Latent Tuberculosis Infection (LTBI) Service Specification

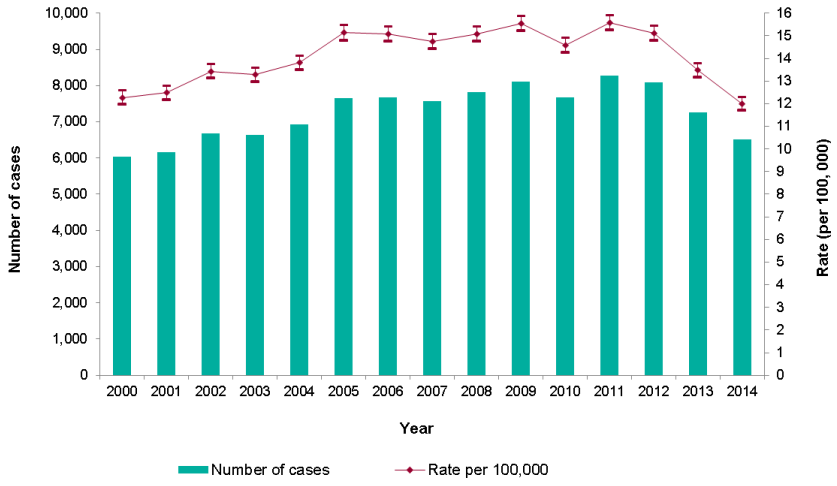
Schedule 2 Part A Service Specification

Service Specification No.	**12**
Service	Latent tuberculosis infection (LTBI) testing and treatment
Commissioner Lead	Elective Care
Provider Lead	University Health Service and Porter Brook Medical Centre
Period	1st April 19 to 31 March 2020
Date of Review	September 2019

1. Population Needs

1.1. National/local context and evidence base

Tuberculosis (TB) rates in England remain high and are associated with significant morbidity, mortality and costs. The onset of TB can be difficult to detect with significant diagnostic delays. Late diagnoses are associated with worse outcomes for the individual and in the case of pulmonary TB, with a transmission risk to the public.



Since 2013 there has been a year on year decline in the number of TB cases in England, down to 6,520 in 2014, a rate of 12.0 per 100,000. The recent reduction in TB cases is mainly due to a reduction in cases in the non-UK born population, which make up nearly three-quarters of all TB cases in England. The majority of non-UK born cases (86%) are now notified more than two years after entering the UK, and are likely to be due to reactivation of latent TB infection.

The Collaborative Tuberculosis Strategy for England: 2015 to 2020 (published in January 2015 by NHS England and Public Health England (PHE)) sets out approaches to support

TB prevention, treatment and control (1). This includes the setting up of regional TB control boards to plan, oversee, support and monitor all aspects of local TB control. The control boards have representation from Clinical Commissioning Groups (CCGs), NHS England, PHE, local authorities, local TB service providers and other stakeholders. The formal responsibility for commissioning NHS TB services remains with CCGs.

The Strategy identifies ten areas of action to reduce TB in the UK. This service specification specifically addresses action eight which is 'Systematically implement new entrant latent TB testing'. LTBI testing and treatment ('LTBI testing') of new entrants to England is also supported by the National Institute of Health and Care Excellence (NICE).

Evidence shows that the effectiveness and cost effectiveness of LTBI testing depends on the accurate identification and targeting of eligible recipients. To support this service NHS England has identified £10 million in 2015/16 for development of latent TB infection identification, testing and treatment. Sheffield CCG has accessed this additional funding on the basis of a locally developed latent TB implementation plan signed off by the relevant TB control board and approved by the national NHS England / PHE TB programme team.

1.2. Local context

The number of people diagnosed with TB in Sheffield has been steadily increasing over the last five years. The annual number of cases in the city has risen from 77 in 2009 to 97 in 2013. This translates to an increase in incidence from 14.3 per 100,000 in 2009 to 17.3 per 100,000 in 2013. The burden of TB across Sheffield is extremely variable with the vast majority of cases in the central, north east and eastern parts of the city. This reflects both the distribution of socioeconomic disadvantage and the geographical locations where new arrivals and settled migrants live. There are 128,000 people (23% of the population of Sheffield) living in neighbourhoods where TB incidence is greater than 20 per 100,000. The average TB incidence for these neighbourhoods is 50 per 100,000.

