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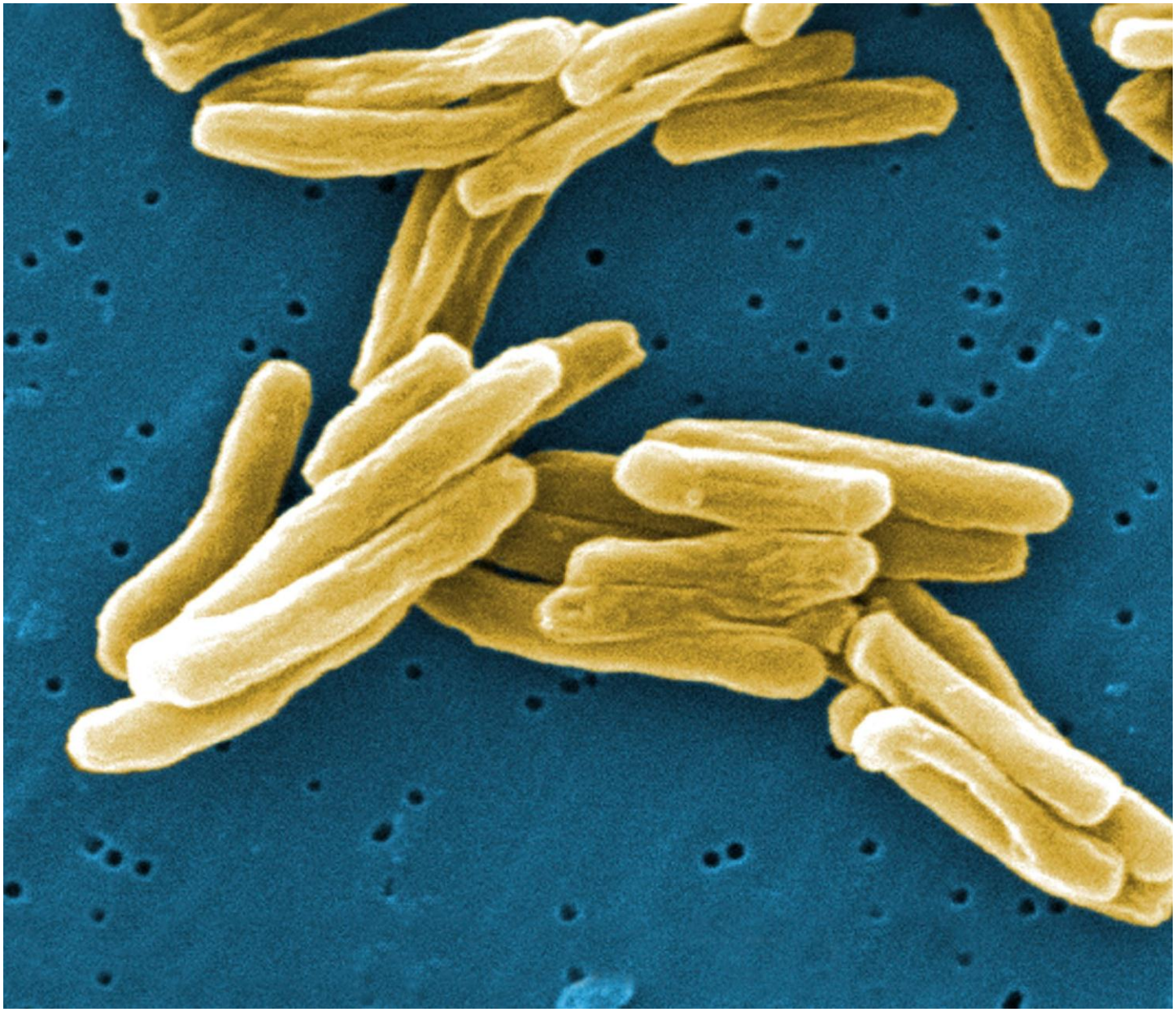
Collaborative Tuberculosis Strategy for England

2015 to 2020



Acknowledgements

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The strategy also benefited from extensive input during a public consultation that ran from 24 March to 24 June 2014. A full list of organisations that contributed to the consultation is provided in Annexe 3.

The preparation of this document was made possible by a small writing group comprising Ibrahim Abubakar, Sarah Anderson, Hiran Hirani, Ishani Kar-Purkayastha, Lucy Thomas, Leonora Weil and Dominik Zenner.

Equality statement

Promoting equality and addressing health inequalities are at the heart of NHS England's and PHE's values. Throughout the development of the policies and processes cited in this document, we have:

- given due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010) and those who do not share it

- given regard to the need to reduce inequalities between patients in access to, and outcomes from, healthcare services and in securing that services are provided in an integrated way where this might reduce health inequalities

Contents

1. Introduction

The incidence of tuberculosis (TB) in England is higher than most other Western European countries (1), and more than four times as high as in the US (2). Trends in England are in marked contrast to some comparable countries that have achieved consistent reductions by concerted approaches to TB prevention, treatment and control (3).

TB in England is largely focused in a small number of high incidence areas (4) although highly complex cases, such as those with multidrug-resistant (MDR) disease, can occur anywhere in the country. Some areas have had notable achievements in strengthening TB services and there is great commitment from those involved in delivering and organising services.

Despite that commitment, and the fact that there is good evidence of what works in TB control, overall rates of the disease have not shown a sustained reduction in recent years (4). A stronger approach to TB control is needed in England in order to build on the assets that the NHS and Public Health England (PHE) already have in place, and to reduce the harm that TB causes to many individuals and communities.

TB has been identified as a priority, and indicators of TB incidence and TB treatment outcomes are included in the Public Health Outcomes Framework (5). PHE and NHS England believe that concerted action, supported by national expertise, can significantly reduce the suffering and harm caused by the disease, meet the WHO End TB Strategy milestone of reducing TB incidence by 50% by 2025 (6) and contribute eventually to the elimination of TB as a public health problem.[1]

PHE and NHS England are jointly launching this strategy, and are committed to working in partnership with the NHS, clinical commissioning groups (CCGs) and local authorities, whose leadership through their directors of public health and health and wellbeing boards is critically important in bringing together all the local agencies, including third sector partners in order for this strategy to succeed.

This strategy outlines how we intend to organise and resource services to tackle TB. It focuses on building on the assets already in the NHS and the public health system, to support and strengthen local services in tackling TB (particularly in areas of high incidence), to ensure clear lines of accountability and responsibility, and to provide national support for local action.

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[1] The WHO Stop TB Strategy target is, by 2050, to eliminate TB as a public health problem (<1 case per million population) (7).

2. What is our shared ambition?

The collaborative TB strategy brings together best practice in clinical care, social support and public health to strengthen TB control, with the aim of achieving a year-on-year decrease in incidence, a reduction in health inequalities and, ultimately, the elimination of TB as a public health problem in England.

To meet these goals, the strategy will stimulate action in all local areas, with a particular focus on areas where incidence is highest and the greatest reductions can be achieved.

3. Why focus on TB?

3.1 The burden of TB in England

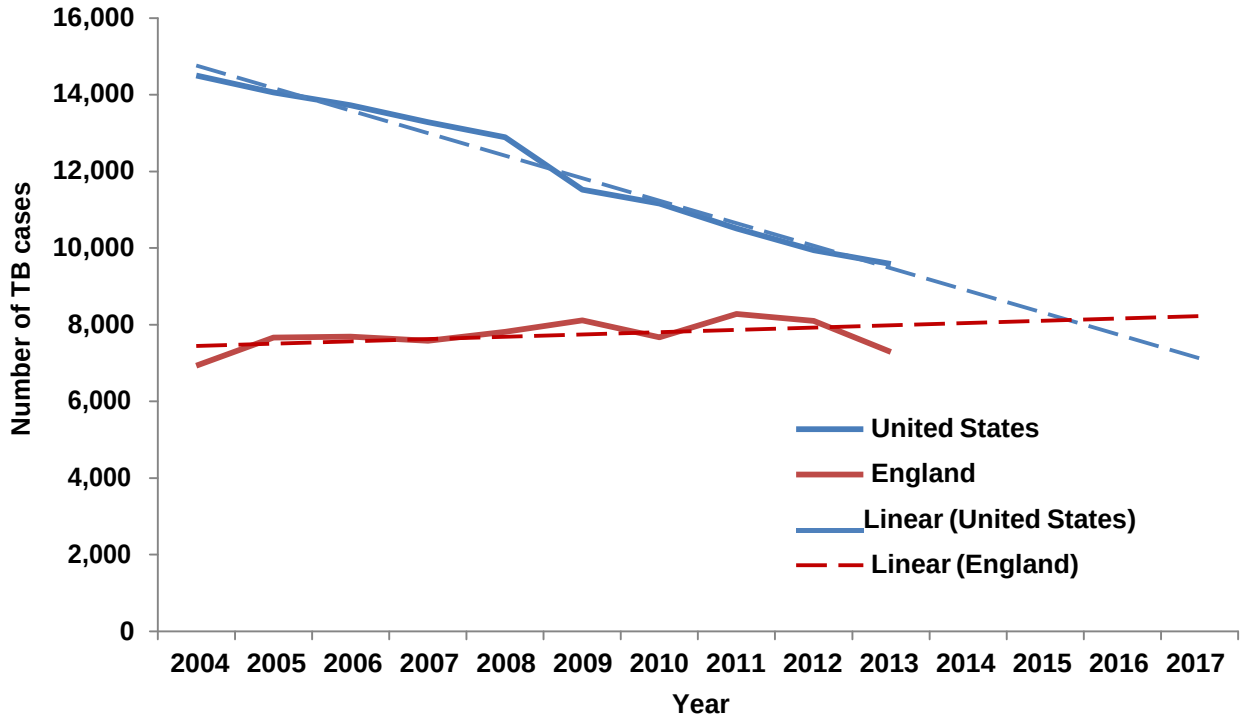
Following major declines in the incidence of TB during most of the 20th century, the incidence of TB in England increased steadily from the late 1980s to 2005, and has remained at relatively high levels ever since.

England has one of the highest TB rates in Western Europe (43), and there are examples of outbreaks in other European countries originating in the UK. The incidence[2] of TB in England is more than four times higher than in the US, and if current trends continue England will have more TB cases than the whole of the US within two years (Figure 1).

In 2013, there were 7,290 TB cases reported, an incidence of 13.5 cases per 100,000 population (4). Although there has been a small decline in incidence in the past two years, it is too early to tell whether this is the start of a downward trend.

[2] The number of new cases developing in a population at risk during a specific time frame.

Figure 1: Numbers of TB cases in England versus the US, 2000–2016



England has very marked inequalities in the geographical and socioeconomic distribution of cases. TB is concentrated in large urban centres, with rates in London, Leicester, Birmingham, Luton, Manchester and Coventry more than three times the national average (Figure 2) (4). Other areas with high caseloads include: Bradford, Leeds, Kirklees, Slough and Reading. Nearly three quarters of all TB cases occur in those born abroad, mainly in high TB burden countries, and the vast majority of these cases (85%) occur among settled migrants who have been in the country for more than two years, rather than in new entrants. There is a strong association between TB and social deprivation, with 70% of cases occurring among residents of areas in the two most deprived quintiles in the country (Figure 3), and 9% of all TB cases having at least one social risk factor (a history of alcohol or drug misuse, homelessness or imprisonment) (4).

