

## BCG vaccination in England since 2005: a survey of policy and practice in England

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# BCG vaccination in England since 2005: a survey of policy and practice in England

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#### Abstract

**BACKGROUND:** Vaccination with BCG is a cornerstone of tuberculosis control in England. In 2005, the school age vaccination programme was abandoned in favour of a targeted infant vaccination programme. We aimed to assess the current BCG vaccination policies and delivery pathways for immunisation in Primary Care Trusts (PCT) in England since the 2005 change in recommendations.

**METHODS:** We conducted a survey of key informants across 152 PCTs in England using a standardised, structured questionnaire.

**RESULTS:** Complete questionnaires were returned from 127 (84%) PCTs. 16 (27%) PCTs reported universal infant vaccination and 111 (73%) had selective infant vaccination. Selective vaccination outside infancy was also reported from 94 (74%) PCTs. PCTs with selective infant policy most frequently vaccinated on postnatal wards (51/102, 50%) whereas PCTs with universal infant vaccination most frequently vaccinate in community clinics (9/13, 69%; p=0.011). To identify and flag up eligible infants in PCTs with targeted infant immunisation, those that mostly vaccinate on postnatal wards depend on midwives and maternity records, whereas those that vaccinate primarily in the community rely more often on various healthcare professionals.

CONCLUSIONS: Targeted infant vaccination has been implemented in most PCTs across the UK. PCTs with selective infant vaccination provide BCG vaccine via a greater variety of health-care professionals than those with universal infant vaccination policies. Data on vaccine coverage would help evaluate the effectiveness of delivery. Interruptions of delivery noted here emphasise the importance of not just an agreed, standardised, local pathway, but also a named person in charge.

#### **INTRODUCTION**

Tuberculosis (TB) remains a public health problem in England. After a century of consistent decline in the incidence and annual infection risk, the incidence of TB has been rising since the late 1980s.[1] TB is concentrated within certain groups of the population (including migrants from high prevalence countries, prisoners, homeless persons and other marginal populations) and in urban areas.[2]

Since the 1950s, immunisation with the Bacillus Calmette-Guerin (BCG) vaccine, which has been shown to be highly effective in the UK population,[3] has been a part of TB control efforts in England. The routine policy had been primarily to administer the BCG vaccine to all tuberculin-negative schoolchildren aged 10 to 14 years. In some areas BCG was given during infancy and it was recommended that it should also be given to "children of immigrants in whose communities there is a high incidence of tuberculosis", amongst other high risk groups.[4] In 2005, this policy was replaced by a targeted immunisation programme directed at children with high risk of TB exposure.

The change in policy came after several years of discussion in the independent government advisory committee, the Joint Committee of Vaccination and Immunisation (JCVI). In the 1990's it was estimated that due to the low TB incidence, universal school-age vaccination was no longer cost-effective.[5] Universal BCG vaccination, however, remained policy largely because the incidence was rising slowly and health authorities were unsure about the impact that the emerging HIV epidemic could have on TB epidemiology.[5, 6] In 2005, after the HIV epidemic had stabilised and the UK had already fulfilled the criteria of the International Union Against Tuberculosis and Lung Diseases (IUATLD) to stop routine immunisation (which recommends different policies for different levels of TB, based on economic appraisals and the balance between the benefits and risks of BCG vaccination),[7] the JCVI recommended stopping universal school age vaccination and replacing it with a targeted infant vaccination programme.[5]

As part of this targeted infant programme, it is agreed that universal vaccination is the most effective way to reach all eligible children in areas of the country with TB incidence  $\geq$  40 per 100 000 person-years (pyrs). In areas with TB incidence < 40 per 100 000 pyrs, a selective approach is recommended to immunise only infants at high risk i.e. if their parents or grandparents originate from a country with an incidence  $\geq$  40 per 100 000 pyrs, if travelling

to a high incidence country for three or more months, or when in contact with a TB case. In addition, children of any age at high risk of TB should be vaccinated at suitable opportunities.[8]

In view of possible organisational changes in the NHS and given the current TB epidemiology in the country, we considered it important and timely to assess the BCG vaccine policy and the main vaccine delivery pathways across the commissioning bodies for community and hospital care (Primary Care Trusts, PCTs) in England.

#### **METHODS**

A standardised, mostly closed ended structured questionnaire was designed; (available from the authors). The questionnaire covered the vaccination policy in and outside infancy, eligibility criteria and their documentation, delivery pathways and constraints to service delivery. The questionnaire was piloted in 4 London PCTs.

In November 2010, we contacted all 152 PCTs in England. Immunisation leads and other staffs involved in TB control and BCG vaccination implementation were electronically mailed a copy of the questionnaire and a web-link to an internet equivalent created using the survey engine SurveyMonkey®. As delivery of BCG vaccine involves a chain of activities and responsibilities, respondents were asked to gather information from other key informants as needed. A reminder was sent after four weeks. After an additional 4 weeks, we contacted non-respondent PCTs by telephone to gather the information required.

At completion of the active data collection, as an additional data check, between August 2011 and September 2011 we searched PCTs' websites and related NHS sources for publicly available documents on their current BCG vaccination policy. We assessed the agreement between the information on these publicly available documents and the data collected from the survey. We compared distribution frequencies using a chi-square test or Fishers exact test where appropriate. For each variable, we only included observations for which data was available.

#### **RESULTS**

Between November 2010 and March 2011, 123 questionnaires representing 129/152 PCTs (85%) were returned: 72 (59%) as electronic documents and, 51 (41%) via the Internet survey. No difference in TB notification rates was found between responding and non-responding PCTs (data not presented). We found publically available current BCG policy

documents for 114 (88%) of the 129 PCTs. Two (2%) PCTs were excluded from subsequent analysis because their BCG policy could not be determined from the responses. Sixteen (13%) PCTs reported universal infant vaccination and 111 (87%) selective infant vaccination. The agreement with publically available BCG policy documents was high, with only 3 (2%) PCTs reporting a policy that was different from the information in these documents. Responses from these three PCTs to more detailed questions in the questionnaire were consistent with a selective infant vaccination at that time.

Three PCTs reported changing their policy between 2006 and 2011; 1 PCT followed the national recommendation and changed from targeted infant vaccination to universal infant vaccination as TB incidence exceeded 40 per 100 000 pyrs; 1 PCT changed to universal infant vaccination although their TB incidence was < 40 per 100 000 pyrs but justified doing so because of a borderline TB rate, high TB rates in neighbouring areas and high population mobility; 1 PCT had a universal infant vaccination programme prior to 2006, although their TB incidence was below the threshold, and changed to targeted infant vaccination.[9]

Some PCTs reported vaccination policies that did not reflect the JCVI recommendations. Six PCTs reported targeted infant vaccination despite having a 3-year average TB incidence  $\geq$  40 per 100,000.[9] Documents obtained from the websites, however, of 3 of these PCTs, state that they implement universal infant BCG vaccination. Six of the 16 PCTs reporting universal vaccination had 3-year average TB incidence  $\leq$  40 per 100,000.[9] They were all in or close to major conurbations.

#### Vaccination during infancy

PCTs with a selective infant BCG vaccination policy administer BCG via a wider range of health care providers than PCTs with universal infant BCG vaccination (Table 1). PCTs with selective policy most frequently offer vaccination on postnatal wards (51/102, 50%) but also vaccinate in community (24/102, 24%) and hospital clinics (27/102, 26%); PCTs with universal policy more frequently offer vaccination in community clinics (9/13, 69%) and less frequently on postnatal wards (4/13, 31%, p=0.011).

