6th July 2005

CHANGES TO THE BCG VACCINATION PROGRAMME

Dear Colleague

This letter describes changes being introduced to the BCG vaccination programme. In summary:

• An improved targeted neonatal and other at risk based programme will replace the current schools' programme for older children.

Those now recommended to receive BCG are:

• All infants living in areas where the incidence of TB is 40/100,000 or greater.

• Infants whose parents or grandparents were born in a country with a TB incidence of 40/100,000 or higher.

• Previously unvaccinated new immigrants from high prevalence countries for TB.

• Children who would otherwise have been offered BCG through the schools' programme will now be screened for TB risk factors, and tested and vaccinated if appropriate.

The contact, occupational and travel related recommendations remain unchanged.

The Mantoux test will replace the Heaf test as the standard method of tuberculin skin testing. Training in the use of the Mantoux method should be arranged locally. Supplementary training materials will be supplied by the Department.

Primary Care Trusts are the lead in implementing the new BCG vaccination programme and should make appropriate commissioning arrangements.

From the Chief Medical Officer, the Chief Nursing Officer and the Chief Pharmaceutical Officer

Sir Liam Donaldson
MSc,MD,FRCS(Ed),FRCP,FFPHM

Professor Christine Beasley CBE RN

Dr Jim Smith
BPharm, PhD, FRPharmS, MCPP, MIInfSci

Richmond House
79 Whitehall
London SW1A 2NS


For action
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• Immunisation Co-ordinators
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Authorised by the Department of Health:
Gateway no. 5005
Further information on the changes to the programme are attached in an annex to this letter. We will shortly be sending an operational note to local immunisation services on procedures to be followed and materials for Mantoux testing and phasing out of Heaf testing.

Thank you for your continued work on this important vaccination programme.

Sir Liam Donaldson
Chief Medical Officer

Professor Christine Beasley
Chief Nursing Officer

Dr Jim Smith
Chief Pharmaceutical Officer

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PL/CPHO/2005/3

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For further information, please contact:
Dr Jane Leese (Medical issues)
Room 605A

Jeff Porter/Daniel Eghan (BCG policy issues)
Room 602A

Carole Fry (Nursing enquiries)
Room 609A

Lorraine Gershon (Pharmacy enquiries)
Area 602A

June Boggis (Supply enquiries)
Area 602A

Robert Duff (Information enquiries)
Area 602A

Address
Skipton House
80 London Road
London SE1 6LH

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This letter is also available at:
http://www.dh.gov.uk/AboutUs/MinistersAndDepartmentLeaders/ChiefMedicalOfficer/CMOPublications/CMOLetters/fs/en
Background to the changes to BCG vaccination policy

BCG vaccination was first introduced in the UK in the 1950s, and recommended for secondary school age children. At that time, around 50,000 cases of TB were reported each year in the UK, and cases occurred across most sectors of society. The age at which the immunisation was recommended represented the most effective use of the vaccine for the epidemiology that prevailed at that time. In the 1960s, selective immunisation of neonates born to new entrants to the UK from countries with high rates of TB was also introduced. This was due to the concern about the high rates of TB in these populations, and the fact that children born into these communities were at higher risk of infection than the general population. The UK approach, of vaccinating at secondary school age, was unique, with other countries either vaccinating all infants (if the epidemiology supported this) or vaccinating infants selectively or not using BCG at all.

Cases of TB in the UK fell from 50,000 per year in the 1950’s to a nadir of 5,800 in the late 1980s. The epidemiology of TB in the UK also changed from a disease of the general population to one of predominantly high risk groups. Although total cases have increased steadily since the early 1990s to approximately 7,000 new reported cases a year, rates in the indigenous white population have fallen to very low levels. TB is now largely concentrated in the major conurbations, with over 40% of cases in London. Highest rates are in particular risk groups: 60% of reported cases are in people born abroad, the rate being higher in certain ethnic groups in the first few years after they enter the country, and rates remain high in the children of these immigrants, wherever born. Other risk groups include contacts of cases, the homeless and those with HIV infection.

Review of the BCG Programme

A commitment to review BCG policy was included in Stopping TB in England, the Chief Medical Officer’s TB Action Plan which was published in October 2004 as part of his Infectious Disease Strategy for England, Getting Ahead of the Curve, and in equivalent plans in other UK health administrations. A premise of the Action Plan was that to tackle TB effectively, action must be targeted at those areas, and those groups, most at risk of TB.

The Joint Committee on Vaccination and Immunisation (JCVI) has reviewed all available scientific and epidemiological data and recommended that it is now time to stop the national schools’ based programme. Those at high risk will be identified in a selective programme.

The JCVI recommends that the following risk groups be offered BCG vaccination:

- All infants living in areas where the incidence of TB is 40/100,000 or greater.
- Infants whose parents or grandparents were born in a country with a TB incidence of 40/100,000 or higher.
- Previously unvaccinated new immigrants from high prevalence countries for TB.
• Children who would otherwise have been offered BCG through the schools’ programme will be screened for risk factors, tested and vaccinated as appropriate.

BCG vaccination should also continue to be offered to those at risk due to their occupation, such as health care workers, veterinary staff, staff of prisons; to contacts of known cases, and to those intending to live or work in high prevalence countries for extended periods (generally one month or longer).

In most parts of the country selective BCG programmes targeting ‘at risk’ groups have been operational for the last 20 years, and some areas have already stopped the schools’ part of the programme. Stopping the schools’ programme nationally will mean that local arrangements will have to be made to test and vaccinate children at risk of tuberculosis, who have not already been vaccinated and who will no longer be offered BCG through the schools programme.

In order to support the changes to the programme, the Department will continue to consult closely with primary medical services and front-line staff. Guidance and training materials will be produced and disseminated widely. This will include information on high incidence areas in England and high incidence countries. They will be based on good practice, with examples of what works to improve the effectiveness and delivery of services.

**Implications for skin testing**

Mantoux testing is the international standard for determining immunity to TB. Up to now the UK has used both the Mantoux and the Heaf methods of administering tuberculin but has been the only country to widely use the Heaf method for screening before routine BCG vaccination.

The only manufacturer of Heaf strength tuberculin PPD will no longer be supplying tuberculin PPD. We are therefore recommending that Mantoux testing replaces Heaf testing.

The Department has obtained alternative supplies of tuberculin PPD for Mantoux testing manufactured by Statens Serum Institute (SSI) in Denmark. This is available as an unlicensed medicine in the UK. As current stocks of Heaf strength PPD run out, clinics need to change to the Mantoux method of tuberculin testing.

The Mantoux test involves an intradermal injection of tuberculin. This intradermal method is identical to that used to administer BCG vaccine. Where necessary, training on administering and interpreting the Mantoux test should be provided locally.

We will shortly be sending an operational note to local immunisation services on procedures to be followed and materials on Mantoux testing and phasing out of Heaf testing.
Information materials

Guidance for health professionals

The Department has produced a variety of training materials showing how to give and read the Mantoux test, as well as a clinic/surgery chart showing the reactions to the test and how to interpret them. These materials can be used to support local training, and will be sent directly to TB clinics and will be available to order from the end of July.

Guidance for the public

Current childhood immunisation information leaflets have been amended to reflect the changes to the BCG programme, as well as two new resources that explain and describe the change in policy:

- TB – the disease, its treatment and prevention leaflet
- Tuberculosis - Factsheet

Sample supplies of these materials will be sent directly to surgeries and TB clinics and will be available to order from mid July.

Department of Health Publications
PO Box 777
London
SE1 6XH
Phone: 08701 555 455
Email: dh@prolog.uk.com

The resources, including translated versions, will also be available on the web at: www.immunisation.nhs.uk

The new Green Book chapter on Tuberculosis will be available on the web in August. In the meantime, advice contained in the 1996 Green Book Immunisation against Infectious Disease is still current, except where superseded by this new guidance.