While the majority of cases are due to reactivation of latent infection acquired some years before, transmission of TB continues to occur, leading to spread of infection and outbreaks.

Drug-resistant TB is an increasing problem in England (8) with numbers of cases of MDR TB increasing from 46 (1.2% of cases) in 2004 to 68 (1.6% of cases) in 2013 (4).

Figure 2: TB rate per 100,000 by local authority and PHE centre, England 2011–2013

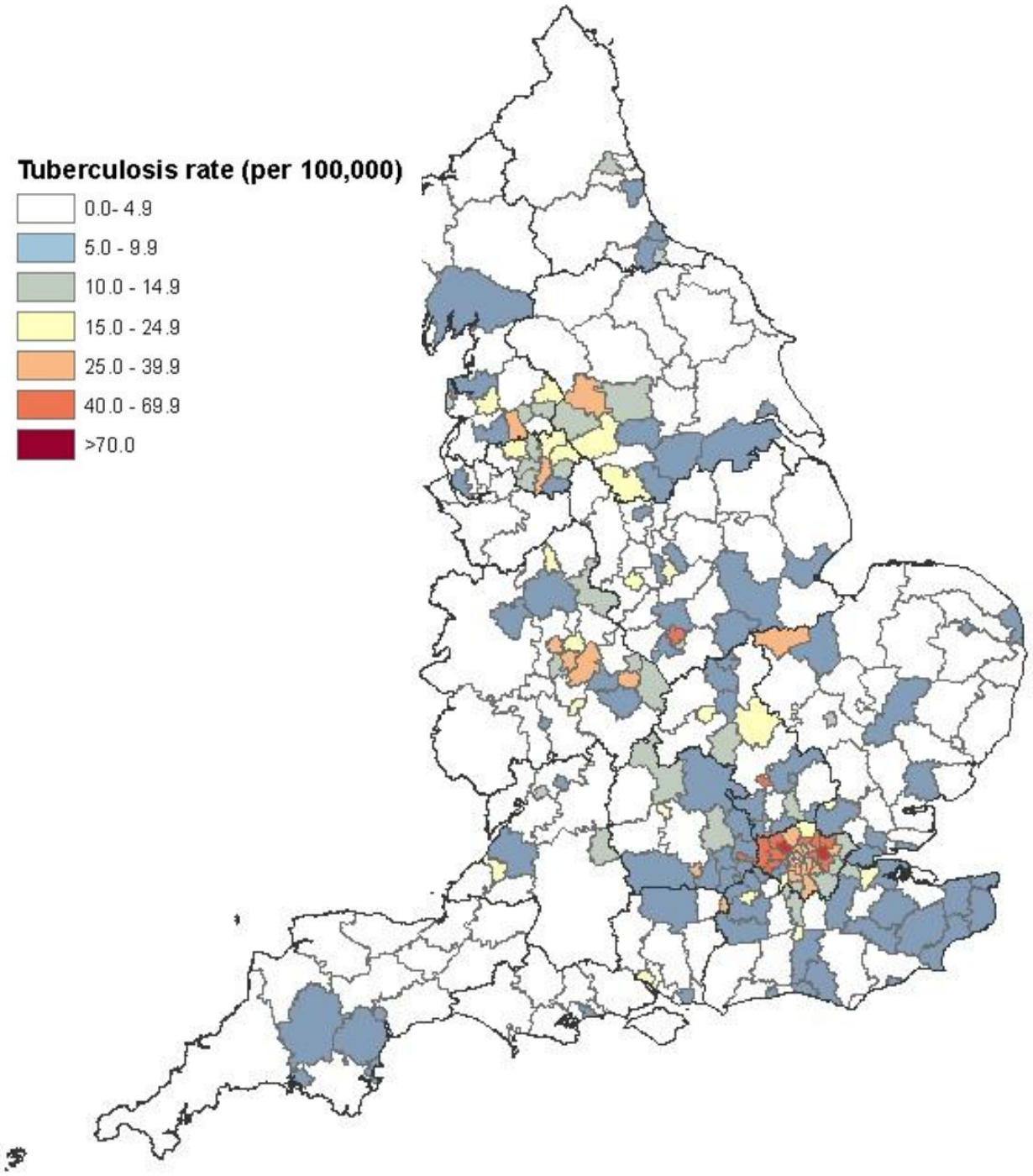
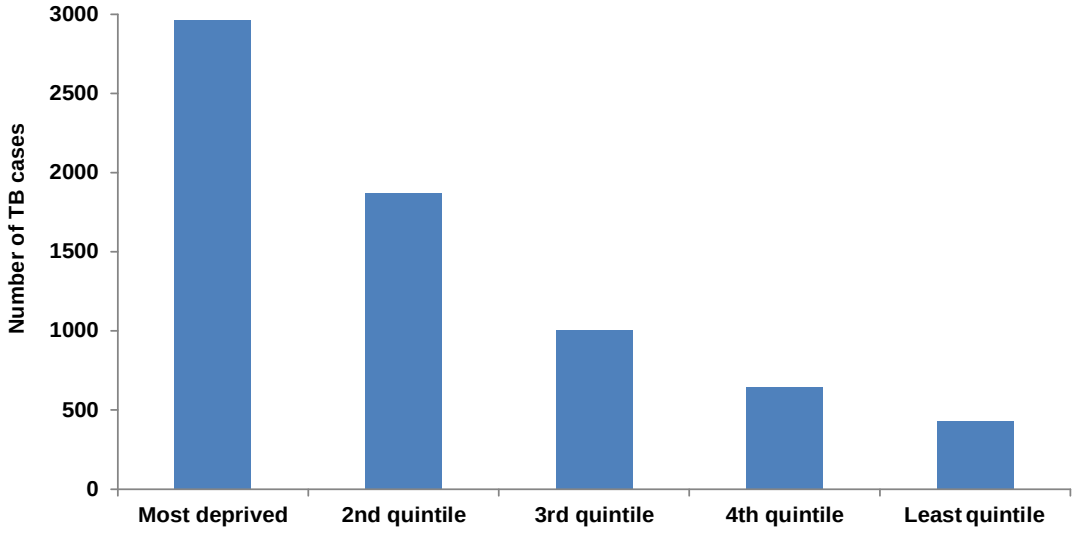


Figure 3: Number of TB case reports by deprivation quintile of area of residence (IMD 2010), UK, 2013



3.2 The case for change

TB has major health and social impacts for those affected. In addition, it contributes to increasing health inequalities in already deprived populations. Each infectious case represents a risk of onward transmission and the failure to protect communities from TB transmission should be regarded as a failure of public health systems.

The majority of TB cases are curable. However, the increasing numbers of drug-resistant cases present a particular challenge; they require longer and more complex treatment regimens, which are associated with significantly increased side effects and treatment costs, and poorer outcomes.

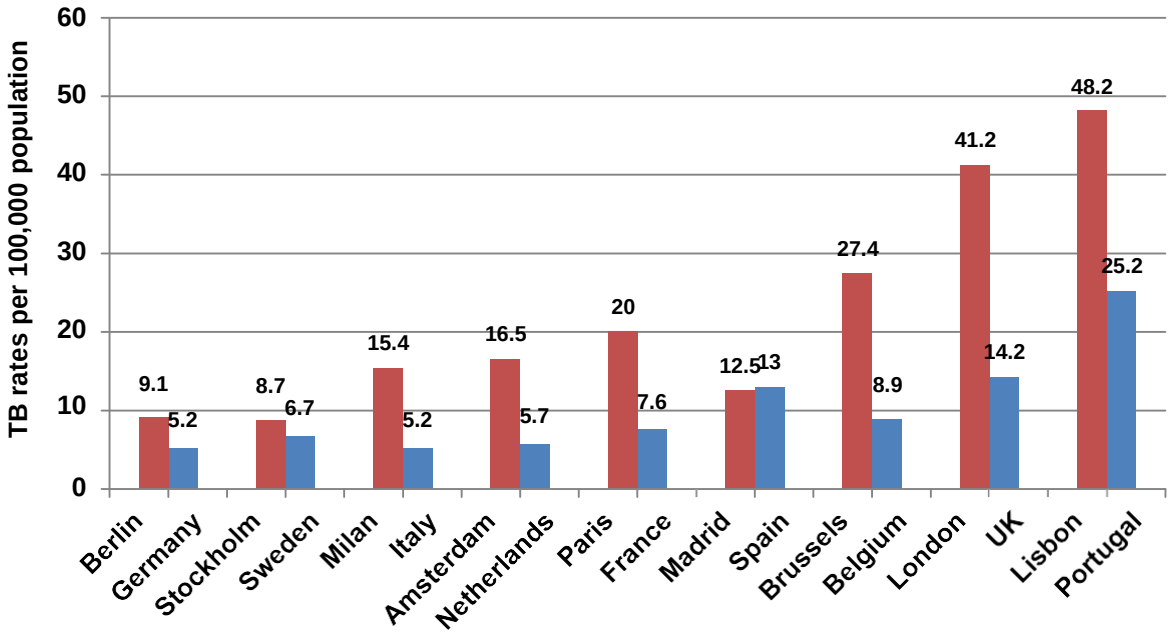
There are marked inequalities associated with TB both in terms of who gets TB (Figure 3) and the outcome of care. The Chief Medical Officer has identified the inequalities associated with TB, and rising levels of antimicrobial resistance, as an important priority for England (8). The Health and Social Care Act 2012 has placed a duty on local government, CCGs, PHE and NHS England to reduce inequalities.

TB prevention, control and its eventual elimination would result in savings to the NHS, CCGs and public health, from avoidable costs associated with diagnosis and treatment of drug-sensitive and resistant forms of TB, from the public health activity that is undertaken to prevent further cases and from the wider socio-economic impacts of the disease on families and communities. Estimates from the London Model of Care (35) suggests that specific interventions will be cost saving.

Considerable evidence exists about what works in terms of TB prevention, treatment and control (9,10) including published clinical and policy guidance (10–12). There is also clear evidence of the devastating consequences of failing to invest in TB services: disinvestment in services in New York in the 1970s and 1980s led to a tripling of cases and widespread community TB transmission, including major outbreaks of MDR-TB, which required more than one billion dollars of reinvestment to reverse (13).

In the UK, there is a risk that the current situation could worsen if we fail to prevent, diagnose and adequately treat TB cases leading to development of drug resistance, onward transmission and TB outbreaks, including outbreaks of MDR-TB. There are many examples of successful TB control programmes internationally. Comparable countries such as the US, Germany and the Netherlands have seen sustained reductions in their TB rates (9) and now have rates of TB that are considerably lower than England (Figure 4). Features of strong TB control programmes in these countries include clear lines of governance and accountability, adequate resourcing, local implementation of actions and close monitoring of individual and programme outcomes. An effective strategy to improve TB control in England will need to learn from these international examples, be tailored to our particular epidemiology and health system, and build on current examples of good practice.

