

# **Protocol for Delivering Neonatal InterVax (BCG) in London 2017/18**

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## 1. Introduction

- In 2014, the London TB Board and the London Immunisation Board recommended that London region have a universal offer of BCG vaccine for all babies up to the age of one year across London. NHSE (London) had intended to commission the vaccine to be offered in all maternity units in London with a community offer for those parents who missed out on the vaccine in maternity hospitals or who have recently moved into London.
- However a subsequent global shortage of the BCG vaccine in 2015 and 2016 was followed by the PHE national team procuring InterVax, a BCG vaccine from Canada. This vaccine is unlicensed in the UK and as a result has to be offered under a Patient Specific Directive (PSD), i.e. to named patients. Initially there were stock restrictions but these are no longer in place. BCG vaccination providers are able to order as much stock as they need.
- This protocol is the third iteration of the protocol first signed off in November 2016 by the London Immunisation Board and the London TB Board. The intention remains to clarify and simplify the delivery of the Section 7a Targeted BCG Immunisation programme (<https://www.england.nhs.uk/commissioning/pub-hlth-res/>) in London whilst we need to use InterVax as our BCG vaccine. Due to the difficulties in utilising InterVax (unlicensed, PSD and risk of vaccine wastage), we are continuing the universal offer throughout maternity units in London with a targeted follow up in community. It is worth noting that the Section 7a neonatal BCG programme is a targeted programme.

## 2. Aim

- This paper clarifies how neonatal BCG (InterVax) is offered to new-born infants in London.
- This covers priority groups which are covered by the Section 7a service specification:
  1. Those infants aged under 12 months who fall within PHE priority groups A and B (i.e. live in an area of TB incidence of >40 per 100,000)
  2. Those infants aged under 12 months who reside in a household where a parent and/or grandparent comes from a country with a TB incidence rate of 40 per 100,000 and higher).
- Other priority groups that fall outside the Section 7a immunisation programme are outside the remit of the Section 7a service specification and are not covered by this protocol.

## 3. Audience

- This protocol is intended for clinicians involved in giving the BCG vaccine and for those clinicians required to make a referral to a maternity service or community service for eligible infants during 2017/18.

## 4. Background

- In October 2016 PHE published the annual Tuberculosis in England report: *Reports of cases of tuberculosis to enhanced tuberculosis surveillance systems: UK, 2000 to 2015*. This report presented data to the end of 2015 and TB official statistics.
- In London, there were 2,269 TB cases in 2015. That's compared to 2,572 cases notified in 2014.
- London's incidence rate has dropped from 30.1 cases per 100,000 in 2014 to 26.2 in 2015. This is below the high incidence rate of >40 per 100,000.
- London accounts for 40% of all TB cases notified in England.
- TB rates are higher in non-UK born populations compared to UK born residents. In London this was a rate of 57.8 per 100,000 compared to 7.9 in UK born residents.
- In relation to latent TB, 5,622 eligible migrants in England were offered a test for LTBI. The majority (88.4%) were identified in Newham (4971) and 48.5% were tested. Of these, 29% were found to be positive. In the rest of London, 67 eligible migrants were offered a test for LTBI, 83.6% were tested with 29% found positive.
- Table 1 illustrates the three year average rate of TB case notifications and rates per 100,000 for the London Boroughs. It can be seen that 6 boroughs – Brent, Ealing, Harrow, Hounslow, Newham and Redbridge have average annual incidence rates of > 40 per 100,000 for 2013-15 (first column of Table 1).
- This is down from nine boroughs with annual incidence rates of >40 per 100,000 for the years 2012-14.

- Boroughs of Greenwich, Hillingdon and Waltham Forest have dropped from annual incidence of 42, 41.9 and 41.3 per 100,000 respectively to 35.9, 36.5 and 37.8 per 100,000.
- The purpose of the neonatal BCG is to prevent progression to severe disease in infants which includes TB meningitis. In London between 2006 and 2015, there were 6 reported cases of TB meningitis (correspondence from PHE, 2016).

