

දුරකථන) 2698475
தொலைபேசி) 2698490
Telephone) 2698507

ෆැක්ස්) 2692913
பெக்ஸ்) 2694860
Fax)

විද්‍යුත් තැපෑල)
மின்னஞ்சல் முகவரி) postmaster@health.gov.lk
e-mail)

වෙබ් අඩවිය)
இணையத்தளம்) www.health.gov.lk
website)



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சுகாதார பராமரிப்பு மற்றும் போசணை அமைச்சு
Ministry of Healthcare & Nutrition

General Circular No:
08 June 2010

Provincial/ Regional Directors of Health Services,
Directors of Teaching Hospitals / Specialized Campaigns,
M.SS/ D.M.OO of Provincial / Base Hospitals,
Heads of Decentralized Units, Regional Epidemiologists, Medical Officers (MCH)
Medical Officers of Health.

Amendment to General Circular No: 01-23/2009 on Reintroduction of Combined Pentavalent DTP-Hep B – Hib (Pentavalent) Vaccine into the EPI Programme

Combined Pentavalent (DTP-HepB–Hib) Vaccine was reintroduced into the National Immunization Programme from 1st February 2010 on the recommendation of the National Advisory Committee on Communicable Diseases (NACCD).

Initially it was recommended to admit children with certain risk conditions to a health facility for immunization and to keep them under observation for 24 hours following immunization.

Since reintroduction of Pentavalent vaccine to date over 200,000 doses have been administered to several hundreds of children with risk conditions. However, according to the AEFI surveillance data and feedback from MOOH, MOO and paediatricians, there have been no increased risk of adverse events in children with risk condition compared to normal children.

Based on the above findings, NAACD which met on 4th June 2010 has decided to remove the requirement of inward admission and 24 hour observation of children with most of the risk conditions. However this requirement is still applicable for those with a history of HHE (Hypotonic Hyporesponsive Episode) to previous doses of Pentavalent or any other pertussis containing vaccine. Accordingly revised guidelines for the administration of pentavalent vaccine are as follows:

Schedule

The Pentavalent vaccine should be administered to all children completing 2, 4 and 6 months of age. First three doses of OPV should also be given with the Pentavalent vaccine on completion of 2, 4 and 6 months of age. Please note that no pentavalent fourth dose will be given at the age of 18 months but a dose of DTP and OPV will be given.

If any dose of Pentavalent (DTP-Hep B-Hib) vaccine is missed or delayed, it should be given at the next earliest available opportunity. There is no need to restart immunization regime if a dose is missed.

Dosage

The standard dose for infants and children is 0.5 ml.

Route and site of administration of the Pentavalent vaccine

Pentavalent vaccine should be given as an INTRAMUSCULAR (IM) injection to the anterolateral aspect of the thigh in infants. Even though there is no special concern of which side/site to be used, it is advisable to use the left thigh/deltoid muscle as an uniform practice.

Pentavalent vaccine SHOULD NOT be given in the buttock or administered intradermally because these routes of administration do not produce adequate antibody response. In addition there is a possible risk of injuring to the sciatic nerve, if it is given in the buttock.

Contra-indications

There are very few reasons to withhold or postpone administration of Pentavalent vaccine.

It should be avoided only for children with:

- A history of severe allergic reaction (e.g. generalized urticaria, difficulty in breathing, swelling of mouth and throat, shock) to a previous dose of Pentavalent vaccine or with known hypersensitivity to any vaccine component
- A history of encephalopathy of unknown aetiology after a previous immunization with a vaccine containing pertussis, fever with more than 40°C temperature within 48 hours of vaccination (not due to other identifiable causes); persistent crying for more than 3 hours during the 48 hours of vaccination; convulsions, with or without fever within 3 days of vaccination.

In these circumstances, the vaccination course should be continued with DT and Hepatitis B, vaccines. Since the monovalent Hib vaccine is not available in the government clinics, these children may not be able to receive the Hib vaccine in the routine immunization clinics.

It should be postponed for children with:

- A severe acute illness with temperature above 38.5°C. As with other vaccines, vaccination should be postponed for children suffering from acute febrile illness
- A progressive neurological illness

The following are NOT contra indications;

- Minor illnesses such as respiratory tract infection or diarrhoea with temperature below 38.5°C
- Allergy or asthma
- Family history of convulsions
- Treatment with antibiotics

- Treatment with topical corticosteroids or systemic use of corticosteroids at low dosage (<0.5 mg/kg of prednisone or equivalent) in case of skin diseases like dermatitis, eczema, or other localised skin disorders
- Infection with HIV
- Breast feeding
- History of seizures (convulsions, fits)
- Chronic illnesses such as those of heart, lung, kidney or liver
- Stable neurological conditions e.g. cerebral palsy, Down syndrome
- Prematurity or low birth weight
- History of jaundice at birth.

Precautions for Use

Precautions should be taken to avoid undesirable reactions and co-incidental conditions before administering the vaccine. These precautions include review of the child's obstetric history, medical history, particularly regarding hypersensitivity reactions to previous administration of any type of vaccine and history of any recent health problems. Children with poor obstetric and bad medical history should be immunized at the central immunization clinic under the supervision of a Medical Officer

Children with history of HHE to previous doses of Pentavalent or any other pertussis containing vaccine should be immunized with Pentavalent vaccine inward and be observed inward for 24 hours for occurrence of further episodes of HHE and for early management.

Storage temperature and shelf-life

Pentavalent vaccine should be stored and transported between 2°C-8°C. IT SHOULD NOT BE FROZEN. Hence this vaccine should **NEVER** be stored in the freezer compartment and should preferably be kept in the middle shelf of the main compartment of the refrigerator in all places storing the vaccine including MOH offices.

While transporting the vaccine vials should **NOT** be kept in contact with ice in vaccine carriers/flasks and during clinic sessions Pentavalent (DTP-Hep B-Hib) vials should **NOT** be kept in contact with ice.

Please note that instructions given in the Epidemiologist's letter No. EPI/81/VII/2007 dated 15/10/2007 with regard to the introduction of Pentavalent into the national immunization programme should be adhered to in concurrence with the instructions given in this circular.

Thank You



Dr. U.A. Mendis
Director General of Health Services

- Cc: 1. Secretary, Ministry of Health – f,l
2. DDG (PHS) I & II, Ministry of Health – f.i.
3. D/MCH, D.HEB, D/NIHS – f.i.