Figure 4: Comparison of TB rates per 100,000 population in Western European countries and cities (2012)



Source: TB in European Cities Group, http://www.metropolitantb.org

The arrangements for commissioning public health and NHS services, introduced in April 2013, provide an opportunity for PHE, the NHS, CCGs and local authorities to work together with health and wellbeing boards to take a new approach to TB control.

There is a need to ensure clear accountability structures at local and national levels, develop appropriate commissioning frameworks, and address gaps in public health and clinical services, such as specific interventions to address the large reservoir of latent TB infection, and outreach services to address the needs of under-served[3] populations.

4. What are we trying to achieve?

To achieve the strategy ambitions and make significant advances in TB control, improvements need to be made in the following key areas (see Annexe 1 for further details):

1. **Improve access to services and ensure early diagnosis**
2. **Provide universal access to high quality diagnostics**
3. **Improve treatment and care services**
4. **Ensure comprehensive contact tracing**
5. **Improve BCG vaccination uptake**
6. **Reduce drug-resistant TB**
7. **Tackle TB in under-served populations**
8. **Systematically implement new entrant latent TB screening**
9. **Strengthen surveillance and monitoring**
10. **Ensure an appropriate workforce to deliver TB control**

3 Under-served populations are those consisting of individuals whose social circumstances, language, culture or lifestyle make it difficult to recognise the clinical onset of TB, access diagnostic and treatment services; self-administer treatment or attend regular appointments for clinical follow up.

5. How will success be achieved?

To achieve success, five main steps need to be taken:

1. Strengthen the co-ordination and oversight of all aspects of TB control by establishing formal TB control boards

Local health and wellbeing boards are the forum at which key partners come together to agree the local priorities to improve the health and wellbeing of people and communities within a local authority area.

However, tackling TB requires the co-ordinated action of many partners, working together across local authority and NHS boundaries and across a larger footprint than the 152 local health and wellbeing boards. To establish clear responsibility and accountability arrangements, TB control boards will be established to serve appropriate geographical footprints. This is supported by evidence from the US and other countries where strong local leadership and local accountability arrangements have led to marked improvements in TB control.

TB control boards will have the following responsibilities:

- to plan, oversee, support and monitor all aspects of local TB control, including clinical and public health services and workforce planning
- to work closely with local clinical and TB networks and engage with other key stakeholders such as local government and the third sector
- to include representation from PHE, NHS England, CCGs, local authority directors of public health and social care, the NHS (primary and secondary care, adult and paediatric TB specialists and front line nursing representation), patient advocates and the third sector
- to develop a local TB control plan based on the national strategy, local services, local need and evidence-based models
- to agree and ensure the appropriate commissioning of TB services, and through collaborative working and the use of existing accountability arrangements, hold providers and commissioners of clinical care and public services to account
- to ensure TB cohort review is undertaken regularly (every 3–4 months) and fed back to the TB control board, commissioners, TB service provider management and the local directors of public health; and that appropriate action is taken as a result of cohort review
- to ensure full and consistent use of current national guidelines in particular those of the National Institute for Health and Care Excellence (NICE) (10,11,14)
- to ensure an appropriate workforce strategy is developed and implemented

- to ensure the needs of under-served populations are addressed and health inequalities are reduced
- to involve under-served populations in designing and shaping services so that they are responsive to the specific needs of these groups
- to ensure the delivery of a quality-assured local programme of new entrant latent TB screening focused on areas of high TB incidence
- to consider commissioning a team to undertake extended community contact tracing of incidents and outbreaks
- to ensure appropriate TB awareness-raising in collaboration with the third sector, local authorities and other organisations who provide this

A clear message from the three-month TB Strategy consultation was that respondents favoured universal coverage of England with enhanced TB support through TB control boards, rather than TB control boards solely covering areas of high incidence. In keeping with this nine TB control boards will be created to coincide with PHE Centre boundaries and provide overarching support to large geographic areas (Figure 5). The boards will link to a number of locally focused TB networks covering the full geographic footprint. The TB control boards will concentrate their efforts on high incidence areas; but at the same time liaise, guide and share work and expertise with lower incidence areas. Collaborative working arrangements will be key to successful delivery. TB control boards will work through appropriate arrangements with commissioning structures, CCGs, local authorities and health and wellbeing boards, in addition to using the Director of Public Healths ‘assurance role’ to hold commissioners to account.

This will bring additional focus and drive to improving TB control across England and at the same time ensure that enhanced clinical and public health interventions are focused on the areas of greatest need.

The nine TB control boards will be established to broadly cover: North West England, North East England, Yorkshire and Humber, East Midlands, East of England, West Midlands, London, South East England and South West England (Figure 5). TB control boards will cover geographic patches along commissioning lines, using the appropriate CCG boundaries and will be led by a director, an acknowledged leader in TB treatment or control in the area served, with dedicated time and appropriate support to lead local TB services and TB control.

The precise arrangements for TB control boards and TB networks will be determined by local NHS organisations, CCGs, PHE Centres, local authorities and other key stakeholders to allow flexibility in the local delivery of improved TB control. PHE, working with NHS England, will lead the process to appoint TB control board directors and other staff. The director of the TB control board will be responsible for bringing together all elements of the local clinical and public health TB control services in the area served to ensure they are well-co-ordinated and provide a comprehensive TB

control programme, including cohort review. The directors of the TB control boards will be responsible to the national TB programme director, who will in turn lead the network of TB control board directors. PHE will establish and provide resources for the TB control boards in liaison with partners in the NHS and local government.

Each control board, working with the national TB programme, and using information contained within the TB Strategy consultation report, will develop further detail on how the boards will function and how arrangements for the diagnosis and treatment of TB patients in high and low incidence areas can be strengthened. The boards will outline and agree functions for individuals as well as contributing partner organisations, including the mechanisms they might use, so partners can hold each other to account to ensure improved TB control.

The national TB programme will be led by a director and will report to the national TB Oversight Group, which brings together PHE, NHS England and all stakeholders. The functions of the national TB programme are outlined on page 17.

Figure 5: Map showing TB control board areas and number of TB cases (2013) per area

Source: Analytics, NHS England (London Region)

2. Develop clear, evidence-based model service specifications of the clinical and public health actions required to control TB

A clear, evidence-based model service framework of the clinical services and public health measures that are required to control TB will be developed. This framework will outline a series of specifications for what local government, CCGs and NHS England would commission. Informed by NICE guidelines, the framework will provide local partners with a description of a high-quality, integrated TB service from which a more detailed local specification, commissioning plans and contracts can be developed. This framework will encourage the commissioning of services in a way that responds to the needs of specific risk groups to reduce health inequalities and will cover the ten key areas for action set out in Section 4 and covered in more detail in Annexe 1.

3. Assess local services against the service specifications and develop plans to secure improvements

TB control boards and their local TB networks will review the commissioning and provision of services within their geographic area against the evidence-based service specifications proposed above. The process will utilise a sector-led improvement model, using local review of each area covered by the TB control board. Subsequent action will include peer review between the control boards to ensure consistency in service delivery between areas.

Control boards will need to ensure that commissioning arrangements are in place to secure both the clinical and public health aspects of these services. This work will inform the work of TB control boards to ensure that all of the services required are being commissioned through an appropriate route, and gaps addressed. Currently, most TB services are commissioned by CCGs. The overlap between clinical and public health domains, such as extended close contact tracing, latent TB infection (LTBI) screening and TB incident management needs particular focus.

As part of this process, TB control boards will need to ensure that there is an appropriate staff skill mix and numbers to deliver all aspects of the service specification, including improved close contact screening with community outreach and, where appropriate, enhanced case management and timely support to public health led actions, such as management of TB incidents and outbreaks.

National support will be provided to produce summaries of the latest evidence, information on return on investment from improved TB control, and other evidence that may be required to support this process.

4. Establish arrangements to cover the cost of additional services to address specific gaps in current TB control arrangements

The model specifications will set out the range of interventions and services that most effectively improve TB control in a locality. Local reviews will identify gaps in some parts of the current integrated service and TB pathway.

While many of the proposed TB control interventions recommended in this strategy could be funded within existing budgets, some strengthening of existing services will be needed. In addition, there are three defined areas, which require new resources as currently there is no systematic commissioning nor provision of service for these areas, and they have the potential to lead to a significant improvement in local TB control.

A collaborative financial impact assessment considered the impact of the strategy on the resources of the NHS, PHE and other organisations associated with TB care, the requirement for additional funding to support the actions of the strategy, and how the strategy would improve the health outcomes of people affected by TB. This impact assessment showed that the investment required to implement the TB strategy is relatively inexpensive. The additional investment required to support implementation would be recovered from year five onwards, with net savings at year ten and beyond totalling 20–30% (approximately £8–9 million per year) compared with not implementing the strategy. The reduction in costs is directly associated with a reduction in TB numbers and associated decreases in inpatient and outpatient episodes as a result of implementing the various elements of the TB strategy. With decreasing incidence, the precise level of resource for TB control boards and interventions beyond ten years will need to be reviewed, while ensuring that TB remains monitored, supported and controlled.

The three areas for new investment are:

- the establishment of nine TB control boards, each including a dedicated clinical/public health lead (TB Control Board Director), programme manager, administrative support and vital input from clinicians, GPs and the TB nursing service. It is estimated that the annual cost of TB control boards would be around £1.5 million
- the establishment of testing for, and treatment of, latent TB in new entrants from countries of high TB incidence. This is a key evidence-based intervention with clear return on investment and part of the NICE TB pathway. The impact assessment estimated around £2m for testing across England, and £8 million for treatment of latent infection and any disease that is subsequently identified. With a decreasing TB burden, this would decrease to an estimated £6.3 million after ten years

- the expansion of an outreach service, similar to the ‘Find and Treat’ service in London, to the rest of England, to meet the needs of under-served populations. This will help reduce the inequalities in health experienced by under-served populations and there is good evidence for the cost-effectiveness of this approach. The impact assessment estimated the cost of developing these services in areas of highest TB incidence to be around £900,000

TB control boards will be funded by PHE through a specific allocation to PHE Centres to supplement their existing spending in this area. PHE will establish a bespoke “memorandum of understanding” between PHE and each TB control board to explain what is expected as part of the investment—both in terms of the additional support to the TB control boards and the deliverables that they will supply.

LTBI testing and treatment and the expansion of provision for under-served populations will be funded by NHS England. This funding will be channelled from NHS England to primary care, CCGs and TB service providers. Arrangements will be put in place between PHE and NHS England that ensures delivery of LTBI testing and treatment with appropriate performance management mechanisms in place to monitor achievement of the strategy aims.

