SCOTTISH EXECUTIVE

Health Department

Dear Colleague

CHANGES TO THE BCG VACCINATION PROGRAMME

This letter describes changes being introduced to the UK BCG vaccination programme.

An improved targeted programme directed towards those most at risk will replace the current universal (schools) programme.

Those now recommended to receive BCG are:

- All infants living in UK areas where the incidence of TB is 40/100,000 or greater (no NHS Board areas in Scotland fall into that high risk category)
- Infants whose parents or grandparents were born in a country with a TB prevalence 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 use of the Mantoux method should be arranged locally. SEHD will ensure that supplementary training materials will be supplied in due course.

NHS Boards will take the lead in implementing the new BCG vaccination programme, and should make appropriate arrangements.

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

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8 July 2005

SEHD/CMO(2005)5

For action
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Medical Directors, NHS Boards (to cascade to General Practitioners; Infectious Disease Consultants; Consultant Paediatricians; Consultant Physicians)
Practice Nurses
Health Visitors
Community Pharmacists
Chief Pharmacists
Immunisation Co-ordinators
Consultants in Public Health Medicine
Scottish Prison Service
Directors of Nursing, NHS Boards
Specialists in Pharmaceutical Public Health

For information
Directors of Public Health
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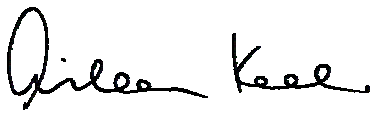
Further information on the changes to the programme is attached in an annex to this letter.

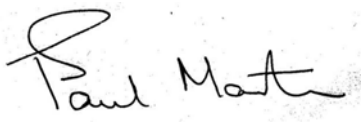
We will shortly be sending an operational note to local immunisation services on procedures to be followed, and material for Mantoux testing and phasing out of Heaf testing.

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

Yours sincerely



Dr Aileen Keel
Deputy Chief Medical Officer



Mr Paul Martin
Chief Nursing Officer

Professor Bill Scott
Chief Pharmaceutical Officer

ANNEX 1

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 a high prevalence 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 1980's. 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 in England since the early 1990s (and particularly in London), numbers have remained stable in Scotland since 1990 at around 400-450 cases per year. The situation in Scotland also differs from England in that only about one quarter of our TB cases are in people born outwith the UK compared with 60% in the UK overall.

TB is now largely concentrated in the major conurbations, with over 40% of cases in London. Highest rates are in particular risk groups, notably people born abroad, the highest rates being in certain ethnic groups in the first few years after they first enter the country. Rates remain high in the children of these immigrants, wherever born. Other risk groups include contacts of cases, the homeless, alcohol abusers and those with HIV infection.

Review of the BCG Programme

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 prevalence 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 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 in the UK 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 according to the new recommendations, who have not been vaccinated and will no longer be offered BCG through the schools programme.

In order to support the changes to the programme, SEHD will continue to consult closely with primary care 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

Health Scotland and NHS Education for Scotland will support the availability of appropriate materials for professional training, 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 in the near future.

Guidance for the public

Current childhood immunisation information leaflets will be 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 the appropriate clinical centres, and will be available to order in the near future from:

NHS Health Scotland
Woodburn House
Canaan Lane
Edinburgh
EH10 4SG

Phone: **0131 536 5500**
www.healthscotland.com

Leaflets will also be made available in other languages and on the web at www.healthscotland.com/immunisation/.

The new 'Green Book' chapter on BCG 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.