



Guidelines for BCG Immunisation Service administered by the Area Health Boards in the Eastern Region i.e. Dublin, Kildare and Wicklow

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AUTHORITY EASTERN REGIONAL
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Main Changes to 1999 Guidelines

SCAR INSPECTION

- ◆ Routine scar inspection is no longer recommended and an alternative process is outlined
- ◆ With regard to checking of scars, the current advice is that “any scar will be sufficient evidence of effectiveness”
- ◆ If BCG scar is present, BCG vaccination is not recommended
- ◆ If no scar is formed, it is now recommended that the child be followed up with Mantoux testing at time of presentation. It is not necessary to wait until the child is one year of age.

AGE

The age at which neonates may be given BCG has changed, i.e. any baby born before midnight, who is stable and has tolerated one feed, may be vaccinated the following morning, provided there are no other contraindications.

TUBERCULIN TEST

2T.U. is recommended for Mantoux testing. 10T.U. is not generally recommended. Comment is included concerning the boosting effect of repeated tuberculin tests, and the interval which should be left between viral infections or live viral vaccines and the performance of the tuberculin test.

BCG DOSAGE

There is a change in dosage of BCG with the **current** vaccine manufacturer. The dosage instructions for BCG vaccine from Statens Serum Institute (SSI) are given.

HIV

Specific guidelines for BCG in newborn babies of immigrants from areas of high incidence of HIV infection are included.

HEPATITIS B IMMUNOGLOBULIN

General guidelines for neonates where hepatitis B immunoglobulin may be indicated are included.

ALGORITHMS

Age specific algorithms are given as guidelines for Mantoux testing and BCG vaccination.

FOCUS ON BCG VACCINATION FOR INFANTS AND CHILDREN

The focus of the area BCG clinics is on babies and children. It is now recommended that Mantoux testing (and possible vaccination with BCG) for occupational health and travel reasons should be carried out in the appropriate health care setting.

CHANGES TO FORMS

Changes have been made to the return forms, consent forms and information leaflets.



Introduction

The BCG service provided by the three Area Health Boards in the Eastern Regional Health Authority (ERHA) is in accordance with the recommended Childhood Immunisation Programme drawn up by the Immunisation Advisory Committee of the Royal College of Physicians of Ireland. Therefore, these guidelines focus mainly on neonatal/childhood BCG vaccination.

These guidelines update those previously brought out in the former Eastern Health Board region in 1999. A number of changes have been made in line with current best practice. These guidelines also incorporate the changes recommended in the 1999 guidelines.

The committee which worked on the present guidelines was comprised of Senior Area Medical Officers (SAMOs) Area Medical Officers (AMOs) and Specialists in Public Health Medicine. It was chaired by Dr. Rosalea Watters, (SAMO) and included the following: Drs. Anne O'Connor, Sylvia Eakins (replaced by Dr. Brenda Corcoran), Adrian Murphy, Mary O'Meara and Evan Murphy (all SAMOs), Drs. Mary Lucey, Moira Woolfson and Barbara Senior (all AMOs) and Dr. Mary Cronin (replaced by Dr. Joan O'Donnell and later by Dr. Mary Scully), Specialists in Public Health Medicine.

The *main* changes to the 1999 Guidelines are summarised at the beginning of the document.

Please Note:

The guidelines should be used in conjunction with the most recent Immunisation Guidelines for Ireland published by the Immunisation Committee, Royal College of Physicians of Ireland, 2002 Edition.



Chapter 1

Guidelines for the Proper Management, Storage, Stock Control, Distribution and Disposal of BCG Vaccine

The “Guidelines for Management, Storage, and Distribution of Vaccines and the School Immunisation Programme (EHB) August 1998” should be followed.

These guidelines are as follows;

The General Manager is the person who has overall responsibility for vaccine matters in the area. An Administrative Officer, designated by the General Manager, should have responsibility in regard to the day to day receipt, storage, issuing and recall of vaccine. This officer should have a designated deputy to cover in times of absence. All significant difficulties should be brought to the attention of the General Manager.

1.1 RECEIPT OF VACCINE

Care should be taken that on receipt the order is checked so that the BCG vaccine received is the BCG vaccine ordered. The person receiving the vaccine must make a physical count of the vaccine before signing the delivery docket. The number of doses, date received, the manufacturer, batch numbers, expiry dates and invoice/delivery docket number should be recorded on a stock control system (manual or computer). The temperature of the vaccine on delivery must be checked and recorded. If it is outside the desired range of +2°C to +8°C, the vaccine must be returned forthwith.

1.2 MANAGING VACCINE STOCKS

Care should be taken to avoid over-ordering or stockpiling of vaccine. When stocks deplete to about 20% of the normal amount, supplies should be ordered from the approved pharmaceutical company. A stock control system, preferably computerised, should be in place and rotation of stock should be monitored. Checks on stock levels and expiry dates of vaccine and removal of expired vaccine should be made weekly or fortnightly, depending on local usage. It is recommended that vaccine nearing its expiry date should be towards the front of the fridge. This applies to diluent as well as vaccine.