*Table 1*  
*BCG uptake rates for London Boroughs, ranked in order of TB incidence rates per 100,000 (2013-15)*

<b>London Borough</b>	<b>TB rate (per 100,000) 2014-16 estimates</b>	<b>TB rate (per 100,000) 2013-15 estimates</b>	<b>TB rate (per 100,000) 2012 - 2014 estimates</b>
<b>Barking and Dagenham</b>	28.7	30.1	35
<b>Barnet</b>	19.5	19.5	23.2
<b>Bexley</b>	9.1	9.7	10.7
<b>Brent</b>	57.8	67.6	82.9
<b>Bromley</b>	6.6	7.5	8.1
<b>Camden</b>	18	17.9	21.8
<b>City of London</b>	3.8	8.2	12.9
<b>Croydon</b>	22.1	24.5	27.6
<b>Ealing</b>	47.3	56.6	65.3
<b>Enfield</b>	20.9	21.5	22.5
<b>Greenwich</b>	30.2	35.9	42
<b>Hackney</b>	25.4	27.7	32.4
<b>Hammersmith and Fulham</b>	20.5	23.3	24.2
<b>Haringey</b>	26.1	28.4	33.2
<b>Harrow</b>	38.6	46.4	60.4
<b>Havering</b>	9.8	10.4	10.9
<b>Hillingdon</b>	34.4	36.5	41.9
<b>Hounslow</b>	47.5	53.7	64
<b>Islington</b>	21.6	25.4	29.3
<b>Kensington and Chelsea</b>	16.4	19.6	22.2
<b>Kingston upon Thames</b>	11.2	14.1	15.8
<b>Lambeth</b>	20.1	22.3	26.6
<b>Lewisham</b>	21.9	23	25.9
<b>Merton</b>	23.5	25.4	29.6
<b>Newham</b>	69	85.6	100
<b>Redbridge</b>	41.5	44.9	50.5
<b>Richmond upon Thames</b>	5.5	5.9	5.9
<b>Southwark</b>	25.3	27.1	31.7
<b>Sutton</b>	11.8	11.9	13.3
<b>Tower Hamlets</b>	30.1	32.5	38.3
<b>Waltham Forest</b>	33	37.8	41.3
<b>Wandsworth</b>	17.1	18.5	21.7
<b>Westminster</b>	18.1	20.6	24

Source: PHE (2017)

## 5. Important Points to Note

- InterVax is an unlicensed product and has to be delivered via a Patient Specific Directive (PSD). Each box consists of 20 vials which have to be constituted, making up between 10-18 doses a vial. Once made up, the doses/vaccines need to be administered within 6 hours.
- The InterVax BCG pathway is intended to be a temporary solution until NHS England (London) receives notification about the future of BCG stocks and whether the licensed version will become available again.
- The pathway affects babies **born on the 1<sup>st</sup> September 2016 onwards**.
- The pathway was reviewed in February 2017 and in November 2017.
- The pathway consists of two offers:
  - All contracted London maternity units will offer BCG vaccination to all neonates born within their units.
  - For infants who fall into one of the PHE priority groups A or B who have missed the vaccination in maternity, have moved into the borough or were born in a maternity unit outside London, they are eligible to be referred to a community BCG clinic up to the age of 12 months.
- The groups eligible for vaccination for the groups covered in the Section 7a BCG Immunisation Service Specification:
  - A. All infants (aged 0 to 12 months) with a parent or grandparent who was born in a country where the annual incidence of TB is 40/100,000 or greater.
  - B. All infants (aged 0 to 12 months) living in areas of the UK where the annual incidence of TB is 40/100,000 or greater.
- For London an area of high annual incidence of 40 per 100,000 or greater is defined as a borough with high annual incidence of 40 per 100,000 or higher.
- As of November 2017, there are 5 boroughs in London which have an average TB incidence rate of >40 cases per 100,000 (using 2014-2016 estimates). Rates in these five boroughs have decreased since November 2016 version of the London BCG InterVax protocol (which used 2013-2015 estimates) and the number of high risk boroughs has reduced from six to five (Harrow is now under 40 per 100,000).
- According to the PHE TB report (2017), these boroughs are:

1. Newham - annual TB incidence rate of 69 per 100,000
2. Brent - annual TB incidence rate of 57.8 per 100,000
3. Ealing - annual TB incidence rate of 47.3 per 100,000
4. Hounslow - annual TB incidence rate of 47.5 per 100,000
5. Redbridge - annual TB incidence rate of 41.5 per 100,000
- The overall TB rate in London is 25 per 100,000 (PHE TB report, 2017) and this has been declining over the past decade.

