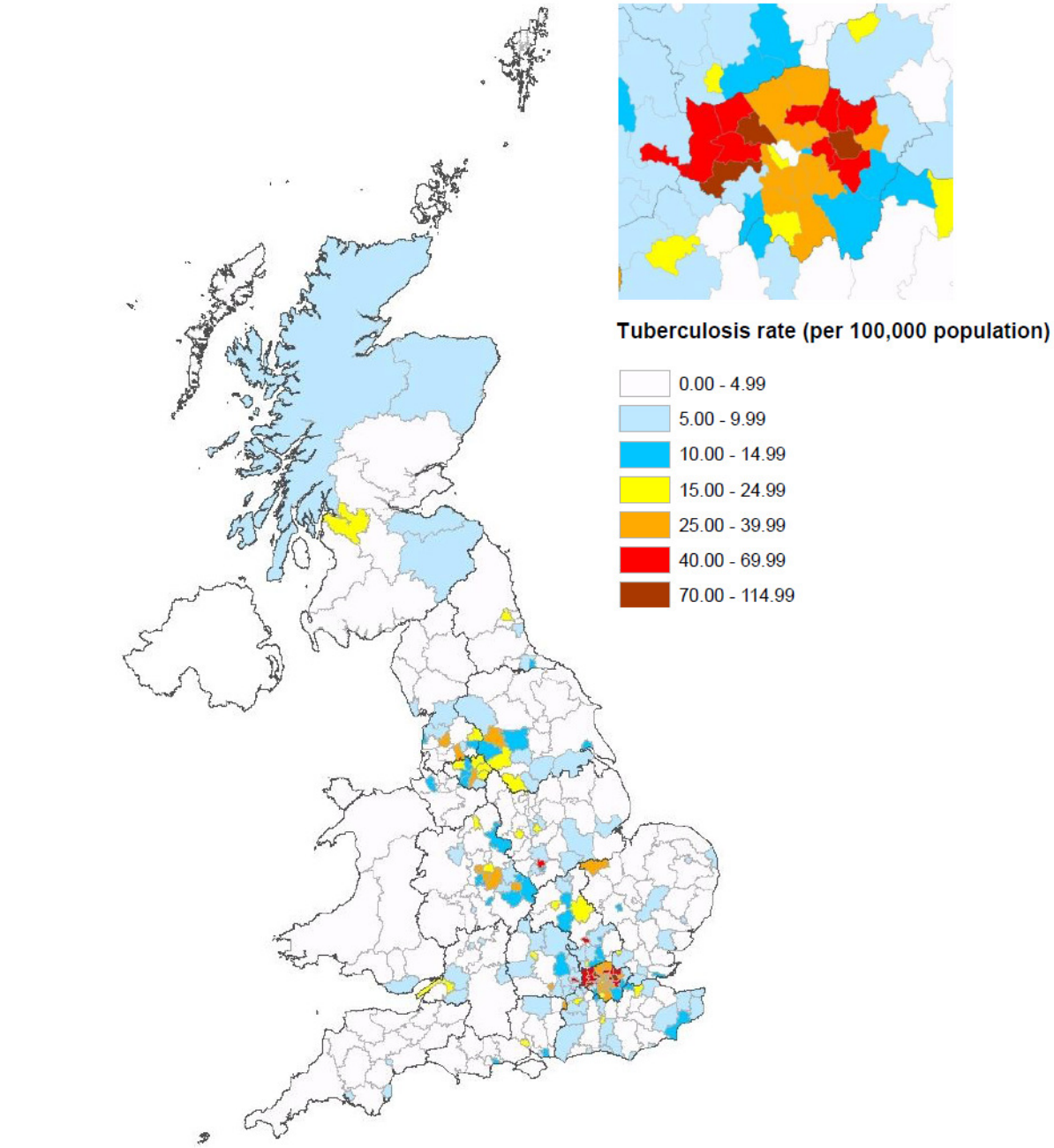


Figure 4 Three year average tuberculosis case rates by local authority (England), health board (Scotland and Wales) and Northern Ireland, UK 2010-2012

3.2 Leicester, Leicestershire and Rutland TB epidemiology

3.2.1 TB disease

Contrary to the UK as a whole and most PHE regions including the East Midlands TB case report rates in LLR have gradually fallen since 2005 (figure 5). In Leicester City the TB incidence rate has fallen from 77/100,000 to 56/100,000 during this time period. The TB

incidence rates in the county 2005 - 2012 have remained at a very low level (5/100000) (figure 6).

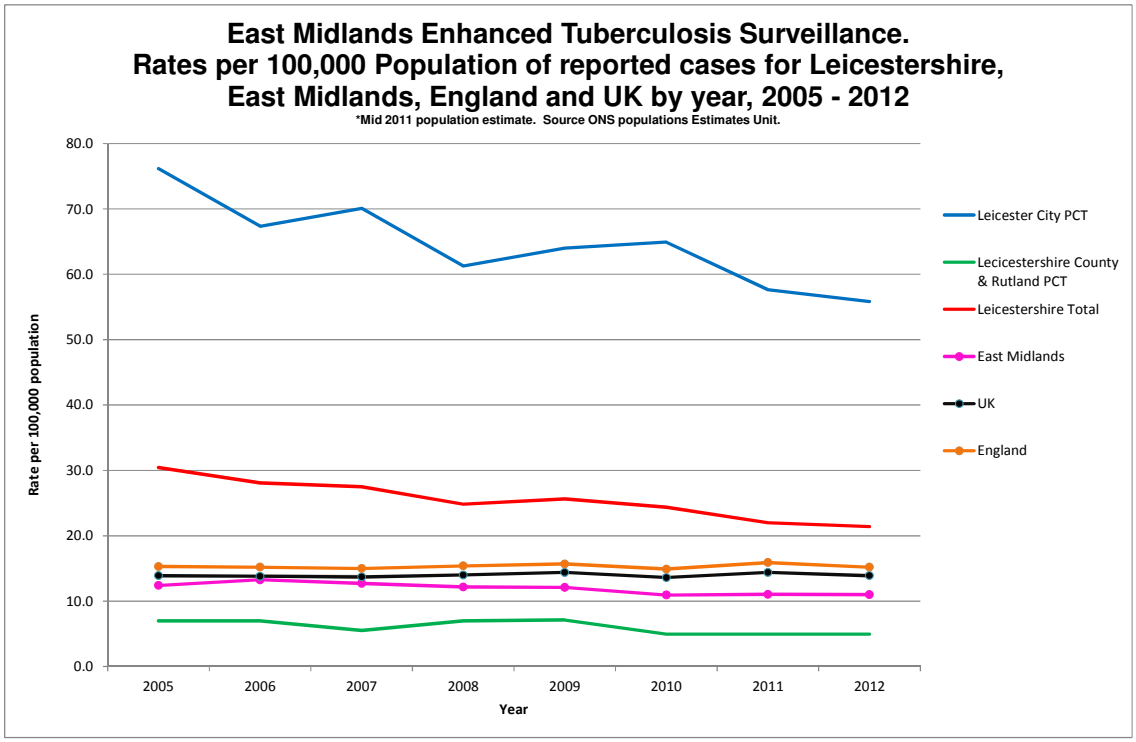


Figure 5 Rates of Reported cases of TB across LLR 2005 - 2012

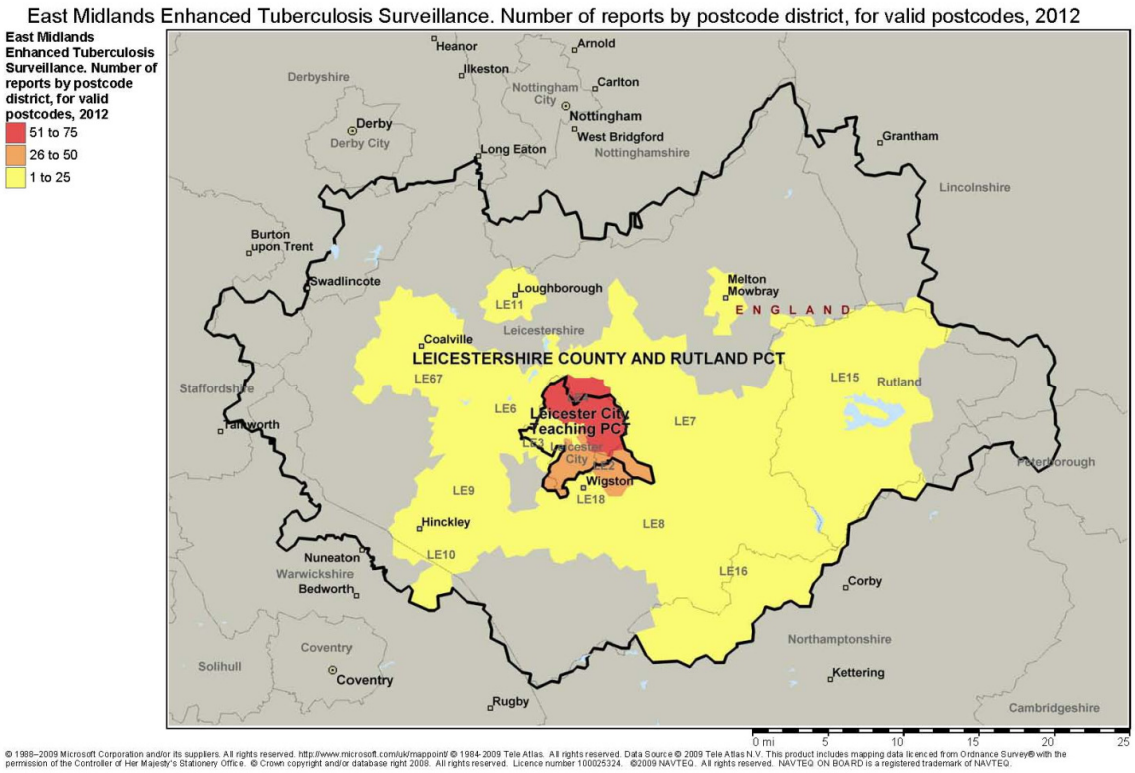


Figure 6 Mapping of TB incidence rates for LLR 2012

3.2.2 Population change and latent TB infection

50% of all TB notifications in the UK are from individuals born outside the UK. Leicester residents come from 50 countries across the world, making it one of the most ethnically diverse cities in the UK.

In 2011 34% of Leicester residents were born outside the UK, and nearly half of these arrived between 2001 and 2011. The most commonly reported country of birth of non UK born Leicester residents is India (11%). 68% of foreign born residents were aged between 15 and 44 when they arrived in the UK [13].

Leicester is a designated National Asylum Seeker Service dispersal city, and home to approximately 450 asylum seekers. Recently there have been increasing numbers of asylum seekers from sub-Saharan Africa, predominantly from Zimbabwe, but with others from Afghanistan, Somalia and Eritrea.

The vast majority of active TB cases develop the disease after previously acquired latent TB infection. The burden of TB in Leicester is, to a large extent, driven by the unidentified latent infection in these migrant populations.

A local retrospective analysis of 1323 cases of TB recorded over 58 months from across Leicester, Leicestershire and Rutland found:

- 79% occurred in non-UK born patients, and of these, 62% were of Indian Sub Continent (ISC) origin and 30% were African.
- 84% were aged between 16 and 35 at the time of entry to the UK and of these 51% and 79% developed TB within 5 and 10 years of arrival respectively.
- 90% of cases are thought to have occurred spontaneously (i.e. not following close contact with a case) [14].

Despite the on-going high levels of immigration from South Asia and sub-Saharan Africa in particular, Leicester has been more successful in overall disease control than other inner city areas in the UK with a similar ethnic population mix. However, Leicester City continues to have substantially higher rates of TB infection than the East Midlands regional average and the England average (figure 5).

In comparison to other major urban areas, Leicester TB services have achieved a consistent reduction in the overall number of active cases of TB. The number of active cases managed by the Leicester TB service has fallen by 30% from 310 cases in 2005 to 218 cases in 2012.

The same is not true of other major urban areas in the UK as can be seen when comparing the local data with West Midlands surveillance data (figure 7).

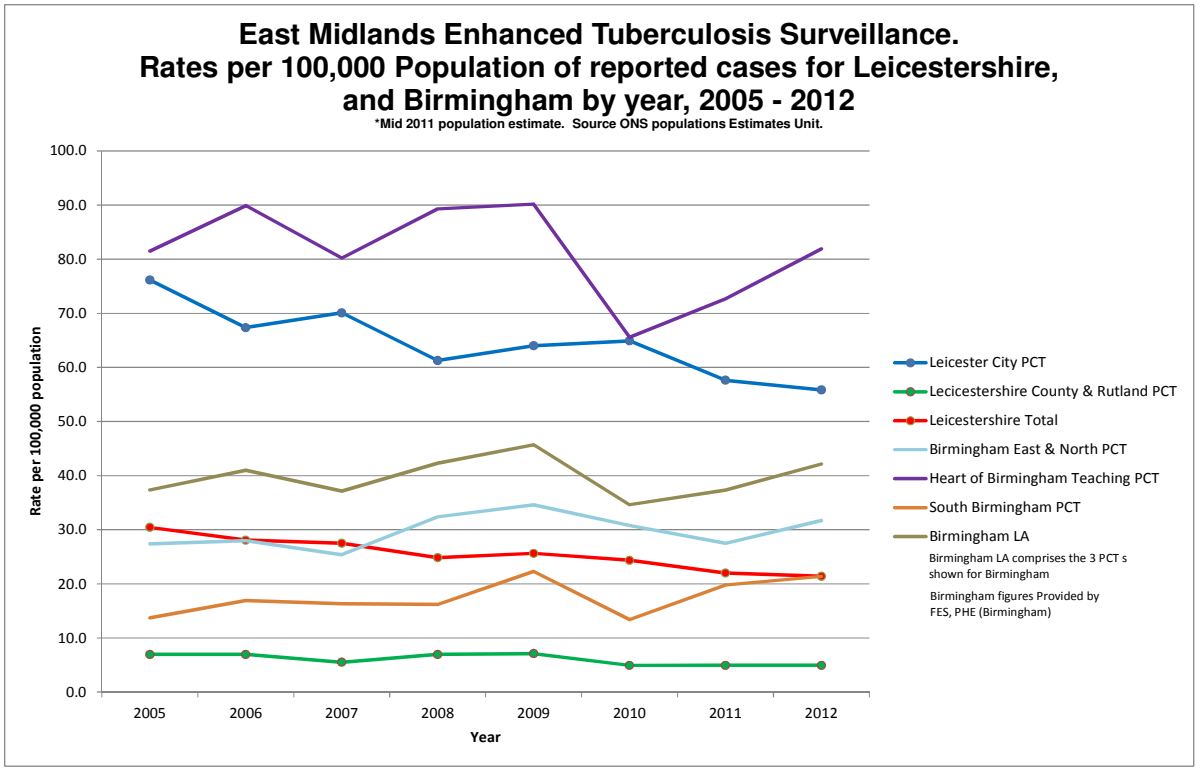


Figure 7 Comparison of TB epidemiology and incidence rates for LLR and Birmingham

3.2.3 Pulmonary and Non Pulmonary disease

As in all UK regions approximately 50% of all managed TB cases are diagnosed with pulmonary TB who would potentially transmit the organism to close contacts through coughing, particularly when the diagnosis is delayed or treatment is inadequate (figures 8a&b and 9a&b).

While case numbers are significantly lower in Leicestershire and Rutland compared to the UK average we tend to see significantly higher proportions of infectious pulmonary cases in this cohort. This is due to higher proportions of reactivated tuberculosis in UK born older people and cavitating pulmonary tuberculosis cases in young and middle-aged white adults in the context of alcohol and drug misuse. This means that despite overall low case numbers in the county there is still a substantial risk of local outbreaks and clustering of cases.