All PCTs that vaccinate primarily on postnatal wards do so during the infants' first month of life whereas only 13/37 (35%) PCTs that mainly vaccinate in community clinics do so in the infants' first month of life (p<0.001).

BCG vaccination receipt in infancy is documented in various ways across PCTs, and this did not depend on the vaccination policy (Table 1). It is most consistently documented in the Red For peer review only - http://bmjopen5.bmj.com/site/about/guidelines.xhtml

Book (119/123, 97%) and in the Child Health Information Systems (114/123, 93%). It is also noted in other registers and notes (Table 1), but always in combination with either or both of the former two (Figure 1).

Table 1. Place were BCG is primarily administered and systems reported to document BCG vaccination in 127 PCT with infant vaccination policy.

|                                      | Selective infant vaccination N=102* | Universal infant vaccination N=13** |
|--------------------------------------|-------------------------------------|-------------------------------------|
| Place of primary BCG administration  | n (%)                               | n (%)                               |
| Postnatal ward                       | 51 (50)                             | 4 (31)                              |
| At home                              | 0                                   | 0                                   |
| At community clinic                  | 24 (23)                             | 9 (69)                              |
| At chest clinic                      | 17 (17)                             | 0                                   |
| At hospital paediatric clinic        | 10 (10)                             | 0                                   |
| Systems in use for BCG documentation | N=107***                            | N=16                                |
| Antenatal/Maternity records          | 43 (40)                             | 5 (31)                              |
| Birth notification records           | 15 (14)                             | 2 (12)                              |
| Paper log books held by midwives     | 6 (6)                               | 1 (6)                               |
| Child health information system      | 100 (93)                            | 14 (88)                             |
| School health records                | 27 (25)                             | 5 (31)                              |
| GP                                   | 50 (46)                             | 3 (19)                              |
| Red Book                             | 103 (96)                            | 16 (100)                            |
| Discharge letters                    | 37 (35)                             | 2 (12)                              |

<sup>\*9, \*\*3, \*\*\*4</sup> observations with missing data

#### **Selective infant vaccination**

In the 111 PCTs with selective infant vaccination, 71% reported routinely assessing eligibility for BCG. They all offer BCG vaccination to children with parents or grand parents born in countries with TB incidence  $\geq$  40 per 100 000 pyrs (Table 2). Six PCTs reported that travel to a high incidence country for three or more months is not an eligibility criterion; and 2 PCTs reported that contact with a TB case is not a selection criterion either.

Table 2. Selection criteria employed to decide eligibility for BCG vaccination in 111 PCTs with a targeted infant vaccination policy.

|                                 | n (%)*    |
|---------------------------------|-----------|
| Infant of parents born in       | 107 (100) |
| country with incidence > 40 per |           |
| 100 000.                        |           |
| Contact with TB                 | 93 (87)   |
| Prolonged travel                | 94 (88)   |
| Parental request                | 14 (13)   |
| Insecure accommodation          | 13 (12)   |
| Socially deprived               | 2 (2)     |
| Asylum seeker/refugees          | 2 (2)     |

<sup>\* 4</sup> observations with missing data

Two main BCG delivery pathways were apparent from the information on identification and primary place of immunisation, but with considerable overlap. Where midwives are primarily responsible for identifying eligible infants, they are more frequently vaccinated on postnatal wards (37/56, 66%) than when eligibility is flagged by GPs, health visitors (HVs) or paediatricians (12/44, 27%; p<0.001). Conversely, in PCTs in which eligible infants are primarily flagged up by GPs, HVs or paediatricians, they are more frequently vaccinated in community clinics (32/44, 73%) than when midwives identify them (19/56, 34%; p<0.001). In line with these delivery pathways, when infants are identified by midwives or vaccinated on postnatal wards, their eligibility is most frequently flagged up in maternity records, whereas when infants are identified by GPs, HVs or paediatricians or when they are vaccinated in community clinics, various systems are used with no clear preference (Table 3).

Table 3. Systems in use to flag up infants' eligibility for BCG vaccination stratified by main responsible for identification in 111 PCTs with targeted infant vaccination.

| Systems used to flag up         | Identification primarily by | Identification primarily by GP, HV |  |  |  |  |
|---------------------------------|-----------------------------|------------------------------------|--|--|--|--|
| eligibility                     | midwifes*                   | or paediatrician*                  |  |  |  |  |
|                                 | N=51                        | N=38                               |  |  |  |  |
| Maternity records               | 43 (84%)                    | 14 (37%)                           |  |  |  |  |
| Baby's hospital notes           | 28 (55%)                    | 18 (47%)                           |  |  |  |  |
| Red Book                        | 25 (49%)                    | 22 (56%)                           |  |  |  |  |
| Birth notification records      | 10 (20%)                    | 6 (16%)                            |  |  |  |  |
| Child health information system | 10 (20%)                    | 6 (16%)                            |  |  |  |  |

<sup>\*22</sup> observations with missing data

#### **Vaccination outside of infancy**

Vaccination outside infancy was reported in 94/127 (74%) PCTs. In 14/94 (14%) PCTs vaccination outside of infancy is offered to preschool children only, in 9/94 (9%) to schoolchildren only and in the remaining PCTs to both groups. HVs are most frequently involved in identifying eligible pre-school children (51/85, 51%). GPs alone were mentioned by 3/85 (4%) PCTs but 33/85 (36%) PCTs reported that both GPs and HV identify eligible pre-school children. A similar pattern was seen for the identification of school children: school nurses alone identify eligible school children in 56/80 (70%) PCTs, GPs alone in 9/80 (11%) PCTs and in 15/80 (19%) PCTs both school nurses and GPs identify school children.

All PCTs offering vaccination outside infancy reported assessing previous BCG immunisation in eligible children using at least one of the criteria recommended by the Green Book. Sixty-four of 94 (68%) PCTs use a combination of reliable parental recall, documentary evidence and presence of a scar as evidence of previous BCG vaccination. Seventy of 94 (18%) PCTs use the combination of a BCG scar and reliable recall; whereas 13/94 (14%) consider only one criteria as sufficient evidence.

#### Logistic constraints hindering BCG administration

Of all PCTs, 26/127 (20%) reported periods between 2005 and 2010 during which they could not administer BCG due to logistic constraints. The most frequent reasons are vaccine supply shortage and lack of trained health workers (including access to training) to administer the vaccine. One PCT reported various episodes where no BCG could be administered as a result of a pending business case over who was to carry out BCG vaccination when the previously appointed community paediatrician retired. A similar problem was reported in a different PCT reporting unclear responsibilities after the adult respiratory department stopped seeing paediatric patients. In one PCT, BCG could not be administered over a two-year period due to absence of funding agreements and was only re-introduced after a school outbreak.

#### **DISCUSSION**

Six years after its introduction, the 2005 recommendation for BCG vaccination has been implemented in the vast majority of England PCTs. All surveyed PCTs have an infant vaccination policy in place, but a quarter of these PCTs do not report offering vaccination outside infancy. Selective infant vaccination mostly takes place on the postnatal ward and during the first month of life whereas universal infant vaccination mainly happens in

community clinics and after the first month of life. In PCTs with a selective infant vaccination policy, this survey found greater variation in the organisation of BCG vaccine delivery.