### Maternity Units:

- All contracted maternity units are expected to offer BCG universally to all babies born in London hospitals up to the age of 28 days.
- 'Universal' offer means all babies are offered BCG. This is to mitigate against 'at risk' infants missing the opportunity to be vaccinated with BCG.

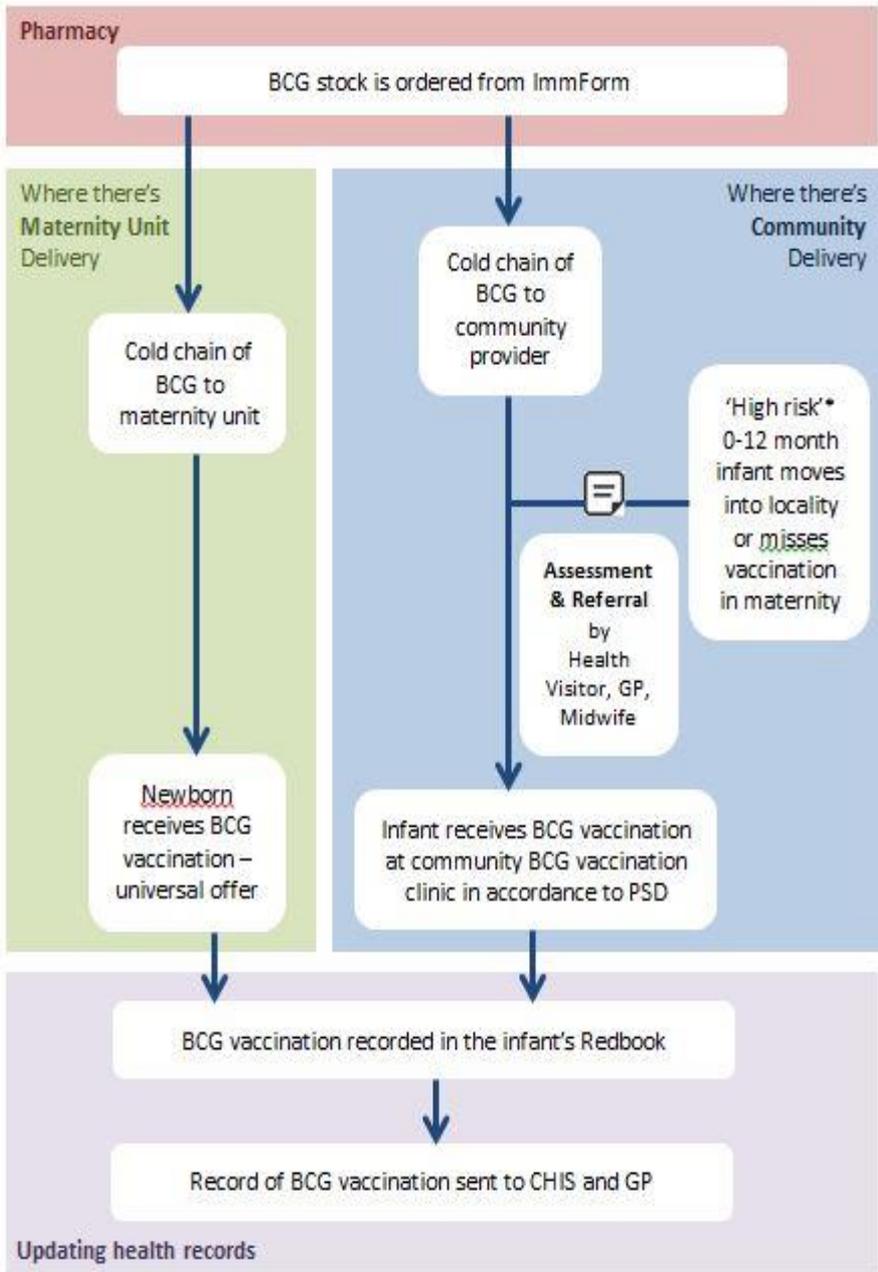
- One offer per baby is expected, if a parent refuses, no follow up is expected.
- It is the responsibility of the birthing maternity unit to offer the BCG vaccine whether it is in the birthing suite, on postnatal wards or whether parents will be called into a maternity clinic within 28 days. Offer is universal up to 28 days if given in hospital.
- Where a new born has been transferred to another contracted maternity unit within the 28 days, it is the duty of care of the receiving maternity unit to check BCG status and vaccinate if necessary.
- Community midwives should check BCG vaccination status of babies who fall within the defined two categories above and refer unvaccinated babies back to the maternity unit within 28 days, if contracted to do so.
- The 2017/18 maternity tariff states that all maternity units are required to offer targeted BCG vaccination as part of their maternity services. NHSE (London) Immunisation Team will continue to work with maternity units in relation to resourcing the universal offer.
- NHSE (London) is monitoring the uptake of BCG within maternity units and community clinics via monthly data returns.