5. Strengthen national support for local TB control arrangements

Local TB control activities will be supported by nationally co-ordinated functions, such as reference microbiology services, surveillance and monitoring activities, a programme of research and development, and appropriate workforce development. Each of these areas of TB control will be strengthened by ensuring the delivery of the measures outlined in the ten areas for action in Annexe 1.

In addition, achieving TB control in England requires international measures, such as a quality-assured, pre-entry TB screening programme for active disease and a contribution to global TB control efforts.

Existing national TB control functions will be strengthened through partnership between PHE, NHS England and other national stakeholders that PHE will lead.

The national TB control functions are:

- to support local TB control
- to co-ordinate nationally-delivered PHE functions including surveillance and monitoring, reference and specialist microbiology and pre-entry screening quality assurance

- to co-ordinate any programme of work between NHS England and PHE nationally, including the developments of frameworks and expert advice
- to provide leadership through a national director supported by a programme manager
- to work with TB control boards to provide assurance that the right arrangements are in place for TB control
- to provide assurance and co-ordination for TB control activities that require national oversight, such as LTBI screening
- to ensure liaison with international partners, including planning for an international review of TB control activities
- to liaise with the Department of Health and other government departments on TB control
- to analyse and prioritise research and development needs

6. What will success look like?

6.1 Successful local implementation

A fully functioning TB control board will have strong leadership through an appointed director, programme management support and access to clinical advice. The board will have full engagement of all relevant local stakeholders including local government, CCGs, NHS England, the NHS, PHE and the voluntary sector. The board will lead local networks to deliver the key changes outlined in this strategy, using the levers available through existing health and accountability structures to ensure the appropriate commissioning and delivery of services. The board will also support mutual peer review. TB control boards will be accountable to PHE and NHS England and will deliver sustained improvement in TB control, monitored through the indicators in this strategy.

6.2 Successful national implementation

A successful national TB programme will deliver effective TB control by providing leadership and co-ordination of activities, through the national TB Oversight Group, from all major partners including NHS England, the NHS, PHE, the Local Government Association, other government departments, the voluntary sector and other partners. It will take a lead role in developing frameworks and areas of work that only need to be developed once nationally and support TB control boards in all other areas. The national TB programme will ensure sustained improvement in existing nationally-delivered functions such as surveillance and international reporting, reference microbiology, pre entry screening for TB, input into research and quality assurance of latent TB screening.

Overall, success will be evident through:

- systematic, joined-up care between health services, health and social care, public health and housing that specifically reaches under-served or vulnerable groups
- improved access to services that ensure earlier diagnosis and that raise awareness among specific ethnic communities of the symptoms and signs of TB and where to seek care
- a highly motivated workforce that is diligent in identifying and treating patients and their contacts, and that ensures patient care meets both the clinical and social needs of the patient
- improved treatment completion rates and a big and significant reduction in TB incidence

7. How will progress be demonstrated?

TB control boards will want to track the outcomes of local implementation of the strategy to be able to demonstrate progress and to identify areas that need greater focus.

PHE's intelligence and surveillance functions play a crucial role in providing relevant, appropriate and timely information to support local decision-makers and to provide a national picture of progress. Thus it is planned that:

- a formal monitoring framework will be put in place to ensure clear lines of accountability for monitoring TB service performance at local and national level
- PHE will provide annual monitoring reports on a suite of indicators relevant to the control of TB at an appropriate geographical/organisational level
- local TB control boards will publish results of their cohort reviews every 3–4 months
- local TB control boards should conduct an audit of their local TB microbiology services every year[4]
- each TB control board will provide regular reports on progress to their constituent local authorities, NHS organisations, CCGs and PHE; and these will also be sent to health and wellbeing boards
- a summary report of progress across England will be published by PHE at regular intervals
- further work will be conducted by the national TB programme and TB control boards to further review the monitoring indicators

[4] The annual audit of local TB microbiology services should be conducted using the PHE 2012 TB Microbiology Services audit tool (15)

The initial suite of monitoring indicators for which data is currently available across the country is as follows:

- **Reducing TB incidence**
  - National and TB control board level: Overall TB incidence, TB incidence in UK-born and non-UK born populations
  - Local level: TB incidence three-year rolling average

- **Reducing health inequalities associated with TB**
  - National: slope index of inequalities in TB rates

- **Reducing TB transmission**
  - National: incidence of TB in UK-born children aged under 15 years

- **Improving access to services and ensuring early diagnosis**
  - National, TB control board and local level: Proportion of pulmonary TB cases starting treatment within two months and four months of symptom onset (exclusions: cases diagnosed post-mortem)

- **Providing universal access to high-quality diagnostics**
  - National, TB control board and local level: Proportion of pulmonary TB cases that were culture confirmed
  - National, TB control board and local level: Proportion of culture confirmed cases with drug susceptibility testing reported for the four first-line agents

- **Improving treatment and care services**
  - National, TB control board and local level: Proportion of drug-sensitive TB cases who had completed a full course of treatment by 12 months (exclusions: cases with rifampicin resistance or MDR-TB and cases with CNS, spinal, miliary or disseminated TB)
  - National, TB control board and local level: Proportion of drug-sensitive TB cases who were lost to follow up at last reported outcome (exclusions: cases with rifampicin resistance or MDR-TB)
  - National, TB control board and local level: Proportion of drug-sensitive TB cases who had died at last reported outcome (exclusions: cases with rifampicin resistance or MDR-TB)
  - National: Proportion of drug-resistant TB cases (rifampicin resistance or MDR-TB) who had completed treatment at 24 months
  - National: Proportion of drug-resistant TB cases (rifampicin resistance or MDR-TB) who were lost to follow up at last reported outcome
  - National: Proportion of drug-resistant TB cases (rifampicin resistance or MDR-TB) who had died at last reported outcome

  - National, TB control board and local level: Proportion of TB cases offered an HIV test (exclusions: HIV status already known, cases diagnosed post-mortem)

- **Tackling TB in under-served populations**
  - National and TB control board level: Proportion of drug-sensitive TB cases with at least one social risk factor who completed treatment within 12 months (exclusions: cases with rifampicin resistance or MDR-TB and cases with CNS, spinal, miliary or disseminated TB)

- **Reducing drug-resistant TB**
  - National, TB control board level: Number and proportion of culture confirmed TB cases with any first-line drug resistance (exclusions: *Mycobacterium bovis* cases with resistance to pyrazinamide)
  - National: Number and proportion of culture confirmed TB cases with MDR-TB

Additional indicators for which data collection mechanisms will need to be established

- **Tackling TB in under-served populations**
  - National and TB control board level: Proportion of TB patients with social risk factors recorded who received enhanced case management. (exclusions: cases diagnosed post-mortem)

- **Improving comprehensive contact tracing**
  - National, TB control board and local level: Proportion of pulmonary TB cases who had close contacts identified
  - National, TB control board and local level: Proportion of identified close contacts of pulmonary TB cases that were evaluated

- **Implementing new entrant latent TB screening**
  - National, TB control board and local level: The number of local authorities that have a systematic new entrant LTBI screening initiative in place
  - National, TB control board and local level: Proportion of eligible new entrants covered by screening programmes who accept LTBI screening
  - National, TB control board and local level: Proportion of individuals who complete LTBI treatment amongst those who start treatment

- **Improving BCG vaccination uptake**
  - National, TB control board and local level: Proportion of babies in areas with a universal BCG programme who received BCG vaccine

Baseline monitoring data for national-level indicators, and associated metadata, is presented in Annexe 4. Full baseline monitoring data at national and local level will be published in March 2015.

8. Next steps

This TB Strategy for England sets out how, through collaboration, we can reverse the trend of the past two decades and make England an exemplar of high-quality, cost-effective TB control.

The ambitions of the strategy will only be achieved through the participation and commitment of a range of stakeholders and partners. Having consulted widely on the strategy content for three months, from March to June 2014, (http://www.hpa.org.uk/Publications/InfectiousDiseases/Tuberculosis) and revised the strategy accordingly, the aim is that this revised document will provide a successful approach to improve TB control in England. A full analytic response to the strategy consultation can be found at: www.gov.uk/phe (39).

During and following the consultation period, PHE and NHS England worked together to map the current resources and the future additional requirements of the actions recommended in the strategy. PHE agreed to meet the costs of the TB control boards and the national TB programme; whilst the costs of the clinical interventions to control TB, as laid out in this strategy, will be met by the NHS.

The next steps to take this strategy forward include:

- appoint TB control board staff to enable the boards to be functional from April 2015
- implement the national TB programme from April 2015
- TB control boards to review TB services in their area and develop financial and operational plans to meet any gaps in service provision during the first and second quarters of 2015/16. This will include undertaking the workforce review as detailed in the strategy
- develop links between TB control boards and local TB networks to ensure universal coverage of TB control efforts
- finalise and publish the indicator set to monitor the implementation of this strategy, including measures of improved TB prevention and treatment services and, ultimately, reductions in numbers of people with TB and drug-resistant TB. To commence publication in the last quarter of 2014/15

Annexe 1. The ten evidence-based areas for action

To deliver the strategy, ten areas of action have been identified, which will provide a framework for commissioners and providers within which to develop specific services and targets that address TB control needs.

In England we have good TB surveillance, high-quality diagnostics and treatment services, and while some action needs to be taken in these areas, other areas need greater strengthening.

For each area a brief summary of why this area is important is followed by the specific actions that need to be taken:

- improve access to services and ensure early diagnosis
- provide universal access to high quality diagnostics
- improve treatment and care services
- ensure comprehensive contact tracing
- improve BCG Vaccination uptake
- reduce drug-resistant TB
- tackle TB in under-served populations
- systematically implement new entrant latent TB (LTBI) screening
- strengthen surveillance and monitoring
- ensure an appropriate workforce to deliver TB control

A1 Improve access to services and ensure early diagnosis

Poor access and late diagnosis result in more advanced and complex disease with greater morbidity, mortality and cost, and higher rates of onward transmission of TB. Late diagnosis reinforces pre-existing health and social inequalities, which affect under-served populations to a greater degree.

Late diagnosis may be caused either by delays in presentation to health services or in the diagnostic process. Delays in presentation may occur due to low levels of symptom awareness exacerbated by high levels of TB-related stigma among certain populations, in particular under-served populations and new entrants (14). This is further compounded by reluctance to engage with statutory health services among some migrant populations. An additional factor that frequently delays diagnosis is the lack of TB awareness among health professionals and appropriate training among social care staff (16). Efforts to raise awareness will be supported nationally by the National

Knowledge Service for TB and the leading national TB charity, TB Alert, and other third sector organisations.

