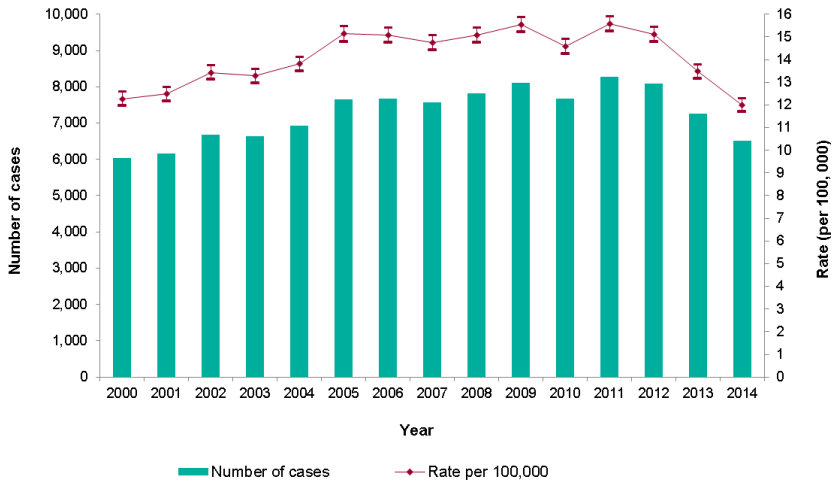
National Latent Tuberculosis Infection (LTBI) Service Specification

Service Specification No.	Version 2.0 - November 2017
Service	Latent Tuberculosis Infection (LTBI) testing and treatment
Commissioner Lead	Redbridge and Barking & Dagenham Clinical Commissioning Group
Other commissioners	N/A
Providers	• GP Practices within Redbridge and Barking & Dagenham • Barking, Havering and Redbridge University Hospitals NHS Trust • Redbridge CVS
Period	24th July 2017 to 31st March 2018
Date of Review	31st March 2018

1. Population Needs

1.1 National 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 (1) (referred to in this document as 'the Strategy') published in January 2015 by NHS England and Public Health England (PHE), sets out approaches to support TB prevention, treatment and control. This includes the setting up of TB control boards to plan, oversee, support and monitor all aspects of local TB control. The control boards will 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 will continue to rest with CCGs. The Collaborative TB Strategy Commissioning Guidance (2) sets out further details, including proposing local lead CCG arrangements for TB commissioning and membership of the relevant control board. The Strategy identifies ten areas of action to reducing TB in the UK.

This service specification specifically addresses area of action number 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. While LTBI testing would be beneficial for all UK areas in England, particular focus is on systematic implementation in areas with high local incidence.

To support this service NHS England has identified £10 million in 2015/16 for development of latent TB infection identification, testing and treatment. Lead CCGs can access the 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 and evidence base

Redbridge

In 2013 the TB rate in Redbridge was among the highest of any London borough. Rates were highest among young adults aged 20 to 39 years old with the majority of TB patients being born abroad. Over half were Indian (mostly born in India), and 24% Pakistani (mostly born in Pakistan).

Indian remains the most common ethnic group in Redbridge with TB. Numbers in the black African population are falling. Redbridge TB cases reported to the London TB register during 2012-14, were mainly in the south of the borough.

TB reports for Redbridge from notifications shows that;

- The three year average number of reported new cases per year (based on notifications) in Redbridge per 100, 000 of the population is 54.13 for 2010-12, similar to the 2009 -11 rate (54.04/100.000).
- Based on these notifications the TB rate in Redbridge is considerably higher than England average of 15.1/100, 000 and is the second highest TB rate of the thirteen local authorities in NENCL.

Barking and Dagenham

The rate of TB in LBBD was 34.96 per 100,000 population in 2012 and latest data for 2013 shows an increase to 38.6/100,000 population. Based on 2013, unlike most boroughs in London, the TB rate in Barking and Dagenham increased from 2012 to 2013, continuing an upward trend since 2002, and above the London rate for the first time. The provisional 2014 data indicates that this trend has reversed.

Provisional data for 2014 shows there were 67 Tuberculosis (TB) cases (provisional data from LTBR), out of 734 TB notifications from North East London, and 2679 TB notifications overall in London. This was a reduction on 76 Tuberculosis cases in 2013.

