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18th August 2005,

To: PCT Immunisation Co-ordinators in England

This information will be required by all professionals who are involved in BCG vaccination (e.g. Commissioners, Immunisation Coordinators and Nurses, Consultants in Communicable Disease Control, Midwives, Health Visitors, Practice Nurses and School Nursing Services, Chest Physicians, TB Nurse Specialists, General Practitioners).

Dear Colleague,

CHANGES TO THE BCG VACCINATION PROGRAMME IN ENGLAND

On 6 July 2005, a letter from the Chief Medical Officer, Chief Nursing Officer and Chief Pharmaceutical Officer (PL/CMO/2005/3) detailed changes in national BCG vaccination policy.

This operational note provides further information and advice to help PCTs and local BCG services to adapt to these policy changes.

NEW POLICY

From 1 September 2005, the new policy is to provide an improved targeted BCG vaccination programme for -

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

Previously unvaccinated older children with specific risk factors for TB who would formerly have been offered BCG through the schools' programme, should now be identified at suitable opportunities, and tested and vaccinated if appropriate.

The contact, occupational and travel-related recommendations remain unchanged.

Please refer to the revised TB chapter of 'Immunisation against Infectious Disease' (The 'Green' book) for detailed information. The new edition of the Green book will be available shortly.

Please note: *for children over the age of 12 months, living in, or moving into an area of the UK where the incidence of TB is 40/100,000 or greater is NOT on its own an indication for vaccination*

Organisation of local BCG services

The aim of the new programme is to ensure that BCG coverage is as high as practically possible among all eligible neonates and infants up to the age of 12 months. In practice, this means that services should be in place to actively identify and vaccinate eligible infants as early in life as possible and before they reach 12 months of age. Wherever possible, neonates eligible for BCG vaccination should be identified antenatally and vaccinated soon after birth, and ideally before discharge from hospital.

PCTs should develop policies relevant to their local populations covering: –

1. Identifying neonates who should receive BCG vaccination (preferably antenatally) and appropriate recording systems to flag those identified
2. Identifying previously unvaccinated school age children with TB risk factors who would previously have received BCG routinely through the schools' programme
3. When BCG vaccination is to be offered
4. Where BCG vaccination is to be provided
5. Who is to administer the BCG vaccine, bearing in mind that the priority for the use of clinical TB services should be in the diagnosis and management of cases with active and latent disease and contacts of cases
6. The opportunities and arrangements to identify eligible children not vaccinated as originally planned
7. Record keeping, including revised KC50 data returns
8. Training
9. Audit and feedback into implementation arrangements
10. Roles and responsibilities

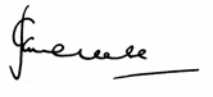
Practical advice on implementation of local policy is offered in Appendix 1.

In PCTs where demand for skin testing and BCG vaccination for older children is likely to remain high it is recommended that appropriate specific provision for BCG vaccination should be made alongside existing community immunisation services.

If you require further information please contact the relevant member of the Department's Immunisation Team, as follows:

Dr Jane Leese (Clinical issues) Tel: 020 7972 4255
Alistair Story (Clinical and operational issues) Tel: 020 7972 4523
Jeff Porter (Policy issues) Tel: 020 7972 4295
Loraine Gershon (Pharmacy issues) Tel: 020 7972 1227
June Boggis (Vaccine Supply issues) Tel: 020 7972 4039

Yours sincerely



JANE LEESE FRCP
Senior Medical Officer

This document has been authorised by the Department of Health: **Gateway reference no: 5360**

Appendix 1

OPERATIONAL ADVICE

There are two key areas:

1. developing local policy and practice for neonatal and infant BCG vaccination

2. developing local policy and practice for previously unvaccinated older children with specific risk factors for TB who will not now be offered BCG vaccination through the schools programme

1 Neonatal policy and practice

DH recommends that PCTs develop their local programmes starting from consideration of the rates of TB within their PCT boundaries.

Table 1 provides a list of PCTs whose rates of TB were 40/100,000 population or greater, either for any single year within the last three years, or for the three year average.

Universal neonatal BCG vaccination
Universal BCG vaccination should be offered to neonates (0 to 12 months of age) in a PCT with an overall tuberculosis rate of 40/100,000 or greater.

However, it is recognised that there may be large variations in local tuberculosis rates that do not conform to PCT boundaries. The overriding concern should be to ensure that population groups defined by place of residence with high rates of tuberculosis are offered universal neonatal BCG.

Selective neonatal BCG vaccination
In areas where the rates of TB are below the level recommended for universal neonatal vaccination, local policy and practice should still ensure that neonates with a parent or grandparent born in a country with TB incidence of 40/100,000 or greater should be vaccinated.

General information for both options

BCG may be given at any time. For infants not vaccinated at birth, BCG may be conveniently given at the same time as other primary childhood immunisations by Health Visitors and Practice Nurses who routinely see children. (Note - BCG must be given in a different limb to other vaccinations). Appendix 2 identifies some of these immunisation opportunities. Arrangements to identify and refer infants eligible for BCG vaccination will depend on the local service configuration as well as the local epidemiological situation.