### **Community Offer:**

- Infants up to the age of 12 months who are risk assessed as being resident within a high incidence borough or reside in a household whereby parent(s) or grandparent(s) come from a high risk country should be referred to a community BCG vaccine clinic.
- This referral can be done by a midwife, health visitor, GP or other clinician, who has undertaken the risk assessment.
- Providers providing BCG clinics are required to accept clinical referrals from clinicians within their allocated area of London.
- As clinics are operating under a PSD, only infants referred with appointments can be vaccinated and only one appointment can be made per child. The clinic is expected to contact the parent with the appointment and to clarify that the parent will only be offered one appointment.
- For those community providers operating in the five high risk boroughs, the offer will be universal to the borough. However, since the vast majority of neonatal BCG will be given in maternity units, the number of children being referred to community BCG clinics should be small.
- Where a GP practice is operating as a vaccine clinic hub, this will be operated under the open access SLA with NHSE (London). These practices are expected to receive clinical referrals for neonates needing BCG that are not registered patients at the GP practice.

# 6. Algorithm

Figure 1  
Proposed Pathway for InterVax BCG Delivery in London 2016/17



\*High risk infants are defined as:

- A. All infants (aged 0 to 12 months) with a parent or grandparent who was born in a country where the annual incidence of TB is 40/100,000 or greater.
- B. All infants (aged 0 to 12 months) living in London boroughs where the annual incidence of TB is 40/100,000 or greater.

## 7. Risk Assessment

- If an infant misses the BCG vaccination in maternity, a health visitor, midwife, GP or other clinician needs to do a risk assessment and make the appropriate clinical referral to the relevant community clinic.
- The clinician needs to assess whether or not the infant falls within the PHE priority group A or B:
  - A. All infants (aged 0 to 12 months) with a parent or grandparent who was born in a country where the annual incidence of TB is 40/100,000 or greater. For grandparents, the grandparent may not be living with the child but if the child spends close prolonged contact with the grandparent – e.g. grandparent babysits the baby regularly- then the baby is eligible. Baby is not eligible if grandparent lives abroad.
  - B. All infants (aged 0 to 12 months) living in areas of the UK where the annual incidence of TB is 40/100,000 or greater. For London this equates to the boroughs of Brent, Ealing, Harrow, Hounslow, Newham and Redbridge.
- Clinicians can check which countries have a high incidence rate by looking at <https://www.gov.uk/government/publications/tuberculosis-tb-by-country-rates-per-100000-people>
- Clinicians should then check [How to Refer to Relevant Community Provider](#) section on this form to see which community clinic to refer the baby to. All community providers have a referral form which will need to be completed by the clinician making the referral. It is a standard London template but each community provider has reiterated it under their own branding. Forms can be emailed straight to the provider.
- It is important for the receiving community clinic that the referral letter has a completed and signed off risk assessment for the referring clinician.

### Preterm Babies

- Preterm babies may miss out on the neonatal vaccination as it is likely they will have spent over 28 days in a neonatal unit and/or may be considered too small to be vaccinated intradermally if they are <1.5kg.
- Preterm babies are eligible for BCG prior to discharge irrespective of age and should be referred to the maternity unit of the hospital for vaccination.

### Exclusions

- Infants who do not fall within these 2 groups are not covered by the NHSE Section 7a service specification for neonatal BCG vaccination and are not covered by this pathway.

## 8. How to Refer to Relevant Community Provider

- Using the below set of tables, the referring clinician checks the borough that the infant resides in against the community provider providing BCG for that borough. Then using the contact details, please contact the provider for the referral form (this can be done in advance and kept in case you come across an eligible infant). The completed referral form will need to be sent to that email address.
- NHSE (London) have received copies of the referral forms from all community providers involved. Should you have difficulty in accessing a referral form, please contact the team but please do not submit referrals to the NHSE team.
- Please do not ask parents to download the form.