Since the JCVI issued their recommendations in 2005, there has been an on-going discussion about how to define areas of high TB incidence in the context of the policy.[10-12] Universal infant vaccination is, for operational reasons, recommended in PCTs where the TB incidence is  $\geq 40$  per 100 000 pyrs, as it is agreed that this is the most efficient way to reach all infants at high risk of TB in such areas. Nevertheless, the cut-off incidence for targeted infant vaccination is debated as children in PCTs with an incidence < 40 per 100 000 pyrs can still be at high risk of TB.[13]

In this survey, six PCTs in or close to urban areas reported vaccinating all infants although their PCT-specific incidence is < 40 per 100 000 pyrs. This could indicate that some PCTs in urban areas are considering regional incidence to inform their policies, rather than PCT specific incidence. Nevertheless, it remains uncertain if this strategy ensures that the maximum number of eligible children are being immunised, and if it is more cost-effective than a PCT-specific informed targeted vaccination policy. Further analysis of the economic efficiency of regional BCG vaccination is required.

Surveys of BCG vaccination policies and practices in England and Wales in 1982 and 1992 indicated considerable variations across health districts.[14, 15] In 1992, 15 of the 186 health districts in England had already stopped their routine school immunization programme; 148 offered BCG to selected groups of neonates and five districts routinely gave BCG to all their neonates.[15] Today, variation in local BCG vaccination policies is lower but the organisation of BCG delivery remains highly variable. We find that PCTs commission a wide range of healthcare providers to deliver the vaccine. This heterogeneity across PCTs also demands a high level of organisation between PCTs if services such as maternity care straddle PCT borders. Hospitals may not be coterminous with PCTs and hence infants from PCTs with different policies and practices can be born in the same hospital. In this light, it is of concern that many PCTs don't have service level agreements (SLA) to organise BCG administration either within the PCT and across boundaries.[4] This and the complexity of managing a localised service could also explain why some PCTs were unable to deliver BCG during periods where service providers changed.

The commissioning of BCG may become more complex if it becomes the responsibility of Clinical Commissioning Consortia. In its current form, the suggested changes to the NHS structure could lead to consortia responsible for overlapping geographical areas. If services For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

are not commissioned across boundaries and responsibilities are not clearly assigned, the current heterogeneity in policies and practices could increase and seriously compromise the targeted infant vaccination. Infant hepatitis B vaccination is another selective programme, being given to infants of mothers screened antenatally and found to be positive for hepatitis B carriage. It works best when there is an identified person in each area, who is responsible for co-ordinating the programme.[16] This model should be considered for the BCG programme.

While the structural organisation of the NHS poses challenges for the 2005 recommendations, the implementation of a targeted vaccination policy is, in its self, demanding.[17] Hence, it is vital to monitor the implementation to assure high vaccination coverage. Good data on BCG immunisation coverage is complicated to assemble in PCTs with targeted infant vaccination where the denominator is unclear. Data from audits, however, show that vaccination coverage in areas with targeted infant vaccination can be low [18] and that even in PCTs with high coverage, it can vary greatly between maternity units [19] and ethnic groups.[20] We find that a wide range of health care professionals are involved in the identification of eligible children. It is therefore conceivable that infants are not identified due to unclear responsibilities. In addition, our findings suggest that some health professionals involved in the BCG vaccination program might be unfamiliar with recommended eligibility criteria; this could contribute to low coverage rates.[21] A standardised pathway to identify eligible infants, with clear responsibilities and roles and regular training of staffs involved could contribute to high vaccination coverage in PCTs with selective vaccination policy.[22, 23]

In addition to the correct identification of infants at risk, assuring that the vaccine is administered is another challenge of a targeted vaccination policy.[17, 22] Half of the PCTs vaccinate on postnatal wards – a vaccine delivery pathway associated with high vaccination coverage in local audits.[22-24] The other half, however, vaccinate in a community setting or clinics which in this survey was associated with vaccination at an older age. The different delivery pathways probably reflect local circumstances. Immunising newborns in postnatal wards may be more optimal in conditions in which the workload is manageable at that level, with either a relatively lower number of eligible newborns, or a sufficient number of skilled personnel to administer BCG. Vaccinating in the community might be more effective in areas with higher numbers of eligible newborn (especially if universal BCG vaccination) and limited number of trained staffs to administer the vaccine in postnatal wards. However, the latter could mean a higher risk of attrition as parents may not return their children to immunisation appointments, as reported in previous audits.[23, 25] A study in South London found that

parents would be more interested if the vaccine was accessible on a "drop-in" basis from community clinics [18] in such areas.

Another aspect that might affect efficient delivery is that the most commonly used systems for documentation of BCG receipt are often not the systems used to flag up eligibility. Aligning the systems used to identify eligible children with the system used to document BCG vaccination could be an effective way to ensure that identified infants receive the vaccine and a means to estimate coverage. [24] Also, BCG vaccination was not delivered with other routine infant vaccinations possibly because of the need for specific training for an intradermal vaccination. The addition of BCG vaccination to the offer of other routine infant vaccinations in specific regions could be another way of ensuring coverage of those at risk.

The 2005 BCG policy for the UK also recommends vaccinating previously unvaccinated children who are at high risk of TB. Despite the policy, a quarter of all PCTs do not report vaccinating outside infancy. Although the absence of vaccination outside infancy may conserve resources in areas with low levels of migration, some PCTs in urban centres with presumably high levels of migration do not report vaccinating outside infancy. This suggests that greater efforts are needed to strengthen targeted BCG vaccination outside infancy.

In conclusion, a targeted infant BCG vaccination has been implemented in most PCTs across England, either as part of postnatal hospital care or a community vaccination programme separate from other childhood vaccinations via a number of locally agreed health-care professionals. Information to assess coverage would be useful to monitor successful provision of an effective measure to prevent childhood tuberculosis.

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"All authors have completed the Unified Competing Interest form at www.icmje.org/coi\_disclosure.pdf (available on request from the corresponding author) and declare: no support from any organisation for the submitted work other than mentioned in acknowledgements; no financial relationships with any organisations that might have an interest in the submitted work in the previous 3 years; no other relationships or activities that could appear to have influenced the submitted work."

#### **CONTRIBUTION OF AUTHORS**

PM, IA, LR had the initial idea for the study and design the survey instrument with DE. VE and DP helped test the instrument. DP collected responses, analysed and interpreted them and did the initial draft of the manuscript. PND helped with data collection, analysis, and with DP and PM interpreted the results and edited the manuscript. JW contributed to the interpretation of results. All authors contributed to the final manuscript. All authors had access to all data in the study and held final responsibility for the decision to submit for publication.

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**Box**: What does this paper adds

#### What is known

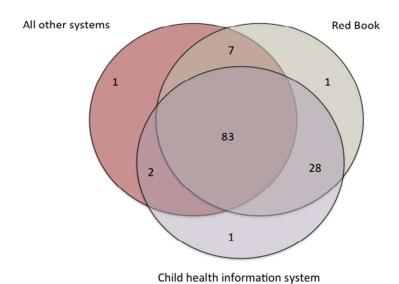
An important control measure, especially in the era of multidrug resistant tuberculosis, is BCG vaccination. In 2005 the UK moved from a school aged universal BCG vaccination policy to a targeted policy towards children at high risk. To date, it is unknown how this vaccination policy is operating at the local level (via Primary Care Trusts, PCTs)

What this study adds

Targeted infant vaccination has been implemented in most areas in England, but delivery pathways are complex and appear to vary between PCTs. Areas with selective infant vaccination provide BCG vaccine via a larger number of healthcare providers than those with universal infant vaccination policies. These findings emphasize the need to standardize local pathways, allocate clear responsibilities and to monitor vaccination coverage.