TB rates were highest among males aged 20 to 39 years old. Almost a quarter of TB patients were UK born (higher than in most areas of London).

The following has been implemented to deliver improved health and wellbeing in Barking and Dagenham:

- Universal BCG vaccination at birth. The Director of Public Health introduced a universal BCG vaccination policy in 2009. At the time when this policy was introduced, the known TB rates in LBBD were just below 40/100,000. Since April 2009, all babies born in LBBD have been given the BCG vaccination at birth. This is in line with the policy in the neighbouring boroughs of Newham, Redbridge and Waltham Forest, and an example of an informed public health decision making based on epidemiological data and population needs.

Barking and Dagenham has been identified as a priority area to implement a LBTI testing and treatment programme and the Director of Public Health has recommended that the programme be implemented locally.

References

1. Collaborative Tuberculosis Strategy for England: 2015 to 2020 (www.gov.uk/government/publications/collaborative-tuberculosis-strategy-for-england) Collaborative Tuberculosis Strategy: Commissioning Guidance (NHSE Gateway reference: 03634)

2. 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

3. 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 Update 2015, NICE are currently consulting on draft revision and update - Tuberculosis: prevention, diagnosis, management and service organisation. This update is expected late 2015.
4. Tuberculosis in the UK-PHE2014 Annual report www.gov.uk/government/publications/tuberculosis-tb-in-the-uk
5. Royal College of Nursing (RCN): www.rcn.org.uk/__data/assets/pdf_file/0010/439129/004204.pdf
6. BCG – Details within www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book
7. British Thoracic Society (BTS) www.brit-thoracic.org.uk/clinical-information/tuberculosis/

2. Outcomes

NHS Outcomes Framework Indicators

"The NHS Outcomes Framework (NHS OF) indicators provide national level accountability for the outcomes the NHS delivers; they drive transparency, quality improvement and outcome measurement throughout the NHS.
Indicators in the NHS OF are grouped around five domains, which set out the high-level national outcomes that the NHS should be aiming to improve." (The NHS Outcomes Framework, 2011/12)

This LTBI screening programme encompasses the following domains:

Domain 1	**Preventing people from dying prematurely**	**X**
Domain 2	**Enhancing quality of life for people with long-term conditions**	**X**
Domain 3	**Helping people to recover from episodes of ill-health or following injury**	**X**

3. Scope

3.1 Aims and objectives of service

The aim of this service specification is to support the national LTBI testing and treatment programme which aims to identify eligible migrant populations for LTBI screening, through GP registration. This service aims to reduce the rate of TB in Redbridge and Barking & Dagenham populations, by testing 1462 and 600 people per borough respectively during the financial year 2017/18.

The benefits of LTBI testing (of new GP registrant patients) and treatment are evidence-based and cost effective. Initial costs would be outweighed by savings seen after 3 – 5 years. This process concentrates on decreasing and eliminating TB cases from the local population by reducing the risk of future reactivation of TB.

For the success of this service GP practices will develop and implement processes to:

- Increase the awareness of active and latent TB among GP practices and their practice population to ensure that there is a good uptake of LTBI testing and treatment and early diagnosis of active TB
- Distribute education/information programme for the public (educational materials in practices and other media)
- Incorporate LTBI screening within new registration health checks for those meeting the inclusion criteria
- Use GP systems to identify existing registrants that meet the inclusion criteria.
- Raise awareness of TB 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.

This will be assisted by the Health Buddies who have been funded as part of this project.

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 (Appendix A) and who have arrived in England within the last five years. A list of countries and their country flags of countries of origin eligible for LTBI testing and treatment can be found in Appendix B & C respectively.

Specific acceptance criteria and thresholds are defined in the sections below.

3.3 Any acceptance and exclusion criteria and thresholds

The eligibility criteria for LTBI testing and treatment include all the following:

- New or existing registrant with a Redbridge or Barking & Dagenham GP practice
- Aged 16-35
- Not previously been tested or treated for TB
- Born or spent > 6 months in county of high TB incidence, as listed in Appendix A
- Have arrived in England within the last 5 years.

The initial focus in 2017/18 was for new registrations, and has subsequently been extended to include the existing registered patient population being tested. The eligibility criteria remains as above.