## North West London

Borough infant resides in:	Where infant can be referred to for BCG vaccination:	Contact for referral form and for submission of referrals:
Brent	<ul style="list-style-type: none"> <li>Curzon Crescent Children Centre in Harlesden</li> <li>CNWL - Crowndale Clinic, Crowndale Rd, London NW1 1TU</li> <li>Northwick Park</li> </ul>	<ul style="list-style-type: none"> <li>CNWL: <a href="mailto:patriciastephens@nhs.net">patriciastephens@nhs.net</a></li> <li>Northwick Park: <a href="mailto:Julie.cooper718@nhs.net">Julie.cooper718@nhs.net</a></li> </ul>
Ealing	CNWL- Minet Clinic, Avondale Drive, Hayes, UB3 3NR	<a href="mailto:cnw-tr.HCHImmsTaskForce@nhs.net">cnw-tr.HCHImmsTaskForce@nhs.net</a>
Hammersmith & Fulham	Central London Community Health	Carol Cork- 0-19 Team Leader <b>(Hammersmith &amp; Fulham)</b> Email: <a href="mailto:carol.cork@nhs.net">carol.cork@nhs.net</a>
Harrow	Central London Community Health	Catriona Noble – Immunisation Nurse Email: <a href="mailto:catriona.noble@clch.nhs.uk">catriona.noble@clch.nhs.uk</a>
Hillingdon	CNWL – Uxbridge Health Centre, Chippendale Way, Uxbridge, UB8 1QJ; Westmeade Practice, West Mead, Ruislip, HA4 0TN	<a href="mailto:cnw-tr.HCHImmsTaskForce@nhs.net">cnw-tr.HCHImmsTaskForce@nhs.net</a>
Hounslow	HRCH	<a href="mailto:hrch.bcg@nhs.net">hrch.bcg@nhs.net</a>
Kensington & Chelsea	Central London Community Health	Kathleen Christian – 0-19 Team Leader <b>(Westminster and Kensington &amp; Chelsea)</b> Email: <a href="mailto:kchristian@nhs.net">kchristian@nhs.net</a>
Westminster	Central London Community Health	Kathleen Christian – 0-19 Team Leader <b>(Westminster and Kensington &amp; Chelsea)</b> Email: <a href="mailto:kchristian@nhs.net">kchristian@nhs.net</a>

North East London		
Borough infant resides in:	Where infant can be referred to for BCG vaccination:	Contact for referral form and for submission of referrals:
Barking & Dagenham	NELFT	<a href="mailto:nem-tr.NELCSCChildrensImmunisations@nhs.net">nem-tr.NELCSCChildrensImmunisations@nhs.net</a>
Barnet	Central London Community Health	Adele Edwards – Immunisation Nurse Email: <a href="mailto:adele.edwards@clch.nhs.uk">adele.edwards@clch.nhs.uk</a>
Camden	CNWL - Peckwater Centre, 6 Peckwater Street, London NW5 2TX	<a href="mailto:patriciastephens@nhs.net">patriciastephens@nhs.net</a>
Enfield	North Middlesex Hospital	MaternityDirect <b>020 8887 4238</b> (Mon - Fri, 10am -6pm)
Hackney	Lawson Practice 85 Nuttall Street N1 5HZ	<a href="mailto:t.omisore@nhs.net">t.omisore@nhs.net</a>
Haringey	Whittington health - Child Development Centre. (CDC),M2 WARD, St Ann's Hospital, St Ann's Road, N15 3TH  North Middlesex, Maternity Unit	<a href="mailto:gwenedwards@nhs.net">gwenedwards@nhs.net</a>  MaternityDirect <b>020 8887 4238</b> (Mon - Fri, 10am -6pm)
Havering	NELFT	<a href="mailto:nem-tr.NELCSCChildrensImmunisations@nhs.net">nem-tr.NELCSCChildrensImmunisations@nhs.net</a>
Islington	Whittington health - River Place Health Centre Essex Road London N1 2DE	<a href="mailto:christine.ogundele@nhs.net">christine.ogundele@nhs.net</a>
Newham	Vaccination UK	<a href="mailto:Newham.bcg@nhs.net">Newham.bcg@nhs.net</a>
Redbridge	NELFT	<a href="mailto:nem-tr.NELCSCChildrensImmunisations@nhs.net">nem-tr.NELCSCChildrensImmunisations@nhs.net</a>
Tower Hamlets	St Andrews Medical Centre, 2 Hannaford Walk, London E3 3FF	<a href="mailto:maju.miah@nhs.net">maju.miah@nhs.net</a>
Waltham Forest	NELFT	<a href="mailto:nemtr.NELCSCChildrensImmunisations@nhs.net">nemtr.NELCSCChildrensImmunisations@nhs.net</a>