Actions:

- raise awareness and tackle stigma among populations at high risk and who could self-present to health services through:
  - collaboration between third sector organisations, local authorities and the NHS focusing on targeted awareness-raising of symptoms and curability of TB; the range of local health and care services; eligibility for free treatment
  - use of community workers and health advocates to signpost and facilitate access to local services in culturally-competent ways
  - targeted TB screening and education as part of new patient checks at GP surgeries

- raise awareness of TB among professionals through:
  - workforce development for healthcare professionals in primary and secondary care through basic and postgraduate training and continuing professional development
  - raising awareness of GPs and other health and social care professionals in high-incidence areas about the TB epidemiology in their locality and referral systems

- provision of training for statutory and voluntary agencies working with migrants from countries with high TB incidence and people with chaotic lives or in overcrowded accommodation

- improve the accessibility of clinic venues and times, this should also include exploring and addressing structural barriers to access such as geography and transport and give due consideration to a rapid referral system

- facilitate alternative routes for accessing healthcare through training and resources for community pharmacists in high incidence areas, information for new entrants in community venues such as the Citizens Advice Bureau, libraries and other social setting, and health screening among employers that attract new entrants. In addition, improve the accessibility of clinic venues and times as appropriate

- health services should work with local authorities and health and wellbeing boards to consider and put in place appropriate plans to tackle the social and economic risk factors associated with TB and, in so doing, reduce the health inequalities associated with the disease. Local government has a crucial public health role to play in tackling TB (40)

A2 Provide universal access to high-quality diagnostics

Clinical suspicion of active TB needs to be supported by laboratory and radiological investigations. In England, while standards for microscopy were well achieved in 2013, only 59.4% of all TB cases, and only 68.7% of pulmonary TB cases, were confirmed by culture (4). This is significantly lower than the 80% target set by the European Centre for Disease Prevention and Control for culture confirmation of pulmonary TB.

Timely drug susceptibility testing is crucial to direct appropriate treatment, and reduce the period of infectiousness to protect others. Rapid targeted identification of TB and rifampicin resistance is possible from patient specimens.

Maintaining a high-quality TB diagnostic service, including communication, turnaround times, technology adoption and workforce competence are important.

Molecular typing allows detection and interruption of transmission between patients, and underpins the management of incidents and outbreaks. Whole genome sequencing (WGS) has the potential to demonstrate within days of culture, not just the species identification, but also the drug sensitivities and resistances and chain of transmission. Appropriate application of WGS will lead to better public health control with the identification of “super spreaders” and of individuals with latent disease, so reducing transmission events (17).

Actions:

- ensure that every clinician who treats a case of TB has access to high-quality microbiology advice, if required
- ensure high-quality diagnostic services are available for all patients with suspected mycobacterial infection, and that universally defined standards of best practice are met (10,18)
- ensure interferon-gamma release assays are available to all clinicians
- ensure all suspected pulmonary cases have a sputum sample sent for a smear at first point of contact with the NHS
- ensure that all patients with suspected TB have a chest X-ray
- ensure radiologists refer directly to TB team where relevant X-ray changes are present

- ensure all positive microbiology and histology specimens are notified directly to the TB team
- ensure all TB control boards use a standard audit tool such as that used by the former Health Protection Agency in 2012 (15) to audit TB microbiology services annually
- facilitate implementation in clinical practice of existing techniques for rapid detection of M/XDRTB (19); including use of direct PCR to specimens to detect TB complex and mutations conferring resistance to rifampicin
- develop new methods for diagnosis of drug resistance to existing and new drugs
- strengthen education for service users in the use and performance of modern diagnostics for TB
- continue to develop WGS technology for application in practice

A3 Improve treatment and care services

Treatment outcomes are generally good in the UK, with 83% treatment completion at 12 months (4). However, there is considerable variation in the structure and quality of TB services across England, with provision of specialist TB services, TB clinical nurse specialists (TB CNS) and outreach/directly observed therapy (DOT) workers variable in addition to a mixture of acute and community provision. Not all TB services participate in, or have access to, a TB clinical network (see glossary, for further information) (41) to support expert review of complex and MDR-TB cases or access to specialist unit co-supervision.

Clinically complex TB, such as neurological or spinal TB, MDR-TB, HIV-TB co-infection and TB in children, requires specialist multidisciplinary expertise and often additional social and community support (12).

Without treatment, TB can be fatal, while those who survive without treatment can experience long-term health problems and remain infectious. A high treatment quality standard and treatment completion rate needs to be ensured to avoid the development of drug-resistant TB and to improve TB control.

Actions:

- establish TB clinical networks in all areas of England to co-ordinate treatment centres and support the provision of high standards of care (41)

- delineate the footprint and pathways of these TB clinical networks with:
  - an accountable lead for both clinical and public health aspects of TB control
  - a mixture of units to support simple and more complex TB cases including those with the facility and expertise to manage MDR-TB (MDR-TB treatment centre)

- ensure that TB clinical networks are linked to a TB control board

- ensure full and consistent use of current national guidelines such as NICE and RCN (10,11)

- ensure appropriate staffing(11)(14)[5] and facilities to address case mix and complexity with:
  - all TB cases assigned to a TB specialist and named TB case manager
  - use of enhanced case management (ECM) as appropriate
  - adequate provision of staff (nurses/administrators/lay outreach workers), outreach and venues for directly observed therapy (DOT)
  - more local, and flexible, access points for routine treatment by using community DOT workers, pharmacists and other providers of treatment, home-based contact tracing and DOT
  - adequate provision of negative pressure facilities
  - fast-track referrals and support to necessary social care
  - service users involved in service design

- ensure paediatric cases are managed by a paediatric TB specialist or by a general paediatrician with advice from a paediatric TB specialist, that they are discussed at regional and local multi-disciplinary teams **(**MDTs) and that any service specification considers TB in children as a separate entity

- for TB/HIV co-infected cases ensure that they are managed by a physician with joint HIV/TB expertise or in conjunction with an HIV specialist

[5] NICE recommendations are for one TB case manager per 40 standard patients and one TB case manager per 20 patients requiring enhanced case management (14).

A4 Ensure comprehensive contact tracing

Contact tracing, the screening of people exposed to a case of active TB, has the potential to improve early diagnosis and prevent further transmission. Consequently, contact tracing is an established strategy to find and treat active and latent TB cases (20,21).

The benefits of latent TB case finding and treatment are even more pronounced in contacts at higher risk of disease progression such as children and people with HIV.

In some communities, identification of contacts may be incomplete due to high mobility, TB-related stigma (which may deter index cases from providing information about who they live, work or socialise with), and the lack of social relationships between individuals in shared occupancy accommodation or other reasons for not sharing contact details (22).

Currently, there is considerable variation in the extent to which household and community-based contact tracing is undertaken. Where community outreach workers have been used, particularly to do home-based contact tracing, the effectiveness of local TB control has improved.

Commissioning pathways for contact investigation for non-household contacts are not clearly established; nor are these consistently applied.

Actions:

- ensure comprehensive contact tracing is undertaken, and that it aims to identify all close contacts of active TB cases, not just household contacts, and provides appropriate follow up and treatment (this being particularly important for under-served populations such as the homeless, prisoners and individuals with complex and chaotic lives)

- strengthen arrangements for contact tracing through the use of TB case managers or community outreach workers to undertake home-based contact tracing for all cases where this is appropriate and necessary

- plan and commission TB services for all areas, regardless of incidence, to include an explicit plan for the delivery of contact tracing, screening and follow up of any identified cases in the event of an ‘incident’. This should include provision for extending the contact tracing beyond the immediate household, where appropriate

- ensure routine TB cohort review to improve local TB control in general, and contact investigation; and ensure quality outcomes of contact tracing (23).

- ensure robust contact tracing mechanisms are in place particularly for incidents involving young children

A5 Improve BCG vaccination uptake

There is strong evidence to support the use of BCG in preventing tuberculosis meningitis and miliary tuberculosis in children (24). Reported efficacy in preventing adult pulmonary TB has been variable between trials and settings (25,26) although recent research indicates this may be in part explained by infection prior to vaccination (27)

Vaccination with BCG is cost-effective when used as part of a targeted immunisation strategy for high-risk groups.

In line with Joint Committee on Vaccination and Immunisation (JCVI) recommendations, NICE and Department of Health guidance (10,28) BCG vaccination is offered to certain population sub-groups in England through either a universal or targeted infant vaccination programme dependent on residence in a high-incidence area (one in which TB incidence exceeds 40 cases per 100,000 population) or an assessment of individual risk factors.

Actions:

- strengthen local pathways for delivery of BCG vaccination as part of infant and risk group immunisation, with clear lines of accountability for commissioning, delivery and monitoring

- implement measures to improve BCG uptake including better identification of those eligible for vaccination, provision of neonatal immunisation prior to discharge from hospital and training and education of staff and communities

- in low-incidence areas, ensure processes are in place so that eligible babies are systematically identified and offered BCG vaccination with clear assignment of responsibility, and training to ensure staff awareness of eligibility criteria

- improve systems for monitoring BCG uptake through its inclusion in the Coverage of Vaccination Evaluated Rapidly (COVER) programme to enable reporting on uptake in areas with a universal programme. This should be accompanied by better co-ordination between systems for identification of at risk individuals with systems to record uptake

A6 Reduce drug-resistant TB

The risks to public health of antibiotic resistance have been highlighted in the Chief Medical Officer for England's 2011 annual report (Advocacy Volume) and in the *UK Five Year Antimicrobial Resistance Strategy 2013 to 2018* (8,29), and the importance of consolidated action across Europe has been set out in the *WHO-Euro Roadmap to Prevent and Control Drug Resistant TB*. Drug-resistant TB, especially multi and extensively drug-resistant TB (M/XDRTB), carries a high mortality (particularly in patients co-infected with HIV).

The majority of drug-resistant TB cases in the UK are non-UK born (4). However, there have been a small number of cases initially diagnosed as drug-sensitive TB that then developed resistance, and a large outbreak of isoniazid-resistant TB, as well as clusters of MDR-TB. Risk factors for the development of drug-resistant strains include poor compliance with, or incorrect administration of TB treatment, which may arise as a result of delays in drug susceptibility testing, or due to lack of support to enable a patient to comply with the demands of the lengthy treatment regimen.

Actions:

- improve access to rapid diagnostic tests as described earlier
- ensure that all culture confirmed cases have drug susceptibility testing, and all MDR-TB cases have second-line drug susceptibility testing
- tackle the clinical and social risk factors associated with development of drug resistance in under-served populations
- ensure that all clinicians who treat a case of MDR-TB are informed about, have access to, and are encouraged to use specialist advisory services for MDR-TB provided by the British Thoracic Society or designated expert/centre within their clinical network
- ensure all cases of complex and MDR-TB are discussed at an MDT within the local clinical network
- ensure that best practice for infection control of patients with drug-resistant TB is maintained at all times to prevent further transmission
- ensure patient compliance with treatment by providing case management support, including the flexible delivery of DOT involving community DOT workers, pharmacists and other suitable providers

A7 Tackle TB in under-served populations

The rates of TB and the risks of delayed diagnosis, drug resistance, onward transmission and poor treatment outcomes are greatest among socially marginalised, under-served (hard-to-reach) populations (see glossary for definition). Diagnosing, treating and preventing transmission of TB among under-served groups will pay a "community dividend" by preventing transmission of infection to the wider population and reducing health and social inequalities.