3.4 Service description / care pathway

LTBI testing and treatment will be offered to a defined cohort of new and existing patients (please note comment in 3.3 above). Those identified as meeting the eligibility criteria as suitable for LTBI screening will be referred for an IGRA blood test.

For those patients with a positive IGRA test the GP practice will take the appropriate steps to refer into local TB services for further management / treatment, as defined in the local pathway (see appendix D).

3.4.1 New patient LTBI screening

This pathway aims to offer LTBI testing to eligible recipients when they first register with a GP practice. This remains the preferred method, as the LTBI testing process can be combined with other primary care based registration health checks, making uptake more likely.

When undertaking a new patient registration and health check, the GP practice will use this opportunity to identify patients meeting the LTBI screening eligibility criteria.

The GP practice will then:

- 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. Additionally, patients will be informed of the signs and symptoms of TB.
- Document the presence of a BCG scar, if present.
- Provide patients with an IGRA test phlebotomy form and instructions on local locations for the IGRA test, to be carried out, as per agreed local LTBI screening pathway.
- 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.
- 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 practices should enter the details of LTBI testing using the nationally provided template on their GP system. Templates have been developed for EMIS Web, Vision and SystemOne.
- 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.

If a new registrant has symptoms of active TB, the GP practice will organise immediate referral to local TB services and follow standard national infection control guidelines. Symptoms suggestive of TB include a) Cough> 3 weeks; b) Haemoptysis (cough with blood); c) Night sweats; d) Unexplained weight loss; e) Unexplained fever; f) Lymph node swelling (especially cervical).

3.4.2 Existing patient LTBI screening

This pathway also aims to offer LTBI testing to patients who are already registered with a GP practice.

- GP practices will use GP systems to identify patients who meet the eligibility criteria and then to contact and follow-up identified patients.
- The GP practice will make appropriate arrangements to verify patients meet the eligibility criteria, this may include providing LTBI patient information, a letter of invitation for testing and the necessary forms for an IGRA blood test, for those individuals that have come to the UK from the listed countries (Appendix A) and that meet the eligibility criteria.
- Children from high-risk countries and who have not received BCG vaccination will be offered BCG as per national guidelines.

3.4.3 IGRA testing pathway

The following IGRA testing pathway will be followed:

- Send identified patients for IGRA test at locally agreed location.
- GP practices should consider combining LTBI testing with other health checks, such as for diabetes or other blood-borne viruses (BBVs), including HIV[1], as appropriate.
- If a patient declines to be tested, this will be recorded in their primary care records.
- 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 practice will inform patients of their IGRA test results.

3.4.4 Diagnostics

LTBI testing will be performed with a single IGRA blood test (QuantiFERON TB GOLD PLUS TEST) at a test-processing laboratory as per agreed local pathway.

[1] In particular among those from countries where coexisting infection is common e.g. Sub-Saharan Africa or other HIV high incidence areas.

LTBI tests have been procured nationally by NHS England. The selected test provider for Barking and Dagenham and Redbridge is South West London Pathology – part of St George's University Hospital NHS Foundation Trust.

It is envisaged that IGRA - LTBI tests will be available from selected phlebotomy testing sites for Barking & Dagenham and Redbridge.

At relaunch of LTBI Programme in July 2017 the identified testing site for both Barking & Dagenham and Redbridge remained as:

- Barking Community Hospital, Upney Lane, Barking, Essex IG11 9LX (Monday-Friday, 7am till 3pm)

Patients for LTBI testing can only access IGRA tests using the specified SWLP phlebotomy referral form provided by the GP practice.

GPs will access test results via the secure internet portal supplied by the test provider.

The test results will be available in 3-5 working days.

Positive IGRA results will automatically be tested for HIV as part of the work-up required by secondary care. HIV results will also be provided via the secure internet portal.

3.4.5 Negative IGRA test results

Patients with negative test results will be informed of their results by their GP practice (either by telephone call or letter) and given information on the signs and symptoms of TB disease.

3.4.6 Positive IGRA test results

All positive IGRA test results require referral to Barking, Havering and Redbridge University Trust (BHRUT) chest clinic for agreed LTBI care package.

In line with local LTBI programme intentions, all patients with positive IGRAs will be referred onto BHRUT LTBI service, using the BHRUT LTBI screening proforma (see LTBI workbook), having undergone:

- an HIV test (automatically undertaken with positive IGRA test results by diagnostics provider)
- Hepatitis B and Hepatitis C serology
- Chest X-ray

Via direct access services.