2 BCG vaccination for children aged over 12 months

Following the start of this new vaccination policy, there may be older children with specific risk factors for TB who previously would have received their vaccination through the schools programme.

PCTs and BCG services need to develop local arrangements to meet the new policy.

Children over the age of twelve months should only be routinely offered BCG vaccination whenever they are identified as having specific risk factors which predispose them to a higher risk of infection.

In practice, BCG vaccination of children older than one year should be restricted to children:

- who were born in a country outside UK with a TB incidence of 40/100,000
- who have a parent or grandparent who was born in a country with a TB incidence of 40/100,000 or greater
- who are contacts of a TB case, or are to visit or live in a country with a TB incidence of 40/100,000 or greater for a period of one month or more.

Note that for children over the age of 12 months, living in, or moving into an area of the UK where the incidence of TB is 40/100,000 or greater is NOT on its own an indication for vaccination.

The opportunities to identify such children eligible for BCG include statutory health checks and routine immunisation schedules as well as part of new entrant screening, new patient registration in primary care, as part of contact management and when seeking advice for overseas travel (see Appendix 2).

PCTs may wish to consider inclusion of relevant questions in letters to parents at the time of school entry and when routine adolescent vaccinations are being offered.

People seeking vaccination for themselves or their children should be assessed for specific risk factors for tuberculosis. Those without risk factors should not be offered BCG vaccination but should be advised of the current policy and given written information. Further information is available in Appendix 3 and from the immunisation website (www.immunisation.nhs.uk)**.** People with risk factors should be tuberculin tested and offered BGC vaccination according to local service arrangements.

BCG may be given to infants and children up to and including age of five years without prior tuberculin testing provided that –

- There are no general contraindications as detailed in the Green Book
- There is no history of residence or prolonged stay (>1 month) in a country with a TB incidence of 40/100,000 or greater.
- There is no history of close contact with a case of tuberculosis.

Information about Mantoux testing

The Mantoux test will replace the Heaf test as the standard method of tuberculin skin testing. Tuberculin PPD (SSI) for routine use in the Mantoux test is labelled as 2 TU per 0.1ml dose. See link below for PPD Supply Information:
http://www.dh.gov.uk/PolicyAndGuidance/HealthAndSocialCareTopics/Tuberculosis/fs/en

At present, tuberculin testing and BCG vaccination are provided by an expert workforce in specific locations including delivery units, community immunisation clinics, chest clinics and community clinics established specifically for the purpose of tuberculin testing and BCG vaccination. Given that Mantoux testing and BCG vaccination require specific

expertise in siting the injections, intradermal administration, interpretation and after care of the injection site, it is recommended that commissioning PCTs continue to deliver the service through an expert workforce in specific locations determined by local service configuration.

PCTs should be aware that as of 1 April 2004 the KC50 data returns on BCG vaccination of children under twelve months of age have been revised to provide information on BCG coverage in universal, selective and other programmes (including contact management, new entrant screening and travel-related vaccination).

Where necessary, training in the use of Mantoux and BCG vaccination should be arranged locally. The Department of Health is producing a variety of training materials showing how to give and read the Mantoux test. These materials will be available from September to download from www.immunisation.nhs.uk or available to order from DH Publications: dh@prolog.uk.com or Tel: 08701 555 455.

Table 1. Enhanced Tuberculosis Surveillance TB incidence rates by Primary Care Trust of residence, England, 2001-2003

Primary Care Trust	Rate (per 100,000)			
	r2001	r2002	r2003	Mean r01-03
EASTERN LEICESTER PCT	141.6	92.0	99.9	111.1
NEWHAM PCT	84.2	85.4	98.2	89.3
BRENT TEACHING PCT	84.9	75.6	81.0	80.5
HEART OF BIRMINGHAM TEACHING PCT	77.2	78.3	85.9	80.5
BRADFORD CITY TEACHING PCT	84.3	61.9	78.3	74.8
CITY AND HACKNEY TEACHING PCT	65.7	66.5	72.6	68.3
EALING PCT	62.2	64.0	61.3	62.5
HARINGEY TEACHING PCT	68.7	62.0	56.5	62.4
SLOUGH PCT	52.2	55.9	62.3	56.8
CENTRAL DERBY PCT	51.8	54.8	62.3	56.3
LAMBETH PCT	49.4	58.6	57.7	55.2
TOWER HAMLETS PCT	34.3	60.1	70.7	55.2
CENTRAL MANCHESTER PCT	61.9	55.4	46.0	54.3
HOUNSLOW PCT	58.8	56.2	46.0	53.7
ISLINGTON PCT	48.5	58.3	52.2	53.0
HARROW PCT	48.1	54.4	54.6	52.4
CAMDEN PCT	45.9	56.5	50.3	50.9
OLDBURY AND SMETHWICK PCT	37.2	46.3	50.9	44.8
HAMMERSMITH AND FULHAM PCT	47.2	47.5	36.7	43.8
LUTON PCT	38.2	45.8	42.1	42.0
HILLINGDON PCT	38.7	38.5	46.8	41.4
WALTHAM FOREST PCT	31.1	46.4	44.7	40.7
SOUTHWARK PCT	40.1	41.5	39.8	40.5
REDBRIDGE PCT	38.0	38.0	44.9	40.3
WESTMINSTER PCT	37.4	35.0	40.1	37.5
BLACKBURN WITH DARWEN PCT	35.4	44.5	25.8	35.2