Individuals in under-served groups commonly have multiple health morbidities, requiring access to integrated screening and care packages. The aim of holistic care should be to simultaneously address the patient's clinical needs and the social and environmental factors, which increase the risk of disease and poor treatment outcomes. These factors include, but are not limited to, mental health issues, homelessness, addiction, detention, destitution and exclusion from care services.

NICE has issued guidance on identifying and managing tuberculosis among hard-to-reach groups (14), which should form the basis for action in England.

Actions:

- ensure commissioners and service providers follow NICE guidance on TB in hard-to-reach and vulnerable groups (14)

- ensure commissioning of integrated, multidisciplinary, case management and support for under-served groups and that this multidisciplinary support (which may include third sector organisations) has the skills and resources necessary to manage people with complex social and clinical needs

- provide specific and targeted outreach interventions (informed by proven models such as 'Find and Treat' in London) including specific services for active case finding for pulmonary TB among homeless people and those attending substance misuse services, use of mobile X-ray units (MXUs) with incentives for people to have chest X-rays, enhanced case management and return to service interventions to prevent loss to follow up (14,30,31)

- ensure undocumented migrants diagnosed with TB are supported to complete TB treatment (32,33)

- ensure that people with TB who are homeless are provided with fast-track access to appropriate social care and accommodation for the length of their treatment (14)

- ensure the identification and management of active TB in prisons and immigration removal centres, management of latent TB in prison populations in line with NICE guidance and ensure continuity of care between prisons and the community

A8 Systematically implement new entrant latent TB (LTBI) screening

The majority of active TB cases diagnosed in England are a result of reactivation of LTBI. Individuals with latent TB are at increased risk of developing active TB, especially if they are recently infected or immunocompromised. The systematic screening and treatment of individuals with LTBI is therefore expected to significantly decrease the incidence of TB in England.

LTBI screening for new entrants from TB high incidence areas is an effective and cost-effective public health intervention (34) and is recommended by NICE (10).

While systematic LTBI screening requires an initial resource investment, it has been shown that the prevention of cases will yield budget savings after about four years (35).

A recent UK survey demonstrated significant variations in the organisation and quality of LTBI screening between different localities. Efforts are not well co-ordinated; screening protocols not always in line with best evidence and screening efforts are often inversely correlated with a need to screen (36).

A co-ordinated, local screening programme in areas of high incidence, targeted at new entrants to detect and treat asymptomatic TB infection would avert morbidity and mortality in the affected individuals and reduce the incidence of TB disease in the UK.

Actions:

- establish co-ordinated LTBI screening for new entrants from areas of the world with high incidence living in England and ensure TB control board support to implement systematic LTBI screening nationally and as a high priority intervention in high burden areas (areas with an incidence of TB over 20 per 100,000)

- offer LTBI screening to new entrants who were born or lived in Sub Saharan Africa or countries with an estimated TB incidence of greater than 150 per 100,000 and who arrived in the UK within the last five years

- ensure robust policies for LTBI screening for other high risk population groups, where this is NICE recommended (such as in patients with immunosuppression)

- work with local authorities, communities and third sector organisations to raise awareness and improve health education regarding LTBI screening

- ensure local LTBI screening is well resourced, co-ordinated and quality assured and as appropriate embedded in local health check procedures for other illnesses such as hepatitis or HIV

A9 Strengthen surveillance and monitoring

PHE runs national TB surveillance, with data provided by local clinical services and the mycobacterium reference laboratories. Good quality surveillance data provides the foundation for understanding the epidemiology of TB in England, which is required to direct appropriate TB control activity and monitor its impact. This includes describing trends in incidence and drug resistance, identifying high-risk groups for disease and transmission, and identifying outbreaks. In addition, TB surveillance collects many data items relevant to monitoring the performance of TB control activities, including treatment outcome monitoring.

The data collected through surveillance are disseminated in local and national reports, and at upper and lower tier local authority level in the Public Health Outcomes Framework.

Additional data relevant for monitoring TB service performance are generated through local TB cohort reviews.

Actions:

- to support the TB strategy, a formal monitoring framework will be put in place to ensure clear lines of accountability for monitoring TB service performance at local and national level

- local services to continue to support TB surveillance and monitoring activities

- PHE to develop a single National TB Surveillance System to replace ETS and LTBR, which should be responsive to local needs. In addition to current functionality, the National TB Surveillance System should collect data to support TB Services conduct periodic cohort review; and integrate epidemiological and strain typing data for the whole of England

- PHE to continue to produce annual national TB reports, and standardise the production of local TB surveillance outputs

- PHE will provide an annual suite of TB indicators to enable local TB control boards to monitor the performance of their local TB control activities and support the joint

strategic needs assessments for health and wellbeing boards, to enable local areas to benchmark their performance and to support local commissioners

A10 Ensure an appropriate workforce to deliver TB control

Effective and evidence-based TB investigation and control requires a complex set of clinical and public health interventions and co-ordination, often cross-boundary and, in some cases, cross-border. In England, this is usually provided by nurse-led TB teams with the advice and support of PHE centres where indicated. These multi-disciplinary teams should provide a range of services; demonstrate a high level of knowledge and expertise and, crucially, take on clinical and public health leadership across the health and social care landscape.

Additionally, consideration should also be given to the composition of these multi-disciplinary TB teams, which should include healthcare workers but may also include a range of other skill sets, such as administrative staff, staff with skills to address socioeconomic needs, local authority housing staff, the third sector and, potentially, trained lay workers in community outreach work, which has been a very successful method of delivering care in some countries.

The National Quality Board published a paper (37) setting out the roles and responsibilities that commissioners and providers need to undertake to ensure that staffing capacity and capability are appropriate, so that services can deliver high-quality care and the best possible outcomes for patients. A comprehensive workforce review across England will inform the way the delivery of TB services should be implemented.(37)

Actions:

- PHE and NHS England to work with Health Education England to co-ordinate a TB workforce review/scoping exercise in 2014/15
- each TB control board to develop a workforce strategy in line with the National Quality Board guide to staff capability and capacity (37) and outcomes of the national scoping exercise
- commissioners should specify in contracts the outcomes and quality standards required and actively seek assurance that there are sufficient numbers of nursing and support staff capable to meet these
- commissioners should monitor the quality and outcomes of TB services closely
- providers should work in partnership with stakeholders, both at local, regional and national level to provide the TB workforce with a career framework; continued professional development and opportunities to influence policy at a local and national level

Annexe 2. International activities of the UK TB Programme

UK government contribution to international TB control
The government is committed to helping to achieve the goals of the Global Plan to Stop TB to reduce deaths and prevalence of TB by half by 2015. To help achieve this, the Department for International Development (DFID) prioritises increasing access to effective diagnosis and treatment of TB, including TB-HIV and drug-resistant TB in high-burden countries; investing in research and product development of TB vaccines, diagnostics and treatment; support to high-burden countries to strengthen health systems, so that they can deliver good TB programmes; and work with international partners to tackle TB risk factors, including poverty and malnutrition.

Pre-entry screening
Robust, quality-assured, pre-entry chest X-ray screening will lead to early detection and treatment of drug-sensitive and drug-resistant pulmonary TB cases that may progress, and prevention of TB transmission in the UK or en route to the UK. This is being delivered through a unit run jointly by PHE and the UK Home Office. All individuals from high-incidence countries applying for a UK visa longer than six months are now required to provide evidence that they do not have active pulmonary TB.

Research to inform TB prevention and control
The WHO Global Plan to Stop TB (2011–2015) recognises that new tools are required to control TB and work toward elimination in low-burden countries. In particular, new diagnostics and more effective drugs and vaccines are needed (38).

PHE has an extensive portfolio of research, funded from internal and external sources, which is focused on addressing PHE, Department of Health and international priorities. Much of the research and development is in collaboration with leading academic groups in the UK and overseas. Research on TB is also embedded in several of the newly-created health protection research units, which will combine research groups from academia and PHE.

To support the TB strategy, a number of specific research questions need to be addressed to achieve a reduction in TB rates, tackle antimicrobial resistance and enhance national surveillance and monitoring.

Current areas of research include:

- development of an evidence base to control TB in under-served populations
- assessment of whole genome sequencing to more rapidly detect TB in clinical samples, and apply this approach to outbreak recognition and national surveillance
- trial and development of improved diagnostic tests for latent TB
- evaluation of new anti-TB drugs to shorten treatment times, and target MDR-TB strains, in laboratory and clinical studies
- development and evaluation of more effective vaccines for TB. PHE makes an important contribution to several major EU-funded consortia on vaccine development

Important areas for future research should include:

- new tests and strengthened testing algorithms, for existing tests, to improve the predictive value for latent TB
- emerging technologies to ensure more timely diagnosis, including molecular and other tests to assist in the early identification of cases. Research in this area may radically alter the management and treatment of TB. Areas of advance would include genomics, proteomics, transcriptomics and digital radiology
- a better and simpler regimen for the treatment of latent infection
- to continue to advance the development of new TB treatment regimens including the need for shorter, simpler and better tolerated treatment for drug-sensitive TB and LTBI, and to improve and advance the treatment for drug-resistant TB
- to advance research and development for new TB vaccines with improved effectiveness and a good safety profile, either as a booster for BCG or as recombinant vaccine to prevent TB infection and/or TB disease
- research to improve access by under-served populations to health and social services, ensuring early diagnosis and supporting treatment completion
- evaluating interventions that aim to increase awareness in high-risk populations and staff in contact with such individuals

Future research and development should continue to provide high-quality translational research to generate the evidence base and new tools necessary to improve the control of TB in England.

Annexe 3. Consultees and respondents

Responses to the consultation about the 'Collaborative Tuberculosis Strategy' (39), that ran from March to June 2014, were received from 111 bodies (listed below) including a number from individuals, organisations and multi-stakeholder events.