Results of all these tests must be available at time of referral to BHRUT.

3.4.7 Treatment

The service provision for active or latent TB treatment will be undertaken by BHRUT.

For the purposes of this programme, GPs role is in relation to screening for LTBI and on-ward referral if necessary and not the treatment of LTBI.

There will be an expectation for GP practices to offer support, if required, to all those under-going treatment or further screening as a result of the LTBI screening process.

3.5 Public Health England (PHE) and Health Protection teams (HPT)

Local TB control board (TBCB) together with the lead CCG fulfil a governance function in respect to LTBI testing and treatment. The TBCB as well as staff from the national PHE TB testing team are available to provide support and advice on LTBI testing.

3.6 Payment schedule

The GP practice will determine the amount of human resource needed to fulfil all requirements needed for payment.

Service provision	Prerequisite for payment	Payment
Stage 1a: Testing for LTBI amongst eligible new migrants at GP registration; or existing eligible registrants from previous 5 years.	• Identify new or existing registrants that meet the eligibility criteria detailed in section 3.3. • Record all demographic data as specified into GP system • Offer IGRA test • If IGRA test offer accepted, provide required phlebotomy form. • Record the outcome of the offer in the GP system. • Payment will be made for each patient who is subsequently tested. • Where eligibility is identified and offer of IGRA test declined / refused at face-to-face appointment, payment will still be made.	£5 for each eligible patient receiving IGRA test
	OR	
Stage 1b: Offer declined: Recorded evidence of attempts to contact eligible registrants to offer LTBI testing.	• Those meeting eligibility criteria detailed in section 3.3 are identified • Record all key demographic data into the GP system • Record evidence of at least three attempts to contact identified patient. • Contact can be in the form of a telephone call, letter, text message or any other another communication process already established at the practice *Where any attempt at contact results in the offer of LTBI testing being accepted, only a single Stage 1 payment will apply*.	£5 for each eligible patient, who subsequently do not contact practice to accept offer.
Stage 2: Identified a	• Test result communicated to patient • Patient sent for Chest X-Ray and blood-borne virus screening.	Additional £20 for each patient

patient with a positive IGRA test	• A referral to BHRUT LTBI clinic service is made, once CXR and blood test results known.	with a positive IGRA test result.
Stage 3: An identify patient through LTBI GP testing, who is subsequently diagnosed with active TB	• Payment will be made to the GP if a patient screened for LTBI, is subsequently diagnosed with active TB. • Care package provided by BHRUT • NHS England: Public Health will identify these patients from GP Systems and BHRUT systems using NHS numbers.	£100 for each patient who was screened for LTBI and is subsequently diagnosed active TB
Data entry requirements	See the section below on data requirements.	

3.7 Data entry and data quality assurance

Good data entry will form the basis of all remuneration. As such payments will be made if all required fields listed in Appendix C are entered into the GP practice system template.

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.

3.8 Interdependence with other services/providers

The GP practice will continue to work closely with the CCG, local TB board and other stakeholders to undertake this service provision.

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.

3.10 Engagement with stakeholders

Appropriate engagement is much more likely to lead to successful implementation of a local LTBI testing programme. It will be important to develop local champions to assist in wider engagement activities with i.e. local clinical commissioning groups (CCGs), General practitioners (GPs) and their practices, the local medical council (LMC), acute TB services and local communities. Key stakeholders for practices to be engaged with include:

Clinical commissioning group (CCG) – is key to developing, prioritising and implementing the local programme particularly with regard to commissioning relevant additional secondary healthcare services.

NHS England regional teams – clear arrangements between the regional teams and TB control boards on how local accountabilities for implementation of the TB strategy will operate, and how implementation will link into assurance discussions with CCGs.

Local GPs – who are central to the delivery of the case finding programme. It would also be helpful to have identified GP champions who support the engagement of local GPs and practices. GPs also have a key role as members of their local CCG in advocating for TB to be a priority and reflected in local commissioning.

Local authority public health teams – to ensure TB is prioritised with the local authority and is reflected in relevant local programmes and strategies including joint strategic needs assessments and health and wellbeing strategies. Latent TB Testing and Treatment for Migrants: A practical guide for commissioners and practitioners.