Figure 1. Principal systems used to document BCG vaccination and their combinations in PCTs with infant vaccination policy (N=123).





Principal systems used to document BCG vaccination and their combinations in PCTs with infant vaccination policy (N=123). 254x190mm~(72~x~72~DPI)



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#### Abstract

**BACKGROUND:** Vaccination with BCG is a cornerstone of tuberculosis control in England. In 2005, the school age vaccination programme was abandoned in favour of a targeted infant vaccination programme. We aimed to assess the current BCG vaccination policies and delivery pathways for immunisation in Primary Care Trusts (PCT) in England since the 2005 change in recommendations.

**METHODS:** We conducted a survey of key informants across 152 PCTs in England using a standardised, structured questionnaire.

**RESULTS:** Complete questionnaires were returned from 127 (84%) PCTs. 16 (27%) PCTs reported universal infant vaccination and 111 (73%) had selective infant vaccination. Selective vaccination outside infancy was also reported from 94 (74%) PCTs. PCTs with selective infant policy most frequently vaccinated on postnatal wards (51/102, 50%) whereas PCTs with universal infant vaccination most frequently vaccinate in community clinics (9/13, 69%; p=0.011). To identify and flag up eligible infants in PCTs with targeted infant immunisation, those that mostly vaccinate on postnatal wards depend on midwives and maternity records, whereas those that vaccinate primarily in the community rely more often on various healthcare professionals.

**CONCLUSIONS:** Targeted infant vaccination has been implemented in most PCTs across the UK. PCTs with selective infant vaccination provide BCG vaccine via a greater variety of health-care professionals than those with universal infant vaccination policies. Data on vaccine coverage would help evaluate the effectiveness of delivery. Interruptions of delivery noted here emphasise the importance of not just an agreed, standardised, local pathway, but also a named person in charge.

#### INTRODUCTION

Tuberculosis (TB) remains a public health problem in England. After a century of consistent decline in the incidence and annual infection risk, the incidence of TB has been rising since the late 1980s.[1] TB is concentrated within certain groups of the population (including migrants from high prevalence countries, prisoners, homeless persons and other marginal populations) and in urban areas.[2]

Since the 1950s, immunisation with the Bacillus Calmette-Guerin (BCG) vaccine, which has been shown to be highly effective in the UK population,[3] has been a part of TB control efforts in England. The routine policy had been primarily to administer the BCG vaccine to all tuberculin-negative schoolchildren aged 10 to 14 years. In some areas BCG was given during infancy and it was recommended that it should also be given to "children of immigrants in whose communities there is a high incidence of tuberculosis", amongst other high risk groups.[4] In 2005, this policy was replaced by a targeted immunisation programme directed at children with high risk of TB exposure.

The change in policy came after several years of discussion in the independent government advisory committee, the Joint Committee of Vaccination and Immunisation (JCVI). In the 1990's it was estimated that due to the low TB incidence, universal school-age vaccination was no longer cost-effective.[5] Universal BCG vaccination, however, remained policy largely because the incidence was rising slowly and health authorities were unsure about the impact that the emerging HIV epidemic could have on TB epidemiology.[5, 6] In 2005, after the HIV epidemic had stabilised and the UK had already fulfilled the criteria of the International Union Against Tuberculosis and Lung Diseases (IUATLD) to stop routine immunisation (which recommends different policies for different levels of TB, based on economic appraisals and the balance between the benefits and risks of BCG vaccination),[7] the JCVI recommended stopping universal school age vaccination and replacing it with a targeted infant vaccination programme.[5]

As part of this targeted infant programme, it is agreed that universal vaccination is the most effective way to reach all eligible children in areas of the country with TB incidence  $\geq$  40 per 100 000 person-years (pyrs). In areas with TB incidence < 40 per 100 000 pyrs, a selective approach is recommended to immunise only infants at high risk i.e. if their parents or grandparents originate from a country with an incidence  $\geq$  40 per 100 000 pyrs, if travelling

to a high incidence country for three or more months, or when in contact with a TB case. In addition, children of any age at high risk of TB should be vaccinated at suitable opportunities.[8]

In view of possible organisational changes in the NHS and given the current TB epidemiology in the country, we considered it important and timely to assess the BCG vaccine policy and the main vaccine delivery pathways across the commissioning bodies for community and hospital care (Primary Care Trusts, PCTs) in England.

#### **METHODS**

A standardised, mostly closed ended structured questionnaire was designed; (available from the authors). The questionnaire covered the vaccination policy in and outside infancy, eligibility criteria and their documentation, delivery pathways and constraints to service delivery. The questionnaire was piloted in 4 London PCTs.

In November 2010, we contacted all 152 PCTs in England. Immunisation leads and other staffs involved in TB control and BCG vaccination implementation were electronically mailed a copy of the questionnaire and a web-link to an internet equivalent created using the survey engine SurveyMonkey®. As delivery of BCG vaccine involves a chain of activities and responsibilities, respondents were asked to gather information from other key informants as needed. A reminder was sent after four weeks. After an additional 4 weeks, we contacted non-respondent PCTs by telephone to gather the information required.

At completion of the active data collection, as an additional data check, between August 2011 and September 2011 we searched PCTs' websites and related NHS sources for publicly available documents on their current BCG vaccination policy. We assessed the agreement between the information on these publicly available documents and the data collected from the survey. We compared distribution frequencies using a chi-square test or Fishers exact test where appropriate. For each variable, we only included observations for which data was available.

#### **RESULTS**

Between November 2010 and March 2011, 123 questionnaires representing 129/152 PCTs (85%) were returned: 72 (59%) as electronic documents and, 51 (41%) via the Internet survey. No difference in TB notification rates was found between responding and non-responding PCTs (data not presented). We found publically available current BCG policy

documents for 114 (88%) of the 129 PCTs. Two (2%) PCTs were excluded from subsequent analysis because their BCG policy could not be determined from the responses. Sixteen (13%) PCTs reported universal infant vaccination and 111 (87%) selective infant vaccination. The agreement with publically available BCG policy documents was high, with only 3 (2%) PCTs reporting a policy that was different from the information in these documents. Responses from these three PCTs to more detailed questions in the questionnaire were consistent with a selective infant vaccination at that time.

Three PCTs reported changing their policy between 2006 and 2011; 1 PCT followed the national recommendation and changed from targeted infant vaccination to universal infant vaccination as TB incidence exceeded 40 per 100 000 pyrs; 1 PCT changed to universal infant vaccination although their TB incidence was < 40 per 100 000 pyrs but justified doing so because of a borderline TB rate, high TB rates in neighbouring areas and high population mobility; 1 PCT had a universal infant vaccination programme prior to 2006, although their TB incidence was below the threshold, and changed to targeted infant vaccination.[9]

Some PCTs reported vaccination policies that did not reflect the JCVI recommendations. Six PCTs reported targeted infant vaccination despite having a 3-year average TB incidence  $\geq$  40 per 100,000.[9] Documents obtained from the websites, however, of 3 of these PCTs, state that they implement universal infant BCG vaccination. Six of the 16 PCTs reporting universal vaccination had 3-year average TB incidence  $\leq$  40 per 100,000.[9] They were all in or close to major conurbations.