Abbott Molecular
All Party Parliamentary Group -TB
Anglia and Essex - PHE Centre
Arden Community TB Service, Coventry
Avon, Gloucestershire and Wiltshire - PHE Centre
Barts Health NHS Trust
BHIVA
Bio-Tech Parmacal, Inc
Birmingham and Solihull TB Service
Brighton and Sussex University Hospitals NHS Trust
Bristol City Council
British Red Cross
British Thoracic Society
Cambridgeshire County Council
Chartered Institute of Environmental Health
Cheshire & Merseyside - PHE Centre
Cheshire West and Chester Council
City Health Care Partnership CIC
Cumbria and Lancashire PHE Centre
Department of Health
Devon County Council
Devon, Cornwall and Somerset PHE Centre and TB stakeholders
Doctors of the World UK
Doncaster Council
Dudley Metropolitan Borough Council
East Midlands PHE Centre and TB stakeholders
East Sussex County Council
Essex County Council
Find & Treat Service, London
Greater London Authority
Greater Manchester - PHE Centre
Greater Manchester TB Collaborative
Homerton University Hospital
Hull, Leeds, TB nursing teams
Imperial College Healthcare NHS Trust (St Mary's)
Independent Public Health Practitioner
Individual
Individual
Individual - London Borough of Newham
Jenton International Limited
Joint Paediatric response from – RCPCH, BPAIIG, BPRS/BTS, BAGP, London Paediatric TB Network, UK Paediatric TB Network, CHIVA
Kent Community Health NHS Trust East
Kent County Council
Lambeth & Southwark Public Health
Lancashire Area Team NHS England
Lancashire Care NHS Foundation Trust
Local Government Association
London Borough of Newham
London Borough of Waltham Forest
London Respiratory Clinical Leadership Group
London TB Control Board and London TB Clinical Leadership Group (combined response with contributions from NHSE-London, PHE-London, NHS and the Third Sector)
London TB Workforce
LSHTM TB Centre
LTBeX team, PHE London
Luton Borough Council
Milton Keynes Hospital NHS Foundation Trust
National AIDS Trust
National Association for Voluntary and Community Action
National Institute for Health and Care Excellence (NICE)
NAZ Project London
NHS Dorset Clinical Commissioning Group
NHS England - Birmingham, Solihull & Black Country Area Team
NHS England (Midlands & East)
Norfolk County Council and Suffolk County Council
North Central London (non-inpatient) TB Service
North East – PHE Centre
North West London multi-stakeholder TB Network
North West TB Summit (partnership of NHS England, PHE, Local Government and clinical services across the North West of England)
Oldham Council
PHE – TB Section
PHE Centre Yorkshire & Humber consultation event
Public Health, Coventry City Council and Warwickshire County Council
Public Health, London Borough of Croydon

Public Health, London Borough of Redbridge
RESULTS UK
Royal Bolton Hospital
Royal Brompton Hospital
Royal College of Nursing UK
Salford City Council
Sheffield County Council
Sheffield NHS Trust
Somerset County Council
South East London Health Protection Team
South East London TB Network
South West London TB Group
South Yorkshire Health Protection Team, Barnsley Council and other TB stakeholders including commissioners
Stoke City Council
Surrey and Sussex Health Protection Team
Surrey County Council
TB Action Group
TB Alert
TB Nurse, Cornwall
Thames Valley PHE Centre & Berkshire stakeholders
Thames Valley PHE Centre & Buckinghamshire stakeholders
Thames Valley PHE Centre & Oxfordshire stakeholders
The Association of Directors of Public Health
The Royal College of Pathologists
The Tunbridge Wells Hospital at Pembury
The University of Southampton
Tower Hamlets Local Authority
UCL TB Centre
University Hospital of South Manchester
University Hospitals Bristol NHS Foundation Trust
Virgin Care Limited
Wessex PHE Centre and the HIOW TB Network
West Midlands East Health Protection Team - PHE
West Midlands PHE Centre, local directors of public health and other TB stakeholders
West Midlands Public Health England Centre
West Sussex County Council
Western Sussex Hospitals NHS Foundation Trust
Wolverhampton City Council and Royal Wolverhampton TB Service

Annexe 4. National level baseline data for TB strategy monitoring indicators, England*

Year	Indicator 1			Indicator 2						Indicator 5		
	Overall TB incidence per 100,000 population			TB incidence per 100,000 population by place of birth						Incidence per 100,000 population of TB in UK born children aged under fifteen years		
				UK born			Non UK-born					
	Number of cases	Rate	95% CI	Number of			Number of			Number of cases	Rate	95% CI
2004	6,934	13.8	13.5 - 14.1	1,794	4.0	3.8 - 4.2	4,570	95.4	92.7 - 98.3	264	3.0	2.7 - 3.4
2005	7,665	15.1	14.8 - 15.5	1,808	4.1	3.9 - 4.2	5,187	101.2	98.5 - 104.0	248	2.9	2.5 - 3.2
2006	7,689	15.1	14.8 - 15.4	1,732	3.9	3.7 - 4.1	5,179	93.6	91.1 - 96.2	211	2.5	2.1 - 2.8
2007	7,585	14.8	14.4 - 15.1	1,800	4.1	3.9 - 4.2	5,138	86.5	84.2 - 88.9	291	3.4	3.0 - 3.8
2008	7,814	15.1	14.7 - 15.4	1,867	4.2	4.0 - 4.4	5,418	87.3	85.0 - 89.7	294	3.4	3.0 - 3.8
2009	8,119	15.6	15.2 - 15.9	1,910	4.3	4.1 - 4.5	5,665	88.2	85.9 - 90.5	256	3.0	2.6 - 3.4
2010	7,677	14.6	14.3 - 14.9	1,814	4.0	3.9 - 4.2	5,514	84.4	82.2 - 86.6	238	2.8	2.4 - 3.1
2011	8,284	15.6	15.3 - 15.9	1,961	4.4	4.2 - 4.6	6,018	87.3	85.1 - 89.5	233	2.7	2.4 - 3.1
2012	8,099	15.1	14.8 - 15.5	2,015	4.5	4.3 - 4.7	5,844	83.2	81.1 - 85.4	255	2.9	2.6 - 3.3
2013	7,290	13.5	13.2 - 13.8	1,857	4.1	3.9 - 4.3	5,250	71.8	69.9 - 73.8	196	2.2	1.9 - 2.6

*Indicator 3: not included as not a national level indicator .
Indicator 4 (slope index of inequalities in TB rates): data will be available with release of full baseline monitoring indicators in March 2015.

Year	Indicator 6			Indicator 7			Indicator 8			Indicator 9		
	Number and proportion of pulmonary TB cases starting treatment within two months of symptom onset			Number and proportion of pulmonary TB cases starting treatment within four months of symptom onset			Number and proportion of pulmonary TB cases that were culture confirmed			Number and proportion of culture confirmed cases with drug susceptibility testing reported for the four first line agents		
	Number of cases	Proportion	95% CI	Number of cases	Proportion	95% CI	Number of cases	Proportion	95% CI	Number of cases	Proportion	95% CI
2004	-	-		-	-		2,741	68.4	67.0 - 69.9	4,021	98.6	98.2 - 98.9
2005	-	-		-	-		2,986	69.1	67.7 - 70.5	4,531	98.9	98.6 - 99.2
2006	-	-		-	-		2,978	69.3	67.9 - 70.6	4,605	98.7	98.3 - 99.0
2007	-	-		-	-		2,851	68.7	67.3 - 70.1	4,367	98.2	97.7 - 98.5
2008	-	-		-	-		2,899	67.7	66.3 - 69.1	4,428	97.6	97.1 - 98.0
2009	-	-		-	-		3,004	68.1	66.7 - 69.5	4,519	96.8	96.2 - 97.3
2010	-	-		-	-		2,864	70.4	68.9 - 71.8	4,510	97.9	97.5 - 98.3
2011	1,320	45.1	43.2 - 46.9	2,176	74.3	72.6 - 75.8	3,069	71.6	70.2 - 72.9	4,892	97.3	96.8 - 97.7
2012	1,377	44.2	42.5 - 46.0	2,299	73.8	72.3 - 75.4	2,945	70.3	68.8 - 71.6	4,782	97.8	97.3 - 98.1
2013	1,201	41.3	39.5 - 43.1	2,083	71.6	70.0 - 73.3	2,673	71.3	69.8 - 72.8	4,205	97.5	97.0 - 97.9

Year	Indicator 10			Indicator 1:			Indicator 1:		
	Number and proportion of drug sensitive TB cases who had completed a full course of treatment by 12 months			Number and proportion of drug sensitive TB cases who were lost to follow up at last reported outcome			Number and proportion of drug sensitive TB cases who had died at last reported outcome		
	Number of cases	Proportion	95% CI	Number of cases	Proportion	95% CI	Number of cases	Proportion	95% CI
2003	4,195	69.6	68.4 - 70.8	266	4.4	3.9 - 5.0	353	5.9	5.3 - 6.5
2004	4,431	70.1	69.0 - 71.2	303	4.8	4.3 - 5.4	329	5.2	4.7 - 5.8
2005	4,879	70.3	69.2 - 71.3	342	4.9	4.4 - 5.5	376	5.4	4.9 - 6.0
2006	5,220	75.5	74.5 - 76.5	375	5.4	4.9 - 6.0	357	5.2	4.7 - 5.7
2007	5,288	78.1	77.0 - 79.0	303	4.5	4.0 - 5.0	367	5.4	4.9 - 6.0
2008	5,586	79.9	78.9 - 80.8	323	4.6	4.1 - 5.1	357	5.1	4.6 - 5.6
2009	5,918	81.8	80.9 - 82.7	306	4.2	3.8 - 4.7	342	4.7	4.3 - 5.2
2010	5,633	82.6	81.7 - 83.5	293	4.3	3.8 - 4.8	314	4.6	4.1 - 5.1
2011	6,008	81.8	80.9 - 82.7	368	5.0	4.5 - 5.5	315	4.3	3.8 - 4.8
2012	5,998	83.3	82.4 - 84.2	290	4.0	3.6 - 4.5	310	4.3	3.8 - 4.8

Year	Indicator 13			Indicator 14			Indicator 15		
	Number and proportion of drug resistant* TB cases who had completed treatment at 24 months			Number and proportion of drug resistant* TB cases who were lost to follow up at last reported outcome			Number and proportion of drug resistant* TB cases who had died at last reported outcome		
	Number of cases	Proportion	95% CI	Number of cases	Proportion	95% CI	Number of cases	Proportion	95% CI
2003	-	-	-	-	-	-	-	-	-
2004	36	52.2	39.8 - 64.4	8	11.6	5.1 - 21.6	4	5.8	1.6 - 14.2
2005	36	61.0	47.4 - 73.5	8	13.6	6.0 - 25.0	4	6.8	1.9 - 16.5
2006	40	50.6	39.1 - 62.1	8	10.1	4.5 - 19.0	3	3.8	0.8 - 10.7
2007	26	36.1	25.1 - 48.3	6	8.3	3.1 - 17.3	10	13.9	6.9 - 24.1
2008	38	53.5	41.3 - 65.5	10	14.1	7.0 - 24.4	7	9.9	4.1 - 19.3
2009	34	46.6	34.8 - 58.6	11	15.1	7.8 - 25.4	4	5.5	1.5 - 13.4
2010	37	47.4	36.0 - 59.1	8	10.3	4.5 - 19.2	1	1.3	0.0 - 6.9
2011	43	46.7	36.3 - 57.4	18	19.6	12.0 - 29.1	4	4.3	1.2 - 10.8
2012	-	-	-	-	-	-	-	-	-

Year	Indicator 16			Indicator 17			Indicator 18			Indicator 19		
	Number and proportion of TB cases offered an HIV test			Number and proportion of drug sensitive TB cases with at least one social risk factor who completed treatment within 12 months			Number and proportion of culture confirmed TB cases with any first line drug resistance			Number and proportion of culture confirmed TB cases with multi-drug resistance TB		
	Number of	Proportion	95% CI	Number of cases	Proportion	95% CI	Number of	Proportion	95% CI	Number of	Proportion	95% CI
2004	-	-	-	-	-	-	327	8.1	7.3 - 9.0	46	1.1	0.8 - 1.5
2005	-	-	-	-	-	-	346	7.6	6.9 - 8.4	41	0.9	0.6 - 1.2
2006	-	-	-	-	-	-	370	8.0	7.2 - 8.8	54	1.2	0.9 - 1.5
2007	-	-	-	-	-	-	334	7.6	6.8 - 8.4	51	1.2	0.9 - 1.5
2008	-	-	-	-	-	-	305	6.8	6.1 - 7.6	49	1.1	0.8 - 1.4
2009	-	-	-	-	-	-	370	8.0	7.2 - 8.9	59	1.3	1.0 - 1.7
2010	-	-	-	372	72.8	68.7 - 76.6	321	7.0	6.3 - 7.8	65	1.4	1.1 - 1.8
2011	-	-	-	369	71.4	67.3 - 75.2	415	8.4	7.6 - 9.2	81	1.6	1.3 - 2.0
2012	5,200	66.8	65.8 - 67.9	395	75.0	71.0 - 78.6	360	7.4	6.7 - 8.2	79	1.6	1.3 - 2.0
2013	5,645	81.1	80.1 - 82.0	-	-	-	330	7.8	7.0 - 8.6	68	1.6	1.2 - 2.0

Metadata for TB Strategy Monitoring Indicators, England

Rates presented are crude rates per 100,000 population. 95% confidence intervals (CI) for rates were calculated assuming a Poisson distribution. The remaining indicators are all presented as proportions, with 95% binomial CIs.