Health Protection team (HPT) – based in PHE providing key data to stakeholders to support and better understand prevalence and incidence of TB in the local community and ethnic groups. This will inform decision making around prioritisation and targeting of resources for the programme.

Laboratory services – there are two arms to this. There are specific arrangements for the laboratory services for LTBI tests to be undertaken by South West London Pathology (SWLP). There are agreed links with and between local laboratory services and the LTBI test (IGRA) provider (currently a test site) to inform and agree the pathway, provision and reporting of IGRA tests for primary care.

Communities affected by TB – ensuring that timely and appropriate information and awareness raising activities take place in communities that are at high risk of TB. This will require engagement with representatives from relevant communities, including agreeing test invitation letters and subsequent communication. Understanding the barriers to the uptake of the offer of LTBI testing, uptake of LTBI treatment and treatment completion is vital for the success of this programme.

TB control boards (TBCBs) – will be responsible for all aspects of TB control in a locality and therefore a key player for local LTBI testing and treatment implementation.

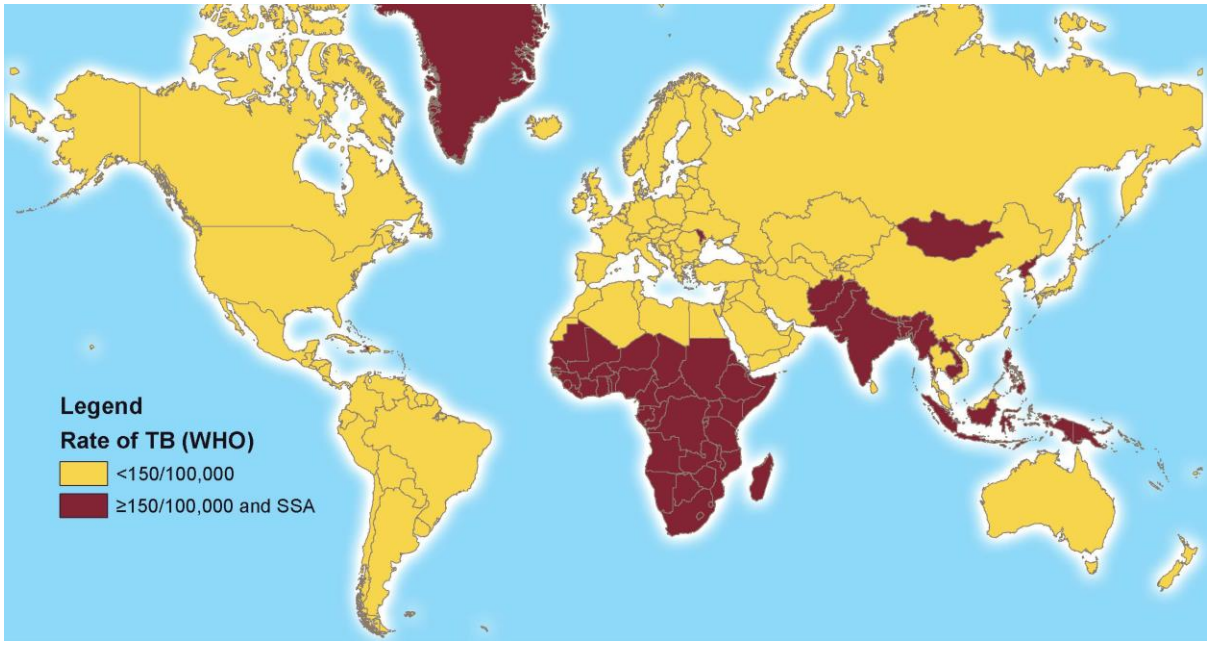
4. Applicable Service Standards

Key performance indicators

1. The number of local authorities that have a systematic new entrant LTBI testing and treatment initiative in place
2. Proportion of eligible new entrants covered by LTBI testing and treatment programmes who accept LTBI testing
3. Proportion of eligible new entrant who test positive for LTBI and take up the offer of treatment
4. Proportion of individuals who complete LTBI treatment among those who start treatment

Appendix A: Map of WHO countries by estimated incidence rates, 2013.