References

1. Collaborative Tuberculosis Strategy for England: 2015 to 2020 www.gov.uk/government/publications/collaborative-tuberculosis-strategy-for-england
2. Collaborative Tuberculosis Strategy: Commissioning Guidance (NHSE Gateway reference: 03634)
3. Latent TB testing and treatment for migrants: A Practical Guide for Commissioners and Practitioners (NHSE Gateway reference: 03508) www.england.nhs.uk/resources/resources-for-ccgs/out-frwrk/dom-1/tb-strategy/

Other key documents

4. NICE CG117, 2011. Tuberculosis. Clinical diagnosis and management of tuberculosis, and measures for its prevention and control. www.nice.org.uk/guidance/cg117/evidence/cg117-tuberculosis-full-guideline3
5. Update 2015, NICE are currently consulting on draft revision and update - Tuberculosis: prevention, diagnosis, management and service organisation. This update is expected late 2015.
6. Tuberculosis in the UK-PHE2014 Annual report www.gov.uk/government/publications/tuberculosis-tb-in-the-uk
7. Royal College of Nursing (RCN): case management and cohort www.rcn.org.uk/ data/assets/pdf_file/0010/439129/004204.pdf
8. BCG – Details within www.gov.uk/government/collections/immunisation-against-

infectious-disease-the-green-book

9. British Thoracic Society (BTS) www.brit-thoracic.org.uk/clinical-information/tuberculosis/

2. Outcomes

2.1. NHS Outcomes Framework Domains & Indicators

Domain 1	Preventing people from dying prematurely	✓
Domain 2	Enhancing quality of life for people with long-term conditions	
Domain 3	Helping people to recover from episodes of ill-health or following injury	✓
Domain 4	Ensuring people have a positive experience of care	
Domain 5	Treating and caring for people in safe environment and protecting them from avoidable harm	✓

2.2. Local defined outcomes

A LTBI testing and treatment service will reduce the number of people developing TB in Sheffield. We have approximately 100 cases of TB in Sheffield each year, a current incidence rate of 17.3 per 100,000 (2013 annual data). We would expect the incidence rate to fall year on year as a direct result of introducing latent TB testing and treatment.

3. Scope

3.1 Aims and objectives of service

The aim of this service specification is to deliver local implementation of the national LTBI testing and treatment programme by identifying and testing eligible migrant populations for LTBI at the point of GP registration. This will lead to a reduction in the rate of TB in Sheffield by improving the early detection and diagnosis of TB.

3.2 Population covered

Based on evidence of cost effectiveness, LTBI testing and treatment will be limited to persons who are from countries with a WHO-estimated incidence of over 150 per 100,000 or from Sub-Saharan Africa, and who have arrived in England within the last five years. Specific acceptance criteria and thresholds are defined in the sections below.

3.3 Any acceptance and exclusion criteria and thresholds

The countries list for LTBI testing and treatment are available on the PRESS portal http://www.sheffieldccgportal.co.uk/pressv2/index.php/resources

The criteria include:

- new registration with a GP practice
- aged 16-35
- not previously been tested or treated for TB
- been in England less than 5 years and

- come from the list of countries found in the attachment 'Countries for LTBI testing'

3.4 Service description/care pathway

LTBI testing and treatment will be offered in the first instance to new patients. The LTBI testing process can be combined with other primary care based registration health checks, which makes uptake more likely. A draft letter of invitation can be found in the PRESS portal here http://www.sheffieldccgportal.co.uk/pressv2/index.php/resources

For patients with a positive IGRA (Inferion Gamma Release Array) test the service will make immediate and appropriate referral to local TB services as defined in local plans. A local algorithm can be found in the PRESS portal here http://www.sheffieldccgportal.co.uk/pressv2/index.php/resources

This service requires the following actions to take place:

- GP staff undertaking a new patient registration and health check will identify patients meeting the criteria outlined above.
- GP staff will explain why the LTBI test is being offered and give patients a copy of the national LTBI patient information sheet. GP staff will also review the content of the leaflet with the patient which includes how their data will be used. Patients will be informed of the signs and symptoms of TB.
- If a new registrant has symptoms of active TB, practice staff will organise immediate referral to local TB services and follow standard national infection control guidelines, as per normal practice. No LTBI testing is needed in these circumstances.
- Record patients with a BCG (Bacillus Calmette-Guérin) scar.
- If the new patients are children from high-risk countries and have not received BCG vaccination they will be offered BCG as per national guidelines.
- GP staff will then provide patients with the IGRA test.
- Pregnant women can be tested and symptomatic TB patients need to be referred to TB services immediately. However for pregnant patients with positive IGRA tests and who are asymptomatic, LTBI treatment should wait until after delivery. A referral and arrangements should be made for treatment to be scheduled after delivery.
- GP practices will make arrangements to follow-up patients who miss appointments or blood tests.
- GP practices are responsible for informing patients of their IGRA test results:
    - All patients will be informed of their results.
    - Patients with a borderline negative result will be recorded and treated as negative.
    - Patients with a borderline positive result will be recorded and treated as positive.
    - Patients who test positive or borderline positive will be advised by their GP that they will be referred on to STH respiratory outpatients for further assessment and treatment. These patients will then be referred to the local TB service for follow-up to rule out active TB, and to initiate treatment. GP practices will put in place pathways to ensure timely referrals to TB service.
- Patients with negative results who have not received BCG vaccination should be offered a vaccination if they are from countries with incidence over 500 per 100,000

(includes patients from Djibouti, Lesotho, Mozambique, Namibia, South Africa, Swaziland and Zimbabwe).

- GP practices should enter the details of LTBI testing using the nationally provided template on their GP system. Templates have been developed for EMIS Web and SystmOne. If GP practices cannot get access to these templates the GP will enter this information on a web-based form provided by PHE.
- GP practices will use this opportunity to test for HIV, if appropriate, in particular among people from countries where co-infection is common (eg Sub-Saharan Africa) or other HIV high incidence areas.
- GP practices will consider combining LTBI testing with other health checks, such as for diabetes or blood born viruses (BBVs) as appropriate.
- If a patient declines to be tested, this will be recorded in their primary care records.
- Awareness should be raised among practice staff to ensure they have an increased index of suspicion for TB in patients who present with any of the common signs or symptoms of TB or who have other, unexplained symptoms.

3.5 Diagnostics

LTBI testing will be performed using a single IGRA blood test. LTBI tests are currently nationally procured and Sheffield CCG will provide details to GPs on how to access these.

3.6 Referral process

Patients with positive or borderline positive results will be referred by GPs into secondary care services (respiratory outpatients at the Northern General Hospital).

3.6 TB treatment

This service provision does not include active or latent TB treatment.

3.7 Data entry and data quality assurance

Good data entry will form the basis of all remuneration. Payments will be made if all required fields listed in data requirements document (PRESS portal http://www.sheffieldccgportal.co.uk/pressv2/index.php/resources) are entered into the GP practice system template. These are the data requirements of Public Health England and NHS England, as this is a national testing and treatment programme. PHE will require monthly uploads of data to the PHE data warehouse (further detail in section 6)

This service requires:

- GP staff to ensure that the data entered into the practice template is correct.
- GP staff to work with PHE to resolve data quality issues, if needed.

3.8 Interdependence with other services/providers

GP screening for LTBI is the first step in the LTBI pathway. People who test positive for LTBI by the GP will be referred to a one stop LTBI clinic in secondary care (respiratory outpatients, Northern General Hospital) for assessment and commencement of treatment. Patients on treatment will be followed up in the community by the community TB nursing team. The GP will be notified when the patient is discharged by the LTBI clinic or by the TB nursing team, either due to repeated DNA, completion of treatment or other reason.

3.9 Community engagement

The relationship between the GPs and migrant populations is likely to be key to the success of this LTBI testing service. This service will:

- Establish a trusting relationship with new migrant registrants.
- Support patients to be well informed about their condition and the actions they need to take in response to it.
- Initiate referral to, and co-ordinate inputs of, other relevant services as appropriate.