Indicator 1: TB incidence per 100,000 population.
Numerator: Annual TB case notifications, England.
Denominator: Office for National Statistics mid-year population estimate, England.

Indicator 2: TB incidence per 100,000 population by place of birth.
Numerator: Annual TB notifications, England, by place of birth.
Denominator: Labour Force Survey annual population estimates by place of birth, England.

Indicator 4: Slope index of inequalities (SII) in TB rates:
Lower super output areas (LSOAs) in England were ranked in order of deprivation using overall index of deprivation 2010 scores. These were then divided into deprivation deciles with approximately equal numbers of LSOAs in each decile. LSOA level TB case data and population estimates were aggregated into these deciles. The SII is the variation in TB rates by deprivation, from the most to least deprived decile. It is calculated using population weighted linear regression.

Indicator 5: TB incidence per 100,000 population in UK born children aged under fifteen years.
Numerator: Annual TB case notifications in UK born children aged under fifteen years, England.
Denominator: Labour Force Survey annual population estimate of UK born children aged under fifteen years, England.

Indicator 6: Number and proportion of pulmonary TB cases starting treatment within two months of symptom onset.
Numerator: Annual number of pulmonary TB cases starting treatment within 61 days of symptom onset.
Denominator: Annual number of pulmonary TB cases notified.
Exclusions: TB cases with no date of symptom onset or no date of treatment start.

Indicator 7: Number and proportion of pulmonary TB cases starting treatment within four months of symptom onset.
Numerator: Annual number of pulmonary TB cases starting treatment within 121 days of symptom onset. Denominator: Annual number of pulmonary TB cases notified.
Exclusions: TB cases with no date of symptom onset or no date of treatment start.

Indicator 8: Number and proportion of pulmonary TB cases that were culture confirmed.
Numerator: Annual number of pulmonary TB cases with a positive culture for *Mycobacterium tuberculosis* complex. Denominator: Annual number of notified pulmonary TB cases.

Indicator 9: Number and proportion of culture confirmed TB cases with drug susceptibility testing reported for the four first line agents.
Numerator: Annual number of culture confirmed notified TB cases with drug susceptibility testing reported for all of the following drugs: isoniazid, rifampicin, ethambutol and pyrazinamide.
Denominator: Annual number of culture confirmed notified TB cases.

Indicator 10: Number and proportion of drug sensitive TB cases who had completed a full course of treatment by 12 months.
Numerator: Number of drug sensitive TB cases notified in a given year who had completed a full course of treatment within 12 months of treatment start date.
Denominator: Number of drug sensitive TB cases notified with TB that year.
Exclusions: cases with rifampicin resistance or multi-drug resistant TB (MDR-TB), and cases with CNS, spinal, miliary or disseminated TB who may require longer than the standard 6 month treatment course.

Indicator 11: Number and proportion of drug sensitive TB cases that were lost to follow up at last reported outcome.
Numerator: Number of drug sensitive TB cases notified in a given year who were lost to follow up at last reported outcome.
Denominator: Number of drug sensitive TB cases notified in that year.
Exclusions: cases with rifampicin resistance or MDR-TB.

Indicator 12: Number and proportion of drug sensitive TB cases that had died at last reported outcome.
Numerator: Number of drug sensitive TB cases notified in a given year who had died at last reported outcome.
Denominator: Number of drug sensitive TB cases notified in that year.
Exclusions: as for indicator 11.

Indicator 13: Number and proportion of drug resistant TB cases who had completed treatment at 24 months.
Numerator: Annual number of notified TB cases with rifampicin resistance or MDR-TB who had completed treatment within 24 months of start of treatment.
Denominator: Annual number of notified TB cases with rifampicin resistance or MDR-TB.

Indicator 14: Number and proportion of drug resistant TB cases who were lost to follow up at last reported outcome.
Numerator: Annual number of notified TB cases with rifampicin resistance or MDR-TB who were lost to follow-up at last reported outcome.
Denominator: Annual number of notified TB cases with rifampicin resistance or MDR-TB.

Indicator 15: Number and proportion of drug resistant TB cases who had died at last reported outcome.
Numerator: Annual number of notified TB cases with rifampicin resistance or MDR-TB who had died at last reported outcome.
Denominator: Annual number of notified TB cases with rifampicin resistance or MDR-TB.

Indicator 16: Number and proportion of TB cases offered an HIV test.
Numerator: Annual number of notified TB cases reported to have been offered an HIV test.
Denominator: Annual number of notified TB cases.
Exclusions: cases where HIV status already known, and cases diagnosed post mortem.

Indicator 17: Number and proportion of drug sensitive TB cases with at least one social risk factor who completed treatment within 12 months.
Numerator: Annual number of drug sensitive TB cases with at least one social risk factor (current or past history of drug or alcohol misuse, homelessness or imprisonment) who have completed treatment within 12 months of treatment start date.
Denominator: Number of drug sensitive TB cases with at least one social risk factor notified with TB that year.
Exclusions: as for indicator 10.

Indicator 18: Number and proportion of culture confirmed TB cases with any first line drug resistance.
Numerator: Annual number of culture confirmed TB cases with resistance to isoniazid, rifampicin, ethambutol or pyrazinamide. Denominator: Annual number of culture confirmed TB cases.
Exclusions: *Mycobacterium bovis* cases.

Indicator 19: Annual number and proportion of culture confirmed TB cases with MDR-TB.
Numerator: Number of culture confirmed cases with resistance to at least isoniazid and rifampicin.
Denominator: Annual number of notified culture confirmed TB cases.

Annexe 5. References

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Annexe 6. Glossary

Cohort review
The systematic review of all TB cases notified by a TB service in a 3–4 month period, to ascertain outcomes for these patients in terms of treatment completion and number of contacts screened.

Contact tracing
Contact tracing is undertaken after notification of an active case of TB to find associated cases, to detect people infected but without evidence of disease (latent infection) and to identify those not infected and for whom BCG vaccination may be appropriate.

Directly observed therapy (DOT)
A trained health professional, or responsible lay person supported by a trained health professional, provides the prescribed medication and observes the patient swallowing every dose.

Elimination of TB
Less than one case per million people per year (42).

Enhanced case management (ECM)
The package of care provided when a patient has clinically or socially complex needs. Enhanced case management commences as soon as TB is suspected. It includes DOT in conjunction with a package of supportive care tailored to the patient's needs. (11)

Extensive drug resistance (XDR)
XDR is defined as resistance to at least isoniazid and rifampicin (MDR), one injectable agent (capreomycin, kanamycin or amikacin) and one fluoroquinolone.

Extra-pulmonary TB
TB of organs other than the lungs (eg pleura, lymph nodes, abdomen, genitourinary tract, skin, joints and bones, meninges).

Latent TB infection (LTBI)
Latent TB is when a person has the bacteria that cause TB in their body but they are not causing any disease or symptoms, ie the bacteria are asleep or dormant. There is a chance that the bacteria may cause disease in the future.

Multi-drug resistance (MDR-TB)
MDR-TB is defined as resistance to at least isoniazid and rifampicin, with or without resistance to other drugs.

Pulmonary
A pulmonary case is defined as a case with TB involving the lungs and/or tracheo-bronchial tree.

TB clinical networks
Local TB clinical networks would have the following functions:

- facilitate local treatment centre MDTs
- set up and co-ordinate network/regional MDTs to allow all complex or MDR cases to be discussed with participation of all local treatment centres and a 'node' associated centre (the exact number and size of each network and the number of MDR centres will be tailored dependent on local case mix and geography) – this will include agreement on prescriptions of centrally funded MDR drugs by a regional MDT
- facilitate cohort review meetings
- ensure that all local services reach a minimum standard of care, through audit, cohort review, regular sharing of good practice and local expertise and benchmarking against national standards
- provide a co-ordinated structure to inform NHS England, PHE and other national organisations of local demographics and pressures on individual services eg changes in migration patterns, prison services, college overseas recruitment
- report to the TB control board and advise on any local deficiencies in service provision or facility

Under-served populations
This term is used to denote individuals previously referred to by NICE and others as 'hard-to-reach', and refers to individuals whose social circumstances, language, culture or lifestyle (or those of their parents or carers) make it difficult to recognise the clinical onset of TB, access diagnostic and treatment services; self-administer treatment (or, in the case of children and young people, have treatment administered by a parent or carer); or attend regular appointments for clinical follow up (14). The term under-served emphasises the responsibility of commissioners and service providers to understand and meet the needs of this population.

Whole genome sequencing
The determination of the sequence of most of the DNA content comprising the entire genome of the mycobacteria. It can help in understanding the molecular relationships between different mycobacteria isolates and may help in understanding potential transmission events and detecting these early.

Annexe 7. List of abbreviations

The following abbreviations are used throughout this document.

BCG	Bacille Calmette Guérin vaccine
CCG	Clinical commissioning group
DOT	Directly observed therapy
ETS	Enhanced tuberculosis surveillance
LTBI	Latent tuberculosis infection
LTBR	London Tuberculosis Register
MDR TB	Multi-drug resistant TB
MDT	Multi-disciplinary team
NICE	National Institute for Health and Care Excellence
TB	Tuberculosis
XDR TB	Extensively drug resistant tuberculosis

About Public Health England

Public Health England exists to protect and improve the nation's health and wellbeing, and reduce health inequalities. It does this through advocacy, partnerships, world-class science, knowledge and intelligence, and the delivery of specialist public health services. PHE is an operationally autonomous executive agency of the Department of Health.

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