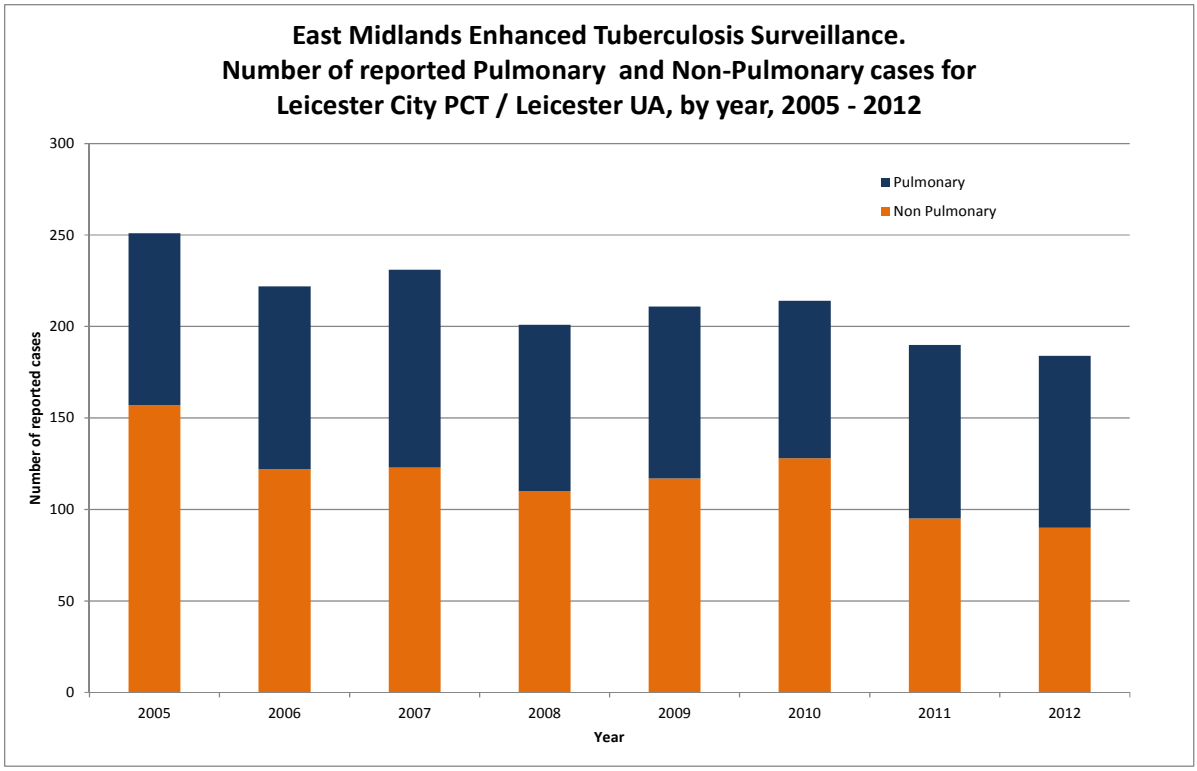


Figure 8a Number of reported TB cases by disease site Leicester City

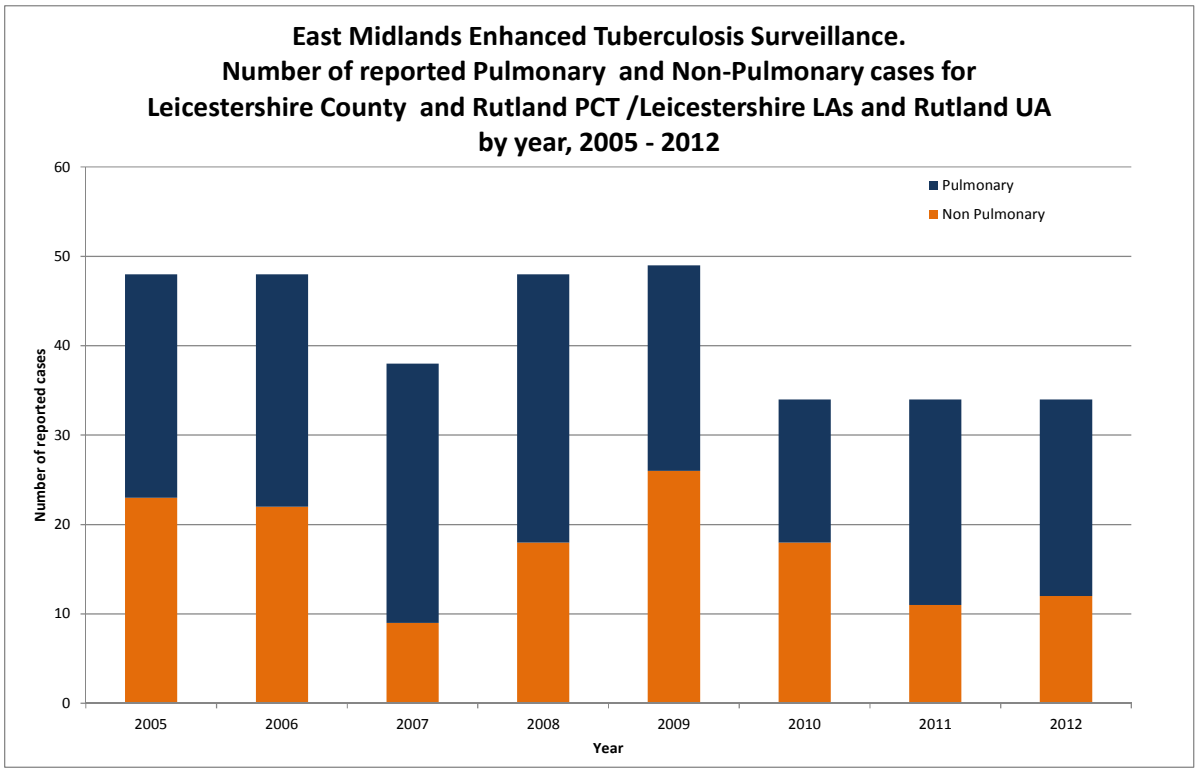


Figure 8b Number of reported TB cases by disease site Leicestershire and Rutland

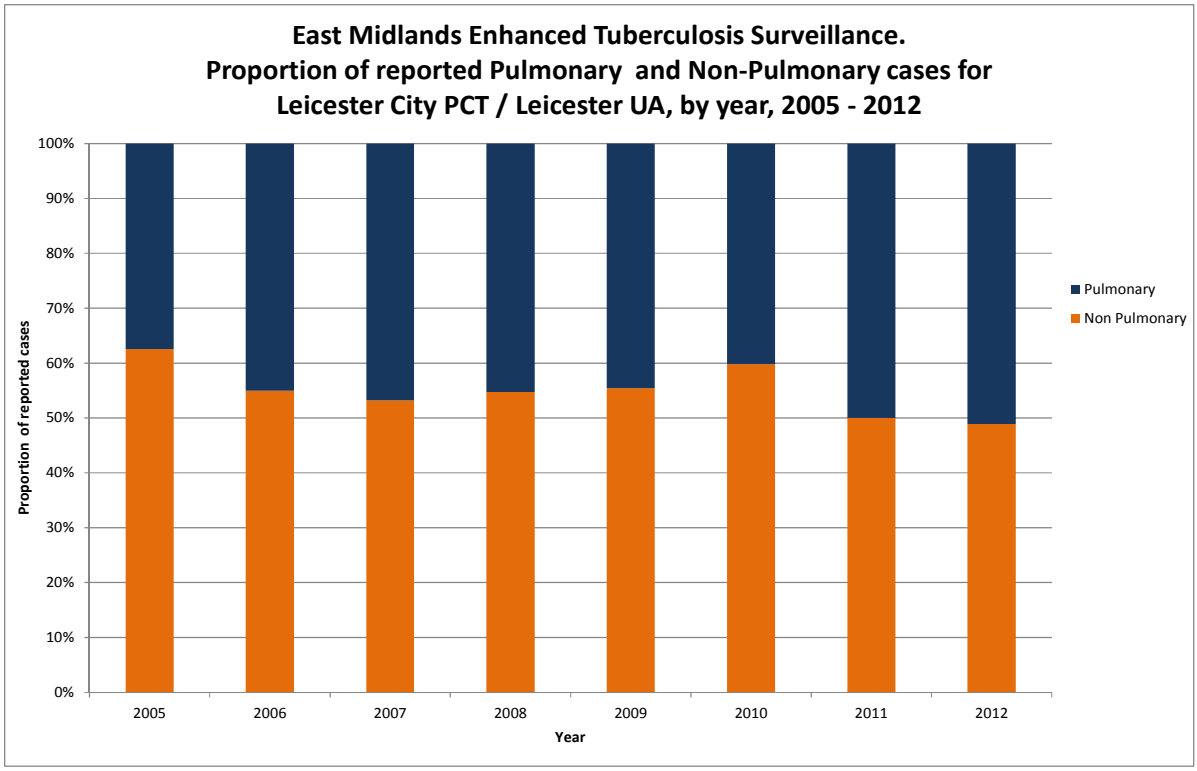


Figure 9a Proportion of reported TB cases by disease site Leicester City

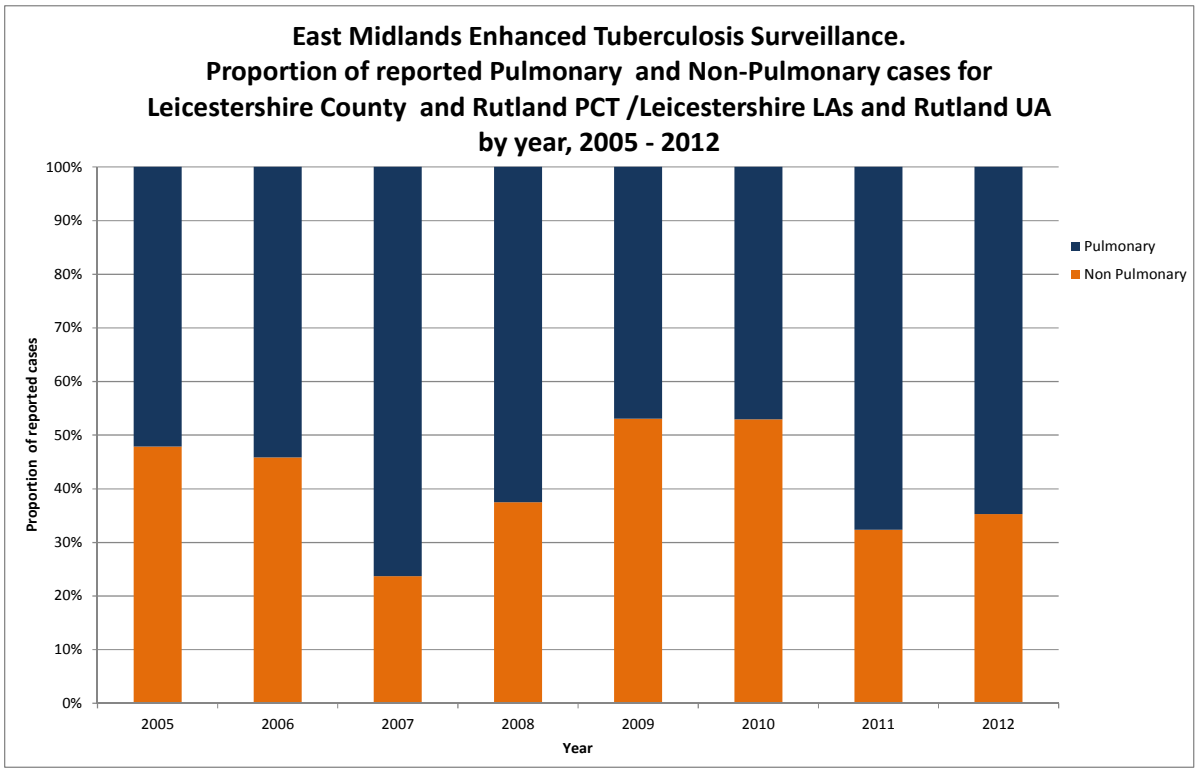


Figure 9b Proportion of reported TB cases by disease site Leicestershire and Rutland

3.2.4 Ethnicity

The ethnic distribution of TB cases is significantly different in Leicester City compared to the county. Although South Asians predominate in the city and the county, there are significantly higher proportions of white caucasians in Leicestershire and Rutland (figures

10a&b and 11a&b). Between 10 and 20% of active TB cases in Leicester City have black African ethnicity and are predominantly recent arrivals from sub-Saharan Africa (Zimbabwe and Somalia).

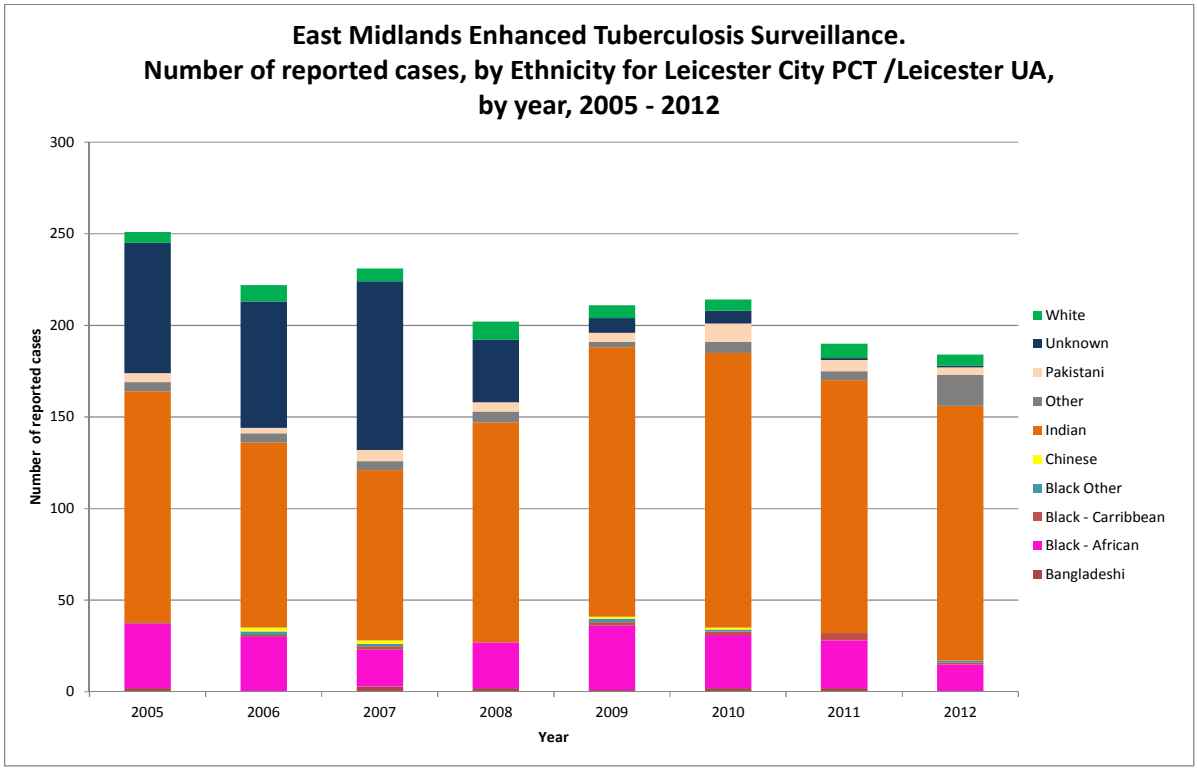


Figure 10a Number of reported TB cases by Ethnicity Leicester City (2005-2012)