4. Applicable Service Standards

4.1. Applicable national standards (eg NICE)

- NICE TB clinical guidelines

4.2. Applicable local standards

Key performance indicators:

- Proportion of eligible new entrants who accept LTBI testing
- Proportion of eligible new entrants who test positive for LTBI and take up the offer of treatment
- Proportion of individuals starting LTBI treatment who achieve completion

Schedule 2 Part B Indicative Activity Plan

Name of Service LTBI testing and treatment service

Funding has been agreed for approximately 400 IGRA tests, positive tests averaging around 20% i.e. about 20 patients requiring referral to Secondary Care.

(Note: this is an estimated number of tests and an estimated % testing positive – the prevalence of latent TB infection in the student population is currently unknown; the LTBI testing programme will help establish prevalence)

Schedule 2 Part C Activity Planning Assumptions

LTBI testing and treatment service
Activity Planning Assumption

- 100% of eligible patients should be tested, with at least 3 documented attempts made to contact eligible patients
- 100% of patients testing positive should be referred to secondary care

Schedule 2 Part F Clinical Networks and National Programmes

No national clinical networks or national clinical audits.

Schedule 2 Part G Other Locally Agreed Policies and Procedures

Policy	Date	Weblink
NONE		

Schedule 2 Part I Exit Arrangements

N/A

Schedule 2 Part K Transfer of and Discharge from Care Protocols

N/A

Schedule 3 Payment

Part A Local Prices

Service Description	Currency	Price	Basis for payment	Regime for future years
• Identify new migrants that met the eligibility requirement as detailed in section 3; offer IGRA test; and complete all data fields in the GP system (SystmOne or EMIS template)	Per eligible patient who has received IGRA test and either tested negative; or tested positive and referred to secondary care	£20	Data submitted via LCS database, paid quarterly in arrears: Data submitted to PHE data warehouse via monthly uploads • As per EMIS or SystmOne	N/A

• For patients who test positive, a referral is made to the local TB service	?	?	template ?	?

- **Note:** At least three attempts to contact identified patient are recorded (if patient fails to attend appointment). Contact can be in the form of a telephone call, letter, text message or any other another communication process already established at the practice

- All data recorded as specified in data payment document http://www.sheffieldccgportal.co.uk/pressv2/index.php/resources

- Payment will only be made if all relevant fields have been completed in the GP system.

- Invoices will be submitted with the following information, each to cover the time period of the invoice:
  - Number of patients found to be eligible
  - Number of patients receiving IGRA test
  - Number of positive LTBI results obtained

Part F Expected Annual Contract Value

Service	**Expected annual contract value**
GP Provider	Dependant on provider

Schedule 4 Part C Local Quality Requirements

Quality Requirement	**Threshold**	**Method of Measurement**	**Consequence of breach**	**Monthly or annual application of consequence of breach**	**Service Spec. Number**
Data quality requirements	Submission of template	Completed template submitted which meets threshold	Payment withheld	6 monthly	16

Schedule 4 Part F Local Incentive Scheme

N/A

Schedule 5 Part B2 Provider's Permitted Material Sub-Contractors

N/A

SCHEDULE 6 Part B Reporting Requirements

Activity information required

Information required	**Reporting Period**	**Format of Report**	**Timing and Method for delivery of Report**
FOR PHE: All data in SystmOne or EMIS LTBI template	Monthly	Submitted electronically using PHE extraction tool	Via direct upload to PHE by15th day of the month
FOR CCG: • Number of eligible patients • Number of patients receiving IGRA test • Number of positive LTBI results obtained	Monthly	As set out in the LCS database	Via LCS database by 15th day of the month

Quality information required

Information required	**Reporting Period**	**Format of Report**	**Timing and Method for delivery of Report**
Currently N/A			

All practices who participate will need to share data with the Public Health England (PHE) secure data warehouse via direct upload. Under regulation 3 of section 251 (National Health Service Act 2006) Public Health England has obtained the legal ability to collect patient identifiable data without patient consent. GPs will provide a patient information leaflet to inform patients on how their information is processed and used along with instructions for patients who would like to opt out of sharing their data http://www.sheffieldccgportal.co.uk/pressv2/index.php/resources

GPs will also provide further information, if needed and requested by the patient. The patient information leaflet will be available at all GP surgeries. Patient identifiable data will not be provided to any other third parties.