South West London		
Borough infant resides in:	Where infant can be referred to for BCG vaccination	Contact for referral form and for submission of referrals:
Croydon	Croydon Health	<a href="mailto:lynne.reed1@nhs.net">lynne.reed1@nhs.net</a>
Kingston	HRCH	<a href="mailto:hrch.bcg@nhs.net">hrch.bcg@nhs.net</a>
Merton	HRCH	<a href="mailto:hrch.bcg@nhs.net">hrch.bcg@nhs.net</a>
Richmond	HRCH	<a href="mailto:hrch.bcg@nhs.net">hrch.bcg@nhs.net</a>
Sutton	HRCH	<a href="mailto:hrch.bcg@nhs.net">hrch.bcg@nhs.net</a>
Wandsworth	St Georges Community Provider Children and Families Universal Services 3rd floor St Johns Therapy Centre St George's University Hospitals NHS Foundation Trust	<a href="mailto:wpct.imms@nhs.net">wpct.imms@nhs.net</a>

South East London		
Borough infant resides in:	Where infant can be referred to for BCG vaccination:	Contact for referral form and for submission of referrals:
Bexley	HRCH	<a href="mailto:hrch.bcg@nhs.net">hrch.bcg@nhs.net</a>
Bromley	HRCH	<a href="mailto:hrch.bcg@nhs.net">hrch.bcg@nhs.net</a>
Greenwich	HRCH	<a href="mailto:hrch.bcg@nhs.net">hrch.bcg@nhs.net</a>
Lewisham	L&GT, Kaleidoscope (community Clinics) Catford London SE6 4JF	<a href="mailto:michaelcorr@nhs.net">michaelcorr@nhs.net</a>
Southwark	GSTT	<a href="mailto:Jennifer.Kasule@gstt.nhs.uk">Jennifer.Kasule@gstt.nhs.uk</a>
Lambeth	GSTT	<a href="mailto:Jennifer.Kasule@gstt.nhs.uk">Jennifer.Kasule@gstt.nhs.uk</a>

## 9. Record Keeping, Monitoring and Surveillance

- Since April 2015, it is mandatory that all Child Information Systems (CHIS) in London submit returns on BCG uptake in their boroughs to COVER. (This is due to London theoretically offering universal BCG but this roll out has been impeded by the stock shortages of 2015 and 2016). However every CHIS

does submit a return although for the boroughs of Croydon, Southwark and Lambeth the returns have been 0%.

- Going forward, it is imperative that where the BCG vaccine has been given that CHIS, the GP and the child's redbook (child development record) are updated. NHSE (London) immunisation team will be working with CHIS and BCG providers to ensure this transfer of data and to prevent a vaccine incident occurring.
- All maternity units will be submitting monthly returns for their maternity given vaccinations to the NHSE (London) Immunisation Team. This will be subjected to 6 monthly audits.
- Community providers will also be required to keep NHSE (London) Immunisation Team updated on process and uptake and provide monthly returns, including Do Not Attends (DNAs).
- There will be regular audits undertaken by the NHSE (London) immunisation commissioning team. Please compile with requests for information.
- Reports on audits and surveillance will be provided at the quarterly London Immunisation Board and updates given at NHSE (London)'s monthly Quality, Safety and Performance Committee. Updates will also be given to ADPH and to the London TB Board.

## 10. Patient Complaints & Further Information

- All patient complaints should be directed to NHS England's patient complaints team at [england.contactus@nhs.net](mailto:england.contactus@nhs.net). Their team are experienced in dealing with BCG complaints and are best placed to help resolve a complaint.
- For other queries, please contact [england.londonimms@nhs.net](mailto:england.londonimms@nhs.net).