#### **Vaccination during infancy**

PCTs with a selective infant BCG vaccination policy administer BCG via a wider range of health care providers than PCTs with universal infant BCG vaccination (Table 1). PCTs with selective policy most frequently offer vaccination on postnatal wards (51/102, 50%) but also vaccinate in community (24/102, 24%) and hospital clinics (27/102, 26%); PCTs with universal policy more frequently offer vaccination in community clinics (9/13, 69%) and less frequently on postnatal wards (4/13, 31%, p=0.011).

All PCTs that vaccinate primarily on postnatal wards do so during the infants' first month of life whereas only 13/37 (35%) PCTs that mainly vaccinate in community clinics do so in the infants' first month of life (p<0.001).

BCG vaccination receipt in infancy is documented in various ways across PCTs, and this did not depend on the vaccination policy (Table 1). It is most consistently documented in the Red

Book (119/123, 97%) and in the Child Health Information Systems (114/123, 93%). It is also noted in other registers and notes (Table 1), but always in combination with either or both of the former two (Figure 1).

Table 1. Place were BCG is primarily administered and systems reported to document BCG vaccination in 127 PCT with infant vaccination policy.

|                               | Selective infant vaccination N=102* | Universal infant vaccination N=13** |
|-------------------------------|-------------------------------------|-------------------------------------|
| Place of primary BCG          | n (%)                               | n (%)                               |
| administration                |                                     |                                     |
| Postnatal ward                | 51 (50)                             | 4 (31)                              |
| At home                       | 0                                   | 0                                   |
| At community clinic           | 24 (23)                             | 9 (69)                              |
| At chest clinic               | 17 (17)                             | 0                                   |
| At hospital paediatric clinic | 10 (10)                             | 0                                   |
|                               |                                     |                                     |
| Systems in use for BCG        | N=107***                            | N=16                                |
| documentation                 |                                     |                                     |
| Antenatal/Maternity records   | 43 (40)                             | 5 (31)                              |
| Birth notification records    | 15 (14)                             | 2 (12)                              |
| Paper log books held by       | 6 (6)                               | 1 (6)                               |
| midwives                      |                                     |                                     |
| Child health information      | 100 (93)                            | 14 (88)                             |
| system                        |                                     |                                     |
| School health records         | 27 (25)                             | 5 (31)                              |
| GP                            | 50 (46)                             | 3 (19)                              |
| Red Book                      | 103 (96)                            | 16 (100)                            |
| Discharge letters             | 37 (35)                             | 2 (12)                              |

<sup>\*9, \*\*3, \*\*\*4</sup> missing values for those variables

**Comment [ M1]:** Clarification on missing observations

#### **Selective infant vaccination**

In the 111 PCTs with selective infant vaccination, 71% reported routinely assessing eligibility for BCG. They all offer BCG vaccination to children with parents or grand parents born in countries with TB incidence  $\geq$  40 per 100 000 pyrs (Table 2). Six PCTs reported that travel to a high incidence country for three or more months is not an eligibility criterion; and 2 PCTs reported that contact with a TB case is not a selection criterion either.

Table 2. Selection criteria employed to decide eligibility for BCG vaccination in 111 PCTs with a targeted infant vaccination policy.

|  | n (%)*    |
|--|-----------|
| Infant of parents born in                | 107 (100) |
| country with incidence > 40 per 100 000. |           |
| Contact with TB                          | 93 (87)   |
|  | ( . )     |
| Prolonged travel                         | 94 (88)   |
| Parental request                         | 14 (13)   |
| Insecure accommodation                   | 13 (12)   |
| Socially deprived                        | 2 (2)     |
| Asylum seeker/refugees                   | 2 (2)     |

<sup>\* 4</sup> observations with missing data

Two main BCG delivery pathways were apparent from the information on identification and primary place of immunisation, but with considerable overlap. Where midwives are primarily responsible for identifying eligible infants, they are more frequently vaccinated on postnatal wards (37/56, 66%) than when eligibility is flagged by GPs, health visitors (HVs) or paediatricians (12/44, 27%; p<0.001). Conversely, in PCTs in which eligible infants are primarily flagged up by GPs, HVs or paediatricians, they are more frequently vaccinated in community clinics (32/44, 73%) than when midwives identify them (19/56, 34%; p<0.001). In line with these delivery pathways, when infants are identified by midwives or vaccinated on postnatal wards, their eligibility is most frequently flagged up in maternity records, whereas when infants are identified by GPs, HVs or paediatricians or when they are vaccinated in community clinics, various systems are used with no clear preference (Table 3).

Table 3. Systems in use to flag up infants' eligibility for BCG vaccination stratified by main responsible for identification in 111 PCTs with targeted infant vaccination.

| Systems used to flag up         | Identification primarily by | Identification primarily by GP, HV |  |  |  |  |
|---------------------------------|-----------------------------|------------------------------------|--|--|--|--|
| eligibility                     | midwifes*                   | or paediatrician*                  |  |  |  |  |
|                                 | N=51                        | N=38                               |  |  |  |  |
| Maternity records               | 43 (84%)                    | 14 (37%)                           |  |  |  |  |
| Baby's hospital notes           | 28 (55%)                    | 18 (47%)                           |  |  |  |  |
| Red Book                        | 25 (49%)                    | 22 (56%)                           |  |  |  |  |
| Birth notification records      | 10 (20%)                    | 6 (16%)                            |  |  |  |  |
| Child health information system | 10 (20%)                    | 6 (16%)                            |  |  |  |  |

<sup>\*22</sup> observations with missing data

#### **Vaccination outside of infancy**

Vaccination outside infancy was reported in 94/127 (74%) PCTs. In 14/94 (14%) PCTs vaccination outside of infancy is offered to preschool children only, in 9/94 (9%) to schoolchildren only and in the remaining PCTs to both groups. HVs are most frequently involved in identifying eligible pre-school children (51/85, 51%). GPs alone were mentioned by 3/85 (4%) PCTs but 33/85 (36%) PCTs reported that both GPs and HV identify eligible pre-school children. A similar pattern was seen for the identification of school children: school nurses alone identify eligible school children in 56/80 (70%) PCTs, GPs alone in 9/80 (11%) PCTs and in 15/80 (19%) PCTs both school nurses and GPs identify school children.

All PCTs offering vaccination outside infancy reported assessing previous BCG immunisation in eligible children using at least one of the criteria recommended by the Green Book. Sixty-four of 94 (68%) PCTs use a combination of reliable parental recall, documentary evidence and presence of a scar as evidence of previous BCG vaccination. Seventy of 94 (18%) PCTs use the combination of a BCG scar and reliable recall; whereas 13/94 (14%) consider only one criteria as sufficient evidence.

#### Logistic constraints hindering BCG administration

Of all PCTs, 26/127 (20%) reported periods between 2005 and 2010 during which they could not administer BCG due to logistic constraints. The most frequent reasons are vaccine supply shortage and lack of trained health workers (including access to training) to administer the vaccine. One PCT reported various episodes where no BCG could be administered as a result of a pending business case over who was to carry out BCG vaccination when the previously appointed community paediatrician retired. A similar problem was reported in a different PCT reporting unclear responsibilities after the adult respiratory department stopped seeing paediatric patients. In one PCT, BCG could not be administered over a two-year period due to absence of funding agreements and was only re-introduced after a school outbreak.