The legend indicates estimates of TB incidence per 100,000 population

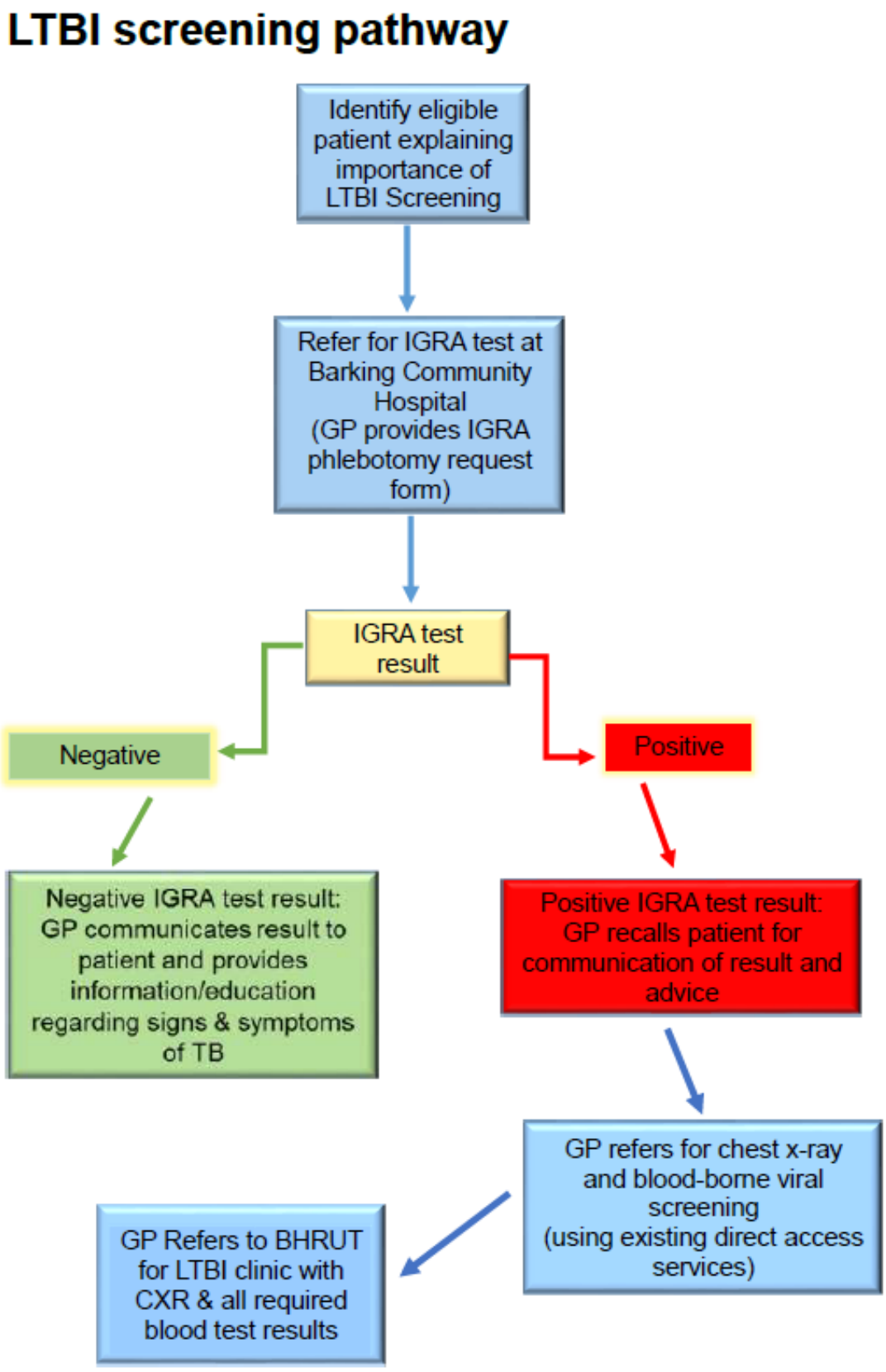


Appendix B: Countries of origin eligible for LTBI testing and treatment

(Estimated TB incidence rate ≥150 per 100,000 population in 2013 or Sub-Saharan Africa) (6) Country	Incident	Country	Incident
Afghanistan	189	Liberia	308
Angola	320	Madagascar	233
Bangladesh	224	Malawi	156
Benin	70	Mali	60
Bhutan	169	Marshall Islands	354
Botswana	414	Mauritania	115
Burkina Faso	54	Mauritius	21
Burundi	128	Micronesia	188
Cote d'Ivoire	170	Mongolia	181
Cabo Verde	143	Mozambique	552
Cambodia	400	Myanmar	373
Cameroon	235	Namibia	651
Central African Republic	359	Nepal	156
Chad	151	Niger	102
Comoros	34	Nigeria	338
Congo	382	Pakistan	275
DRP Korea	429	Papua New Guinea	347
DR Congo	326	Philippines	292
Djibouti	619	Republic of Moldova	159
Equatorial Guinea	144	Rwanda	69
Eritrea	92	Sao Tome & Principe	91
Ethiopia	224	Senegal	136
Gabon	423	Seychelles	30
Gambia	173	Sierra Leone	313
Ghana	66	Somalia	285
Greenland	194	South Africa	860
Guinea	177	South Sudan	146
Guinea-Bissau	387	Swaziland	1382
Haiti	206	Timor-Leste	498
India	171	Togo	73
Indonesia	183	Tuvalu	228
Kenya	268	Uganda	166
Kiribati	497	UR Tanzania	164
Laos PDR	197	Zambia	410
Lesotho	916	Zimbabwe	552

Appendix C: Example NHS England Public Health poster of flags of those countries of origin eligible for LTBI testing and treatment.

Appendix D. Local LTBI screening LIS pathway



Appendix E: LTBI testing and treatment variable list for payment

Field number	Field name	Format or output
1	GP practice national code	Alpha-numeric
2	Patient's NHS number	Alpha numeric
3	Patient's surname	Text
4	Patient's forename	Text
5	Gender	Male/ Female
6	Full Postcode	Alpha-numeric
7	Date of Birth	mm/yyyy
8	Country of birth	Code description and Read code term
9	Ethnicity	Code description and Read code term
10	Date of entry to UK	dd/mm/yyyy
11	IGRA test- 1st invitation	Code description, Read code term and date
12	IGRA test- 2nd invitation	Code description, Read code term and date
13	IGRA test- 3rd invitation	Code description, Read code term and date
14	IGRA test declined	Code description, Read code term and date
15	IGRA test result +ve	Code description, Read code term and date
16	IGRA test result -ve	Code description, Read code term and date
17	Positive IGRA counselling consultation	Code description, Read code term and date