Data prepared by: TB Section, HPA Centre for Infections
Data as of 25/07/05
Key: Mean rate ≥40.0 per 100,000
Sources: Case reports - Enhanced Tuberculosis Surveillance
Population estimates - Office for National Statistics

Appendix 2

Opportunities to identify, test and vaccinate people eligible for BCG vaccination

Hall 4* provides a framework around which local BCG services can be structured to ensure that all eligible infants not vaccinated in delivery units at birth can be identified and referred for BCG vaccination at the earliest opportunity and before they reach the age of one year.

For children aged 0 to 12 months

Antenatal check – **Midwives** - identification of future need for BCG; notes marked, information sheet given to mother
At birth – Midwives – notes marked appropriately
10 days – **Midwives/Health Visitors** – refer to community BCG clinic or BCG given by primary care immunisation team
6-8 - weeks postnatal check – **Health Visitor/General Practitioner** – refer to community BCG clinic or BCG given by primary care immunisation team
8 weeks – primary immunisations - Practice Nurse/Health Visitor – refer to community BCG clinic or BCG given by primary care immunisation team
12 weeks – routine immunisations - Practice Nurse/Health Visitor – refer to community BCG clinic or BCG given by primary care immunisation team
16 weeks – routine immunisations - Practice Nurse/Health Visitor – refer to community BCG clinic or BCG given by primary care immunisation team
12 months – routine MMR - Practice Nurse/Health Visitor – refer to community BCG clinic or BCG given by primary care immunisation team (Note – BCG can be given at the same time as other live vaccines, otherwise they must be given at least 4 weeks apart)

For children aged over 12 months

2, 3 or 4 years – Health Reviews – Health Visitor/GP – refer to community BCG clinic or primary care immunisation team
School checks (if done) – School Nurse
Any time – new entrant screening; contact screening and overseas travel advice

* Hall D, Elliman D. Health for All Children 4th Ed. Oxford University Press, December 2002

Appendix 3

Background information for professions

The contribution of BCG vaccination to overall tuberculosis control *in populations* is limited. The principal measures for tuberculosis control are early case finding, treatment of active disease and latent infection (with directly observed therapy where necessary), contact tracing, infection control and selective screening of high-risk populations.

Key principles of the change in policy

- The principal role of BCG is to protect individuals at high risk of exposure to tuberculosis.
- BCG vaccination does not have a significant impact on the incidence of disease in a population.
- BCG is most effective at preventing severe disease in infants and young children.[1, 2, 3]
- Although the evidence suggest that protection afforded by BCG wanes with time, repeat BCG vaccination does not appear to offer any additional protection.[4, 5]
- Since the introduction of the BCG schools programme in 1953 the epidemiology of tuberculosis has changed from a disease of the general population to one predominantly affecting high risk groups.
- The new policy is aiming to deliver an improved targeted neonatal and other at risk based programme, and will replace the current schools' programme for older children.
- The lower the risks of tuberculosis infection, the lower are the benefits of BCG. Changes in the pattern of occurrence of tuberculosis have meant that increasingly large numbers of children were being vaccinated in the schools' programme who were at very low risk of tuberculosis.
- The widespread introduction of targeted BCG vaccination means that the majority of children at high risk of tuberculosis will now be vaccinated in early life.

[1] Colditz GA, Berkey CS, Mosteller F, et al. 1995. The efficacy of Bacillus Calmette-Guerin vaccination of newborns and infants in the prevention of tuberculosis: Meta-analyses of the published literature. Pediatrics 96: 29–42.
[2] Ferguson RG, Simes AB. 1949. BCG vaccination of Indian infants in Saskatchewan. Tubercle 30: 5–11.
[3] Rosenthal SR, Loewinsohn E, Graham ML, et al. 1961. BCG vaccination against tuberculosis in Chicago: a twenty-year study statistically analysed. Pediatrics 28: 622–41.
[4] WHO. 1995. Global tuberculosis programme and global programme on vaccines: statement on BCG revaccination for the prevention of tuberculosis. Weekly Epidemiologic Record 70(32): 229–31.
[5] Karonga Prevention Trial Group. 1996. Randomised controlled trial of single BCG, repeated BCG, or combined BCG and killed Mycobacterium leprae. Lancet 348: 17–24.