#### DISCUSSION

Six years after its introduction, the 2005 recommendation for BCG vaccination has been implemented in the vast majority of England PCTs. All surveyed PCTs have an infant vaccination policy in place, but a quarter of these PCTs do not report offering vaccination outside infancy. Selective infant vaccination mostly takes place on the postnatal ward and during the first month of life whereas universal infant vaccination mainly happens in

community clinics and after the first month of life. In PCTs with a selective infant vaccination policy, this survey found greater variation in the organisation of BCG vaccine delivery.

We were unable to gather information from 15% of the PCTs. However, TB notification rates between responding and non-responding PCTs were similar, suggesting results presented are not likely to be biased.

Since the JCVI issued their recommendations in 2005, there has been an on-going discussion about how to define areas of high TB incidence in the context of the policy.[10-12] Universal infant vaccination is, for operational reasons, recommended in PCTs where the TB incidence is  $\geq$  40 per 100 000 pyrs, as it is agreed that this is the most efficient way to reach all infants at high risk of TB in such areas. Nevertheless, the cut-off incidence for targeted infant vaccination is debated as children in PCTs with an incidence < 40 per 100 000 pyrs can still be at high risk of TB.[13]

In this survey, six PCTs in or close to urban areas reported vaccinating all infants although their PCT-specific incidence is < 40 per 100 000 pyrs. This could indicate that some PCTs in urban areas are considering regional incidence to inform their policies, rather than PCT specific incidence. Nevertheless, it remains uncertain if this strategy ensures that the maximum number of eligible children are being immunised, and if it is more cost-effective than a PCT-specific informed targeted vaccination policy. Further analysis of the economic efficiency of regional BCG vaccination is required.

Surveys of BCG vaccination policies and practices in England and Wales in 1982 and 1992 indicated considerable variations across health districts.[14, 15] In 1992, 15 of the 186 health districts in England had already stopped their routine school immunization programme; 148 offered BCG to selected groups of neonates and five districts routinely gave BCG to all their neonates.[15] Today, variation in local BCG vaccination policies is lower but the organisation of BCG delivery remains highly variable. We find that PCTs commission a wide range of healthcare providers to deliver the vaccine. This heterogeneity across PCTs also demands a high level of organisation between PCTs if services such as maternity care straddle PCT borders. Hospitals may not be coterminous with PCTs and hence infants from PCTs with different policies and practices can be born in the same hospital. In this light, it is of concern that many PCTs don't have service level agreements (SLA) to organise BCG administration either within the PCT and across boundaries.[4] This and the complexity of managing a localised service could also explain why some PCTs were unable to deliver BCG during periods where service providers changed.

**Comment [ M2]:** Paragraph addressing the limitations of the study and non-response bias.

The commissioning of BCG may become more complex if it becomes the responsibility of Clinical Commissioning Consortia. In its current form, the suggested changes to the NHS structure could lead to consortia responsible for overlapping geographical areas. If services are not commissioned across boundaries and responsibilities are not clearly assigned, the current heterogeneity in policies and practices could increase and seriously compromise the targeted infant vaccination. Infant hepatitis B vaccination is another selective programme, being given to infants of mothers screened antenatally and found to be positive for hepatitis B carriage. It works best when there is an identified person in each area, who is responsible for co-ordinating the programme. [16] This model should be considered for the BCG programme.

While the structural organisation of the NHS poses challenges for the 2005 recommendations, the implementation of a targeted vaccination policy is, in its self, demanding.[17] Hence, it is vital to monitor the implementation to assure high vaccination coverage. Good data on BCG immunisation coverage is complicated to assemble in PCTs with targeted infant vaccination where the denominator is unclear. Data from audits, however, show that vaccination coverage in areas with targeted infant vaccination can be low [18] and that even in PCTs with high coverage, it can vary greatly between maternity units [19] and ethnic groups.[20] We find that a wide range of health care professionals are involved in the identification of eligible children. It is therefore conceivable that infants are not identified due to unclear responsibilities. In addition, our findings suggest that some health professionals involved in the BCG vaccination program might be unfamiliar with recommended eligibility criteria; this could contribute to low coverage rates.[21] A standardised pathway to identify eligible infants, with clear responsibilities and roles and regular training of staffs involved could contribute to high vaccination coverage in PCTs with selective vaccination policy.[22, 23]

In addition to the correct identification of infants at risk, assuring that the vaccine is administered is another challenge of a targeted vaccination policy.[17, 22] Half of the PCTs vaccinate on postnatal wards – a vaccine delivery pathway associated with high vaccination coverage in local audits.[22-24] The other half, however, vaccinate in a community setting or clinics which in this survey was associated with vaccination at an older age. The different delivery pathways probably reflect local circumstances. Immunising newborns in postnatal wards may be more optimal in conditions in which the workload is manageable at that level, with either a relatively lower number of eligible newborns, or a sufficient number of skilled personnel to administer BCG. Vaccinating in the community might be more effective in areas with higher numbers of eligible newborn (especially if universal BCG vaccination) and limited

number of trained staffs to administer the vaccine in postnatal wards. However, the latter could mean a higher risk of attrition as parents may not return their children to immunisation appointments, as reported in previous audits.[23, 25] A study in South London found that parents would be more interested if the vaccine was accessible on a "drop-in" basis from community clinics [18] in such areas.

Another aspect that might affect efficient delivery is that the most commonly used systems for documentation of BCG receipt are often not the systems used to flag up eligibility. Aligning the systems used to identify eligible children with the system used to document BCG vaccination could be an effective way to ensure that identified infants receive the vaccine and a means to estimate coverage. [24] Also, BCG vaccination was not delivered with other routine infant vaccinations possibly because of the need for specific training for an intradermal vaccination. The addition of BCG vaccination to the offer of other routine infant vaccinations in specific regions could be another way of ensuring coverage of those at risk.

The 2005 BCG policy for the UK also recommends vaccinating previously unvaccinated children who are at high risk of TB. Despite the policy, a quarter of all PCTs do not report vaccinating outside infancy. Although the absence of vaccination outside infancy may conserve resources in areas with low levels of migration, some PCTs in urban centres with presumably high levels of migration do not report vaccinating outside infancy. This suggests that greater efforts are needed to strengthen targeted BCG vaccination outside infancy.

In conclusion, a targeted infant BCG vaccination has been implemented in most PCTs across England, either as part of postnatal hospital care or a community vaccination programme separate from other childhood vaccinations via a number of locally agreed health-care professionals. Information to assess coverage would be useful to monitor successful provision of an effective measure to prevent childhood tuberculosis.

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#### **COMPETING INTERESTS**

"All authors have completed the Unified Competing Interest form at www.icmje.org/coi\_disclosure.pdf (available on request from the corresponding author) and declare: no support from any organisation for the submitted work other than mentioned in acknowledgements; no financial relationships with any organisations that might have an interest in the submitted work in the previous 3 years; no other relationships or activities that could appear to have influenced the submitted work."

#### **CONTRIBUTION OF AUTHORS**

PM, IA, LR had the initial idea for the study and design the survey instrument with DE. VE and DP helped test the instrument. DP collected responses, analysed and interpreted them and did the initial draft of the manuscript. PND helped with data collection, analysis, and with DP and PM interpreted the results and edited the manuscript. JW contributed to the interpretation of results. All authors contributed to the final manuscript. All authors had access to all data in the study and held final responsibility for the decision to submit for publication.