1.3 STORAGE OF VACCINE

Vaccine refrigerators only should be used for storage of vaccine. Manufacturer’s recommendations on storage should be observed. Vaccine should be stored between +2°C and +8°C, should never be frozen and should be protected from light. Vaccine must never be kept at temperatures below 0°C as freezing can cause deterioration of the vaccine and breakage of the container.



Ideally, if space in the refrigerator permits, different vaccines should be stored on different shelves. Vaccine should be stored in the refrigerator proper, allowing air to circulate around the packages. They should not be stored on the shelves or in storage compartments of the refrigerator door. Food and drink must not be stored in refrigerators used for vaccine. Door opening should be kept to a minimum.

Care should be taken to ensure that the electricity supply to the vaccine storage refrigerator is not accidentally interrupted. This can be achieved by using a switchless socket or by placing cautionary notices on plugs and sockets.

A maximum/minimum thermometer should be used in refrigerators where BCG vaccine is stored, irrespective of whether the refrigerator incorporates a temperature indicator dial. The maximum and minimum temperatures reached should be monitored and recorded daily by the Clerical Officer responsible for vaccine matters. Temperature record logs are best kept close to the refrigerator for ease of reference. If temperatures recorded fall outside the permitted range or if there is breakdown in supply or equipment, the Senior Area Medical Officer (SAMO) should be contacted for further advice.

Refrigerators should be defrosted regularly. Special care should be taken during defrosting to ensure that the temperature of the vaccine does not go outside the specified range. An alternative refrigerator or insulated containers should be used for vaccine storage during defrosting of refrigerators.

All vaccine refrigerators should be kept locked and keys should be kept in a safe location, known to all relevant staff.

1.4 MAINTAINING THE COLD CHAIN

1.4.1 Maintaining the cold chain during transport of vaccine

The cold chain must be maintained during the transport of vaccine. Vaccine should be collected from Community Care refrigerators on the day it is to be used in hospitals or clinics. In exceptional circumstances, e.g. travelling distances involved, vaccine may be kept overnight by an Area Medical Officer (AMO) for use the following day. In these circumstances, the recommended procedure at 1.4.3 must be strictly adhered to.

1.4.2 Recommended procedure when vaccine is returned to vaccine fridge within 6 hours of removal

When Health Board staff are transporting vaccine to schools or clinics, cool boxes with two freezer packs must be used. Frozen ice-packs, which have been left at room temperature for 15 to 20 minutes, must be wrapped with foil bubble wrap in order to prevent vaccine adjacent to these packs from freezing. This procedure will keep vaccine at the required temperature of between +2°C to +8°C for 6 hours.



1.4.3 Recommended procedure when vaccine is kept overnight by AMO for use at a clinic the following day

To keep vaccine for over 12 hours and maintain the integrity of the cold chain, two frozen ice packs, which have been left at room temperature for 15 to 20 minutes, should be wrapped in foil bubble wrap and placed in the cool box 20 minutes prior to the vaccine, together with a min/max thermometer. After this time, the AMO should check that the temperature has reached the required range of between +2°C and +8°C and place the vaccine in the cool box.

The ice packs should be replaced with pre-frozen ones approximately 6 hours later and the temperature should be checked again. The following morning, the temperature should be checked and the ice packs should be replaced with the original ice packs which have been frozen overnight in a domestic freezer. The vaccine should then be transported to the clinic and the temperature checked in the usual way at the beginning and at the end of the immunisation session.

1.5 DISPOSAL OF VACCINE

Reconstituted vaccine must be used within the recommended period, varying from two to four hours, according to the manufacturer's instructions. Once opened, multidose vials must not be kept after the end of the session and any vaccine left unused must be discarded in accordance with existing best practices i.e. in a sharps bin.

Unused vaccine (spent or partly spent vials) must be disposed of safely, preferably by heat inactivation or incineration. Contaminated waste and spillage should be dealt with by heat sterilisation, incineration or chemical disinfecting, as appropriate.

1.6 NEEDLES AND SYRINGES

Needles and syringes should be securely stored. A stock control system, similar to that used for vaccine, should be in operation. Needles and syringes should be disposed of in a sharp bin, should not be left unattended. They should be collected regularly and disposed of safely.

1.7 DISTRIBUTION OF VACCINE

BCG vaccine should be stored and distributed from Community Care Area Headquarters only. A log book, manual or computerised, should be kept to record the distribution of vaccine. This log book should contain the following information:

- ◆ The date
- ◆ Name of manufacturer
- ◆ Number of vials of vaccine issued
- ◆ Batch numbers
- ◆ Expiry dates
- ◆ Number of unopened vials of BCG vaccine which are returned
- ◆ Temperature of vaccine at issue and on return

When distributing the vaccine, the named Clerical Officer and the AMO collecting the vaccine should sign the logbook. As General Practitioners are not routinely involved in BCG vaccination, the vaccine or tuberculin material should not be issued to them.



1.8 AUDIT

It is advisable that each area should undertake regular audits of the management, storage, stock control, distribution and disposal of BCG vaccine. These audits should cover both procedure, as laid down in this document (to ensure compliance with written guidelines) and outcome, in order to inform future policy.

Audit of outcome is usually based on the examination of records. This can only occur if information is routinely recorded and returned from the Maternity Hospitals and the BCG clinics in the community. The return forms are shown at Appendix B & C.