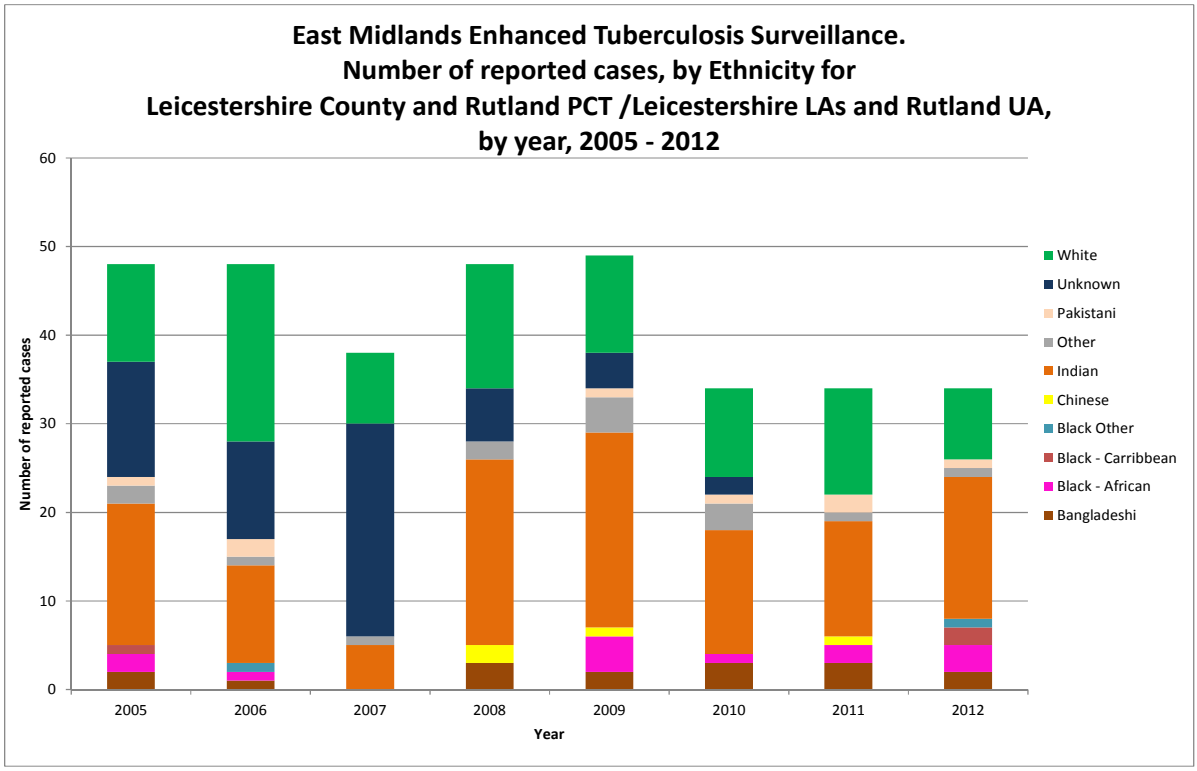


Figure 10b Number of reported TB cases by ethnicity Leicestershire and Rutland

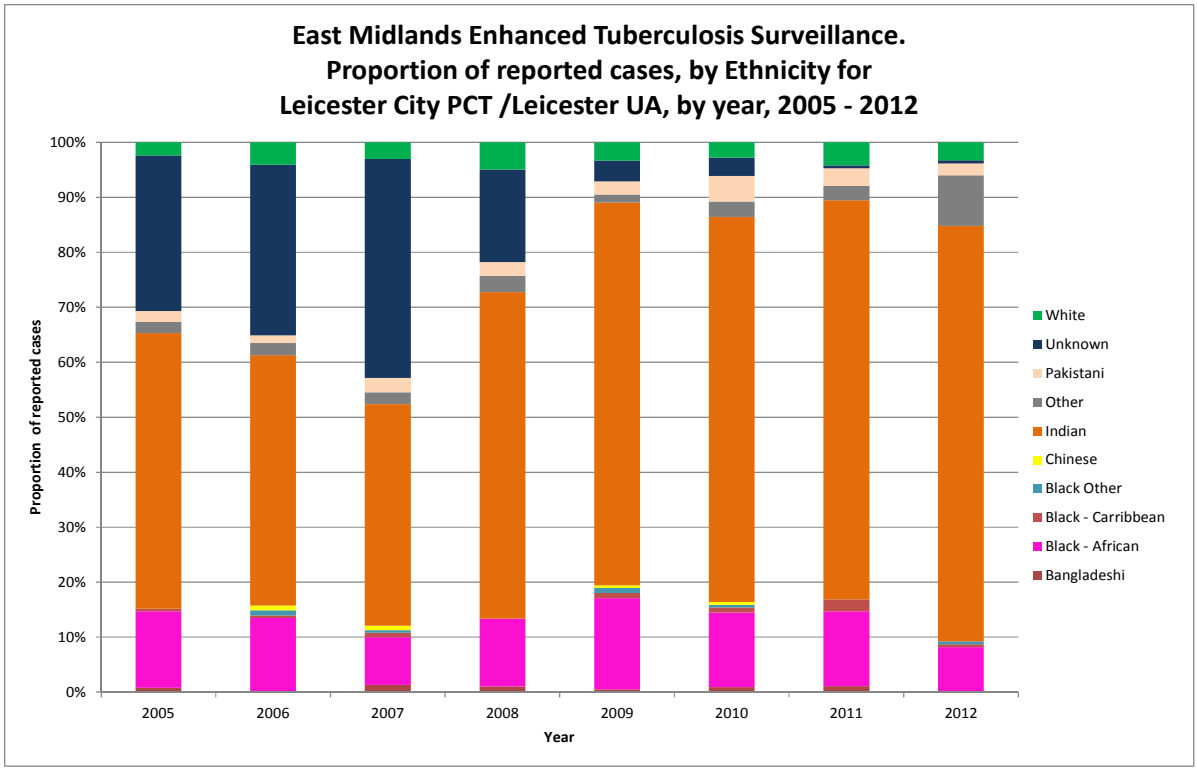


Figure 11a Proportion of reported TB cases by ethnicity Leicester City (2005-2012)

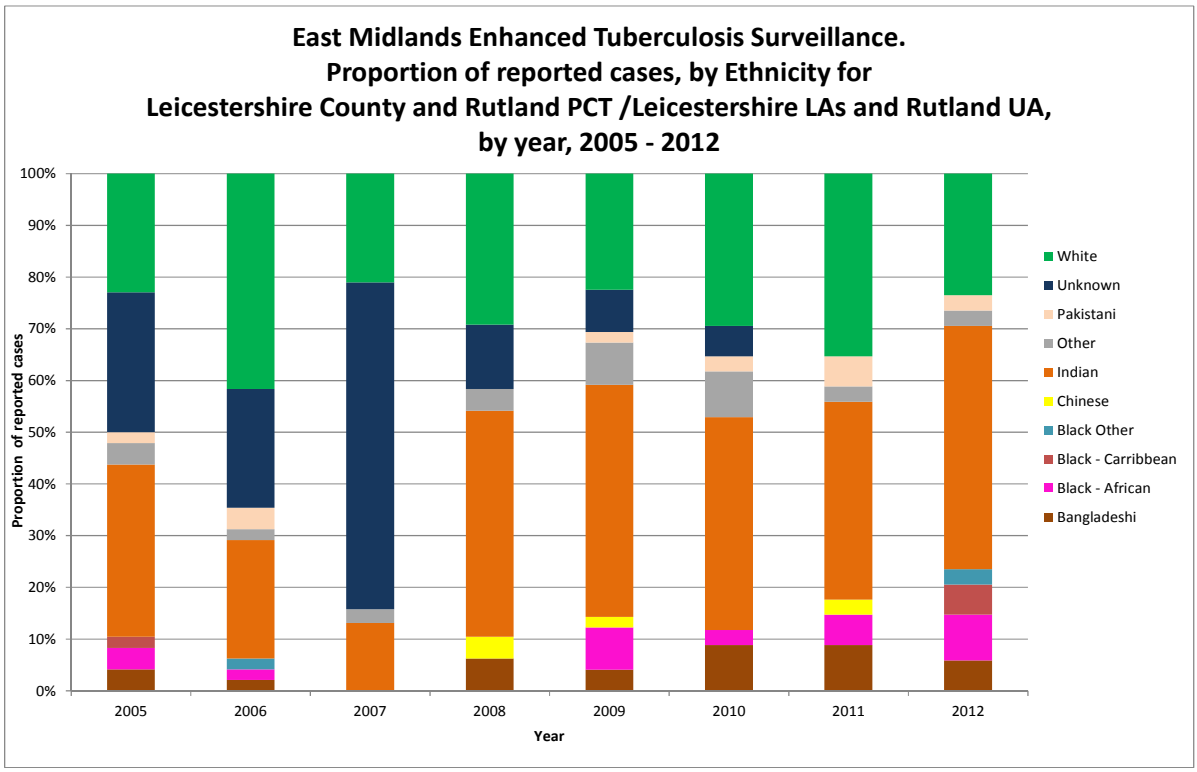


Figure 11b Proportion of reported TB cases by ethnicity Leicestershire and Rutland (2005-2012)

3.2.5 Age

Independent of gender, active tuberculosis is significantly more common in young adults aged 16-45 and most years there are also small numbers of newly diagnosed child cases and neonates (figures 12a&b). The vast majority of newly diagnosed young adult cases are non-UK born with a date of arrival within 5 years prior to diagnosis. Child cases tend to be

UK born and are generally associated with previous transmission from immigrant adult cases in the same family or household.

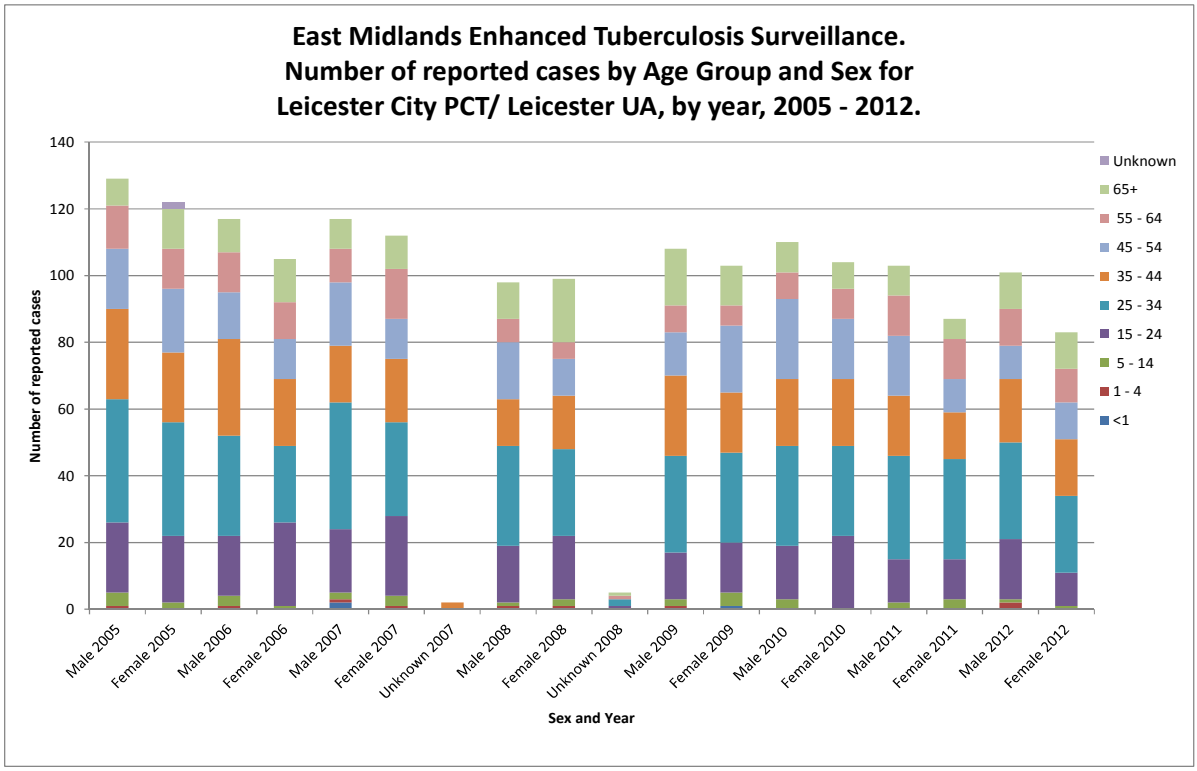


Figure 12a Number of reported TB cases by age and sex Leicester City (2005-2012)

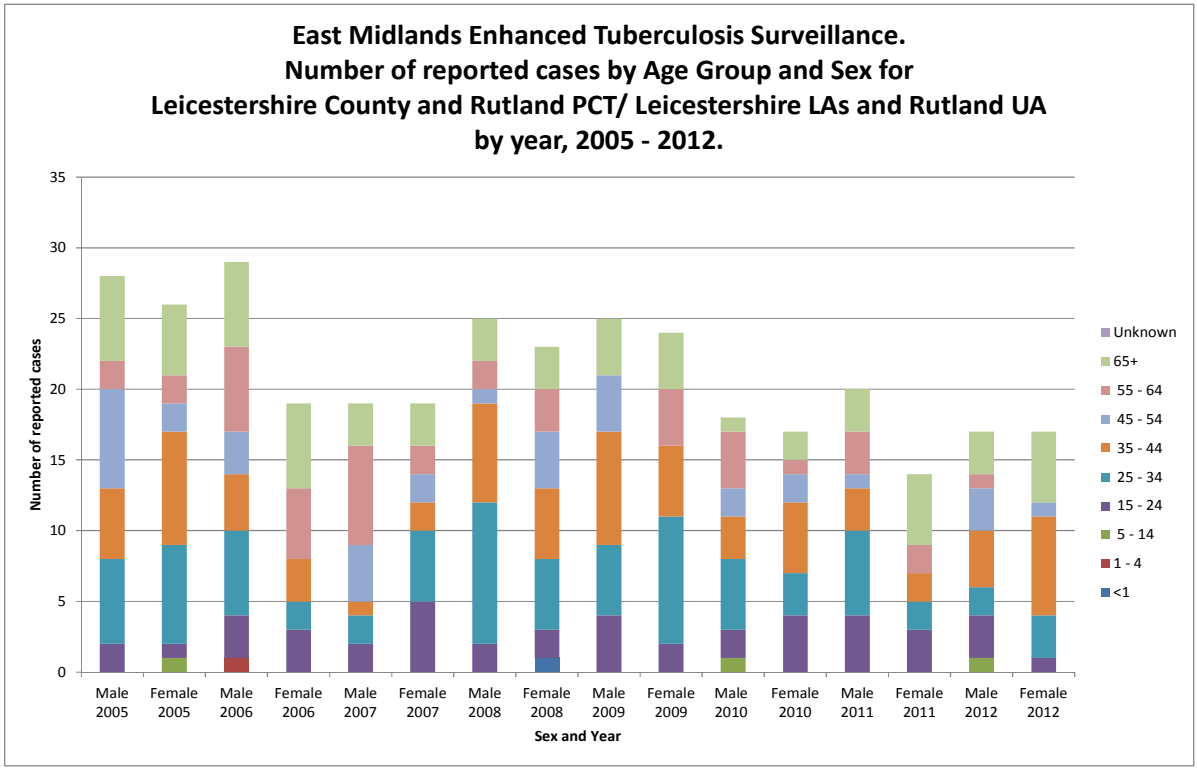


Figure 12b Number of reported TB cases by age and sex Leicestershire and Rutland (2005-2012)

3.2.6 Drug resistance

As a reflection of excellent treatment completion rates and TB nurse treatment supervision both isolated primary drug resistance rates and rates of multidrug resistance (MDR) are persistently low for LLR (figure 13)

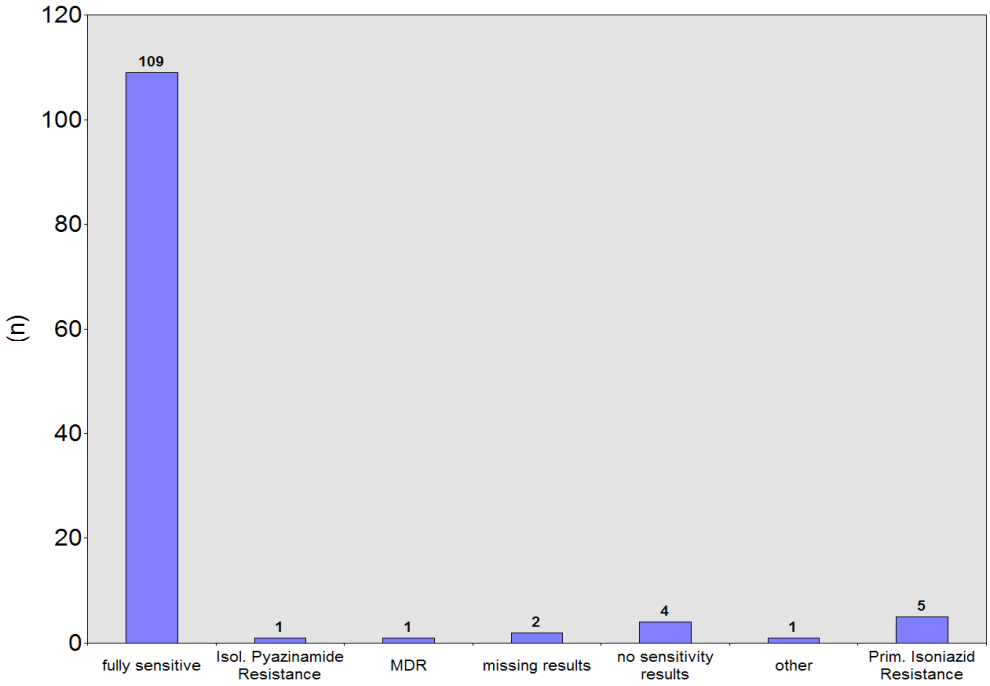


Figure 13 Drug resistances for LLR 2012

Prevention 50% of cases who develop active TB after an identifiable contact with another active TB case, do so within 2 years of this contact. This has highly relevant consequences for public health and represents three important opportunities for disease prevention:

i It is vitally important that active TB cases are diagnosed and treated early to minimise exposure of those closest to them to highly infectious cavitating pulmonary disease. In this way the absolute number of individuals with LTBI will be reduced significantly. Locally we have established a comprehensive rapid access system for patients with suspected disease based on their chest x-ray findings which has been in operation for almost 10 years.

ii There is a real opportunity to prevent active TB in recent TB contacts by promptly identifying and selectively treating those with LTBI.

iii It is now also widely accepted that there is an opportunity to prevent TB in immigrants from high prevalence countries (> 150/100000) with identifiable latent TB infection, particularly recent arrivals below the age of 36.

Based on blood test (IGRA) diagnosis the LLR TB services have gradually increased provision of treatment for LTBI (Isoniazid and Rifampicin for 3 months = 3RH) over recent years (figure 14). Preventive treatment was offered mostly in the context of contact screening but also in other high risk groups including patients eligible for anti-TNF treatment, patients on renal replacement therapy and some recent immigrants from high prevalence countries. Despite higher numbers of patients receiving treatment for LTBI than provided at most other UK centres, it is unlikely that active disease case numbers for LLR will fall further without more systematic screening for LTBI and preventive treatment of recent immigrants from high prevalence countries for TB. In other words, the remaining case burden is to a large part a simple reflection of the prevailing levels of non-UK acquired LTBI progressing to active disease after UK immigration.

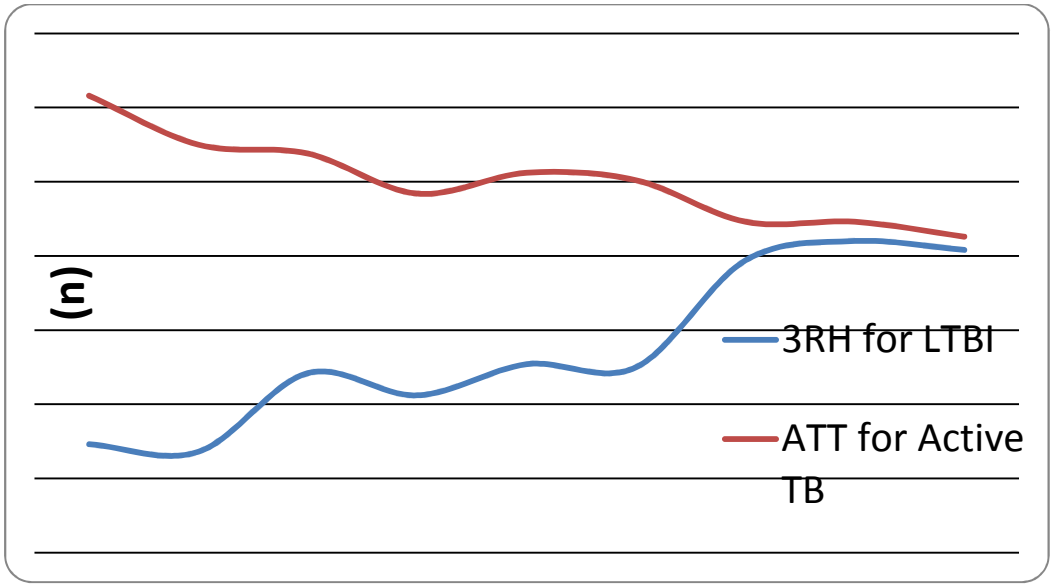


Figure 14 TB treatment and prevention trends for LLR 2005-2012 (2013 data extrapolated 08/10/13)

4 Current Services in LLR

The objectives of a comprehensive TB service are the investigation (detection), management and prevention of TB. Effective TB services require integrated and coordinated actions between Primary Care, Public Health , Health Protection, Acute Trusts, laboratories, other care services and increasingly, local authorities.

4.1 Background, Context & Rationale for Current Service Configuration

In 2001, Leicester experienced the biggest school outbreak of tuberculosis that had been recorded. The subsequent service review made the following recommendations;

1. formation of the *Tuberculosis Strategy Board* with terms of reference to include the development of guidelines and care pathways
2. additional specialist tuberculosis nurses; to a level of one per forty notifications
3. additional administrative / support staff for the TB nursing service
4. development of a comprehensive single database for the management and surveillance of patients with TB, contact tracing and screening of high risk groups

As a result of this review a service development plan was agreed and has been overseen by the TB Strategy Board since 2002.

4.2 TB Nursing Service

The TB nursing service coordinates a range of services that work in partnership to deliver a comprehensive TB service across Leicester, Leicestershire and Rutland. Within UHL these include respiratory medicine, infectious diseases, paediatric secondary care, and microbiology services. These services work closely with colleagues from Public Health England (formerly the Health Protection Agency).

Previously the TB nursing service was centralised under the management of Public Health and hosted in the City PCT on behalf of LLR. However, organisational change within the NHS led to the nursing service being transferred into the acute sector in April 2011 and the

service is now managed by UHL. To date, centralised, integrated service provision has been maintained to the model developed over the last 10 years.

4.2.1 Aims of the TB nursing service

- To promote and protect the health of individual patients and the general public through investigation, management & prevention of Tuberculosis (TB).
- To achieve the best health and well being outcomes for all individuals who receive treatment, screening, immunisation, health promotion / education.
- To avoid the development and spread of TB and drug resistant TB.
- To ensure a seamless service that promotes detection, concordance and cure.
- To constantly improve and adapt the service to meet changing requirements.

4.2.2 Remit of the TB nursing service

The Specialist TB Nursing Service operates across Leicester, Leicestershire & Rutland. It provides care to the population of the City and County and is responsible for;

- The investigation of suspected but unconfirmed TB
- The clinical nursing management of all TB cases (active and latent). This includes: comprehensive assessment and monitoring of concordance and compliance with the prescribed treatment regimen; monitoring for potential adverse treatment effects; & ensuring treatment completion. This includes the supervision of Directly Observed Therapy (DOT) when appropriate.
- Contact tracing and contact screening across the district.
- All patients with TB who are transferred in from other areas; including patients diagnosed and commenced on treatment abroad or within other UK healthcare trusts outside Leicester.
- The referral of TB patients and contacts to other areas for follow up and investigation.
- Delivery of the Selective Neonatal BCG Programme & New Entrant Screening for children and young people up to the age of 16.
- Assessment, processing and triage of all TB Rapid Referrals.
- Reducing hospital admissions and taking care of patients in the community by performing blood tests and taking sputum samples at home; acting as a first point of contact if problems occur with treatment
- Continually monitoring and reporting TB Notifications in order to detect potential incidents or outbreaks

Services are provided from dedicated TB clinics, nurse-led follow-up clinics and outreach services in patient's place of residence and a wide range of community settings.

Neonatal BCG Clinics are held at the following community settings:

- Springfield Health Centre
- Melbourne Community Health Centre
- Cossington Street Sure Start Centre
- Braunstone Health & Social Care Centre
- St Peters Health Centre

New Entrant Screening Clinics for children and young people up to the age of 16 are held at the Merlyn Vaz Health & Social Care Centre.

4.2.3 Service model

The TB Nursing Service operates a centralised integrated service across the primary/secondary interface and provides care to patients on hospital wards / OPD as well as community domiciliary visits. Neonatal BCG immunisation clinics are all community based. The service provides care to TB cases and contacts on treatment with a diagnosis of Active or Latent Tuberculosis, or under investigation for either of these conditions. National (JVCI) BCG vaccination selection criteria apply. A commissioned service currently only exists for New Entrant Screening performed up to and including age 16yrs.

The nursing establishment is currently 10.2 whole time equivalent posts structured as;

1 WTE Lead Nurse/Clinical Nurse Manager (Band 8b)

3 x WTE TB Nurse Specialists (Band 6)
3 x Part time TB Nurse Specialists (2.2 WTE Band 6)
} 5.2 WTE Specialist Nurses

1 x WTE Support Officer (Band 4)
1 x Part time Cultural Link Worker (0.6 WTE Band 4)

Neonatal BCG Vaccination Programme / New Entrant Screening Programme:
1 WTE BCG Co-ordinator (Band 7)
2 Part time Support Workers (1.4 WTE Band 3)

Admin & Clerical Support:
2 WTE Administrators (contact screening clinics)

In addition to the permanent resident population of Leicester, Leicestershire & Rutland, the Specialist Nurses provide care to the following groups:

- Travelling families when resident in Leicester, Leicestershire & Rutland
- Homeless population
- Non resident clients for duration of their TB treatment or residency-then handed over to specialist services in their own area as appropriate
- Temporary residents
- Unregistered patients
- Prisoners & Inmates of YOI
- Neonates BCG programme
- New UK Entrants <16yrs old
- Asylum Seekers / Refugees

4.2.4 Summary Quality and Performance Indicators

The TB nursing service works to maintain local as well as national standards.

For newly diagnosed cases of TB:

- Patient to be referred within 1 day of diagnosis (80% target)
- Patient to be contacted by TB Nurse specialist within 2 working days from receipt of referral (100% target)
- Home visit to be undertaken within 5 working days from receipt of referral (for outpatients) or discharge from hospital (100% target)

For Rapid Referrals:

- All referrals discussed with TB Physician within 1 working day of receipt (100%)

For Neonatal BCG Programme:

- Routine referrals seen before 8 weeks of age
- Urgent referrals (for travel etc) seen within the same working week

For all cases:

- All cases to be managed by appropriately trained people with expertise in TB (100%)
- All cases to receive the standard recommended drug regimen *except in the presence of* contraindications; meningeal TB; CNS involvement; drug resistance (100%)
- All local referral & care pathways are updated & reviewed
- All local prescribing policies & practices are updated & reviewed
- All local paediatric & neonatal management protocols are updated and reviewed
- All cases to have clinical notes that document treatment monitoring and treatment completion (100%)
- All patients to have an individual case manager/ TB specialist nurse or named key worker (100%)
- All patients to be risk assessed for adherence to treatment. Risk assessment protocols incorporate consideration of DOT and enhanced treatment support mechanisms (100%)

All cases of TB (active and latent) have an individual, agreed plan of care, developed in conjunction with patients, carers and any other relevant healthcare provider. Written and verbal information is provided to all patients in an appropriate language / format.

There is an emphasis on relieving anxiety, helping to achieve concordance and treatment completion through awareness of different treatment options, awareness of side effects, and the importance of adhering to the treatment regimen. A Cultural Link Worker (0.6WTE) is employed by the nursing service to promote effective case management and to raise community awareness about TB to combat stigma and myths, which may delay presentation and impede contact tracing.

Since 2002, the complexity of TB cases has increased and the number of patients requiring DOT in order to meet successful treatment outcomes has increased. In 2009 6 patients received DOT. In 2012 there were 18 active cases requiring this level of support.

4.3 Rapid Access Service

Early diagnosis and treatment of infectious TB is an important strategy for controlling the burden of disease by minimising both the spread of infection and secondary disease in close contacts.

Since 2005, a centralised Rapid Referral System has been in place in Leicester and Leicestershire for the early assessment of suspected TB by a specialist physician. The system is triggered by a list of “red-flag” symptoms submitted on a questionnaire template and/or appropriate radiology coding by the reporting radiologist of all abnormal chest radiographs (CXRs) compatible with a possible diagnosis of TB.

The Rapid Access Service is integral to the Specialist TB service. It is co-ordinated full-time by a Specialist Support Officer and supported by TB Physicians with the provision of a specific weekly ‘ad-hoc’ outpatient clinic. The patient pathway is illustrated in figure 15.

The Rapid Access Clinic model [13] currently manages between 300 and 400 referrals with suspected TB disease per year. It promotes early diagnosis and treatment of the disease to prevent progression to more infectious cavitating and smear positive disease.

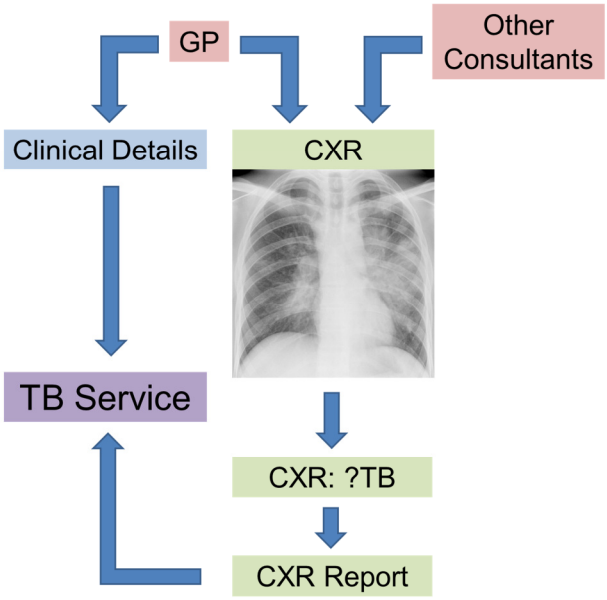


Figure 15 Rapid Referral Service Pathway

Between 2007-2009, 288 cases were identified through the Rapid Access System and 300 cases were diagnosed through other pathways. These patient cohorts were used to undertake a published analysis of the service [13] which found:

- Radiological coding of CXR reports was the primary trigger for 93.8% of referrals.
- A significantly higher proportion of cases identified through Rapid Access were pulmonary.
- The mean symptom duration before TB notification and specialist assessment was shorter in those clients referred through Rapid Access.
- No differences existed in age, gender or ethnicity of patients identified through Rapid Access or other pathways.

4.4 Infectious Diseases Unit

At the Infectious Diseases Unit (IDU) there are four consultant physicians who specialise in treating TB, led by a lead clinician. There are ten inpatient negative pressure isolation rooms on the IDU, including 2 medium secure isolation rooms for management of patients with suspected or proven MDR-TB. A 'hot' referral system for TB is available onto IDU and there are rapid access outpatient clinic slots allocated for TB patients. IDU manage and lead on all HIV related TB disease and LTBI.

4.5 Respiratory TB service

The TB nursing service is managed and led by the Department of Respiratory Medicine with a named respiratory TB lead consultant. Within the department there are 20 respiratory consultants trained in the diagnosis and treatment of tuberculosis with a TB Lead physician taking responsibility for all contact screening, new entrant screening of children and young people and LTBI clinics.

The team also leads on the integrated TB database maintenance and development and TB board quality assurance through reporting of epidemiology and outcome. There is an active TB cohort research unit led by a Senior Lecturer with TB interest who provides the rapid access TB clinics at Glenfield Hospital. This respiratory team offer inpatient facilities at Glenfield Hospital and outpatient services at Glenfield Hospital and Leicester General Hospital. All bed holding respiratory consultants have access to negative pressure facilities on Ward 17 at Glenfield Hospital.

4.6 Children's services

The Children's hospital is based on the Royal Infirmary site. There is one paediatric consultant lead for TB within the Children's hospital

4.7 Multidisciplinary Team

There is a monthly TB MDT, chaired by the TB Lead Clinician for Infectious Diseases. This is attended by Consultant Physicians from Infectious Diseases, Paediatrics and Respiratory Medicine, Consultants in Medical Microbiology and Public Health, TB Specialist Nurses and Specialist Pharmacists. This provides a forum for the discussion of difficult TB cases, including those with drug resistance or major intolerance, or other obstacles to routine care.

4.8 Voluntary Sector Service Provision

LLR has no TB specific voluntary organisations working with TB patients. Patients co-infected with HIV have access to LASS (Leicester Aids Support Services). NHS TB services work with LASS on TB/HIV awareness raising projects.

All patients with TB are made aware of TB Alert, the national voluntary sector organisation that can provide information and support.

4.9 The role of Public Health England- Health Protection Services- in TB

PHE undertake disease surveillance, outbreak and information management, and support in service planning [9]. Consultants in Communicable Disease Control (CCDC) are employed by PHE and work closely with TB services and the health protection leads in the local authorities.

The CCDCs and Health Protection Units (HPU) have a public health leadership and coordination role in the timely investigation and management of TB incidents or outbreaks in various situations including prisons and schools (with support from local TB services).

In prisons the CCDC should be made aware when a case is believed to be possibly, probably, or definitely infectious (defined as sputum microscopy smear-positive pulmonary or laryngeal TB). The HPU also works with the prisons pro-actively in TB prevention, detection and control in prisons [16].

In a school or educational institution following diagnosis of TB in a pupil or member of staff, the CCDC will explain the prevention and control procedures to staff, parents and the press. Advice on managing these incidents and their public relations is also available from the HPU [3].

The CCDC will provide advice in cases of doubt when planning contact tracing after diagnosing sputum-smear-positive TB in an inpatient. Further advice is available from the regional or national Health Protection Directorate of Public Health England [3].

When a TB incident is identified as an outbreak which may pose a threat of transmission to the wider population in general current guidance states that it is the responsibility of the CCDC to declare an outbreak and convene and chair an outbreak control team (OCT) [17]. Following the formation of Public Health England the guidance is under review and it is envisaged that the CCDC will make this decision in conjunction with the DPH.

4.10 Governance and Performance Management

The service in Leicester has been overseen by the TB Strategy Board since 2002 and this governance structure has ensured that TB care pathways and case management protocols are monitored, maintained and reviewed against national and global recommendations.

The TB Board meets on a quarterly basis and receives regular reports of audits, research, performance statistics and trends.

Following the implementation of the Health and Social Care Act 2012 and the transfer of commissioning responsibility to CCGs, the Board is reviewing its membership to ensure it is accountable to appropriate organisations and structures and able to continue to deliver improvements in TB care. The service commissioner is not currently represented on the Board and there is also no patient representative.

4.11 LLR Patient Pathway

Details of the TB patient pathway will vary but, in the absence of an outbreak, patients will generally be referred with suspicious symptoms to the relevant secondary care speciality (Respiratory / Infectious Diseases / Paediatrics). In LLR, urgent referrals that occur via the Rapid Referral route are triaged and initially investigated by the nursing service in the community prior to TB physician appointment or potential admission as appropriate. Admissions to Glenfield Hospital usually occur via CDU.

All patients with HIV and/or suspected or known MDR TB should be referred through the IDU to ensure adequate infection prevention procedures.

Most adult TB patients should be investigated and seen to commence treatment as outpatients; hospital admission is not recommended unless the patient is clinically very unwell or social circumstances dictate (e.g.; homelessness, hostel dweller or prison inmate).

All children up to the age of 16years are treated by the Children's TB lead at the Children's Hospital and regular TB contact screening clinics occur for the screening and investigation of children at the Children's outpatient department.

After diagnosis and initiation of treatment, the patient will be allocated to a named specialist nurse case manager. The case manager will have responsibility for individual patient assessment, and will develop and monitor care plans in the community for a minimum of 6 months or until treatment completion. Contact tracing is commenced at the time that a referral is received by the TB nursing service.

Outpatient monitoring in TB Physician and/or nurse-led clinics occurs regularly throughout case management. Follow-up clinics take place on all 3 UHL sites. In LLR, the TB nursing service performs a centralised, coordinating function. The specialist nurses ensure integrated and seamless provision of care to every TB patient, as well as timely and appropriate contact screening, and the submission of statutory surveillance data, regardless of which TB physician is responsible for their clinical care.

Referrals to the specialist nurses are received through the following different routes :

- Routine referral by TB physicians / paediatrician on suspicion or diagnosis of TB
- Rapid Referral of suspected cases [usually resulting from abnormal chest x ray] from GP's, other clinicians, occupational health, prison healthcare providers, leading to immediate triage, investigation & clinical assessment within defined timeframes.
- BCG's / New Entrants (<16yrs) via Immunisation Dept. LPT Child Health Services, Bridge Park Plaza or directly to the BCG Coordinator. Also via the Health protection agency from Port Health.
- Open access to TB Specialist Nurses Monday to Friday (08.30am – 17.00pm).
- Contacts are identified by the TB nursing service but may also be referred by GP's, other TB services or the Health Protection Agency

Appendix A provides a schematic representation of the patient pathway.

Specialist nurses provide general advice & guidance to clinicians throughout primary & acute care organsiations, and also to the general public and voluntary and statutory organisations.

5 Commissioning arrangements

Following the implementation of the Health and Social Care Act 2012 the responsibility for commissioning TB diagnostic and treatment services transferred from Primary Care Trusts to the newly formed Clinical Commissioning Groups (CCGs).

In Leicester, Leicestershire and Rutland the Leicester City CCG is the lead commissioner for TB diagnosis and treatment services on behalf of all CCGs in the area.

The 2013/14 contract for TB services is held with University Hospital Leicester (UHL). The TB nursing service is commissioned as a block contract with a value of £456,000. There is an additional block contract value of £109,000 that is believed to cover the costs of providing IGRA diagnostic tests in the rapid access clinic, although this is labelled in the contract as TB out patients.

These two values do not represent the total investment in TB services as funding for TB diagnosis and treatment will form part of the wider investment in thoracic medicine, infectious diseases, and pathology and radiology services within UHL. However it is not possible to separate out the TB element of these services in order to identify the total value of the contract concerned with diagnosing, and treating TB.

NHS England has commissioning responsibility for the Neonatal BCG vaccination programme where the vaccination is not given as part of the maternity pathway. A local review of the neonatal BCG vaccination programme was undertaken in 2005 which resulted in agreement that the programme should be delivered by the TB nursing service. At that time a business case was submitted and approved to fund additional nursing capacity and administrative support to deliver the programme. These posts form part of the substantive staffing complement of the TB nursing service. Currently NHS England does not hold a contract with UHL for the neonatal BCG vaccination programme, and this is encompassed within the TB nursing service block contract held by Leicester City CCG.

Health protection services provided by Public Health England are not commissioned in the same way as diagnosis and treatment services as PHE activities are funded directly by NHS England. As a result, it is not possible to identify the resource input from PHE relating to the control of TB. Details of this service are given in section 3, TB services in LLR.

6 Guidance and Best Practice

6.1 Key policy documents and guidance

6.1.1 Chief Medical Officer's Action Plan

In 2004 the Chief Medical Officer published a TB action plan [4]. This formally recognised TB as a significant threat to public health and identified the government's long term goal for the reduction and elimination of TB within England.

It set out three main aims:

- Reduce the risk of people being newly infected with TB

• Provide high quality treatment and care for all people with TB
• Maintain low levels of drug resistance, especially for Multi-drug Resistant TB (MDR-TB)

It was envisaged that these aims would be achieved through the implementation of a 10 stage action plan which would direct government, health service's (commissioners and providers) and local communities to reverse the rise in TB.

The 10 Key Actions:

1. To maintain high awareness of TB, particularly among health professionals, high-risk groups and people who work with them, teachers, and the public.
2. Strong commitment and leadership: aim to create a strongly led, well co-ordinated and adequately resourced national TB programme, with all those working to deliver the programme having a clear focus on what needs to be achieved and best practice for doing these.
3. High quality surveillance: aim to provide the information required to local, national and international levels to identify outbreaks, monitor trends, inform policy and the development of services, and monitor the success of the TB programme.
4. Excellence in clinical care: aim to provide uniformly high-quality, evidence based treatment and care for patients with suspected and diagnosed TB, with all patients having their outcome of treatment recorded and at least 85 per cent successfully completing treatment.
5. Well organised and co-ordinated patient services: provide high-quality co-ordinated services for TB diagnosis, treatment and continuing care, which also meet the needs of individual patients.
6. First class laboratory services: aim to provide laboratory services of consistent high quality which support clinical and public health needs, in keeping with the overall pathology modernisation programme.
7. Highly effective disease control at population level: aim to increase the evidence base for, and the consistency of application of public health interventions for TB.
8. An expert workforce: aim to ensure TB control has an appropriately skilled workforce and that physicians and nurses with expertise in TB continue to be recruited, trained and retained.
9. Leading edge research: aim to increase our understanding of TB and its control; improve the evidence base for its control; and develop better tools for its diagnosis, treatment and prevention.
10. International partnership: aim to contribute effectively to the global control of TB.

6.1.2 Toolkit for Planning, Commissioning and Delivery

In order to assist commissioners and service providers to implement the action plan, the Department of Health released a comprehensive Toolkit for Planning, Commissioning and Delivering High-Quality Services in England [9]. The toolkit provided a framework for assessing the local needs to support the planning and commissioning of high quality services. It recognised that commissioning of TB service need to go beyond the treatment of active TB cases, and highlighted the need to integrate the 3 levels of services, primary secondary and tertiary and indicates which might be best placed to commission each key element of a comprehensive TB service.

6.1.2.1 Key recommendations for commissioners:

- To undertake a local TB needs assessment to supporting the planning and development of local TB services, considering their local TB incidence and population demography, and potential changes to that demography, for example new demands as a result of population migration.
- Every PCT (CCG) 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 (level 1 and 2 services) may initiate investigations, a formal diagnosis should be best made by specialist service providers, reflecting the fact that TB is best diagnosed and managed by experienced specialists.
- Primary care has an important role in providing support to the patient throughout the treatment period.

6.1.2.2 Key recommendations for providers:

- TB (and suspected TB) must be 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 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 enhanced case management (ECM).
- Microbiology laboratories should be accredited and have sufficient throughput to maintain competency.
- Reporting information should be in line with current national surveillance standards.

The TB toolkit provides a more detailed commissioning framework, which identifies the essential components of a comprehensive TB care pathway. This is available at http://www.britishinfection.org/drupal/sites/default/files/DOHTBToolkit15June2007_0.pdf

6.1.3 Nice TB guidelines

The National Institute for Health and Clinical Excellence (NICE) 2011 guideline '*Clinical diagnosis and management of tuberculosis, and measures for its prevention and control'* [3] identifies key priorities for implementation. The guidelines expand the 2006 guidance which remains and underpins the 2011 guidelines. The Key priorities from 2006 which still stand are:

- The management of active TB through delivery of a standard drug regimen;
- Improvement of adherence to treatment through a named case worker and, if necessary, using Directly Observed Therapy (DOT)
- New entrant screening at port of arrival, primary care registration, entry to education and via links with statutory and voluntary groups working with new entrants.
- BCG vaccination for any baby at increased risk of TB.
- Diagnosing active TB
- Infection control and isolation of infectious cases
- Risk assessment and infection control in drug resistant TB
- Management of latent TB
- Active case finding and contact tracing
- Preventing infection in specific settings including healthcare and prisons

Extensions and amendments to the 2006 guidance are in the areas of:

- Diagnosing and management of latent TB – including when to use mantoux testing as opposed to IGRA and referral of patients with inconclusive results and management of close contacts of smear positive cases
- Diagnosing active TB
- DOT
- Screening new NHS employees, including healthcare workers from overseas

The NICE 2012 guideline *'Identifying and managing tuberculosis among hard-to-reach groups'* [5] recognises that the incidence of TB among new migrants and people with a history of drug use, alcohol use, homelessness and prisoners is much higher than in the general population.

The following recommendations were made to improve the way TB is identified and managed in hard to reach groups:

1. NHS commissioning board and Public Health England to maintain strategic oversight and commissioning of TB prevention and control activities
2. Public Health Teams to undertake health needs assessments
3. Public Health leads to undertake Cohort Review of TB patients
4. Commissioning of multidisciplinary TB support for hard-to-reach groups
5. Raising awareness and sustaining awareness of TB among health professionals and those working with hard-to-reach groups
6. Raising and sustaining awareness of TB among hard-to-reach groups
7. Identifying active pulmonary TB among those using homeless and substance misuse services
8. Identifying and managing active TB in prisons or immigration centres
9. Identifying and managing active and latent TB among vulnerable migrants; substance misusers and prison populations
10. Improving contact investigations
11. Maintaining and promoting rapid-access TB services
12. Enhanced case management for hard-to-reach groups

The guidance concerning TB in hard to reach groups [5] further recommends enhanced case management (ECM) is provided when someone has clinically or socially complex needs. It commences as soon as TB is suspected. As part of ECM, the need for directly observed treatment (DOT) is considered, in conjunction with a package of supportive care tailored to the person's needs.

6.1.4 WHO annual Global Report 2012

The World Health Organisation published its Global Plan to Stop TB 2011-2015 [14]. This sets targets for the scale up of interventions for TB care and control. This applies to treatment success rates in drug susceptible TB, testing and successful treatment of cases of Multi Drug Resistant TB (MDR-TB) and HIV testing. EU targets also include rates relating to culture of new pulmonary cases (80%) and a higher treatment success rate in the annual cohort (85% as opposed to 75%).

6.1.5 Royal College of Nursing Guidance

Guidance from the Royal College of Nursing [15] recommends that 'staffing levels for all TB services should be based on one WTE TB case manager per 40 notifications annually requiring standard case management, and one WTE TB case manager per 20 notifications annually requiring enhanced case management. While cases of LTBI should receive the same level of support as active cases, the duration of treatment for LTBI is 3 months as opposed to 6 months for an active case. This effectively reduces the ratio to 0.5 WTE TB case manager per 40 LTBI cases annually. This proposed staffing ratio does not include essential administrative staff, health advocates, interpreters and non-clinically qualified outreach staff working alongside TB MDTs'.

6.2 Best Practice

Immunocompromised individuals have been shown to be at a higher risk of progression from LTBI to active TB, and the utility of IGRA testing in particular patient groups is well recognised [20]. These groups include patients eligible for anti-TNF treatment and those receiving renal replacement therapy. TB in these groups often proves difficult to diagnose, progresses rapidly and can be complex to treat due to significantly higher rates of adverse effects. For patients attending haemodialysis units 3 times weekly there is also potential for transmission to other vulnerable patients and staff closely involved in their care. In a recent incident on a local haemodialysis unit such transmission is thought to have occurred to a number of staff members, when there was an active case of TB on RRT.

Local guidelines have been developed and implemented to identify patients who should be considered for LTBI screening.

7 Service User & Stakeholder Feedback

The last organisational Patient Experience Survey was conducted in 2010 and the results are set out in figures 16 and 17.

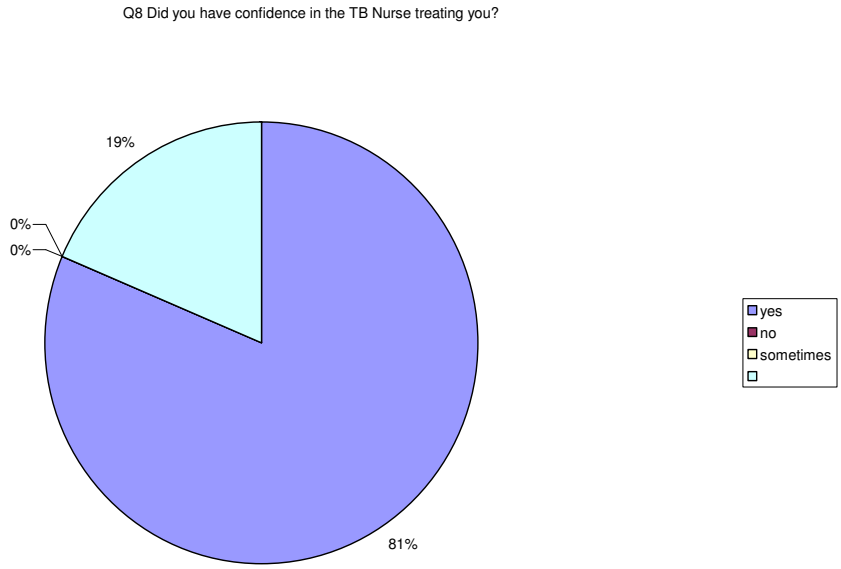


Figure 16 Level of confidence in the TB nurse

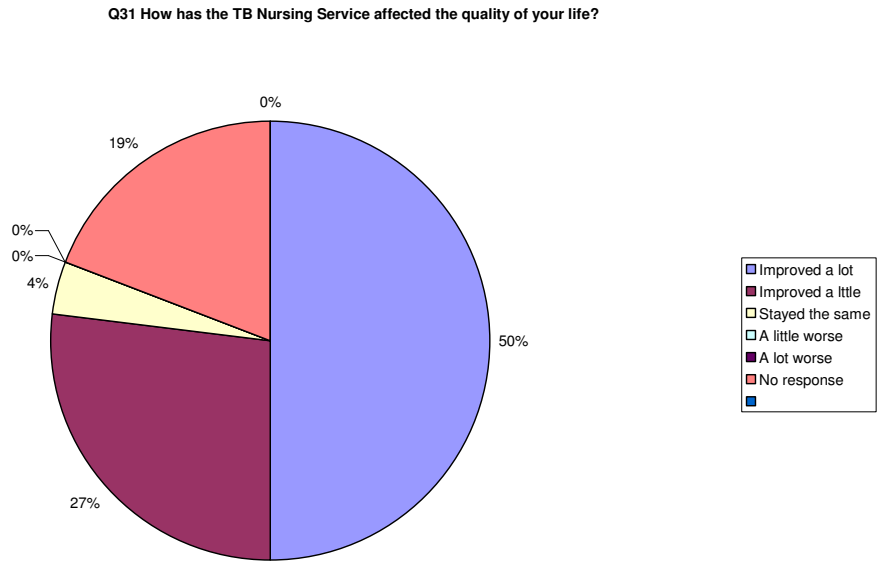


Figure 17 Perception of impact on quality of life

Further demonstration of the patient pathway experience can be seen in figure 18 which shows consistently high treatment completion rates for people on preventive treatment for latent TB infection (LTBI).

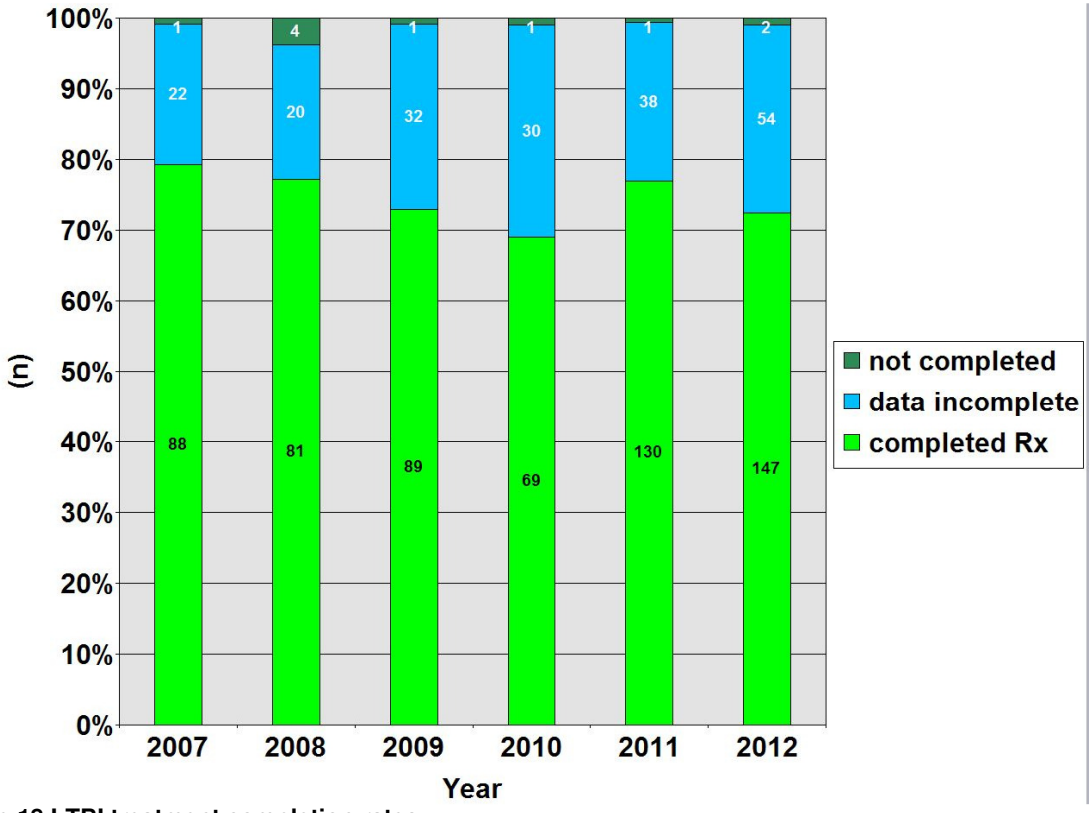


Figure 18 LTBI treatment completion rates

7.1 Audit of the TB Rapid Access Clinic and Patient Experience 2012

A specific audit of the rapid access clinic was undertaken with 30 patients to measure patient satisfaction with the referral process. The outcomes showed

- that average length of time from referral to being seen was 9.36 days (figure 19)
- that the majority of patients rated with the way their referral was handled by the TB service as excellent (figure 20).

7.2 Audit against NICE Recommendations

Following the publication of NICE guidance in 2006, an audit of local service compliance was undertaken. The results of this audit can be found at Appendix B. The service was compliant with 118 of the 134 recommendations in the guidance.

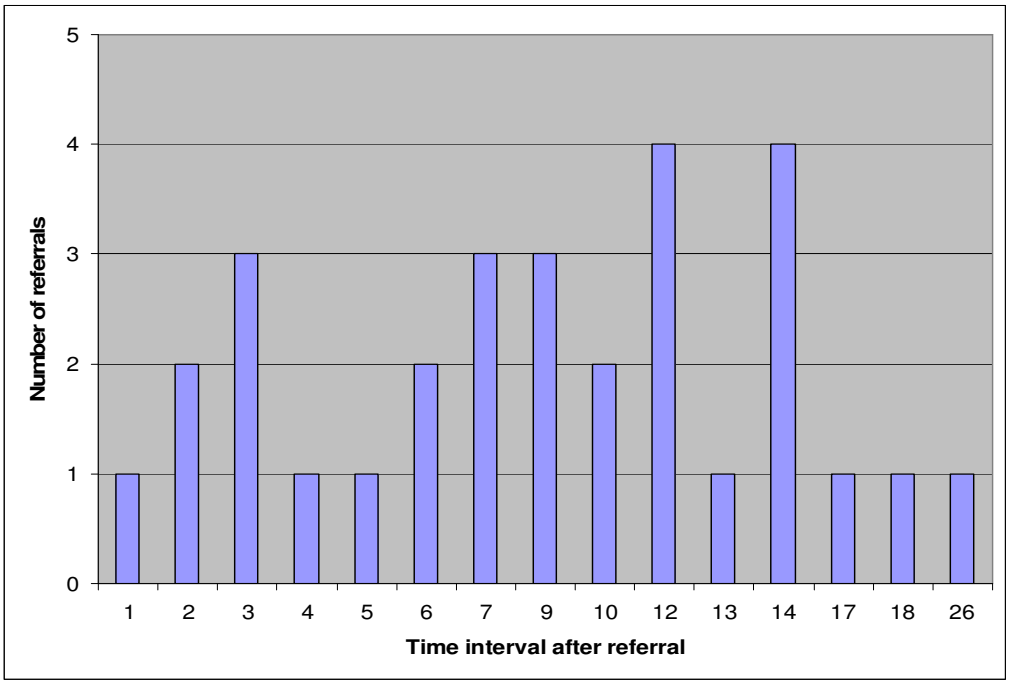


Figure 19 Number of referrals and time taken to be seen

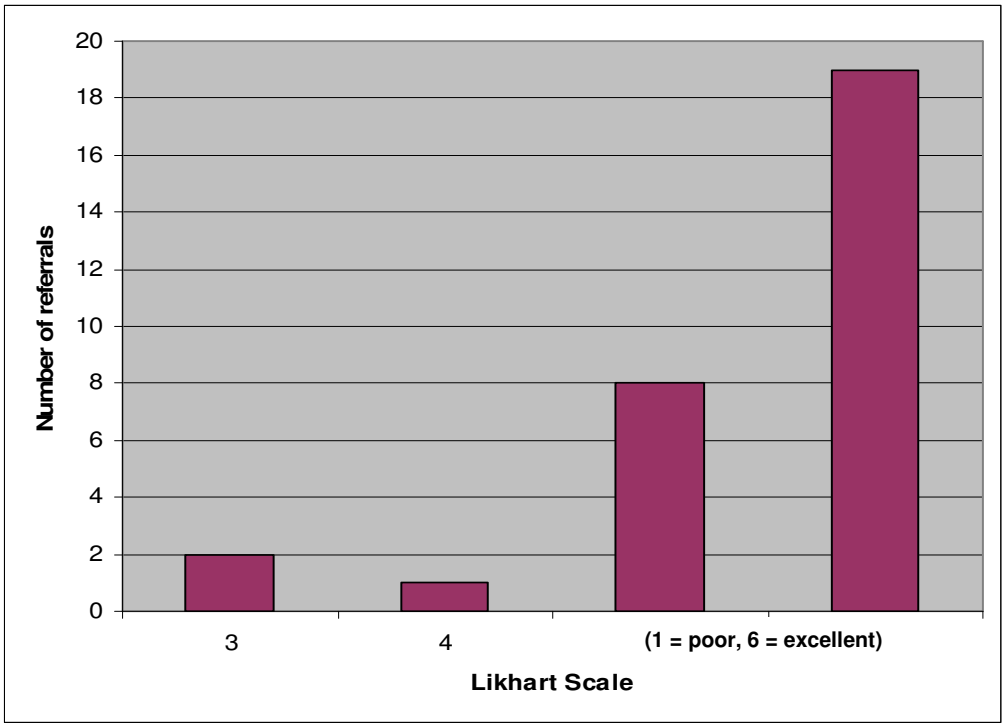


Figure 20 Patient satisfaction with referral process

8 Gap Analysis and Recommendations

The TB Board is an effective mechanism to maintain oversight of the service and facilitate communication between all the partners involved in the control and management of TB in LLR. Following the implementation of the Health and Social Care Act 2012 and the resulting changes in commissioning responsibility there is a need for commissioner representation on the Board. In addition it is important that the views of patients are used to inform how the service is delivered and developed, and a patient representative should be a core member of the Board.

Recommendation:

- **Leicester CCG, as lead commissioner of the service, to consider how they may best be represented on the TB Board**
- **The service provider to determine how best to encourage and support patient representation on the TB Board**

Local epidemiology data demonstrates the effectiveness of the current TB service across LLR in reducing the rates of active TB cases within a national context of increasing active disease. However, there remains a significant gap in the provision of a new entrant screening programme; a key recommendation of NICE guidance. In addition the shift towards a preventative model of care has greatly increased the case load of the TB nursing service in terms of the number of LTBI cases needing management. As a result the capacity of the TB nursing service is no longer compliant with the recommendations of the Royal College of Nursing.

8.1 New entrant screening

Overall case numbers and TB incidence rates are unlikely to fall substantially unless a programme of screening for LTBI in those arriving from countries with high prevalence of TB is introduced. NICE Guidelines and recent research demonstrates that screening will prove

cost effective when applied to immigrants from countries with a WHO TB incidence above a threshold of 150/100000 [18]. This would include arrivals from the Indian subcontinent and sub-Saharan Africa but not most eastern European countries. Treatment should ordinarily only be offered to those immigrants below the age of 36 who arrived in the UK within the last 5 years.

A recent large scale LLR population based retrospective cohort study [18] recorded 857 incident TB cases occurring in foreign born persons arriving to the UK between 2000 and 2010. Based on the interval between the dates of GP registration and TB notification, it was determined that up to 60% of cases were potentially preventable with a programme of LTBI screening initiated at the time of GP registration. Crucially, this model was most effective for new entrants aged between 16 and 35 from countries with an incidence between 150 and 500 /100000. In this group only 65 individuals would have to be screened to identify one future case of active TB, compared with 1003 individuals for immigrants in the same age group arriving from countries below this threshold.

A substantial service gap currently exists to provide widespread diagnostic services for new arrivals from countries with a WHO TB incidence level above 150/100000. A further gap exists that would allow safe and qualified supervision of LTBI treatment by TB nurses in this group.

Recommendation: The development and implementation of a new entrant screening programme in line with national guidance and local research findings should be actively pursued.

8.2 TB Nursing service

The TB nursing service was formally established in its current role in 2001. At that time the overwhelming majority of the nursing caseload related to the management of active TB and screening of contacts of active cases. The rate of detection of LTBI was much lower due to the lower specificity of the testing regime in use at that time. With the introduction of IGRA testing the number of cases of LTBI identified through contact screening has increased substantially, resulting in many more cases of LTBI requiring supervised management from the TB nursing service.

Screening of immunocompromised patients is recognised as best practice and a protocol to undertake screening in patients eligible for anti-TNF therapy and renal replacement therapy has been implemented in the LLR service. This has further increased the workload of the TB nursing service in managing increased numbers of LTBI cases.

A service gap now exists to provide safe and qualified supervision by TB nurses of substantially increased numbers of contacts and immunocompromised patients on LTBI treatment .

Royal College of Nursing Guidance recommends 1 WTE TB nurse per 40 cases annually, and 1 WTE TB nurse per 20 cases requiring enhance d supervision. The treatment duration for LTBI is half that of active disease, therefore this ratio can be adjusted accordingly. Based on the projected number of active and LTBI cases projected for 2013 (projection based on data to 21/11/13) the TB nursing service would require 7.5 WTE TB nurses. This is a prudent assumption based on none of the cases requiring enhanced supervision. The current establishment is 5.2WTE specialist nurses, not including the Clinical Nurse Manager.

Recommendation: The TB nursing capacity should be reviewed in light of the increased case load and changing case mix resulting from the identification of LTBI cases and success in reducing active cases of TB.

9 Conclusion

Leicester City has significantly higher rates of TB infection than the regional or national average. While rates in Leicestershire and Rutland are much lower overall, the higher proportion of pulmonary cases poses particular risks in terms of disease transmission.

Current service provision for diagnosing and treating active TB cases to completion is highly integrated and effective within LLR. The service works well with partner organsiations and the TB Board provides effective oversight.

With the advent and wider availability of blood based diagnostic tests (IGRA) there has been a gradual shift from pure active disease management to systematic prevention of future active TB disease in defined at risk groups. The success of this strategy is clearly demonstrated in the year on year reductions in the number of active TB cases in LLR in the context of increasing numbers in most other major urban areas. The shift to provide a proactive preventative service needs to be maintained and bolstered by the introduction of new entrant screening. Over time this will deliver further reductions in the number of active cases of TB and ultimately be cost saving.

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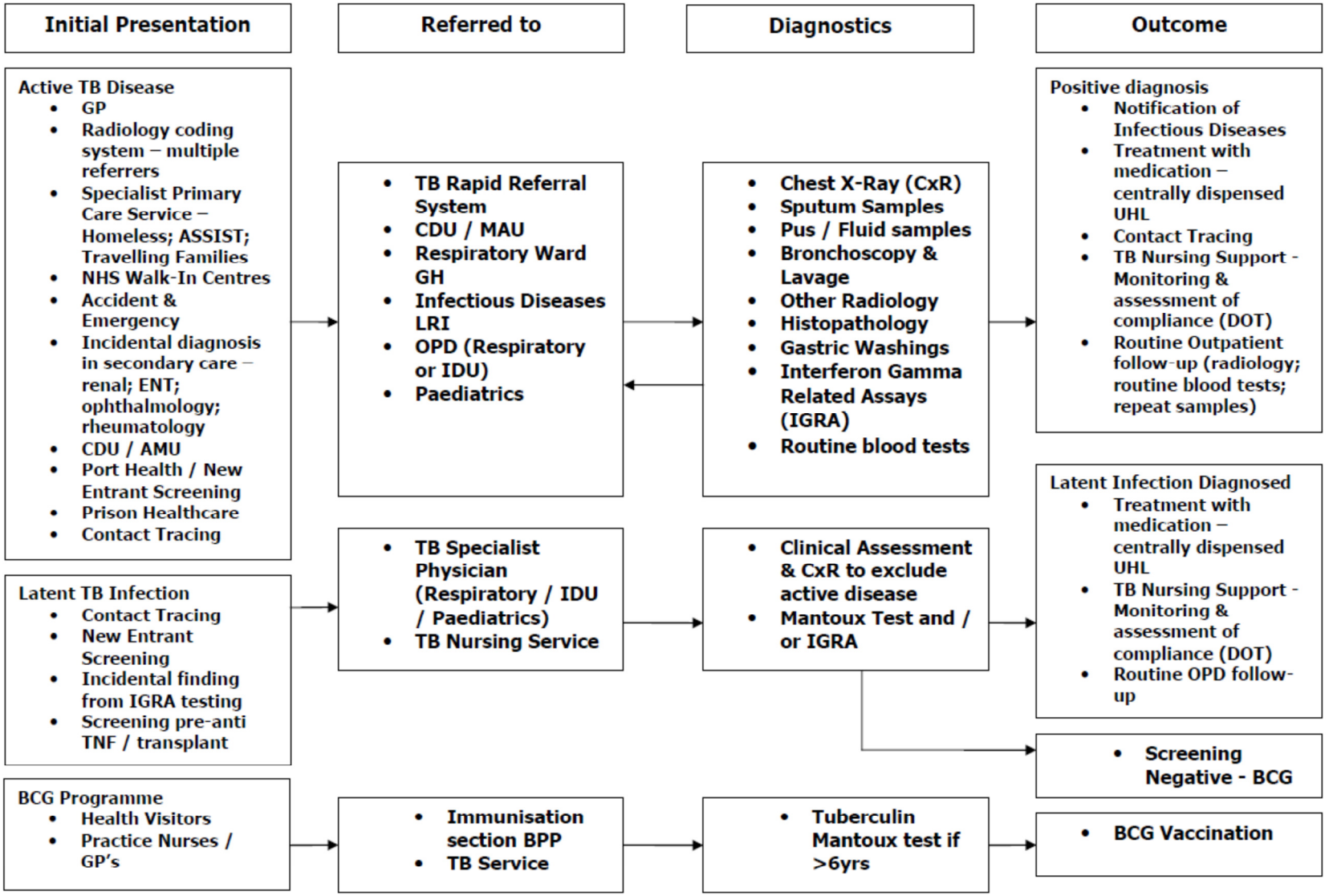
Process Map / TB Care Pathway



Audit of Local Services against NICE (2006) Recommendations

Recommendations		comment	compliant
Diagnosing latent TB			
R1	To diagnose latent TB: **D** ●Mantoux testing should be performed in line with the 'Green Book'21 ●those with positive results (or in whom Mantoux testing may be less reliable) should then be considered for interferon-gamma immunological testing, if available ●if testing is inconclusive, the person should be referred to a TB specialist (see chapter 10 for management of latent TB).		
Diagnosing Active TB			
R2	To diagnose active respiratory TB: ●a posterior–anterior chest X-ray should be taken; chest X-ray appearances suggestive of TB should lead to further diagnostic investigation **C(DS)** ●multiple sputum samples (at least three, with one early morning sample) should be sent for TB microscopy and culture for suspected respiratory TB before starting treatment if possible or, failing that, within seven days of starting **C(DS)** ●spontaneously produced sputum should be obtained if possible; otherwise induction of sputum or bronchoscopy and lavage should be used **B(DS)** ●in children unable to expectorate sputum, induction of sputum should be considered if it can be done safely, with gastric washings considered as third line **B(DS)** ●if there are clinical signs and symptoms consistent with a diagnosis of TB, treatment should be started without waiting for culture results (see section 6.1 for details) **D(GPP)** ●the standard recommended regimen should be continued in patients whose subsequent culture results are negative **D(GPP)** ●samples should be sent for TB culture from autopsy samples if respiratory TB is a possibility. **D(GPP)**		
R3	To diagnose active non-respiratory TB: ●advantages and disadvantages of both biopsy and needle aspiration should be discussed with the patient, with the aim of obtaining adequate material for diagnosis **B(DS)** ●if non-respiratory TB is a possibility, part or all of any of the following samples should be placed in a dry pot (and not all placed in formalin) and sent for TB culture: **D(GPP)** – lymph node biopsy – pus aspirated from lymph nodes – pleural biopsy – any surgical sample sent for routine culture – any radiological sample sent for routine culture – histology sample – aspiration sample – autopsy sample ●microbiology staff should routinely perform TB culture on the above samples (even if it is not requested) **D(GPP)** ●the appropriate treatment regimen should be started without waiting for culture results if the histology and clinical picture are consistent with a diagnosis of TB (see		

	chapters 6 and 7) **C(DS)** ●□all patients with non-respiratory TB should have a chest X-ray to exclude or confirm coexisting respiratory TB; in addition, tests as described in Table 7 should be considered **D(GPP)** ●□the appropriate drug regimen (see chapters 6, 7 and 9) should be continued even if subsequent culture results are negative. **D(GPP)**		
Rapid diagnostic tests – molecular methods			
R4	Rapid diagnostic tests for *M. tuberculosis* complex *(M. tuberculosis, M. bovis, M. africanum)* on primary specimens should be used only if: **D(GPP)** ●□rapid confirmation of a TB diagnosis in a sputum smear-positive person would alter their care, or ●before conducting a large contact-tracing initiative.		
R5	Clinicians should still consider a diagnosis of non-respiratory TB if rapid diagnostic tests are negative, for example in pleural fluid, CSF and urine. **B(DS)**		
R6	Clinical signs and other laboratory findings consistent with TB meningitis should lead to treatment (see section 7.1), even if a rapid diagnostic test is negative, because the potential consequences for the patient are severe. **D(GPP)**		
R9	Rapid diagnostic tests for *M. tuberculosis* complex identification should be conducted on biopsy material only if: **D(GPP)** ●□all the sample has been inappropriately placed in formalin, and ●□AFB are visible on microscopy	Current practice	
Rapid diagnostic tests: automated liquid culture			
R10	Clinical samples should ideally be sent for culture by automated liquid methods, bearing in mind that laboratories need a certain level of throughput to maintain quality control. **D(GPP)**		
Management of respiratory tuberculosis – drug treatment			
R11	Once a diagnosis of active TB is made, the clinician responsible for care should refer the person with TB to a physician with training in, and experience of, the specialised care of people with TB. The TB service should include specialised nurses and health visitors. TB in children should be managed either by a paediatrician with experience and training in the treatment of TB, or by a general paediatrician with advice from a specialised physician. If these arrangements are not possible, advice should be sought from more specialized colleagues throughout the treatment period. **C**	Fully compliant	
R12	A six-month, four-drug initial regimen (six months of isoniazid and rifampicin supplemented in the first two months with pyrazinamide and ethambutol) should be used to treat active respiratory TB in: ●adults not known to be HIV positive **A** ●adults who are HIV positive **B** ●children. **B** This regimen is referred to as 'standard recommended regimen' in this guideline.	Fully compliant	

R13	Fixed-dose combination tablets should be used as part of any TB treatment regimen. **C**	Fully compliant	
R14	A thrice-weekly dosing regimen should be considered for patients receiving DOT (see section 8.2). **D(GPP)**	In selected cases	
R15	A twice-weekly dosing regimen should not be used for the treatment of active TB. **D(GPP)**	Not used in Leicester	
Infection Control			
R16	All patients with TB should have risk assessments for drug resistance (see section 9.1) and for HIV. If risk factors for MDR TB are present, see section 9.3 for recommendations on infection control. **D(GPP)**	Generally compliant, Essentially routine testing for HIV inplace as of 2007	
R17	Unless there is a clear clinical or socioeconomic need, such as homelessness, people with TB at any site of disease should not be admitted to hospital for diagnostic tests or for care. **D(GPP)**	Variable practice and threshold for hospital admission	?
R18	If admitted to hospital, patients with suspected respiratory TB should be given a single room. **D(GPP)**	Compliant – in most cases neg. pressure room	
R19	Patients with respiratory TB should be separated from immunocompromised patients, either by admission to a single room on a separate ward, or in a negative pressure room on the same ward. **D(GPP)**	compliant	
R20	Any visitors to a child with TB in hospital should be screened as part of contact tracing, and kept separate from other patients until they have been excluded as the source of infection. **D(GPP)**	compliant	
R21	Smear-positive TB patients without risk factors for MDR TB (see section 9.1) should be cared for in a single room, until: **D(GPP)** ●they have completed two weeks of the standard treatment regimen (see section 6.1), or ●they are discharged from hospital.	compliant	
R22	Aerosol-generating procedures such as bronchoscopy, sputum induction or nebulizer treatment should be carried out in an appropriately engineered and ventilated area for: **D(GPP)** ●all patients on an HIV ward, regardless of whether a diagnosis of TB has been considered ●all patients in whom TB is considered a possible diagnosis, in any setting.	compliant	
R23	Healthcare workers caring for people with TB should not use masks, gowns or barrier nursing techniques unless: **D(GPP)** ●MDR TB is suspected ●aerosol-generating procedures are being performed. When such equipment is used, the reason should be explained to the person with TB. The equipment should	compliant	

	meet the standards of the Health and Safety Executive. See section 9.3 for further details of MDR TB infection control.		
R24	TB patients admitted to a setting where care is provided for HIV-positive or other immunocompromised patients should be considered infectious and, if sputum smear-positive at admission, should stay in a negative pressure room until: **D(GPP)** 1. the patient has had at least two weeks of appropriate multiple drug therapy, *and* 2. if moving to accommodation (inpatient or home) with HIV-positive or immunocompromised patients, the patient has had at least three negative microscopic smears on separate occasions over a 14-day period, *and* 3. the patient is showing tolerance to the prescribed treatment and an ability and agreement to adhere to treatment, *and either* 4. any cough has resolved completely, *or* 5. there is definite clinical improvement on treatment, for example remaining afebrile for a week. 6. Tuberculosis *For people who were sputum smear negative at admission* (that is, three negative samples were taken on separate days; samples were spontaneously produced sputum if possible, or obtained by bronchoscopy or lavage if sputum samples were not possible): *all* of 1, 2, 3 and 5 above should apply.	compliant	
R25	Inpatients with smear-positive respiratory TB should be asked (with explanation) to wear a surgical mask whenever they leave their room until they have had two weeks' drug treatment.	compliant	
Treatment of non-respiratory tuberculosis			
R26	Patients with active meningeal TB should be offered: ●□a treatment regimen, initially lasting for 12 months, comprising isoniazid, pyrazinamide, rifampicin and a fourth drug (for example, ethambutol) for the first two months, followed by isoniazid and rifampicin for the rest of the treatment period **D(GPP)** ●□a glucocorticoid at the normal dose range – adults equivalent to prednisolone 20–40 mg if on rifampicin, otherwise 10–20 mg **A** – children equivalent to prednisolone 1–2 mg/kg, maximum 40 mg **D(GPP)** with gradual withdrawal of the glucocorticoid considered, starting within 2–3 weeks of initiation. **D(GPP)**	Consistent with current practice	
R27	Clinicians prescribing treatment for active meningeal TB should consider as first choice: ●a daily dosing schedule **B** ●using combination tablets.	Current practice	
R28	For patients with active peripheral lymph node tuberculosis, the first choice of treatment should: ●be the standard recommended regimen (see section 6.1 for further details) **B** ●use a daily dosing schedule **B** ●include combination tablets. **D**	Current practice	

R29	Patients with active peripheral lymph node TB who have had an affected gland surgically removed should still be treated with the standard recommended regimen. **D(GPP)** .	Current practice in all cases ensured by histology notification system	
R30	Drug treatment of peripheral lymph node TB should normally be stopped after six months, regardless of the appearance of new nodes, residual nodes or sinuses draining during treatment	Generally represents Leicester practice	
R31	The standard recommended regimen (see section 6.1 for details) should be planned and started in people with: ●active spinal TB **B** ●active TB at other bone and joint sites. **C**	Generally compliant with low threshold for extended treatment if CNS element suspected	
R32	Clinicians prescribing treatment for active bone and joint tuberculosis should consider as first choice: ●a daily dosing schedule **B** ●using combination tablets. **D** See section 6.1 for details.	Compliant	
R33	CT or MR scan should be performed on patients with active spinal TB who have neurological signs or symptoms. If there is direct spinal cord involvement (for example, a spinal cord tuberculoma), management should be as for meningeal TB (see section 7.1).	Current practice	
R34	In patients with spinal TB, anterior spinal fusion should not be performed routinely. **B**	compliant	
R35	In patients with spinal TB, anterior spinal fusion should be considered if there is spinal instability or evidence of spinal cord compression.	Compliant in close collaboration with spinal surgeons	
R36	For patients with active pericardial TB, the first choice of treatment should: ●be the standard recommended regimen (see section 6.1 for details) **B** ●use a daily dosing schedule **B** ●include combination tablets. **D**	Standard practice	
R37	In addition to anti-TB treatment, patients with active pericardial TB should be offered: ●for adults, a glucocorticoid equivalent to prednisolone at 60 mg/day **A** ●for children, a glucocorticoid equivalent to prednisolone 1 mg/kg/day (maximum 40 mg/day), with gradual withdrawal of the glucocorticoid considered, starting within two to three weeks of initiation. **D(GPP)**	Standard practice	
R38	For patients with disseminated (including miliary) TB, the first choice of treatment should: ●□be the standard recommended regimen (see section 6.1 for details) **B** ●use a daily dosing schedule **B** ●include combination tablets. **D**	Standard practice	
R39	Treatment of disseminated (including miliary) TB should be started even if initial liver function tests are abnormal. If the patient's liver function deteriorates significantly on drug treatment, advice on management options should be sought from clinicians with specialist experience of these circumstances. **D(GPP)**	Standard practice	

R40	Patients with disseminated (including miliary) TB should be tested for CNS involvement by: ●brain scan (CT or MRI) and/or lumbar puncture for those with CNS signs or symptoms ●lumbar puncture for those without CNS signs and symptoms. If evidence of CNS involvement is detected, treatment should be the same as for meningeal TB (see section 7.1).	Standard practice	
R41	For patients with: ●active genitourinary TB, or ●active TB of any site other than: – respiratory system – CNS (typically meninges) – peripheral lymph nodes – bones and joints – pericardium – disseminated (including miliary) disease the first choice of treatment should: ●be the standard recommended regimen (see section 6.1 for details) **B** ●use a daily dosing schedule **B** ●include combination tablets.	Standard practice	
Treatment completion and follow-up			
R42	Follow-up clinic visits should not be conducted routinely after treatment completion. **D**	(Recent change of practice) Now implemented but implications for outcome monitoring	?
R43	Patients should be told to watch for symptoms of relapse and how to contact the TB service rapidly through primary care or a TB clinic. Key workers should ensure that patients at increased risk of relapse are particularly well informed about symptoms. **D(GPP)**	Standard practice	
R44	Patients who have had drug-resistant TB should be considered for follow-up for 12 months after completing treatment. Patients who have had MDR TB should be considered for prolonged follow-up.	Standard practice	
Improving adherence: directly observed therapy			
R45	Use of DOT is not usually necessary in the management of most cases of active TB. **A** All patients should have a risk assessment for adherence to treatment, and DOT should be considered for patients who have adverse factors on their risk assessment, in particular: ●street- or shelter-dwelling homeless people with active TB **B** ●patients with likely poor adherence, in particular those who have a history of non-adherence. **D(GPP)**	Standard practice	
R46	Clinicians who are planning to start a patient on a course of DOT should consider ways to mitigate the environmental, financial and psychosocial factors that may reduce adherence, including stability of accommodation, prescription charges and transport. The setting, observer and frequency of treatment should be arranged to be most practicable for the person with TB. The person with TB and his or her assigned key worker should be involved in deciding these arrangements. DOT should also be supported by frequent contact with the key worker .	Difficult to implement in all cases Coordinated by TB Nurse Casemanagers	
Improving adherence: non-pharmacological strategies			

R47	To promote adherence, patients should be involved in treatment decisions at the outset of treatment for active or latent TB. The importance of adherence should be emphasised during discussion with the patient when agreeing the regimen. **D(GPP)**	Standard practice	
R48	The TB service should tell each person with TB who their named key worker is, and how to contact them. This key worker should facilitate education and involvement of the person with TB in achieving adherence. **D(GPP)**	Standard practice in all notified cases	
R49	TB services should consider the following interventions to improve adherence to treatment for active or latent TB if a patient defaults: ●reminder letters in appropriate languages **B** ●health education counselling **B** ●patient-centred interview and health education booklet **B** ●home visits **D(GPP)** ●□patient diary **D(GPP)** ●□random urine tests and other monitoring (for example, pill counts) **D(GPP)** ●□information about help with paying for prescriptions **D(GPP)** ●□help or advice about where and how to get social security benefits, housing and social services. **D(GPP)**	Close monitoring of compliance in place with at least monthly contacts by Tb nurses	
R50	Pharmacies should make liquid preparations of anti-TB drugs readily available to TB patients who may need them – for example children and people with swallowing difficulties. **D(GPP)**	Standard practice	
R51	TB services should assess local language and other communication needs and, if there is a demonstrated need, provide patient information accordingly.* **D(GPP)**	Standard practice for all but the most esoteric languages	
MDR TB			
R52	A risk assessment for drug resistance should be made for each patient with TB, based on the risk factors listed below: **C** 1. History of prior TB drug treatment; prior TB treatment failure. 2. Contact with a known case of drug-resistant TB. 3. Birth in a foreign country, particularly high-incidence countries as defined by the HPA on its website.* 4. HIV infection. 5. Residence in London. 6. Age profile, with highest rates between ages 25 and 44. 7. Male gender.	Standard practice	
R53	The TB service should consider the risk assessment for drug resistance and, if the risk is regarded as significant, urgent molecular tests for rifampicin resistance should be performed on smear-positive material or on positive cultures when they become available (see section 5.2). **D(GPP)**	Standard practice but few cases in this category	
R54	Response to treatment should be closely monitored in patients at increased risk of drug resistance. If there is no clinical improvement, or if cultures remain positive after the fourth month of treatment ('treatment failure'), drug resistance should be suspected and treatment reviewed with a clinician experienced in the treatment of MDR TB. **D(GPP)**	Standard practice	

R55	The options for organising care for people with MDR TB should be discussed with clinicians who specialise in this. The views of the patient should be sought and taken into account, and shared care should be considered.	Standard practice	
R56	Patients with suspected or known infectious MDR TB who are admitted to hospital should be admitted to a negative pressure room. If none are available locally, the patient should be transferred to a hospital that has these facilities and a clinician experienced in managing complex drug-resistant cases. Care should be carried out in the negative pressure room until the patient is found to be non-infectious or non-resistant, and ideally until cultures are negative. **D(GPP)**	Standard practice	
R57	Staff and visitors should wear FFP3 masks,* during contact with a patient with suspected or known MDR TB while the patient is considered infectious. **D(GPP)** Risk assessment and infection control in drug-resistant TB * European standard EN149:2001; masks should meet the standards in the Health and Safety Executive's *Respiratory protective equipment at work: a practical guide HSG53*.385	Standard practice but few cases	
R58	Before the decision is made to discharge a patient with suspected or known MDR TB from hospital, secure arrangements for the supervision and administration of all anti-TB therapy should have been agreed with the patient and carers. **D(GPP)**	Standard practice	
R59	The decision to discharge a patient with suspected or known MDR TB should be discussed with the infection control team, the local microbiologist, the local TB service, and the consultant in communicable disease control. **D(GPP)**	Standard practice	
R60	Negative pressure rooms used for infection control in MDR TB should meet the standards of the Interdepartmental Working Group on Tuberculosis,386 and should be clearly identified for staff, for example by a standard sign. Such labelling should be kept up to date.	Standard practice	
Treatment on non MDR resistance			
R61	Patients with drug-resistant TB, other than MDR, should be under the care of a specialist physician with appropriate experience in managing such cases. First-choice drug treatment is set out in Table 11.	Standard practice	
Management of latent infection			
R62	Treatment of latent TB infection should be considered for people in the following groups, once active TB has been excluded by chest X-ray and examination: **D(GPP)** ●□people identified through screening who are: – younger than 36 years (because of increasing risk of hepatotoxicity with age) – any age with HIV – any age and a healthcare worker and are either: – Mantoux positive (6 mm or greater), and without prior BCG vaccination, *or* – strongly Mantoux positive (15 mm or greater), interferon-gamma positive, and with prior BCG vaccination ●children aged 1–15 years identified through opportunistic screening, to be: – strongly Mantoux positive (15 mm or greater), *and* – interferon-gamma positive (if this test has been performed), *and*	Probably considered and not done in most cases of Tb scarring on CXR	?

	– without prior BCG vaccination ●□people with evidence of TB scars on chest X-ray, and without a history of adequate treatment.		
R63	People with HIV who are in close contact with people with sputum smear-positive respiratory TB should have active disease excluded and then be given treatment for latent TB infection. Mantoux testing may be unreliable in people with HIV. **D(GPP)**	Standard practice	
R64	Treatment for latent TB infection should not be started in close contacts* of people with sputum smear-positive MDR TB who are strongly Mantoux positive (15 mm or greater), as no regimen is of proven benefit, and only a small proportion of people infected will develop the disease. Long-term monitoring should be undertaken for active disease. **D(GPP)**	Standard practice	
R65	People who have agreed to receive treatment for latent TB infection should be started on one of the following regimens: **C** ●either six months of isoniazid (6H) or three months of rifampicin and isoniazid (3RH) for people aged 16–35 not known to have HIV **A** ●either six months of isoniazid (6H) or three months of rifampicin and isoniazid (3RH) for people older than 35 in whom treatment for latent TB infection is recommended (see R62) and who are not known to have HIV **D(GPP)** ●□six months of isoniazid (6H) for people of any age who have HIV **A** ●six months of rifampicin (6R) for contacts, aged 35 or younger, of people with isoniazid-resistant TB. **D(GPP)** People eligible for treatment of latent TB infection, but who decline to take this treatment, should be given 'inform and advise' information about TB and have chest X-rays three and 12 months later. **D(GPP)**	3RH as current standard practice in Leicester if index case fully sensitive	
R66	Neonates who have been in close contact with people with sputum smear-positive TB who have not received at least two weeks' anti-tuberculosis drug treatment should be treated as follows. **D(GPP)** test performed after three months' treatment. TB (see section 5.2). If this assessment is negative, then isoniazid should be continued for a total of six months. vaccination performed (see chapter 11).	Paediatricians to comment	
R67	Children older than four weeks but younger than two years who have not had BCG vaccination and are in close contact with people with sputum smear-positive TB should be treated as follows. **D(GPP)** ❑+ive TB (see section 5.2). If active TB is ruled out, full treatment for latent TB infection should be given (see R69). * Close contacts may include a boyfriend or girlfriend and frequent visitors to the home of the index case, in addition to household contacts. ❑ . . . . . . (see chapter 11). If this is positive, full treatment for latent TB infection should be given. If the test is not available, the child should be started on treatment for latent TB infection after a positive repeat Mantoux test result. Contact tracing for	Paediatricians to comment	?

	children younger than two years when the index case is sputum smear positive is summarised in an algorithm (section 12.2).		
R68	BCG-vaccinated children aged older than four weeks but younger than two years, in close contact with people with sputum smear-positive respiratory TB, should be treated as follows. **D(GPP)** ❑should be assessed for active TB (see section 5.2). If active TB is excluded, then treatment for latent TB infection should be given (see R69). 5 mm or more over the previous test), an interferon-gamma test should be conducted, if available. If this is positive, the child should be assessed for active TB (see section 5.2). If the interferon-gamma test is not available, the child should be assessed for active TB after a positive repeat Mantoux test result. If active TB is excluded, treatment for latent TB infection should be given.	Paediatricians to comment	?
R69	For children requiring treatment for latent TB infection, a regimen of either three months of rifampicin and isoniazid (3RH) or six months of isoniazid (6H) should be planned and started, unless the child is known to be HIV positive, when 6H should be given (see R69). **D(GPP)**		
R70	Healthcare workers should be aware that certain groups of people with latent TB are at increased risk of going on to develop active TB, including people who: **D(GPP)** ●□are HIV positive ●are injecting drug users ●have had solid organ transplantation ●have a haematological malignancy ●have had a jejunoileal bypass ●have chronic renal failure or receive haemodialysis ●have had a gastrectomy ●are receiving anti-tumour necrosis factor (TNF)-alpha treatment ●have silicosis. Patients in these groups should be advised of the risks and symptoms of TB, on the basis of an individual risk assessment basis, usually in a standard letter of the type referred to as 'inform and advise' information.	A trust wide policy for these high risk groups (anti-TNF in particular) has been developed. General awareness needs to be improved and routine IGRA assays considered in high risk groups	?
BCG vaccination			
R71	When BCG is being recommended, the benefits and risks of vaccination and remaining unvaccinated should be discussed with the person (or, if a child, with the parents), so that they can make an informed decision. This discussion should be tailored to the person, be in an appropriate language, and take into account cultural sensitivities and stigma. **D(GPP)**	Current practice	
R72	People identified for BCG vaccination through occupational health, contact tracing or new entrant screening who are also considered to be at increased risk of being HIV positive, should be offered HIV testing before BCG vaccination. **D(GPP)**	Standard practice	
R73	Neonatal BCG vaccination for any baby at increased risk of TB should be discussed with the parents or legal guardian. **D(GPP)**	Standard practice	
R74	Primary care organisations with a high incidence of TB* should consider vaccinating all neonates soon after birth. **D(GPP)**	Now standard practice but audit required	

R75	In areas with a low incidence of TB,* primary care organisations should offer BCG vaccination to selected neonates who: **D(GPP)** ●□were born in an area with a high incidence of TB,* or ●□have one or more parents or grandparents who were born in a high-incidence country,† or ●□have a family history of TB in the past five years.	Now standard practice but audit required	
R76	Mantoux testing should not be done routinely before BCG vaccination in children younger than six years.	Standard practice	
R77	Routine BCG vaccination is not recommended for children aged 10–14. ●Healthcare professionals should opportunistically identify unvaccinated children older than four weeks and younger than two years at increased risk of TB (see section 10.2) who would have qualified for neonatal BCG and provide Mantoux testing and BCG (if Mantoux negative). **C** ●This opportunistic vaccination should be in line with the Chief Medical Officer's advice* on vaccinating this age group following the end of the school-based programme. **D(GPP)**	Now standard practice	
R78	Mantoux testing should not be done routinely before BCG vaccination in children younger than six years unless they have a history of residence or prolonged stay (more than one month) in a country with a high incidence of TB. **D(GPP)**	Standard practice	
R79	BCG vaccination should be offered to Mantoux-negative new entrants who: ●□are from high-incidence countries,* *and* **B** ●are previously unvaccinated (that is, without adequate documentation or a characteristic scar), *and* **B** ●are aged 35 or younger.†	No systematic capture in place	?
R80	BCG vaccination should be offered to healthcare workers, irrespective of age, who: **D(GPP)** ●□are previously unvaccinated (that is, without adequate documentation or a characteristic scar), *and* 131 11 BCG vaccination ●□will have contact with patients or clinical materials, *and* ●are Mantoux (or interferon-gamma) negative.	Standard practice	
R82	BCG vaccination should be offered to previously unvaccinated, Mantoux-negative people under 35 in the following groups at increased risk of exposure to TB, in accordance with the 'Green Book':21 **D(GPP)** ●□veterinary and other staff such as abattoir workers who handle animal species known to be susceptible to TB, such as simians ●prison staff working directly with prisoners ●staff of care homes for elderly people ●staff of hostels for homeless people and facilities accommodating refugees and asylum seekers ●people going to live or work with local people for more than 1 month in a high-incidence country.*		
Active case finding			
R83	Once a person has been diagnosed with active TB, the diagnosing physician should inform relevant colleagues so that the need for contact tracing can be assessed without delay. Contact tracing should not be delayed until	Fully compliant	

	notification. **D(GPP)**		
R84	Screening should be offered to the household contacts of any person with active TB, irrespective of the site of infection. Household contacts are defined as those who share a bedroom, kitchen, bathroom or sitting room with the index case. Screening should comprise: **D(GPP)** ●□standard testing for latent TB for those aged 35 or younger, and consideration of BCG or treatment for latent TB infection once active TB has been ruled out ●□interferon-gamma test six weeks after the Mantoux test, and consideration of BCG or treatment for latent TB infection once active TB has been ruled out, for those who: – are previously unvaccinated *and* – are household contacts of a person with sputum smear-positive TB *and* – are Mantoux negative (<6 mm) ●□chest X-ray (if there are no contraindications) for those older than 35, possibly leading to further investigation for active TB.	Partly compliant. Differential assessment of contacts of respiratory (pulmonary/pleural/IT nodes/miliary) and non-respiratory (all others) index cases in Leicester. Routine IGRA testing for all contacts of respiratory index cases (2/3rd). CXR for all contacts at different time points.	
R85	For people with sputum smear-positive TB, other close contacts should be assessed. These may include boyfriends or girlfriends and frequent visitors to the home of the index case. Occasionally, a workplace associate may be judged to have had contact equivalent to that of household contacts, and should be assessed in the same way. **D(GPP)**	Standard practice	
R86	Casual contacts of people with TB, who will include the great majority of workplace contacts, should not normally be assessed. **C**	Standard practice	
R87	The need for tracing casual contacts of people with TB should be assessed if: **D(GPP)** ●□the index case is judged to be particularly infectious (for example, evidenced by transmission to close contacts), *or* ●□any casual contacts are known to possess features that put them at special risk of infection (See section 10.1).	Standard practice	
R88 '	Inform and advise' information should be offered to all contacts of people with smear-positive TB.	Standard practice	
Contact tracing: cattle-to-human transmission			
R89	'Inform and advise' information should be given to people in contact with TB-diseased animals. Diagnostic tests for latent TB should be considered only for children younger than 16 who have not had BCG vaccination and have regularly drunk unpasteurized milk from animals with TB udder lesions.	Rare.	
Contact tracing: cases on aircraft			
R90	Following diagnosis of TB in an aircraft traveler, contact tracing of fellow passengers should not routinely be undertaken.	Standard practice.	
R91	The notifying clinician should inform the relevant consultant in communicable disease control (CCDC) if: **D(GPP)** ●□less than three months has elapsed since the flight and the flight was longer than eight hours, *and* **D(GPP)** ●□the index case is sputum smear positive, *and* **D(GPP)**	Standard practice	

	●□the index case has MDR TB, *or* **C** ●the index case coughed frequently during the flight. **D(GPP)** The CCDC should provide the airline with 'inform and advise' information to send to passengers seated in the same part* of the aircraft as the index case. **D(GPP)**		
R92	If the TB index case is an aircraft crew member, contact tracing of passengers should not routinely take place. **D(GPP)**	Standard practice.	
R93	If the TB index case is an aircraft crew member, contact tracing of other members of staff is appropriate, in accordance with the usual principles for screening workplace colleagues (see section 12.4).	Standard practice	
Contact tracing: cases in schools			
R94	Following diagnosis of TB in a school pupil or member of staff, the CCDC should be prepared to explain the prevention and control procedures to staff, parents and the press. Advice on managing these incidents and their public relations is available from the HPU. **D(GPP)**		
R95	If a school pupil is diagnosed with sputum smear-positive TB, the rest of his or her class (if there is a single class group), or the rest of the year group who share classes, should be assessed as part of contact tracing. **B**		
R96	If a teacher has sputum smear-positive TB, the pupils in his or her classes during the preceding three months should be assessed as part of contact tracing. **C**		
R97	Clinicians conducting contact tracing in a school should consider extending it to include children and teachers involved in extracurricular activities, and non-teaching staff, on the basis of: **D(GPP)** ●the degree of infectivity of the index case ●the length of time the index case was in contact with others ●whether contacts are unusually susceptible to infection ●the proximity of contact.		
R98	Secondary cases of sputum smear-positive TB should be treated as index cases for contact tracing (see R94–R97 above for class of recommendation).		
R99	If the index case of a school pupil's TB infection is not found, and the child is not in a high-risk group for TB, contact tracing and screening (by either symptom enquiry or chest X-ray) should be considered for all relevant members of staff at the school. **D(GPP)**		
Contact tracing: community childcare			
R100	When an adult who works in childcare is diagnosed with sputum smear-positive TB, management is as for contact tracing (see section 12.2).		
Contact tracing: cases in hospital inpatients			

R101	Following diagnosis of TB in a hospital inpatient, a risk assessment should be undertaken. This should take in to account: ●the degree of infectivity of the index case ●the length of time before the infectious patient was isolated ●whether other patients are unusually susceptible to infection ●the proximity of contact. Contact tracing and testing should be carried out only for patients for whom the risk is regarded as significant. **D(GPP)**	Compliant (very few actual cases). Always investigated as an incident.	
R102	Patients should be regarded as at risk of infection if they spent more than eight hours in the same bay as an inpatient with sputum smear-positive TB who had a cough. The risk should be documented in the contact's clinical notes, for the attention of the contact's consultant. The contact should be given 'inform and advise' information, and their general practitioner should be informed. **D(GPP)**	Standard practice	
R103	If patients were exposed to a patient with sputum smear-positive TB for long enough to be equivalent to household contacts (as determined by the risk assessment), or an exposed patient is known to be particularly susceptible to infection, they should be managed as equivalent to household contacts (see section 12.2). **D(GPP)**	Standard practice	
R104	If an inpatient with sputum smear-positive TB is found to have MDR TB, or if exposed patients are HIV positive, contact tracing should be in line with the Interdepartmental Working Group on Tuberculosis guidelines.386 **D(GPP)**	Standard practice	
R105	In cases of doubt when planning contact tracing after diagnosing sputum smear-positive TB in an inpatient, further advice should be sought from the regional or national Health Protection Agency and/or people experienced in the field. **D(GPP)**	Standard practice	
New entrants (people recently arriving in or returning to the UK)			
R106	Healthcare professionals, including primary care staff, responsible for screening new entrants* should maintain a coordinated programme to: ●detect active TB and start treatment **B** ●detect latent TB and start treatment **B** ●provide BCG vaccination to those in high-risk groups who are not infected and who are previously unvaccinated **D(GPP)** ●provide relevant information to all new entrants. **D(GPP)**		?
R107	New entrant screening for tuberculosis should be incorporated within larger health screening programmes for new entrants, linked to local services. **D(GPP)**		?
R108	Assessment for, and management of, TB in new entrants should consist of the following. **D(GPP)** taken into account for Mantoux testing and BCG vaccination. – younger than 16, *or* – aged 16–35, from sub-Saharan Africa or a country with a TB incidence greater than 500 per 100,000. – children younger than 11 years – pregnant women. -someone who has not had BCG vaccination, or strongly positive (15 mm or greater) in someone who has been		?

	vaccinated. been excluded, with a positive Mantoux test inconsistent with their BCG history, and a positive interferon-gamma test (if this test was available), and who are: – younger than 16, *or* – aged 16–35, from sub-Saharan Africa or a country with a TB incidence greater than 500/100,000. offered BCG or treatment for latent TB infection. *See the algorithm in Figure 10 for further detail.*		
R109	New entrants should be identified for TB screening from the following information: ●□port of arrival reports **D(GPP)** ●new registrations with primary care **B** ●entry to education (including universities) **D(GPP)** ●links with statutory and voluntary groups working with new entrants. **D(GPP)**		?
R110	Any healthcare professional working with new entrants should encourage them to register with a GP.		?
Street homeless people			
R111	Active case finding should be carried out among street homeless people (including those using direct access hostels for the homeless) by chest X-ray screening on an opportunistic and/or symptomatic basis. Simple incentives for attending, such as hot drinks and snacks, should be considered. **D(GPP)**	Standard practice	☑
Healthcare environments: new employees			
R112	Healthcare professionals working with people with TB should reinforce and update education about TB, and referral pathways, to primary care colleagues, social workers and voluntary workers who work with homeless people. **D(GPP)**	Standard practice	☑
R113	Employees new to the NHS who will be working with patients or clinical specimens should not start work until they have completed a TB screen or health check, or documentary evidence is provided of such screening having taken place within the preceding 12 months. **D(GPP)**		☑
R114	Employees new to the NHS who will not have contact with patients or clinical specimens should not start work if they have signs or symptoms of TB. **D(GPP)**		☑
R115	Health checks for employees new to the NHS who will have contact with patients or clinical materials should include: **D(GPP)** ●assessment of personal or family history of TB ●symptom and signs enquiry, possibly by questionnaire ●documentary evidence of TB skin testing (or interferon-gamma testing) and/or BCG scar check by an occupational health professional, not relying on the applicant's personal assessment ●Mantoux result within the last five years, if available.		☑

R116	If an employee new to the NHS has no (or inconclusive) evidence of prior BCG vaccination, a Mantoux or interferon-gamma test (see section 5.1) should be performed. **D(GPP)**		
R117	Employees who will be working with patients or clinical specimens and who are Mantoux negative (less than 6 mm) should have an individual risk assessment for HIV infection before BCG vaccination is given. **D(GPP)**		
R118	Employees new to the NHS should be offered BCG vaccination, whatever their age, if they will have contact with patients and/or clinical specimens, are Mantoux negative (less than 6 mm) and have not been previously vaccinated. See section 11.5 for more detail. **D(GPP)**		
R119	Employees of any age who are new to the NHS and are from countries of high TB incidence, or who have had contact with patients in settings with a high TB prevalence should have a Mantoux test. If negative (less than 6 mm), recommendations R117 and R118 should be followed. If positive (6 mm or greater), the person should be referred for clinical assessment for diagnosis and possible treatment of latent infection or active disease. **D(GPP)**		
R120	If a new employee from the UK or other low-incidence setting, without prior BCG vaccination, has a positive Mantoux or interferon-gamma test, they should have a medical assessment and a chest X-ray. They should be referred to a TB clinic for consideration of TB treatment if the chest X-ray is abnormal, or for consideration of treatment of latent TB infection if the chest X-ray is normal. **D(GPP)**		
R121	If a prospective or current healthcare worker who is Mantoux negative (less than 6 mm), declines BCG vaccination, the risks should be explained and the oral explanation supplemented by written advice. If the person still declines BCG vaccination, he or she should not work where there is a risk of exposure to TB. The employer will need to consider each case individually, taking account of employment and health and safety obligations. **D(GPP)**		
R122	Clinical students, agency and locum staff and contract ancillary workers who have contact with patients or clinical materials should be screened for TB to the same standard as new employees in healthcare environments, according to the recommendations set out above. Documentary evidence of screening to this standard should be sought from locum agencies and contractors who carry out their own screening. **D(GPP)**		
R123	NHS trusts arranging care for NHS patients in non-NHS settings should ensure that healthcare workers who have contact with patients or clinical materials in these settings have been screened for TB to the same standard as new employees in healthcare environments (see R113–R122).	No formal regulation of staff in non-NHS care settings / agency carers	?
Healthcare environments: occupational health			
R124	Reminders of the symptoms of TB, and the need for prompt reporting of such symptoms, should be included with annual reminders about occupational health for staff who: **D(GPP)** ●are in regular contact with TB patients or clinical materials, *or*	Not sure this is happening	?

	●have worked in a high-risk clinical setting for four weeks or longer. One-off reminders should be given after a TB incident on a ward.		
R125	If no documentary evidence of prior screening is available, staff in contact with patients or clinical material who are transferring jobs within the NHS should be screened as for new employees (see section 13.1). **D(GPP)**		
R126	The risk of TB for a new healthcare worker who knows he or she is HIV positive at the time of recruitment should be assessed as part of the occupational health checks. **D(GPP)**		
R127	The employer, through the occupational health department, should be aware of the settings with increased risk of exposure to TB, and that these pose increased risks to HIV-positive healthcare workers. **D(GPP)**		
R128	Healthcare workers who are found to be HIV positive during employment should have medical and occupational assessments of TB risk, and may need to modify their work to reduce exposure. **D(GPP)**		
Prisons and remand centres			
R129	Healthcare workers providing care for prisoners and remand centre detainees should be aware of the signs and symptoms of active TB (see section 5.2). TB services should ensure that awareness of these signs and symptoms is also promoted among prisoners and prison staff. **D(GPP)**		
R130	Prisoners should be screened for TB by: ●a health questionnaire on each entry to the prison system, *then* **D(GPP)** ●for those with signs and symptoms of active TB, a chest X-ray, **C** and three sputum samples taken in 24 hours for TB microscopy, including a morning sputum sample (see section 5.2). **D(GPP)**	Current compliance doubtful but education ongoing	?
R131	All prisoners receiving treatment for active or latent TB should receive DOT. **D(GPP)**	Standard practice with daily medication.	
R132	Prison medical services should have liaison and handover arrangements to ensure continuity of care before any prisoner on TB treatment is transferred between prisons. **D(GPP)**		
R133	If a prisoner is being treated for active or latent TB, the prison medical services should draw up as early as possible a contingency plan for early discharge, which could happen directly from a court appearance. This plan should include firm arrangements for clinical follow-up and treatment monitoring in the intended district of residence, and should take into account that there may not be a fixed residence arranged for the prisoner after release. The prisoner should be given contact details for a named key worker, who will visit and monitor the prisoner after release and liaise between services involved. **D(GPP)**	Continuity of care needs to be improved	?
R134	Prison service staff and others who have regular contact with prisoners (for example, probation officers and education and social workers) should have pre- and on-employment screening at the same level as for healthcare workers with patient contact (see sections 13.1 and 13.2).	Standard practice