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**Box**: What does this paper adds

#### What is known

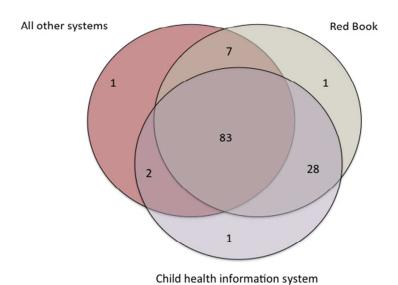
An important control measure, especially in the era of multidrug resistant tuberculosis, is BCG vaccination. In 2005 the UK moved from a school aged universal BCG vaccination policy to a targeted policy towards children at high risk. To date, it is unknown how this vaccination policy is operating at the local level (via Primary Care Trusts, PCTs)

What this study adds

Targeted infant vaccination has been implemented in most areas in England, but delivery pathways are complex and appear to vary between PCTs. Areas with selective infant vaccination provide BCG vaccine via a larger number of healthcare providers than those with universal infant vaccination policies. These findings emphasize the need to standardize local pathways, allocate clear responsibilities and to monitor vaccination coverage.

Figure 1. Principal systems used to document BCG vaccination and their combinations in PCTs with infant vaccination policy (N=123).





Principal systems used to document BCG vaccination and their combinations in PCTs with infant vaccination policy (N=123). 254x190mm (72 x 72 DPI)

### Questionnaire

### Part 0. PCT and contact details:

| 14110.101  | and contact details.   |
|--|--|
| Name of PCT:                                       |  |
|  |  |
|  |  |
| 1.Details of perso                                 | on completing questionnaire  |
| Name   |  |
| Title:   |  |
| Responsible for:<br>(e.g. child<br>health records) |  |
| Contact details:                                   |  |
| should contact?                                    | people responsible now for local BCG vaccine policy or BCG vaccine data we (We will ask about past policy later. There are also extra spaces at the end of to add names of people who may have information about the past) |
| Name   |  |
| Title:   |  |
| Responsible for:                                   |  |
| Contact details:                                   |  |
|  |  |
| Name   |  |
| Title:   |  |
| Responsible for:                                   |  |
| Contact details:                                   |  |

Part 1. Recent and current infant vaccination Policy

(Please fill in by adding an "x" to all that apply) 1. a. What was BCG vaccine policy in this PCT after the national school-aged BCG vaccination programme was discontinued in 2005? Selected infant groups\* Opportunistic (in >1 year olds) All infants Not sure School-aged Other (please specify) \*to those at "high risk" e.g. parent/grandparent originating from a high incidence country **b**. Is this your current policy? Yes **c**. If No, what is the current BCG vaccine policy in this PCT? Selected infant groups Opportunistic (in >1 year olds) All infants School-aged Not sure and in what year did the current policy start? **2.a.** If BCG vaccination is offered in this PCT to any infants (either to selected groups or all infants), at what age is it **usually** given? from 1 week to 1 month from 1 month to 2 months 0-6 days from 2 months to 3 months from 3 months to 1 year Other (please specify).....

**b.** If BCG is given at or after 2 months, is it given at the same time as the routine childhood immunisations in this PCT?

Yes No Not sure

| c. If this PCT vaccinates any groups of infants, where is it <b>primarily</b> carried out? (tick <b>on</b> | e box) |
|--|--------|
| Post natal ward by midwife or paediatrician?   |        |
| At home by health visitor, midwife or specialist TB nurse?   |        |
| At a community paediatric clinic by staff nurses or health visitor?  |        |
| At the chest clinic?   |        |
| At hospital paediatric clinic?   |        |
| Other (please specify).  |        |
|  |        |
| d. Where else is BCG vaccination in infants given? (tick all boxes that apply)                             |        |
| Post natal ward by midwife or paediatrician?   |        |
| At home by health visitor, midwife or specialist TB nurse?   |        |
| At a community paediatric clinic by staff nurses or health visitor?  |        |
| At the chest clinic?   |        |
| At hospital paediatric clinic?   |        |
| Other (please specify).  |        |

**e.** When BCG is administered, where is documentation maintained? Roughly what year did this start? (*please add a "x" to all that apply*)

| Ways of recording receipt of vaccine      | Yes | No | If Yes since about | Not sure when |
|---|-----|----|--------------------|---------------|
|   |     |    | what year          |               |
| In electronic antenatal/maternity         |     |    |                    |               |
| records                                   |     |    |                    |               |
| Paper antenatal/maternity records         |     |    |                    |               |
| raper antenatal materiaty records         |     |    |                    |               |
| In electronic birth notification records  |     |    |                    |               |
| In paper birth notification records       |     |    |                    |               |
| In electronic child health information    |     |    |                    |               |
| systems                                   |     |    |                    |               |
| In paper child health information records |     |    |                    |               |
| lecords                                   |     |    |                    |               |
| In the child's "red book" (Parent Held    |     |    |                    |               |
| Child Health Record, PHCHR)               |     |    |                    |               |
| In paper log books held by midwives       |     | 9, |                    |               |
| In electronic school health records       |     |    |                    |               |
| Microfiched school health records         |     |    | 0,                 |               |
| GP Medical Notes (manual)                 |     |    | 2                  |               |
| GP Computer System                        |     |    | O <sub>A</sub>     |               |
| Discharge letter from hospital            |     |    |                    |               |
| Other                                     |     |    |                    |               |

| <b>3.</b> W | ere  | there  | any  | years <b>sinc</b> | e 20 | 005 when | BCG | vaccine | to infant | s was | not g | iven ir | ı this | PCT | for |
|-------------|------|--------|------|-------------------|------|----------|-----|---------|-----------|-------|-------|---------|--------|-----|-----|
| logis       | tica | l or o | thei | reasons?          |      |          |     |         |           |       |       |         |        |     |     |
|             |      |        |      |                   |      |          |     |         |           |       |       |         |        |     |     |
| Yes         |      | No     |      | Not sure          |      |          |     |         |           |       |       |         |        |     |     |

| If Yes, please state year(s) and the reasons |  |
|--|--|
|  |  |

## PLEASE GO TO PAGE 8 (PART 2, QUESTION 6) IF THIS PCT'S POLICY IS UNIVERSAL INFANT VACCINATION

- . If **selected** infant groups are offered BCG vaccine in this PCT
- **a**. Which groups are offered the vaccine? (please add a "x" to all that apply)

| Risk groups  | Yes                       | No           |
|--|---------------------------|--------------|
| Infant of a parent or grandparent born in a country with incidence of TB above 40 per 100,000                    |                           |              |
| Prolonged travel to a high incidence country for   |                           |              |
| more than three months   |                           |              |
| Children in insecure accommodation or part of  |                           |              |
| traveller household  |                           |              |
| Close contacts with someone who has had TB   |                           |              |
| Infants in socially deprived households  |                           |              |
| Parental request for BCG   |                           |              |
| Other (please specify)   | <b>)</b>                  |              |
|  |                           |              |
| <b>b.</b> When and by whom are (potentially) eligible child identified in this PCT? (please tick <b>one</b> box) | lren in the selected grou | ps primarily |
| Before birth by midwife  |                           | Yes No       |
| After birth by midwife   |                           | YesNo        |
| After birth by paediatrician at post natal assessment  |                           | Yes No       |
| After birth by health visitor  |                           | Yes_No_      |
| After birth by General Practice staff responsible for o  | childhood immunisation    | s Yes No     |
| Not sure   |                           |              |
| Other (please specify)   |                           |              |