18	Positive IGRA referral to respiratory specialist nurse	Code description and Read code term
19	TB chemotherapy regimen prescribed	
20		3 months of Isoniazid and Rifinah
21		6 months Isoniazid
22		6 months Rifinah
23	TB chemotherapy started	Code description, Read code term and date

24	TB chemotherapy refused by patient	Code description , Read code term & date
25	TB chemotherapy completed	Code description , Read code term & date
26	Adverse reaction to LTBI treatment	Code description , Read code term , date & associated freetext describing reaction
27	Date chemotherapy completed	Code description , Read code term & date
28	Adverse reaction to rifnah	Code description , Read code term , date & associated freetext describing reaction
29	Adverse reaction to isoniazid	Code description , Read code term , date & associated freetext describing reaction
30	Side effects specifics	Prescribing module and associated text as above
31	BCG Vaccination	Code description and Read code term
32	cough present	Latest Code description and Read code terms
33	fever present	Latest Code description and Read code terms
34	drenching night sweats	Code description and Read code terms
35	abnormal weight loss	Code description and Read code terms
36	positive examination of lymphadenopathy	Latest code description and Read code terms
37	Plasma C reactive protein	Code description , Read code term , date & value
38	Serum total bilirubin level	Code description , Read code term , date & value
39	ALT/SGPT serum level	Code description , Read code term , date & value
40	HIV status	Latest code description, Read code term & date
41	Hep B status	Latest code description, Read code term & date
42	Hep C status	Latest code description, Read code term & date
43	Erythrocyte sedimentation rate	Code description, Read code term, value & date
44	TB Chest X ray	Latest code description, Read code term, date & associated text
45	Co- morbidities categorised by their impact on TB risk and outcome	
46	Immunosuppression (disease or medication)	Latest code description, Read code term & date
47	Diabetes	Latest code description, Read code term & date

48	Any chest damage	Latest code description, Read code term & date
49	Any liver disease	Latest code description, Read code term & date
50	Current smoker	Latest code description, Read code term & date