

General Circular No: 01 - 06 / 2005

Ministry of Healthcare, Nutrition & Uva Wellassa Development
"Suwasiripaya", 385, Baddegama Wimalawansa Mawatha,
Colombo 10.
11/02/ 2005

To all Provincial Directors / Deputy Provincial Directors of Health,
All Heads of Medical Institutions,
All Medical Officers of Health,

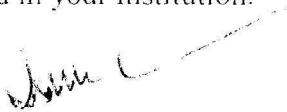
Implementation of Open Vial Policy in National Immunization Programme

EPI programme of Sri Lanka has been procuring its total vaccine requirement using government budgetary allocation since 1995. Since 2003 the GAVI is supplying the Hepatitis B vaccine and AD syringes. The government will have to purchase AD syringes from 2006 and Hepatitis B vaccine from 2008 onward. The estimated cost for all vaccines and AD syringes for 2006 is over Rs 300 million. Every year the cost of vaccine procured by the government of Sri Lanka is increasing and the Epidemiological unit is preparing a financial sustainability plan to ensure the financial sustainability for successful implementation of the EPI programme in Sri Lanka.

In order to reduce the financial burden on governments throughout the world, WHO has endorsed a policy for the use of opened multi dose vials of liquid vaccines in subsequent immunization sessions without compromising the quality of vaccines and the safety. This has been the practice in many other countries for the last few years.

After considering all relevant factors the National Advisory Committee on Communicable Diseases decided to introduce the open vial policy in Sri Lanka from February 2005. Therefore open multi dose vials of all liquid vaccines (**OPV, DPT, TT, DT, aTd, JE and Hepatitis B**) could be reused in subsequent sessions.

Please find the attached specific guidelines to be followed when implementing the open vial policy. Please be kind enough to bring the contents of this circular to the notice of all concerned in your institution.



Dr. H.A.P. Kahandaliyanage

Director General Health Services

Cc All Deputy Generals of Health Services
Epidemiologist
Director / Family Health Bureau
Director / Health Education Bureau
Director / NIHS
Principals of all Nurses Training Schools

Guidelines for Use of Opened Multi Dose Vials of Vaccine in Subsequent Immunization

Sessions

This applies **only to multi dose liquid vials of OPV, DPT, TT, DT, aTd , JE and Hepatitis B** vaccines.

After using one or more doses of vaccines from these vaccine vials during an immunization session, they could be reused in subsequent immunization sessions **within 4 weeks** of their opening. However all the following conditions must be fulfilled before reusing the vaccines so that the potency of vaccines and the safety of their administration could be guaranteed.

1. The expiry date has not been reached.
2. The vaccines should be stored and transported under appropriate cold chain conditions. All conditions which apply for the maintenance of cold chain for the unopened vials should apply for the opened vials as well.

The potency of all **inactivated vaccines (DPT, TT, DT, aTd, JE and Hepatitis B)** could be affected when these vaccines are exposed to a temperature below 0° C. This may occur when they come in contact with ice or ice packs. The following measures should be adapted to prevent inactivated vaccines from coming in contact with ice or ice packs while packing and transporting in a vaccine carrier.

- a) The ice packs should be well frozen in a deep freezer for a minimum of 48 hours before using. When the ice packs are taken out from the freezer, keep them in the room temperature for at least 10 minutes until the outer layer of ice in the ice packs gets removed (thawing effect). This will prevent inactivated vaccines getting exposed to sub zero temperatures on packing and transporting.
- b) Above inactivated vaccine vials should be placed in a small plastic container and then placed in the vaccine carrier, instead of wrapping a thick paper around the vial or separating with a cardboard as is practiced now.

- c) Indicated number of cold packs must be used when a vaccine carrier is being used to transport vaccines to maximize the cold holding time.
- d) Vaccine vial monitors (VVM) attached to the Polio and Hepatitis B vaccine vials (if available) can be used as an indicator of the maintenance of the cold chain. **Hepatitis B is the most heat resistant vaccine, if VVM attached to the Hepatitis B vaccine has reached discard point all vaccines in that vaccine carrier should be discarded.**
- e) **Polio vaccine is the most heat sensitive vaccine,** if VVM attached to the Polio vials has reached the discard point only the Polio vaccine vials are to be discarded.
- f) When VVMs of the Polio vaccines have reached the discard point and VVMs in the Hep. B vaccine vials have not reached the discard point, decision on the status of the cold chain of the other vaccines should be based on the presence of still unmelted ice in the ice packs of the vaccine carrier.

3. Vaccine vials should not be submerged in water.

- a) **The vaccine vials should not be submerged in water while being transported in the vaccine carrier and during the clinic session because there is a possibility of contamination through the vaccine vial septum.** The vial septum should remain dry and clean during the transport and during the clinic session.
- b) **All inactivated vaccine vials** should be kept in a dry container without using cold water in the container during the session. Inactivated liquid vaccines can withstand a few hours of room temperature without compromising their potency.
- c) **All live vaccines** should be kept in contact with ice or ice water as practiced now.

4. All doses of vaccines should be withdrawn from vaccine vials under aseptic conditions.
 - a) AD syringes should be used when ever they are available.
 - b) When AD syringes are not available, only sterile reusable needles and syringes (given with the steam sterilizers) should be used.
5. The opened vials that are returned to the MOH office should be kept in a separate container when they are stored in the refrigerator after the clinic sessions.
6. In every clinic session previously opened vaccine vials should be used first, before opening any new vaccine vial.
7. Approximate number of doses in the opened vials should also be included in the vaccine movement register before sending vaccines to the clinics and after receiving from the clinic.