**c.** Where is eligibility noted/flagged by this PCT, and roughly what year did this start? (please tick all that apply)

| Ways of recording eligibility                  | Yes | No | Since about the year: | Not sure about when |
|--|-----|----|-----------------------|---------------------|
| In electronic antenatal/maternity records      |     |    |                       |                     |
| In paper antenatal/maternity records           |     |    |                       |                     |
| In the baby's hospital notes                   |     |    |                       |                     |
| In electronic birth notification records       |     |    |                       |                     |
| In paper birth notification records            |     |    |                       |                     |
| In the child's "red book" (PHCHR)              |     |    |                       |                     |
| In electronic child health information systems |     |    |                       |                     |
| In paper child health information records      |     |    |                       |                     |
| Other (please specify)                         |     |    |                       |                     |

| <b>5.</b> Is the assessment to identify the selecte routinely for all infants born in this PCT? | d infant groups noted above in question 4 done |
|---|--|
| Yes No Not sure   |  |

## Part 2: Recent and current vaccination policy outside infancy

| <b>7.a.</b> If you routinely vaccinate any groups of <b>school-aged</b> children normally carried out? | , is prior Mantoux testing |
|--|----------------------------|
| Yes No   |                            |
| <b>b</b> . Where is school-aged BCG vaccine <b>primarily</b> given?                                    |                            |
| At school by the school nurses   | Yes No                     |
| At a community paediatric clinic by staff nurses or health visitor                                     | Yes No No                  |
| At the chest clinic  | Yes No No                  |
| Other (please specify)   |                            |
|  |                            |

### Part 3. History of BCG policy and practice

We are interested in local policies for infant and adolescent BCG vaccination in order to decide who to include in a new study of how long BCG vaccine protects against TB disease. We are trying to find out what policy was locally from 1968 to 2005. We do realise this may be difficult given the number of changes but we would appreciate you completing as much as you can even if you do not have information on the whole of the time period. We will ask later for names of people who may have more information.

| <b>8.</b> School-aged BCG vaccination was routine in many areas from 1950s to 2005 when it was discontinued. Do you think this was routine policy from 1968 to 2005 in the areas now covered by the present PCT(s)?   |
|---|
| Yes No Not sure   |
| a. Several local areas had interruptions of either BCG vaccine supply or material to test for TB infection. We realise that there may have been several boundary changes as well over time but do you know if there were years (before 2005) in which the school-aged vaccination programme was suspended or discontinued in the areas (partially or fully) covered by the present PCT? |
| Yes No Not sure   |
| If Yes, please state which years prior to 2005 in which school-aged BCG vaccination was not given and in which district/area health authorities/PCTs  |
|   |
| <b>b.</b> Primary care groups and then primary care trusts were created in 2002. What area health authority was this PCT in before these changes?   |
| Not sure  |
| c. Where there other boundary changes that occurred in the time period 2002 until today?  |
| Yes No Not sure   |
| d. If Yes please specify what and when  |
|   |
|   |
|   |

| 9. Did these district/area health authorities/PCTs also routinely offer BCG vaccination in infancy or to children before the age of 11 before 2005? |
|---|
| Yes, universal infant year started  |
| Yes, selected infant year started.  |
| Yes, opportunistic vaccination  year started.   |
| No  |
| <b>10.</b> Some district/areas used jet injectors as well or instead of needle and syringe around the late 1970s.                                   |
| Did these district/area health authorities/PCTs ever use jet injectors?   |
| Yes No Not sure   |
| If Yes,  a. Do you know approximately during which years jet injectors were used?   |
| Year startedto year ending(inclusive)   |
|   |
|   |
|   |
|   |

11. Records of school-aged vaccinations or midwifery records of infant BCG vaccines given are kept routinely till after the child leaves school usually to at least the age of 25 years. We would like to know about the availability of any past individual records on BCG vaccinations in infants or children any time from now to 1968.

Do you know if the following historical records might be available? (please tick all that apply)

| Do you know if the following historical rec | ords migh | it be avai | lable? (please tick all | that apply) |
|---|-----------|------------|-------------------------|-------------|
| Ways of recording vaccine receipt           | Yes       | No         | If Yes, from what       | Not sure    |
|   |           |            | year to what year?      | when        |
| In electronic antenatal/maternity records   |           |            |                         |             |
|   |           |            |                         |             |
| Paper antenatal/maternity records           |           |            |                         |             |
|   |           |            |                         |             |
|   |           |            |                         |             |
| In electronic birth notification records    |           |            |                         |             |
|   |           |            |                         |             |
| In paper birth notification records         |           |            |                         |             |
|   |           |            |                         |             |
| In electronic child health information      |           |            |                         |             |
| systems                                     |           |            |                         |             |
| In paper or microfiched child health        |           |            |                         |             |
| information records                         |           |            |                         |             |
|   |           |            |                         |             |
| In the child's "red book" (PHCHR)           |           |            |                         |             |
|   |           |            |                         |             |
| In paper log books held by midwives         |           |            |                         |             |
| F.F. Street                                 | •         |            |                         |             |
| In paper log books held by health visitors  |           |            |                         |             |
| In puper regional new of meaning visitors   |           |            |                         |             |
| In electronic school health records         |           |            |                         |             |
| in electronic sensor nearth records         |           |            |                         |             |
| Microfiched school health records           |           |            |                         |             |
| Tribioned school nearth records             |           |            |                         |             |
| Paper child health records                  |           |            |                         |             |
| r aper emia nearm records                   |           |            |                         |             |
| Other (please specify:                      |           |            |                         |             |
| Ciner (prouse specify.                      |           |            |                         |             |
|   | 1         | ĺ          | I                       | I           |

| <b>a.</b> Who could we contact to ask about these records?   |
|--|
| Name   |
| Title:   |
| Responsible for:   |
| Contact details: Address Telephone Email   |
|  |
| <b>b</b> . If you currently have electronic child health records that capture BCG vaccination, What system is it and how long have you had it in the current format?                 |
| years  |
| c. Do you know what systems were in place before then?   |
| system fromyear toyear   |
| <b>d.</b> Have records in the old system been copied into the current system?  |
| Yes No Not sure  |
| <b>12.</b> We are also interested in whether there are any past written reports or audits of coverage by infant and adolescent BCG vaccination in your area/PCT between 1968 to now. |
| <b>a.</b> Do you know of any reports or audits on past overall PPD positive rates and/or BCG vaccination uptake rates in your area or region?  |
| Yes No Not sure  |
| <b>b</b> . Who might we contact for any such reports?  |
| Name   |
| Title:   |
| Responsible for:   |
| Contact details:   |
|  |

Thank you for your time. We realise BCG vaccination policy has changed over a large number of years and have varied often depending on the local epidemiology of TB and availability of testing and vaccines. The next part gives you some space if you wish to add more details.

How and why did BCG policy change in your area since 1968? (please could you add any changes in the administrative boundaries i.e. changes in the catchment population)

Please use this space if you can let us know any more about where any BCG vaccine records might be stored or archived.

If you think there is anyone else you have not mentioned before you think we should contact please use the space below.

Name

Title:

Responsible for:
(e.g. past infant vaccination records)

Contact details: