Immunization Handbook

National Expanded Programme on Immunization, Sri Lanka- 2002

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Epidemiological Unit
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IMMUNIZATION

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PREFACE

The provision of routine immunization services in Sri Lanka constitutes a major preventive health activity of the Ministry of Health. Routine immunization has reduced the incidence of several vaccine preventable diseases. The first manual for Medical Officers on technical and implementation information on the Expanded Programme on Immunization was published by the Ministry of Health in 1979 with the assistance of UNICEF and WHO. Since then all instructions on new developments regarding EPI have been sent as circulars and letters to Medical Officers.

As the epidemiological pattern of the EPI diseases changed over the years and more cost effective vaccines are now available, the Department of Health Services decided to revise the immunization schedule following a consultative meeting held in March 2000. Objectives of the EPI programme were also changed accordingly as coverage of immunization has improved. Hence improvement of quality of services provided and changing of target age groups were considered. The WHO consultant reviewed the immunization programme as a pre-requisite for GAVI application.

As the immunization schedule and the objectives of the immunization programme changed, the Ministry of Health decided to update the Manual on Immunization. I am pleased this Immunization Handbook, published by the Epidemiology Unit would serve this purpose.

I would like to take this opportunity to thank the Consultant Epidemiologists of the Epidemiology Unit, the Consultant Virologist of the Medical Research Institute, the Consultant Community Physician (M.C.H.) of the Family Health Bureau for their contributions to the book as well as the office staff who helped to make this task a reality.

Appreciation is extended to WHO and UNICEF for the technical guidance and assistance given for publication of the Immunization Handbook and special thanks to WHO for providing necessary funds for its publication.

Dr A M L Beligaswatte
Director General of Health Services. February 2002.

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Some settings of the Handbook were based on publications of the W.H.O. Global Programme for Vaccines and Immunization, Department of Vaccines and Biologicals, Geneva.

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Appreciation is extended to WHO and UNICEF for their assistance given to make this a success and special thanks to WHO for providing necessary funds for its publication.

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I. INTRODUCTION

1.1. Introduction

In the year 1798, Edward Jenner first demonstrated that vaccination offered protection against smallpox. He used cowpox (poxvirus bovis) for the immunization of man against the smallpox virus (poxvirus varialae). For the last 200 years, the use of vaccines has continued to reduce the burden of many bacterial and viral diseases.

Smallpox itself has been eradicated, and poliomyelitis no longer occurs in the Americas. In Sri Lanka, the last case of virologically confirmed poliomyelitis patient was reported in 1993.

In Sri Lanka, the introduction of routine immunization has generally reduced the incidence of several vaccine preventable diseases. Similar success in disease reduction has been demonstrated by immunization programmes in many other countries. The World Health Organization's (WHO) Expanded Programme on Immunization (EPI) ,with assistance from the United Nation's Children's Fund (UNICEF) and other donors, has made great strides in extending these benefits to developing countries. Immunizations permitted the global eradication of smallpox, and may do the same for poliomyelitis and some other diseases.

Immunizing a child not only protects that child but also other children by increasing the general level of immunity and minimising the spread of infection.

History of Immunization in Sri Lanka

The history of immunization in Sri Lanka goes back to the 19th century. The law relating to compulsory vaccination (against smallpox) is referred to in the Vaccination Ordinance of 1886.

The Expanded Programme on Immunization (EPI) established in 1978, has continued to make excellent progress over the past two decades, most notably in terms of achieving high immunization coverage and disease control.
The milestones of immunization in Sri Lanka are given below.

1886	Vaccination against smallpox introduced under the Vaccination Ordinance
1949	BCG Vaccination introduced against tuberculosis
1961	"Triple" vaccination introduced against diphtheria,whooping cough and tetanus
1962	Oral polio vaccine introduced
1963	BCG vaccination of newborn introduced
1969	Tetanus Toxoid administration to pregnant mothers introduced
1978	Launching of the Expanded Programme on Immunization
1981	Revision of the immunization schedule and the introduction of a modified list of contraindications
1984	Measles vaccination introduced
1985	Strengthening of cold chain and logistics in EPI
1989/90	Universal Childhood Immunization (UCI) achieved with 80% coverage among infants with the vaccines in the EPI
1991	Revision of Tetanus Toxoid schedule
1995	First National Immunization Days conducted.
1996	Introduction of Rubella vaccine
1996	Second National Immunization Days conducted.
1997	Third National Immunization Days conducted.
1998	Fourth National Immunization Days conducted.
1999	Fifth National Immunization Days conducted.
2000	Sub- National Immunization Days conducted.
2000	Consultative meeting held to review the National Immunization Schedule
2001 April	Introduction of the new National Immunization Schedule
2001	Sub-National Immunization Days conducted.

The first manual for Medical Officers, giving technical information on the Expanded Programme on Immunization was published in 1979 by the Ministry of Health with the assistance of UNICEF and WHO. Since then all instructions on new developments regarding EPI has been sent as circulars and letters to Medical Officers.

An in-depth review on the Expanded Programme on Immunization was carried out jointly by the Department of Health Services, WHO and UNICEF in February 2001. The team observed that there were no up-to date immunization specific manuals available in the Medical Officer of Health (MOH) offices and clinics visited. They strongly recommended that a revised and updated manual on immunization be prepared and made available in all MOH offices and clinics.

The purpose of this manual is to give Medical Officers a clear guidance about immunization (National EPI) and to provide an accessible summary of the relevant data on vaccine preventable infectious diseases in Sri Lanka.

1.2. Further reading

1. Last John M. *Dictionary of Epidemiology*,1995.

2. Ministry of Health and Women's Affairs-UNICEF. *Sri Lanka Declares the Achievement of Universal Child Immunization,* 1989.

3. Chen Robert T. and Orenstein Walter A. Epidemiologic Methods in Immunization Programmes, *Epidemiologic Reviews,*
   Johns Hopkins University School of Hygiene and Public Health, 1996,Vol:18,Number 2. Page 99-117.

4. Ministry of Health/UNICEF/WHO. *Expanded Programme on Immunization in Sri Lanka,* Manual for Medical Officers, O – 1979.

5. Epidemiological Unit, Department of Health Services. *Expanded Programme on Immunization National Plan of Action 2001 – 2005 (Multi-year plan),* April 2001.

2. IMMUNITY

2.1. Immunity

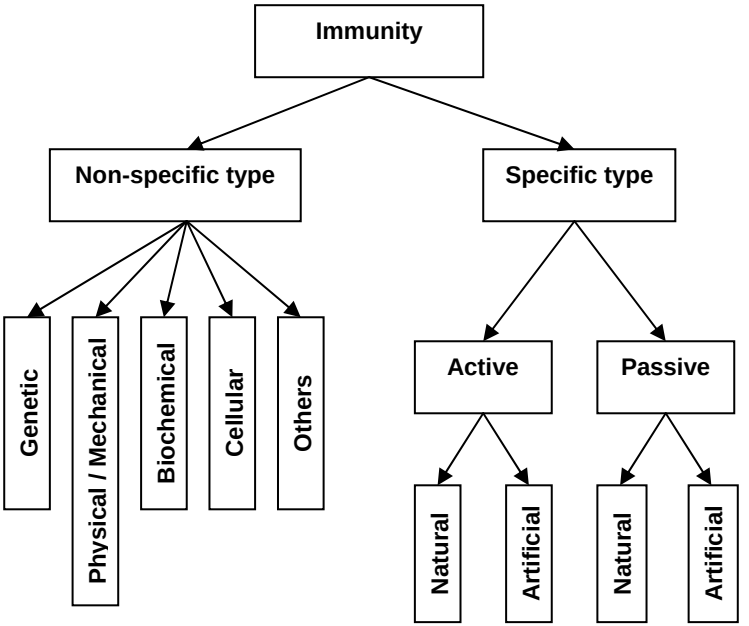
'Immunity' is a term that originally implied exemption from military service or taxes; it was introduced into medicine to refer to those people who did not get further attacks of smallpox or plague once they had had the disease. In a wide sense the term refers to the resistance of a host organism to invasive pathogens or their toxic products.

Immunity is divided into two main types;

- **Non-specific immunity (sometimes called 'innate immunity':** which includes the general protective reaction of the organism against invasion.

- **Specific immunity**: This is a specific reaction of the body against "non-self" foreign agents, in which its immune products react specifically with the stimulating agent. It is conventionally divided into passive and active immunity, both of which may be either natural or artificial (Fig. 1).

Figure 1.


Immunity
Non-specific type
Specific type
Genetic
Physical / Mechanical
Biochemical
Cellular
Others
Active
Passive
Natural
Artificial
Natural
Artificial

2.2. Passive Immunity

Passive immunity involves either the transfer of antibodies or in some diseases, of sensitized white blood cells, from an immune to a non-immune person. Natural passive immunity is transferred from mother to child across the placenta (and in the colostrum in subhuman primate species). Artificial transfer is the therapeutic use of various antitoxines or gammaglobulins, as in the treatment of tetanus, diphtheria, gas gangrene, snake bite, and immuno-deficiency states. The passive immunity is short-lived, depending on the life-span of the antibody or the transferred cells in the recipient. Once they disappear, the host is again susceptible to the disease.

Temporary passive immunization can be produced by administration of an antibody in the form of immunoglobulin in some conditions.

2.3. Active Immunity

When a foreign substance is encountered, one of two responses is observed. Most commonly, there is an active immune response with production of specific antibodies and sensitized cells. Less frequently, an antigen-specific non response referred to as a state of immunologic tolerance may result.

An active immune response can follow natural clinical or sub-clinical infection or be induced artificially, by vaccination. There are three essential characteristics of active immunity:

- Recognition
- Specificity
- Memory

2.4. Immunization (Syn: vaccination)

Protection of susceptible individuals from communicable diseases by administration of a live modified agent (as in yellow fever), a suspension of killed organisms (as in whooping cough) or an inactivated toxin (as in tetanus).

2.5 Further reading

1. Brown T.R ,*Immunology Simplified,* 1984.

2. Last John M. *Dictionary of Epidemiology,* 1995.

3. World Health Organisation.*The immunological basis for Immunization Series Module I General Immunology Global Programme for Vaccine and Immunization,* WHO/EPI/GEN/93-11

3. IMMUNIZATION PROCEDURES

3.1. Pre-vaccination questionnaire

Before vaccination, the doctor, the nurse, the public health inspector or the public health midwife should make sure that the individual to be vaccinated does not have a condition (or a history of a previous condition) which could increase the risk of a severe reaction. One way to do this is to routinely inquire about such conditions.

The following information is needed to assess the fitness of a person for vaccination. (Inform the parents, that the conditions listed below do not necessarily mean that their child cannot be vaccinated today. But they should inform the doctor if any of the following conditions are present):

The person to be vaccinated:

- is unwell today;
- is having treatment which lowers immunity (e.g. steroids such as cortisone and prednisolone, radiotherapy, or chemotherapy);
- has had a severe reaction to any vaccine;
- has any severe allergies to vaccine components (e.g. neomycin);
- has a disease which lowers immunity (e.g. leukaemia, cancer);
- has had a vaccine containing live viruses within the last month (e.g. measles, poliomyelitis, yellow fever or rubella vaccines), or an injection of immunoglobulin or a blood transfusion within the last three months;
- has a disease of the brain or the spinal cord.

3.2. Standard vaccination procedure

Before administering vaccines, the following procedures should be followed:

- Provide details to parents on risks of vaccination and risks of not being vaccinated;

- Check whether preparations have been made to respond immediately to adverse reactions;
- Read the product information;
- Ensure that valid consent is given;
- Provide the parent or guardian with a pre-immunization questionnaire;
- Check whether there are any contra-indications to vaccination from the pre-vaccination assessment;
- Check the identity of the recipient;
- Check the identity of the vaccine to be administered;
- Ensure that vaccines have been stored correctly;
- Check the vaccine to be administered for obvious signs of deterioration (check expiry date and note any particular matter or colour change that may indicate damage to the vaccine);
- Ensure that the correct vaccines are being administered according to the schedule;
- Administer the vaccine, using the correct technique (see details below on needle selection, needle angle, injection location, and position of the subject).

After administering the vaccine, do the following:

- Give instructions, preferably in writing, to the parent or guardian regarding what to do in the event of common reactions or serious adverse reactions;
- Record the vaccination in the child health development record and in the clinical notes.

In situations where large groups of individuals are vaccinated, the detailed arrangements might vary from those recommended above, but the principles of hygiene, valid consent, and thorough pre-immunization assessment must still be adhered to.

3.3. Storage

Vaccines that are not stored and transported correctly will lose potency. The instructions of the product leaflet should be followed. The general rule for most vaccines is that they should be refrigerated at +2^{o}C to +8^{o}C and NOT FROZEN. Some vaccines such as DTP, Hib, hepatitis B and hepatitis A vaccines are inactivated by freezing. Detailed guidelines on correct storage and transport are given under Part VI; i.e. Maintenance of cold chain of E.P.I. vaccines.

3.4. Reconstitution

Freeze-dried vaccines such as BCG, Measles, Measles-Mumps and Rubella which are used in the National EPI programme in Sri Lanka should be reconstituted with the correct diluent only (the diluent supplied with the vaccine) using a sterile syringe and needle. The vaccines should be used within the recommended time period (with gentle shaking the dried cake/power is easily dissolved). They should be kept under proper cold chain conditions and protected from heat and sunlight. Note that reconstituted measles vaccine deteriorates rapidly at room temperature. A sterile 21 gauge needle should be used for reconstitution and a separate 23 gauge needle 25 mm in length should be used for administration of the vaccine.

3.5. Cleaning of skin

The injection site should be cleaned. After cleaning, alcohol and other disinfecting agents must be allowed to evaporate before injection of vaccine since they can inactivate live vaccine preparations. Clean water could be used, if other cleaning agents are not available.

3.6. Route of administration

Almost all vaccines are given by intramuscular or deep subcutaneous injection. The two major exceptions are Oral Polio Vaccine (OPV), which is given by mouth and never injected and BCG, which is given by intradermal injection. Although intramuscular or deep subcutaneous injection route can be used for most vaccines, the intramuscular route is generally recommended because of the difficulties that some health professionals experience with subcutaneous injection of vaccines.

3.7. Standard technique and needle size for injection of vaccines

Persons administering vaccines should observe standard health and safety guidelines given by the Department of Health Services in order to minimize the risk of spread of infection and needle stick injury (Ref. Infection Control Manual for Sri Lanka 1993).

A sterile reusable syringe and needle or a new, sterile, auto-disable syringe and needle should be used for each injection. A syringe or needle which has been used to inject a person should never come in contact with the vial. Auto-disable needles and syringes should be discarded into a safety box.

The standard needle for vaccine injection is 23 gauge and 25 mm in length. Intra-dermal immunization (for BCG vaccination) should be given with a 25 gauge and 10 mm long needle.

3.8. Needle angle for intramuscular injection

The needle should be inserted at an angle of 45 to 60 degrees into the vastus lateralis or deltoid muscle. For the vastus lateralis, the needle should point towards the knee and for the deltoid, the needle should point towards the shoulder. Neural and vascular damage are more likely if the needle is inserted at a 90 degree angle. Insertion at 45 to 60 degrees may result in less tissue resistance as the needle penetrates the muscle.

3.9 Recommended sites of injection for vaccination

The anterolateral thigh is the preferred site for vaccination in infants and children under 12 months of age. The deltoid region is an alternative site for vaccination in older children and adults.

The hepatitis B and rabies vaccines are less immunogenic if injected into the buttock. Therefore, these vaccines should not be injected into the buttock in subjects of any age.

3.10. Drawing up vaccines from ampoules

For vaccines that are drawn through rubber bung, or are reconstituted, a new needle should be used for administration.

A needle or syringe, that has been used to inject a person, must never be used to draw vaccine from vaccine vial because of the risk of cross-contamination.

3.11. Administration of two or more vaccines on the same day

Administration of different antigens/vaccines on the same day is recommended. Inactivated vaccines and live attenuated virus vaccines, particularly those in the national EPI schedule (childhood schedule) can generally be given during the same visit. Vaccines that should be administered by injections should be given at different sites (e.g. DPT, M, MR and hepatitis B). More than one live attenuated virus vaccine may be given on the same day; but if only one is given, a second live attenuated vaccine should not be given within 4 weeks of the first vaccine because the response to the second vaccine may be diminished. In addition there is a specific interaction between some vaccines (e.g. yellow fever and cholera vaccines) and they should not be given within 4 weeks of each other. It is also recommended that a three week interval should be allowed between the administration of live virus vaccines (except O.P.V.) and BCG vaccine.

Different vaccines should not be mixed in the same syringe unless it is clearly stated in the instructions of the manufacturer (given in the information schedule supplied by the vaccine supplier). Different vaccines given to a person on the same day should be injected at different sites using different syringes.

3.12. Consent

Prior to vaccination, parents/guardian should be given adequate information including type of vaccine, disease protected, number of doses needed for protection, contraindications, adverse events and what to do if adverse events occur to make an informed decision.

3.13. Consent in special programmes/mass vaccination/school programmes

In large scale school programmes a valid consent from the parent or guardian should be obtained before administration of vaccine. Prior to vaccination, parents or guardian should be given adequate information in a leaflet to make an informed decision.

If a child's health status or suitability for vaccination cannot be established, vaccination should be postponed.

3.14 Recording of vaccination

Each vaccination provider should record all relevant vaccination data on the child health development card or other immunization card. Parents and guardians should be encouraged to present the record at every time their child is seen by a health professional.

The following should be recorded:

The date of vaccination;
Details of the vaccine given, including batch number;
The name/signature of the person providing the vaccination;
Any severe or moderate adverse event;
Date the next vaccination is due.

3.15. Immunization Registers

The health staff conducting the immunization clinic (health unit, other clinics or hospital clinics) should enter the necessary information in the relevant registers according to the instructions given by the Department of Health Services.

3.16. Adverse Events Following Immunization (AEFIs)

Recipients of vaccines should remain under observation until they are seen to be in good health and not be experiencing an immediate adverse reaction. It is not possible to specify an exact length of time for post-vaccination observations but it is recommended that recipients should remain in the clinic/hospital for about 15 minutes. Parents or guardian should be provided with the necessary information before leaving the clinic on how to act if the child develops an adverse event following immunization.

Children who have had a serious adverse event following vaccination may be subsequently vaccinated under close medical supervision in a hospital.

3.17. Anaphylaxis

In infants and children, the most important immediate reaction to vaccination is anaphylaxis. The incidence of anaphylaxis reactions varied with the type of vaccine. But the incidence of true anaphylaxis is only 1-3 cases per million vaccinations. Any member of the health staff carrying out vaccination procedures must be able to distinguish between anaphylaxis, convulsions and fainting.

3.18. Reporting of Adverse Events Following Immunization (AEFI)

Adverse events following immunization with EPI vaccines including MR, and adult Td vaccines should be reported to the respective MOH/DDDHS. In the case of very severe adverse events the Epidemiological Unit should be informed promptly (telephone 681548 or fax 696583). The MOOH/DDDHS should investigate and report these events along with the events following other EPI vaccines in the Monthly Surveillance Report on AEFI.

3.19. Further reading

1. National Health and Medical Research Council. *The Australian Immunization Hand Book,* 1997.

2. World Health Organization. Immunization Safety Surveillance Guidelines for Managers of Immunization Programmes on Reporting and Investigating Adverse Events Following Immunization,*Immunization Focus,* WHO/WPRO/EPI/99.01 Manila.

PART II.

THE EXPANDED PROGRAMME ON IMMUNIZATION

PART II. THE EXPANDED PROGRAMME ON IMMUNIZATION

4. NATIONAL IMMUNIZATION SCHEDULE

4.1. National Immunization Schedule

The Expanded Programme on Immunization (EPI) has been in operation in the country since 1978. However, immunization activities had been conducted for more than two decades prior to that.

The immunization schedule introduced in 1978, with the commencement of the EPI, was revised in 1981. The additional antigen against measles was introduced in 1984 – 1985. The schedule was further revised in 1991 to introduce five doses of tetanus toxoid during a pregnancy for prevention of neonatal tetanus. Immunization against rubella was added to the immunization programme in 1996.

As the epidemiological pattern of the EPI diseases changed over the years and more cost effective vaccines are now available, the Department of Health Services decided to review and revise the existing immunization schedule.

A national consultative meeting was held on 6th March 2000 at the Sri Lanka Foundation Institute to review the schedule. Subsequently, recommendations were made to the Advisory Committee on Communicable Diseases to revise the existing National Immunization Schedule – Sri Lanka.

A new national immunization schedule for Sri Lanka was approved by the Advisory Committee on Communicable Diseases at its meeting held on 9th May 2000.

The new national immunization schedule is given in Table 1.3. This new schedule is in operation from 1st April 2001.

According to the new schedule, changes have been made regarding the age of immunization of some existing antigens (Oral Poliomyelitis Vaccine [(OPV) and Diphtheria, Tetanus, Pertussis Vaccine (DTP), and the inclusion of new antigens [(Measles-Rubella (MR) and adult Tetanus-diphtheria (aTd)].

Table 1.3.
National Immunization Schedule for EPI Vaccines – 2001, Sri Lanka
(As approved by the Advisory Committee on Communicable Diseases revised on 9th May 2000)

Age	Vaccine	Remarks
DURING FIRST YEAR OF LIFE (INFANCY)		
0-4 weeks	BCG	Before leaving hospital, even within 24 hours of birth. (If a scar is not present re-vaccinate after 6 months up to 5 years)
Soon after the completion of		
2nd Month	DTP & OPV (1st dose)	
4th Month	DTP & OPV (2nd dose)	Preferably 6-8 weeks after 1st dose
6th Month	DTP & OPV (3rd dose)	Preferably 6-8 weeks after 2nd dose
9th Month	Measles	Measles vaccine should be administered to all infants as soon as they complete 9 months
IN SECOND YEAR OF LIFE		
About 18 months	DTP (Booster) - 4th dose OPV (Booster) – 4th dose	
PRESCHOOL-GOING AGE		
On completion of 3 years of age	Measles and Rubella (MR)	One dose for all children

Continue on next page

Continued Table 1.3.

SCHOOL-GOING AGE		
At school entry (5 years)	OPV (Booster) – 5th dose DT	One dose for those who have received the primary course of DTP/DT.
In school (10-15 years)	aTd (Adult Tetanus and diphtheria)	One dose for those who have received the primary course of DTP/DT.
	Rubella	One dose of Rubella vaccine should be administered to all females between the ages of 10 and 15 years.
PREGNANT WOMEN		
First pregnancy	Tetanus Toxoid – 1st dose (TT1) after the 12th week of pregnancy	
	Tetanus Toxoid – 2nd dose (TT2) 6-8 weeks after the first dose	Two doses of Tetanus Toxoid should be given during the first pregnancy to prevent Neonatal Tetanus
Subsequent pregnancies	Tetanus Toxoid for the subsequent 3 pregnancies (TT3, TT4, TT5)	One dose of Tetanus Toxoid should be administered during every subsequent pregnancy, up to a maximum of five doses in all (i.e. TT1-TT5)
FEMALES IN THE CHILD-BEARING AGE GROUP		
15-44 YEARS	Rubella	One dose of rubella vaccine to all females between 15 and 44 years of age, who have not been immunized earlier.

It is proposed to introduce Hepatitis B vaccine to the National Immunisation schedule for EPI vaccine from the year 2003.

Table 1.4.
Proposed EPI schedule with Hepatitis B vaccine during 1st year of life (Infancy)

Age	Vaccine	Remarks
DURING FIRST YEAR OF LIFE (INFANCY)		
0-4 weeks	BCG	Before leaving hospital, even within 24 hours of birth. (If a scar is not present re-vaccinate after 6 months up to 5 years)
Soon after the completion of		
2nd Month	DTP, OPV & Hep B (1st dose)	
4th Month	DTP, OPV & Hep B (2nd dose)	Preferably 6-8 weeks after 1st dose
6th Month	DTP, OPV & Hep B (3rd dose)	Preferably 6-8 weeks after 2nd dose
9th Month	Measles	Measles vaccine should be administered to all infants as soon as they complete 9 months

4.2. General contraindications to vaccination

1. Immunization should be postponed if the subject is suffering from any established acute illness. Minor infections without fever or systemic upset are not contraindications.

2. Live vaccines should not be routinely administered to pregnant women because of possible harm to the foetus; however when there is a significant risk of exposure, for example to poliomyelitis, the need for vaccination of an unvaccinated mother outweighs any risk to the foetus.

3. Live vaccines should not be given to the following:

   a. Patients receiving high-dose corticosteroids(e.g, prednisolone 2 mg/kg/day for more than a week), Immunosuppressive treatment including general irradiation and chemotherapy.
   b. Those suffering from malignant conditions such as lymphoma, leukaemia, Hodgkin's disease or other tumours of the reticulo-endothelial system.
   c. Patients with impaired immunologica mechanisms for instance, hypogamaglobulinaemia.

   Live vaccines should be postponed until at least 3 months after stopping corticosteroids and 6 months after stopping chemotherapy.

   (a) Children on lower daily doses of systemic corticosteroids (less than 2 mg/kg/day) for less than two weeks.
   (b) Those on lower doses or alternate day regimes for longer periods, may be given live virus vaccines.

4. Some viral vaccines contain small quantities of antibiotics such as penicillin, neomycin or polymyxin; such vaccines should not be given to persons with documented hypersensitivity to such antibiotics.

5. Live virus vaccines should not be given within 3 months of an injection of immunoglobulin because the immune response may be inhibited.

6. HIV positive individuals and contraindications to the individual vaccines are given in the leaflets supplied with the vaccines; it is necessary to take note of them.

4.3 Precautions and contraindications relating to scheduled vaccines

Children with minor illness may be vaccinated safely. But, if they are suffering from a major illness or high fever (102^{o}F) they should not be vaccinated. These children should be vaccinated after they recover.

4.4. Precautions and contraindications for immunocompromised children

Live vaccines are usually contraindicated in immune-suppressed individuals, including those with malignant disease or receiving chemotherapy. However, because immune-suppressed individuals are at great risk of certain infections, the question of vaccination needs to be assessed by a specialist.

4.5. False contraindications to vaccination

The following conditions ARE NOT contraindications for vaccination with any of the vaccines in the standard schedule:

- Family history of any adverse reactions following vaccination;
- Family history of convulsions;
- Previous pertussis-like illness, measles, rubella or mumps infection;
- Prematurity (vaccination should not be postponed);
- Stable neurological conditions such as cerebral palsy and Down syndrome;
- Contact with a patient suffering from an infectious disease;
- Child's mother is pregnant;
- History of jaundice after birth;
- Low weight in an otherwise healthy child.

4.6. Interrupted vaccine doses

If the recommended intervals between doses are exceeded, there is no need to recommence the schedule or give additional doses, because the immune response is not impaired by such delay.

When infants and children have missed scheduled vaccine doses, every opportunity should be taken to check vaccination status and to provide missing doses as early as possible. The next dose should be scheduled after an appropriate minimal interval.

If the process of administration of vaccine is interrupted, by syringe-needle disconnection or vomiting of OPV, the whole dose should be repeated.

4.7. Administration of more than one vaccine on the same day

A number of different injectable vaccines may be given on the same day, but via separate syringes and at different sites. Administration of 2 or more vaccines (including both live vaccines and inactivated vaccines) will not usually interfere with the immunological response and will not increase the incidence of side-effects. For instance, DTP, OPV, measles and hepatitis B vaccines may all be administered on the same day, if necessary. However, if different live virus vaccines cannot be given on the same day, they should be given at least 4 weeks apart.

4.8. Vaccination of pre-term infants

Vaccination of pre-term infants should be commenced according to the standard vaccination schedule; provided there are no contraindications. Pre-term infants have a special need for protection. They have adequate antibody responses and do not have a higher incidence of adverse reactions.

4.9. Frequently Asked Questions (FAQs) about immunization

01. Has our immunization schedule for EPI vaccines changed?

Yes. The immunization schedule introduced in 1978, with the commencement of the EPI, was revised in 1981, and measles vaccine was introduced in 1984 – 1985. The schedule was further revised in 1991 to administer two doses of Tetanus Toxoid (TT) during the first pregnancy, and one dose during every subsequent pregnancy up to a maximum of five doses in all, for prevention of neonatal tetanus. Immunization against Rubella was added to the immunization programme in 1996.

As the pattern of EPI diseases has changed over the years and better vaccines are now available, the Department of Health Services decided to review and revise the existing immunization schedule.

A National Consultative Meeting of experts was held on 06th March 2000 at the Sri Lanka Foundation Institute and a new schedule was recommended to the Advisory Committee on Communicable Diseases. This was approved by the Advisory Committee on Communicable Diseases and this new schedule is in operation from 1st April 2001.

02. What is the new national immunization schedule for EPI vaccines?

The new schedule is given in Table 1.3.

03. What are the main changes?

According to the new schedule there are changes in the age of immunization for some existing antigens [Oral Poliomyelitis Vaccine (OPV) and Diphtheria Tetanus Pertussis Vaccine (DTP)] and inclusion of new antigens [Measles-Rubella (MR) and adult Tetanus-diphtheria (aTd)].

04. From when has the new immunization schedule been in operation in Sri Lanka?

The new schedule has been in operation from the 1st April 2001.

05. Why is combination preparation of Measles-Rubella (MR) vaccination given on completion of three years?

According to available information the vaccine efficacy of measles vaccine at nine months is about eighty five percent (85%). Hence about fifteen percent (15%) of the children will not develop adequate antibodies (vaccine failures) to protect against measles. Immunizing them again at 3 years of age can protect these children and also children who were not immunized against measles previously i.e. as soon as they complete 9 months. In addition, all children (both males and females) will be protected against rubella at this age. By immunizing both males and females at early ages, congenital rubella as well as rubella can be controlled in the country.

06. Why is adult Tetanus-diphtheria vaccine (aTd) given to children at school (10-15 years)?

Outbreaks of diphtheria in adolescents and adults have been reported during the last few years in some Asian and European countries due to the waning of immunity against diphtheria over the years. Re-immunizing them using the adult diphtheria-tetanus combination vaccine can protect these adolescents and young adults, by boosting their immunity against diphtheria and tetanus.

07. Should a child be immunized with measles-rubella (MR) vaccine if the child had been already vaccinated with MMR vaccine?

If there is no satisfactory verbal or written record of immunization with MMR vaccine, the child should be given a dose of measles-rubella (MR) vaccine.

08. What will you do if a child had been already immunized with DTP1/OPV1 or DTP2/OPV2 according to the old schedule?

The vaccination schedule should be safely and effectively continued. The second or third dose of DTP/OPV vaccines should be given 6-8 weeks after the previous dose.

09. Will there be problems if more than one vaccine is given at the same time?

The vaccines recommended for use in infants and children (DTP, hepatitis B, Poliomyelitis, MMR and Hib) can safely be administered at a single visit, as long as they are given in separate syringes at different sites. Combined vaccines, requiring only one injection, are likely to become available in the next few years.

10. Will the schedule need to be restarted after a long break – for example, if a child has received only one injection of DTP or Hepatitis B vaccine, or one dose of Oral Poliomyelitis Vaccine (OPV) in the 1st year, is there a need to start the whole schedule again?

There is no need to repeat doses that have already been given. The vaccine schedule can safely and effectively be continued as if there had been no delay. The usual intervals between further doses should be maintained or reduced. The immune system does not forget.

11. What if a dose was missed?

The immunization course should be resumed. No extra doses need be given.

12. What happens to the rest of the vaccination schedule when a complication occurs after the administration of a vaccine?

Mild local reactions are not a reason to avoid giving further doses of vaccine. However, if the reaction is severe, it may be appropriate to omit further doses of the vaccine. If there has been a severe reaction to Triple Antigen (DTP), it may be necessary to use a preparation without pertussis vaccine (DT) instead of Triple Antigen (DTP). Such reactions should be reported to the medical officer of health.

13. Should premature babies have their vaccinations delayed?

Babies born prematurely should receive BCG when they are fit to be discharged from the hospital. They should also receive their 1st dose of DTP and OPV, two months after birth, unless they are seriously ill.

14. Should vaccination be postponed if a child has a cold or a chest infection?

Babies with minor coughs and colds without fever, or those receiving antibiotics in the recovery phase of an acute illness, can be immunized safely and effectively. Vaccination should only be postponed if a child is seriously ill or has high fever. In such cases, vaccination should be arranged for a week or two later.

15. Should children be given a particular vaccine if they have already had that disease? For example, is a past history of measles, rubella or whooping cough a contraindication to vaccination?

No. It is safe to immunize against these diseases even if there is a history of prior infection. Vaccination boosts the immunity of an individual who is already immune to measles and it carries no risk. In addition, diagnosis of measles and rubella without laboratory confirmation is very unreliable; so children who appear to have had these diseases should certainly be immunized with measles, MR or MMR vaccine.

16. Should a child be immunized if the child's mother is pregnant?

There is no problem with routine vaccine administration to a child whose mother is pregnant. In fact, measles/MR/MMR vaccine given to the child of a pregnant mother will reduce the risk of her being infected by her offspring if she is not immune. Measles, MR and MMR vaccine viruses are not infectious.

17. What if a child has a chronic disease?

In general, children with chronic diseases should be immunized as a matter of priority. Care is needed however, in situations where the child's illness, or its treatment, may result in impaired immunity.

18. What if a child has had a fit or has epilepsy?

Stable neurological disease is not a reason to avoid giving pertussis (whooping cough) or DTP vaccination. A child may develop a fever after administration of any vaccine; parents should be warned of this and advised to give the child paracetamol. It should be remembered that the fever following measles vaccine occurs 5-10 days after vaccination. A family history of fits or epilepsy is not a reason to avoid vaccination. You may also consult the family doctor.

19. Should allergic children be immunized?

Asthma, eczema, hay fever and allergies are not contraindications to any vaccine. An important exception is genuine severe egg allergy. A history of an anaphylactic reaction to egg (generalized hives, swelling of the mouth or throat, difficulty in breathing, wheeze, low blood pressure, or shock) is generally a contraindication to influenza and yellow fever vaccines. Measles/MR/MMR can be given to such children under close observation, as anaphylactic reactions to these vaccines are exceedingly rare, even in children with proven severe egg allergy.

20. Isn't natural immunity better than vaccine-induced immunity?

While vaccine-induced immunity may diminish with time, 'natural' immunity, acquired by catching the disease, is usually lifelong. The problem is that the wild or 'natural' disease can kill or leave a child permanently brain damaged. Children or adults can be re-immunized if their immunity from the vaccines falls to a low level. Vaccines are many times safer than the diseases they prevent.

21. Can too many vaccines overload the immune system?

There is no evidence that this occurs in standard vaccination programmes. All children and adults confront enormous numbers of antigens (substances that provoke a reaction from the immune system) each day, and the immune system responds to each of the antigens in various ways to protect the body. Vaccine antigens have an advantage over their corresponding wild antigens in that the immune response (such as making antibodies) to the wild antigens is usually evident only after a notable illness has occurred. With vaccine antigens, however, the 'illness', if it does occur, is usually insignificant.

22. How can you help a child's immune system function effectively so that it can fight off infections?

Eating, sleeping and exercising adequately will help keep the child's immune system functioning well. Vaccination has an important role to play in protecting children from specific diseases.

23. Is it true that vaccinated children may still contract a disease?

Yes. It is possible, since no vaccine is 100% effective. A small proportion of those who are vaccinated will remain susceptible to the disease. However, in cases in which illness does occur in vaccinated individuals, the illness is usually much less severe than in those who have not been vaccinated.

24. Haven't diseases like polio, tetanus, whooping cough and diphtheria already disappeared from most parts of Sri Lanka? So, do we need to keep immunizing children against these diseases?

These diseases are much less common now, but the bacteria and viruses that cause them are still present. The potential problem is kept in check by routine vaccination programmes. In countries where vaccination rates have declined, the vaccine preventable diseases have reappeared. There have been recent outbreaks of whooping cough, measles and rubella in Sri Lanka, and a number of children have died. Cases of tetanus and measles still occur.

25. Do breast-fed children need a different vaccination schedule?

No. Breast-fed children should be vaccinated according to the standard schedule. Breast milk contains small amounts of antibodies, but these do not interfere with the immunization process.

26. Does vaccination cause allergies?

Some children are allergic to particular components of vaccines. However, vaccination does not provoke the development of a general allergic tendency.

27. What if a baby vomits the oral polio vaccine?

It is quite safe to repeat the dose.

28. Are any other vaccines available in Sri Lanka?

Yes. Hepatitis B, Haemophillus influenzae B, Varicella (chickenpox), Mumps vaccines and several other vaccines are available in Sri Lanka only in the private sector. Decisions about administering these vaccines to children should be taken after consulting your family doctor.

29. What immunizations do you give to a child with no immunization records?

If there is no satisfactory verbal or written record of immunization, the child should be given immunizations from then on as if they were never previously immunized.

30. Should a child with diarrhoea receive oral polio vaccine (Sabin vaccine)?

Yes. Oral polio vaccine should be given and an additional dose should be given at the next clinic session i.e. soon after the child has recovered.

31. For how long after a significant febrile illness should vaccination be delayed?

Vaccination should be delayed until the child has recovered.

32. Does immunization cause asthma?

No. There is no evidence that immunization causes or worsens asthma. It is especially important that children with asthma be immunized like other children, as catching a disease like whooping cough can make an asthma attack worse.

4.10. Further reading

1. World Health Organization. Immunization Policy, *Global Programme for Vaccines and Immunization*, EPI/WHO Geneva – Switzerland ,1995.

2. National Health and Medical Research Council. *The Australian Immunization Hand Book 6th Edition*, 1997.

PART III.

TARGET DISEASES AND VACCINES IN THE EXPANDED PROGRAMME ON IMMUNIZATION

PART III. TARGET DISEASES AND VACCINES IN THE EXPANDED PROGRAMME ON IMMUNIZATION

5. TUBERCULOSIS

5.1. Introduction

Tuberculosis is one of the most important health problems in developing countries and, as infection with human immunodeficiency virus (HIV) becomes more prevalent, tuberculosis is becoming a serious problem in developed countries as well (Styblo 1989).

Tuberculosis is caused by the bacillus *Mycobacterium tuberculosis*. *M. tuberculosis* is responsible for some eight million new illnesses and three million deaths per year, mostly in developing countries, although there are over 400,000 new cases annually in industrialized countries.

By far, the most important source of human infection is an already infected person who spreads the highly infectious bacilli via respiratory droplets. Primary infections can occur at any age, but children are most often affected in areas of high incidence and high population density. Even after resolution, the disease can be reactivated and spread again. Agents that depress the immune system, such as corticosteroid therapy or HIV infection, facilitate reactivation.

Primary infection may be asymptomatic and often resolves spontaneously. However, it may progress by local spread in the lungs to cause pleurisy or bronchopneumonia. If the infection spreads through the bloodstream, it can affect many organs, including the meninges, the bones, or the internal organs. Disease can be accompanied by tuberculous lymphadenopathy, or this manifestation can occur in the absence of other features.

Extrapulmonary tuberculosis is much less common than pulmonary tuberculosis. It may affect any organ or tissue and includes

tuberculous meningitis, acute hematogenous (miliary) tuberculosis. It also may involve lymph nodes, pleura, pericardium, kidneys, bones and joints, larynx, skin, intestines, peritoneum and eyes. Extrapulmonary tuberculosis occurs more frequently among persons who are infected with HIV, but pulmonary tuberculosis remains the most common type of tuberculosis in this group worldwide.

Mode of transmission

By exposure to tubercle bacilli in airborne droplet nuclei is produced by people with pulmonary or laryngeal tuberculosis during expiratory efforts, such as coughing, singing or sneezing. Laryngeal tuberculosis is highly contagious. Prolonged close exposure to an infectious case may lead to infection of contacts. Direct invasion through mucous membranes or breaks in the skin may occur but is extremely rare. Bovine tuberculosis results from exposure to tuberculous cattle, usually by ingestion of unpasteurized milk or dairy products, and sometimes by airborne spread to farmers and animal handlers. Except in rare situations where there is a draining sinus, extrapulmonary tuberculosis (other than laryngeal) is generally not communicable.

Incubation period

The period from infection to demonstrable primary lesion, or significant tuberculin reaction, is about 4-12 weeks. While the subsequent risk of progressive pulmonary or extrapulmonary tuberculosis is greatest within the first year or two after infection, latent infection may persist for a lifetime. HIV infection appears to increase the risk significantly and shortens the interval for the development of clinical tuberculosis.

Susceptibility and resistance

The risk of infection with the tubercle bacillus is directly related to the degree of exposure and does not appear to be related to genetic or other host factors. The most hazardous period for development of clinical disease is the first 6-12 months after infection. The risk of developing disease is highest in children under 3 years of age, lowest in later childhood, and high again among adolescents, young adults, the very old and the immuno-suppressed. Reactivation of long-latent infections accounts for a large proportion of cases of clinical disease in older people. For those infected, susceptibility to disease is markedly increased in the following subjects:

- in those with HIV infection and other forms of immuno-suppression;
- increased among underweight and under-nourished people;
- people with debilitating diseases such as chronic renal failure, cancer, silicosis, diabetes or postgastrectomy;
- among substance abusers.

5.2. Situation in Sri Lanka

As a result of the control measures adopted, the number of Tuberculosis (TB) cases detected each year declined gradually up to 1986. However, there has not been a significant decline in the incidence since then. Around 6500-7000 new cases of TB are detected annually and tuberculosis still continues to pose a major public health challenge in Sri Lanka. A marginal increase in the number of new cases detected since 1996 can be attributed to improved case detection and notification.

In the year 1999, 7157 new TB cases, 336 relapses and 24 treatment failures were registered. The notification rate was 37.6 per 100,000 population. Of the new cases, 82.4% were of pulmonary TB.

5.3. Vaccine

Freeze-dried glutamate BCG vaccine for Intradermal use.
It is a live freeze-dried vaccine made from an attenuated strain of Mycobacterium bovis.

Composition of Vaccine (20 infant doses of vaccine)

a. Live Bacteria of Calmette and Guerin (as approximately 70% moist bacteria) 0.5 mg/ampoule.
b. Sodium Glutamate (as a stabilizer) 2.0 mg/ ampoule.
c. 1.0 ml diluent in a separate ampoule.

The reconstituted vaccine provides 10 adult or 20 infant doses of the vaccine.

5.4. Indications

Should be given to all new born babies; before leaving hospital within 24 hours of birth.

This protects the young children against developing complications of primary infection, such as TB meningitis and miliary TB.

BCG has little or no effect in reducing the number of adult TB cases in the population.

If children are brought without a BCG scar despite BCG vaccination their re-vaccination with BCG may be done after 6 months up to 5 years.

5.5. Schedule

National policy is to give BCG vaccination to all new born babies routinely. BCG should be administered before 'leaving hospital' within 24 hours of birth (if a scar is not present re-vaccinate after 6 months up to 5 years).

5.6. Dose and Administration

Reconstitute the BCG vaccine according to the instructions given in the information leaflet supplied with the vaccine ampoule/vial. The reconstituted vaccine contains a homogeneous suspension of BCG vaccine in a concentration of 0.5 mg. per ml.

For children under one year 0.05 ml and for others 0.1 ml of reconstituted vaccine is given intradermally. Special syringes allow administration of the exact dosage.

Site

The site of inoculation should be in the deltoid region (i.e. half way down the deltoid muscle) in the left upper arm as sites higher on the arm are more likely to lead to keloid formation; the tip of the shoulder should be avoided.

Dosage forms

Lyophilized BCG vaccine for children under one year 0.05 ml. and others 0.1 ml. of reconstituted vaccine is given intradermally.

BCG is supplied freeze-dried with diluent in a separate ampoule. The vaccine and the diluent should be maintained at the correct temperature (+2°C - +8°C). Special care is needed in opening the ampoule and reconstituting the vaccine so that the vaccine is not blown out of the ampoule. Because of sensitivity to daylight, the vaccine must be kept in the dark. When withdrawals are made from the ampoule, the vaccine must be exposed to the light for a minimum period of time, and never for longer than four hours. If not used immediately after reconstitution, the vaccine should be kept cool (+2°C - +8°C) and protected from light, and any opened container remaining at the end of a session (maximum 4 hours) should be discarded.

5.7. Storage

BCG vaccine should be stored and transported between +2°C to +8°C. The diluent should not be frozen but kept cool. Protect the vaccine from light. The expiry is specified on the BCG ampoule label.

5.8. Cautions and Contraindications

1. The general contraindications discussed in 4.2, 4.3 and 4.4 apply.

2. The vaccine is contraindicated in those with cell-mediated immune deficiency. Keloid and lupoid reactions may occur at the site of injection and such children should not be revaccinated. HUMAN IMMUNODEFICIENCY VIRUS (HIV) INFECTED INFANTS: HIV infected, non symptomatic infants should be immunized with BCG vaccine according to the standard schedule. Infants with clinical (symptomatic) AIDS should not receive BCG vaccine (but should receive other EPI vaccine).

3. BCG vaccine may be given concurrently with another live vaccine, but if they are not given at the same time, an interval of at least 3 weeks should be allowed between the administration of BCG vaccine and any other live vaccine, whichever is given first. No further immunization should be given for at least three months in the arm used for BCG vaccination because of the risk of regional lymphadenitis.

5.9. Adverse Events

1. A local reaction is normal after BCG vaccination. A small tender red swelling appears at the site of the injection. The swelling will gradually change to a small vesicle and then an ulcer in 2-4 weeks. The reaction usually subsides in 2/12 - 5/12 and practically in every child it leaves a superficial scar 2-10 mm in diameter. Rarely, the nodule may persist and ulcerate. Occasionally, enlargement of axillary lymph nodes may appear in 2-4 months following immunization. Inadvertent subcutaneous injection produces abscess formation and may lead to ugly retracted scars.

2. Faulty injection technique is the most frequent cause of severe injection site reactions (large ulcers and abscesses).

3. Adenitis with or without suppuration is rare; a minor degree of adenitis may occur in the weeks following vaccination and should not be regarded as a complication; very rarely a lupoid type of local lesion has been reported; a few cases characterized by widespread dissemination of the injected organisms have been reported; anaphylactoid reactions can occur.

5.10. Further reading

1. Chin James, *Control of Communicable Disease Manual*, American Public Health Association Washington DC – 2000.

2. World Health Organization, The immunological basis for immunization series – Modules – *Tuberculosis* – Global Programmes for Vaccines and Immunization EPI, WHO Geneva – WHO/EPI/GEN/93.15

3. Ministry of Health *General Manual for Tuberculosis Control* , Respiratory Disease Control Programme. Sri Lanka – 1997.

4. World Health Organization, Issues relating to the Use of BCG in Immunization Programmes. *A discussion document* – Department of Vaccines and Other Biologicals, WHO/V&B/99.23 Geneva 1999.

5. World Health Organization, BCG in Immunization Programmes – WHO *Weekly Epidemiological Report* No. 5, 2001 76, 33-40.

6. TETANUS

6.1. Introduction

Tetanus is caused by the action of a highly potent neurotoxin, tetanospasmin, which is produced during the growth of the anaerobic bacterium *Clostridium tetani.* *Cl. tetani* is not an invasive organism; infection with *Cl. tetani* remains localized. The disease usually occurs through infection of a skin injury with tetanus spores. Tetanus spores introduced into an area of injury convert to tetanus bacilli in the presence of necrotic tissue with reduced oxygen potential. Neonatal tetanus occurs through infection of the umbilicus when the cord is cut with an unclean instrument or when substances heavily contaminated with tetanus spores are applied to the umbilical stump.

The disease is characterized by painful muscular contractions, primarily of the masseter and neck muscles, secondarily of trunk muscles. A common first sign suggestive of tetanus in older children and adults is abdominal rigidity, though rigidity is sometimes confined to the region of injury. Typical features of the tetanus spasm are the position of opisthotonus and the facial expression known as “risus sardonicus”.

Tetanus neonatorum (NNT)

In neonates, inability to suck is the most common presenting sign. Tetanus neonatorum is typified by a new born infant who sucks and cries well for the first few days after birth and subsequently develops progressive difficulty and then inability to feed because of trismus, generalized stiffness with spasms or convulsions and opisthotonus. The average incubation period is about 6 days, with a range from 3 to 28 days.

Mode of transmission

Tetanus

Tetanus spores are usually introduced into the body through a puncture wound contaminated with soil, street dust, animal or human faeces, through lacerations, burns and trivial or unnoticed wounds.

NNT

The disease usually occurs through introduction via the umbilical cord of tetanus spores during delivery by cutting the cord with an unclean

instrument or after delivery by ‘’dressing” the umbilical stump with substance contaminated with tetanus spores.

Incubation period

Usually 3 – 21 days.

Tetanus

The average incubation period is usually 3-21 days average about 10 days. It may range from 1 day to several months, depending on the character, extent and location of the wound.

NNT

The average incubation period is about 6 days, with a range from 3 to 28 days. Overall, neonatal tetanus case-fatality rates are very high, exceeding 80% among cases with a short incubation period.

Period of communicability

Tetanus and NNT are not directly transmitted from person to person.

Susceptibility and resistance

Susceptibility is general. Active immunity is induced by tetanus toxoid and persists for at least 10 years after full immunization; transient passive immunity follows injection of tetanus immune globulin (TG) or tetanus antitoxin (equine origin). Infants of actively immunized mothers acquire passive immunity that protects them from neonatal tetanus.

6.2. Situation in Sri Lanka

Immunization to prevent tetanus in the newborn during the neonatal period commenced in Sri Lanka in 1969. However, this programme was not organized very satisfactorily, and the cold chain was not well established at this stage of the programme. With the commencement of the National Expanded Programme on Immunization in 1978, these short comings were corrected.

The incidence of Neonatal Tetanus is given in Table 1. Only three cases of neonatal tetanus were reported during 1999 giving an incidence rate of 0.009 cases per 1000 live births.

6.3. Vaccine

1. D.P.T. (given under diphtheria)
2. D.T. – do –
3. aTd - do –
4. Tetanus Toxoid Vaccine

Tetanus toxoid adsorbed is prepared by detoxification of the sterile filtrate of broth cultures of *Clostridium tetani* with formalin and heat. The toxoid is purified by chemical method and is adsorbed onto aluminium phosphate as adjuvant. Thiomersal is added as preservative.

Antibody response to tetanus toxoid (TT) and expected duration of tetanus immunity after different immunization schedules are given in Figures 2 & 3.

Each single dose 0.5 ml human dose contains
Tetanus toxoid ≥ 5 Lt (≥ 40IU)
Adsorbed on Aluminium Phosphate (Al P04) ≥ 1.5 mg.

6.4. Indications

1. Primary immunization of children against tetanus with triple vaccine and dual vaccine.
2. Immunization of non immune persons against tetanus.
3. Pregnant non immune women to prevent neonatal tetanus.
4. Treatment of patients with tetanus prone wounds.

6.5. Schedule

See immunization schedule.

6.6. Dose and Administration

0.5 ml. Tetanus toxoid vaccine adsorbed should be injected intramuscularly into the deltoid muscle in women and older children. If there are indications for the use of tetanus toxoid in younger children, the preferred site for intramuscular injection is the anterolateral aspect of the upper thigh since it provides the largest muscle mass.

6.7. Storage

The vaccine should be stored in a dry place at a temperature between +2^{o}C to +8^{o}C. Transportation should also be at +2^{o}C to +8^{o}C. DO NOT FREEZE.

6.8. Cautions and contraindications

Reinforcing doses of tetanus toxoid at less than 5 year intervals may provoke hypersensitivity reactions and therefore should be avoided. Refer those discussed in section 4.2, 4.3 and 4.4.

6.9. Adverse Events

Local reactions such as pain, redness and swelling round the injection site may occur and persist for several days. General reactions that are uncommon include headache, lethargy and malaise. Pyrexia may occur occasionally.

6.10. Further reading

1. Chin James. *Control of Communicable Disease Manual*, , American Public Health Association Washington DC, 2000.

2. World Health Organization, *The Immunological Basis for Immunization Series Module 3 Tetanus. Global Programme for Vaccines and Immunization*, WHO/EPI/GEN/93.13 Geneva.

Figure 2. Antibody response to tetanus toxoid(TT)

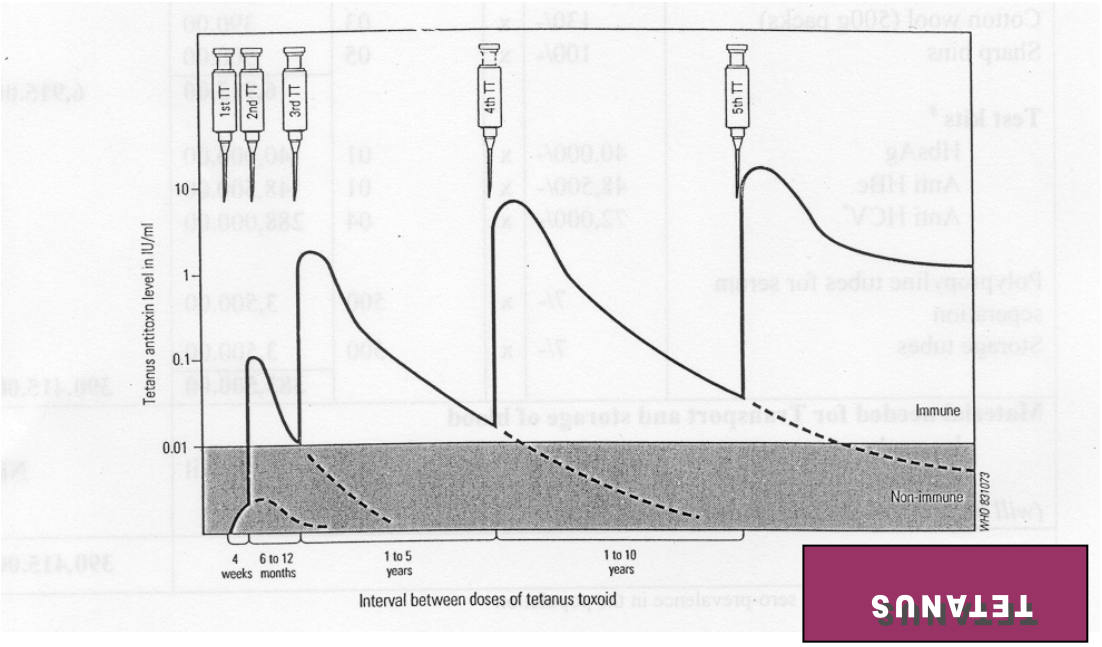
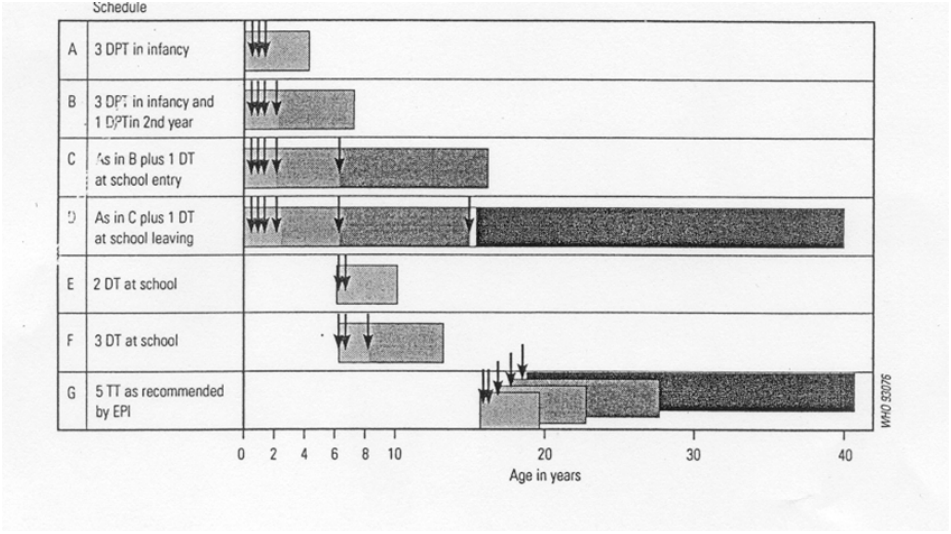


Figure 3. Expected duration of tetanus immunity after different immunization schedule



TETANUS

7. DIPHTHERIA

7.1. Introduction

Diphtheria is a bacterial disease in which the clinical manifestations result from the action of an extracellular substance (exotoxin) produced by *Corynebacterium diphtheriae*, a club-shaped bacterium.

The three types of *Corynebacterium diphtheriae* are *C. gravis, C.mitis or C.intermedias*. Toxin production results when the bacterium is infected by corynebacteriophage containing the diphtheria toxin gene *tox*. Nontoxigenic strains rarely produce local lesions; however, they have been increasingly associated with infective endocarditis.

Diphtheria is acquired through personal contact; the incubation period is generally 2 to 5 days. Diphtheria is a disease affecting the tonsils, the pharynx, the larynx, and the nose. In developing countries skin diphtheria is common with lesions indistinguishable from, or a component of , impetigo. Laryngeal diphtheria is serious, while nasal diphtheria may be mild, often chronic. Inapparent infections outnumber clinical cases. Late effects of diphtheria include cranial and peripheral motor and sensory palsies and myocarditis. The case fatality rate is 5% to 10%.

Mode of transmission

Contact with a particular carrier; more infrequently, contact with articles soiled with discharges from lesions of infected people. In developing countries, a high rate of skin infection caused by a diphtheriae creates a primary reservoir of diphtheriae organisms.

Incubation period

Usually 2-5 days, occasionally longer.

Period of communicability

Variable, until virulent bacilli have disappeared from discharges and lesions; usually 2 weeks or less and seldom more than 4 weeks. Effective antibody therapy promptly terminates shedding. The rare chronic carrier may shed organisms for 6 months.

Susceptibility and resistance

Infants born to immune mothers are relatively immune; protection is passive and usually lost before the end of six months. Lifelong immunity is usually but not always acquired after disease or inapparent infection. Immunization with toxoid produces prolonged but not lifelong immunity. In countries where diphtheria has been successfully controlled, the immunity level acquired through immunization in infancy and early childhood should be maintained through properly timed booster doses of DT or aTd vaccines. These vaccines should be used for older children or adolescents leaving primary or secondary schools.

7.2. Situation in Sri Lanka

Diphtheria is a notifiable disease in Sri Lanka. The last confirmed case was reported from the General Hospital, Kandy in the 1st quarter of 1995. The patient was a 42 year old male who presented with hoarsenses of 1/12 months duration. On examination a greyish membrane was seen in the larynx. The case was confirmed as diphtheria by the microbiology laboratory of the University of Peradeniya.

Incidence of diphtheria is given in Table 1.1. and 1.2. Active immunization is carried out using DPT vaccine which commenced in Sri Lanka in 1961.

7.3. Vaccine

A variety of formulations of diphtheria vaccine are available in Sri Lanka. Vaccines used in the National EPI programme are:

7.3.1. Diphtheria-tetanus-whole cell pertussis vaccine (DTPw)

Diphtheria, tetanus and pertussis adsorbed vaccine is prepared by combining purified diphtheria toxoid, purified tetanus toxoid and killed *Bordetella pertussis* Bacilli. The antigens are adsorbed on to aluminium phosphate as adjuvant.

(DTPw) each single 0.5 ml human dose contains diphtheria toxoid ≤ 25 Lf (≥ 30 IU), tetanus toxoid ≥ 5 Lf (≥ 40 IU) and *B. pertussis* ≤ 16 OU

(≥ 4 PU) Adsorbed on Aluminium Phosphate (Al P04) ≥ 1.5 mg.

7.3.2. Diphtheria and Tetanus Vaccine Adsorbed (Paediatric) D.T.

Diphtheria and Tetanus toxoid Adsorbed is prepared by combining purified diphtheria toxoid and purified tetanus toxoid. The antigens are adsorbed on to aluminium phosphate as adjuvant.

DT each single 0.5 ml human dose contains diphtheria toxoid ≤ 25 Lf (≥30 IU) and tetanus toxoid ≥ 5 Lf (≥ 40 IU) adsorbed on Aluminium Phosphate (Al P04) ≥ 1.5 mg.

7.3.3. Diphtheria and Tetanus Vaccine Adsorbed for Adults and Adolescents (aTd)

Diphtheria and tetanus vaccine adsorbed for adults and adolescents is prepared by combining purified diphtheria toxoid and purified tetanus toxoid. The antigens are adsorbed on to aluminium phosphate as adjuvant.

aTd each single 0.5 ml human dose contains diphtheria toxoid ≤5 Lf (≥2 IU) and tetanus toxoid ≥5 Lf (≥40 IU) adsorbed on Aluminium Phosphate (Al P04) ≥1.5 mg.

7.4. Indications

7.4.1. Adsorbed diphtheria, tetanus and pertussis vaccine (Triple vaccine, DTP)

1. Primary course of immunization against diphtheria, tetanus and whooping cough is recommended for all infants on completion of 2 months of age, unless there is a genuine contraindication; if the primary course is interrupted, it should be resumed but not repeated, allowing appropriate intervals between the remaining doses.

2. Vaccination of unimmunized older children: Vaccination of unimmunized older children against whooping cough is recommended unless there is a genuine contraindication.

7.4.2. Adsorbed diphtheria and tetanus vaccine (Dual vaccine, DT)

1. This vaccine is used for primary immunization in place of the triple vaccine when immunization against whooping cough is contraindicated.

2. It is recommended for children immediately before school entry, preferably after at least 3 years from the last dose of the primary course.

7.4.3. Diphtheria and Tetanus vaccine adsorbed for adults and adolescents (aTd)

It is recommended:

1. for primary vaccination and re-vaccination of adults and adolescents who have contraindications for DTP.
2. for primary vaccination and re-vaccination of children older than 7 years.

In this vaccine, in order to prevent allergic reactions to the protein of diphtheria toxoid, the quantity of the toxoid has been markedly reduced.

7.5. Schedule

See immunization schedule.

7.6. Dose and Administration

7.6.1. Dosage forms: Adsorbed Diphtheria, Tetanus and Pertussis vaccine (DTP). Dose 0.5 ml. vaccine should be injected intramuscularly.

7.6.2. Dosage forms: Adsorbed Diphtheria and Tetanus vaccine (DT). Dose 0.5 ml. vaccine should be injected intramuscularly.

7.6.3. Dosage forms: Diphtheria and tetanus vaccine adsorbed for adults and adolescents (aTd).

Method of inoculation

The preferred site for injection is the deltoid muscle. The vaccine should be shaken well before use.

7.7. Storage
7.8.

The vaccine should be stored in a dry, place at a temperature between +2°C to +8°C. Transportation should also be at +2°C to +8°C. DO NOT FREEZE.

7.8. Cautions and Contraindications

7.8.1. (1) Those discussed in section 4.2, 4.3 and 4.4.

(2) Severe local or general reaction to a preceding dose are explained below;

i. Local reactions: an extensive area of redness and swelling which becomes indurated and involves most of the antero-lateral surface of the thigh or a major part of the circumference of the upper arm; this reaction may increase in severity with each subsequent injection.

ii. General reactions: fever equal to or more than 39.5°C within 48 hours of vaccination, anaphylaxis; bronchospasm, laryngeal oedema, generalized collapse, prolonged unresponsiveness, prolonged inconsolable screaming, convulsions occurring within 72 hours. A personal or family history of allergy is not a contraindication to immunization against whooping cough, nor are stable neurological conditions such as cerebral palsy or spina - bifida.

iii. Progressive neurological disorder (e.g. infantile spasms).

Children with problem histories:

There are certain groups of children in whom the advisability of whooping cough immunization requires special considerations because of their own or their family histories. For them, the risk from vaccine may be higher, but the effects of whooping cough disease could be more severe. The balance of risk and benefit should be assessed in each case. Where there is doubt, appropriate advice should be obtained from a consultant paediatrician before a decision is made to withhold vaccination.

These groups are:

1. Children with a documented history of cerebral damage in the neonatal period.

2. Children with a personal history of convulsions.

3. Children whose parents or siblings have a history of idiopathic epilepsy; in such children there may be a risk of developing a similar condition irrespective of vaccination.

The vaccine should not be given to persons who have shown a severe reaction to previous doses of DTP vaccine.

In those with severe reactions which CONTRAINDICATE further doses of DTP– in such cases DT should be used for subsequent vaccinations i.e.

- Encephalopathy within 7 days, defined as severe acute neurological illness with prolonged seizures and/or unconsciousness and/or focal signs (but not a simple febrile convulsion).

- Immediate severe allergic or anaphylactic reaction to vaccination with DTP.

7.9. Adverse Events

7.9.1. D.T.P.

1. Local reactions such as pain, redness and swelling round the injection site may occur and persist for several days; general reactions, which are uncommon include headache, lethargy, malaise, myalgia and pyrexia; acute anaphylactic reactions and urticaria may occasionally occur and rarely, peripheral neuropathy; persistent nodules at the injection site may arise if the injection is not given deep enough.

2. Crying, screaming and fever may occur due to whooping cough component in triple vaccine; these reactions may also occur after vaccines which do not contain the whooping cough component; attacks of high pitched screaming, episodes of pallor, cyanosis, limpness, convulsions as well as local and general reactions have been reported; neurological events including convulsions and encephalopathy may rarely occur after the whooping cough component.

7.9.2 D.T.

Transient fever, headache, malaise and local reactions may occur; a small painless nodule may form at the injection site but usually disappears without sequelae; severe anaphylactic reactions are rare; neurological reactions have been reported occasionally..

7.9.3. aTd

aTd reactions are generally mild and confined to the site of injection. Some inflammation may occur together with transient fever, malaise and irritability. Occasionally a nodule may develop at the site of injection but this is rare.

7.10. Further reading

1. Chin James. *Control of Communicable Disease Manual*, American Public Health Association, Washington DC, 2000.

2. World Health Organization. *The immunological Basis for immunization series, Module 2, Diphtheria,* Global

Programmes for Vaccines and Immunization, WHO/EPI/GEN/93.14 Geneva.

3. World Health Organization. *Pertussis Surveillance,* A Global Meeting Geneva, 10-18 October 2000, Department of Vaccines and Biologicals WHO/V&B/01.19 – Geneva.

4. Department of Pharmacology, University of Colombo, Ministry of Health. *Sri Lanka Hospital Formulary*, 1994.

8. PERTUSSIS (WHOOPING COUGH)

8.1. Introduction

Bordetella pertussis is a pathogenic organism with multiple biological activities. The first phase of pertussis infection is characterized by attachment of *B. pertussis* to the ciliated epithelium of the respiratory tract. The second phase of infection is thought to be the result of toxin(s) secreted by the organism. Recent studies on the immunochemistry of *B. pertussis* have resulted in the isolation and characterization of several biologically active substances which are important in the understanding the pathogenesis of pertussis and the determinants of immunity after disease and vaccination. This knowledge has contributed to the development of acellular pertussis vaccines and to the improvement of the serological diagnosis of pertussis.

Identification

An acute bacterial disease involving the respiratory tract. The initial catarrhal stage has an insidious onset with an irritating cough that gradually becomes paroxysmal, usually within 1-2 weeks, and lasts for 1-2 months or longer. Paroxysms are characterized by repeated violent coughs; each series of paroxysms has many bouts of coughing without intervening inspiration and can be followed by a chracteristic crowing or high-pitched inspiratory whoop. Paroxysms frequently end with the expulsion of clear, tenacious mucus, often followed by vomiting. Infants less than 6 months, adolescents and adults often do not have the typical whoop or cough paroxysm.

Mode of transmission

The mode of transmission is primarily by direct contact with discharge from respiratory mucous membranes of infected persons by the airborne route, probably by droplets, frequently brought home by older siblings and sometimes by a parent.

Incubation period

The incubation period is commonly 6-20 days.

Period of communicability

Highly communicable in the early catarrhal stages. Thereafter, communicability gradually decreases and becomes negligible in about 3 weeks for non-household contacts.

Susceptibility and resistance

Susceptibility of non-immunized individuals is universal. Transplacental immunity in infants has not been demonstrated. One attack usually confers prolonged immunity although second attacks (some of which may be due to B. parapertussis) can occasionally occur.

8.2. Situation in Sri Lanka

Whooping Cough is a notifiable disease in Sri Lanka. According to hospital in-ward statistics, over 1000 cases per year of the disease were reported during the period 1955 to 1975 (Table 1.1). A gradual decrease has been reported since, with 156 hospital admissions in 1999. A small outbreak of whooping cough occurred in the year 1997 (Table 1.2).

Whooping cough outbreak – 1997

Four hundred and five cases of whooping cough were notified during the year 1997. Only 27 cases were notified during the previous year. The majority of the cases in 1997 were notified from the Colombo, Gampaha and Kurunegala districts. The majority of cases were seen in 3-12 months age group.

8.3. Vaccine

Given under diphtheria, D.T.P. (7.3)

8.4. Indications

Given under diphtheria, D.T.P. (7.4)

8.5. Schedule

Given under diphtheria, D.T.P. (7.5)

8.6 Dose and Administration

Given under diphtheria, D.T.P. (7.6)

8.7. Storage

Given under diphtheria, D.T.P. (7.7)

8.8. Cautions and contraindications

Given under diphtheria, D.T.P. (7.8)

Severe reactions which CONTRAINDICATE further doses of DTP – in such cases DT should be used for further vaccination.

- Encephalopathy within 7 days, defined as severe acute neurological illness with prolonged seizures and/or unconsciousness and/or focal signs (but not a simple febrile convulsion).

- Immediate severe allergic or anaphylactic reaction to vaccination with DTP.

8.9. Adverse Events

Given under diphtheria, D.T.P. (7.9)

8.10. Further reading

1. Chin James. *Control of Communicable Disease Manual,* American Public Health Association Washington DC, 2000.
2. Department of Pharmacology, University of Colombo, Ministry of Health. *Sri Lanka Hospital Formulary*, 1994.
3. World Health Organization. *Immunological Basis for Immunization Series, Module 4 – Pertussis*, Global Programme for Vaccines and Immunization WHO/EPI/GEN/93.12 Geneva.

9. POLIOMYELITIS,
(Polioviral fever, Infantile paralysis)

9.1. Introduction

A viral infection is most often recognized by the acute onset of flaccid paralysis. Poliovirus infection occurs in the Gastro Intestinal (GI) tract with spread to the regional nodes, and, in a small percentage of cases, to the nervous system. Flaccid paralysis occurs in less than 1% of poliovirus infections; greater than 90% of infections are inapparent or presents as a non-specific fever. Aseptic meningitis occurs in about 1% of infections. A minor illness is recognized with symptoms including fever, malaise, headache, nausea and vomiting. If the disease progresses to major illness, severe muscle pain and stiffness of the neck and back with or without flaccid paralysis may occur. The paralysis of poliomyelitis is characteristically asymmetric with fever present at the onset. The maximum extent of paralysis is reached in a short period, usually within 3-4 days. The site of paralysis depends on the location of nerve cell destruction in the spinal cord or brain stem. The legs are affected more often than the arms. Paralysis of the muscles of respiration and/or swallowing is life-threatening. Some improvement in paralysis may be seen during convalescence, but any paralysis still present after 60 days is likely to be permanent. Infrequently, further muscle weakness may occur many years after the original infection has been resolved ('post-polio syndrome'); this is not believed to be related to persistence of the virus itself.

Poliomyelitis is an acute illness following gastro-intestinal infection by one of the 3 types of polio virus (the type 1,2,3). Type 1 is isolated from paralytic cases most often, type 3 less so, and type 2 least commonly. Type 1 most frequently causes epidemics. Most vaccine-associated cases are due to type 2 or 3.

Mode of transmission

The mode of transmission is primarily from person to person principally through the faecal-oral route; virus is more easily detectable and for a longer period in faeces than in throat secretions.

Incubation period

Commonly 7-14 days for paralytic cases, with a reported range of 3 to possibly 35 days.

Period of communicability

Even though not precisely defined, transmission is possible as long as the virus is excreted. Poliovirus is demonstrable in throat secretions as early as 36 hours and in the faeces 72 hours after exposure to infection in both clinical and inapparent cases. Virus typically persists in the throat for approximately 1 week and in the faeces for 3-6 weeks or longer. Cases are most infectious during the first few days before and after onset of symptoms.

Susceptibility and resistance

Susceptibility to infection is common but paralysis rarely occurs. The rate of paralysis among infected, non-immune adults is higher than that among non-immunized infants and young children.

9.2. Situation in Sri Lanka

In Sri Lanka, poliomyelitis was made a notifiable disease in the routine reporting system in 1944. During that year, four cases were notified. However, the first major outbreak occurred in 1962, with 1810 cases and 180 deaths. Since then, epidemics occurred in six yearly cycles, but the number of reported cases during each epidemic gradually decreased.

In 1961, administration of Trivalent Oral Polio Vaccine (TOPV) first commenced as a pilot project. During 1962, with the polio outbreak, administration of trivalent oral polio vaccine (TOPV) was introduced as a preventive measure. In 1963 mass immunization with TOPV was introduced island wide. The Expanded Programme on Immunization (EPI) was commenced in 1978. The number of poliomyelitis cases reported has shown a clear downward trend, which is in no doubt due mainly to the steady increase in the immunization coverage of infants and children with TOPV over the years.

As pledged at the World Health Assembly held in 1988, Sri Lanka adopted the following strategies to eradicate polio by the year 2000.

1. Attaining high immunization coverage with at least three doses of TOPV (achieved in Sri Lanka to a great extent)
2. Surveillance of cases of Acute Flaccid Paralysis (AFP).
3. Immunizing children (under 5 years, under 10 years living in welfare centres and slums) with two extra doses of OPV one month apart in high- risk areas.
4. Conducting National Immunization Days (NIDs).
5. Conducting Sub-National Immunization Days (SNIDs) followed by "mopping up" immunization.

An Expert Committee to review cases of AFP was formed in December 1992, and the first meeting was held on 7th April 1993. The cases discussed by the committee are those in which a diagnosis of polio cannot be ruled out. During 1993 all such cases reported during 1992 were reviewed along with those reported in 1993.

From 1998 Sri Lanka resorted to the virological classification scheme. From 1993 onwards, all AFP cases where two timely "good" samples of stools had been collected and found negative for polio virus have been discarded. The others are reviewed by the polio expert committee.

A National Committee for Certification of Polio Eradication (NCCPE) was formed in 1998. This committee had regular formal meetings with the Epidemiologist and D/MRI. Consultative meetings with the polio expert committee were also held.

The last virologically confirmed case of polio was detected in Sri Lanka in 1993. This case was a child in a family of poor social economic status in the vicinity of a highly venerated religious site at Kataragama. This area is in the DPDHS division of Moneragala. This female child was 2 years old at the time of onset of the illness and had received only two doses of OPV when she should have had four doses. She has had few sessions of physiotherapy on discharge from hospital, and had discontinued it due to difficulty of travel. She was attending school in 1998 and the mother complained that she is reluctant to attend school as she falls down often due to the wasted and shortened lower limb.

Since 1993 no cases has been detected despite intense surveillance. High immunization coverage has been maintained over a decade. However, the polio-free situation in the country now depends to a great extent on the polio situation of the neighbouring countries.

9.3. Vaccine

The vaccine used in the National EPI programme is the Live Attenuated Oral Poliomyelitis Vaccine (Sabin) attenuated polio virus types 1,2, and 3, grown in kidney tissue cultures and stabilized with magnesium chloride.

The concentration of virus types 1,2 and 3 are as follows: Not less than 1,000,000 $TCID_{50}$ (10^5) of type 1,100,000 (10^5) $TCID_{50}$ of type 2, and 600,000 ($10^{5.8}$) of type 3 of polio virus per single human dose of trivalent OPV. (EPI Global Advisory Group Recommendation – EPI 1991).

9.4. Indications

1. Primary and booster immunization of infants and children (see immunization schedule).
2. Immunization of infants and children in NIDs and S-NIDs.
3. “Mopping up” immunization.
4. Outbreak response immunization.

OPV can be safely and effectively given simultaneously with DPT, DT, TT, BCG, Measles, Rubella, Hepatitis B and Yellow Fever Vaccine.

9.5. Schedule

See Immunization schedule.

9.6. Dose and Administration

The dose consists of two drops (0.1 ml). OPV is to be administered exclusively by the oral route. Two drops of vaccine is dropped from the dropper-dispenser directly into the mouth according to the instructions given in the leaflet supplied with the vaccine. The doses

should be repeated if the vaccine is regurgitated; depending on the manufacturer sometimes 3 or even 4 drops are recommended.

9.7. Storage

The vaccine should be stored at minus 20°C (-20°C) in the freezing compartment of the refrigerator.

9.8. Cautions and contraindications

Vaccination is contraindicated in subjects affected by alterations of the immune system (agammaglobulinemia, hypogamaglobulinemia, combined humoral or cell mediated immunodeficiency).

Mild diarrhoea is not a contraindication. These children should be given an additional dose when the chid recover from that diarrhoea episode.

Vaccination should be deferred in the case of acute febrile illness, moderate to severe diarrhoea or treatment with immunosuppressive drugs.

According to the recommendation of the WHO, in subjects affected by symptomatic or asymptomatic HIV, the vaccine can be administered according to the standard schedule.

9.9. Adverse Events

Live, oral sabin poliomyelitis vaccine does not normally induce general or local reactions and the risk of complications is low. Cases of paralytic disease have been very rarely reported even in persons in direct contact with vaccinees (fewer than one case for every 3 million doses administered). Diarrhoea, allergic exanthema and polyneuritis may rarely occur.

9.10. Further reading

1. Chin James. *Control of Communicable Disease Manual*, American Public Health Association Washington DC, 2000.

2. World Health Organization. *The Immunological Basis for Immunization Series, Module 6 – Poliomyelitis,* Global Programme for Vaccines and Immunization WHO/EPI/GEN/93.16 Geneva.

3. World Health Organization. *New Polio Vaccines for the Post-eradication era,* Department of Vaccines and Biologicals WHO/V&B/00.20 Geneva.

POLIOMYEL

10. MEASLES

10.1. Introduction

Measles is an ubiquitous, highly infectious disease affecting nearly every person in a given population by the time of adolescence, in the absence of immunization programmes (*Black 1982*). Measles is transmitted primarily from person-to-person by large respiratory droplets (*Black 1982),* but can also spread by the airborne route as aerosolised droplet nuclei (*Bloch et al. 1985*). Measles is most infectious during the prodrome. First there is localized infection of the respiratory epithelium of the nasopharynx and possibly the conjunctivae, with spread to regional lymphatics. Primary viraemia occurs 2 to 3 days following exposure, and an intense secondary viraemia occurs 3 to 4 days later. The secondary viraemia leads to infection of and further replication in the skin, conjunctivae, respiratory tract and other distant organs. The amount of virus in blood and infected tissues peaks 11 to 14 days after exposure and then falls off rapidly over the next 2 to 3 days.

These events correspond with an incubation period of 10 to 12 days between exposure and the onset of symptoms. The prodomal period then begins with fever, malaise, conjunctivitis, coryza, and tracheobronchitis. Koplik spots appear on the buccal mucosa 1 to 2 days before onset of rash and may be detected for an additional 1 to 2 days. The rash is an erythematous maculopapular eruption which usually appears 14 days after exposure and spreads from the head to the extremities over a 3 to 4 day period. Over the next 3 to 4 days, the rash fades; in severe cases desquamation may occur. Other constitutional signs and symptoms, such as anorexia, diarrhoea and generalized lymphadenopathy may also be present (*Preblud & Katz 1988*).

Mode of transmission

Measles virus is a member of the genus Morbillivirus of the family paramyxoviridae. Mode of transmission is by airborne droplet spread, direct contact with nasal or throat secretions of infected persons, and less commonly, by articles freshly soiled with nose and throat secretions. Measles is one of the most highly communicable infectious

diseases, and a herd immunity of ≥ 94% may be needed to interrupt community transmission.

Incubation period

Incubation period is about 10 days, varying from 7 to 18 days following exposure to onset of fever, usually is 14 days. Rarely it could be as long as 19-21 days.

Period of communicability

Period of communicability is from slightly before the beginning of the prodromal period to 4 days after appearance of the rash; minimal after the 2nd day of rash.

Susceptibility and resistance

All persons who have not had the disease or who have not been successfully immunized are susceptible. Acquired immunity after illness is permanent. Infants born to mothers who have had the disease are immune during the first 6-9 months or more depending on the amount of residual maternal antibody at the time of pregnancy and the rate of antibody degeneration. Immunization at 15 months produce immunity in 95-98% of recipients; re-immunization may increase immunity levels as high as 99%.

10.2. Situation in Sri Lanka

Measles is a highly infectious disease, which primarily affects the respiratory tract. It is an important childhood disease in Sri Lanka. According to the hospital in-ward statistics available at the Medical Statistical Unit, the annual incidence of measles in Sri Lanka during the period from 1951 to 1960 varied from about 20 to 47 cases per 100,000 population. In the periods 1961 to 1970 and 1971 to 1980, the incidence varied from 18 to 38 and 12 to 49 per 100,000 population respectively (Table 1.1 and 1.2).

In the year 1982 the reported number of measles cases increased to 13,273 (87 cases per 100,000 population). One of the factors for this high increase is due to special surveillance activities carried out before embarking on introducing measles vaccine. However, after the introduction of measles immunization to the Expanded Programme on Immunization in 1984/85, the incidence of measles gradually

decreased and in the year 1998 only 263 cases were reported from government hospitals (0.5 per 100,000 population). However, a small outbreak of measles was reported in the year 1990. In that year 4004 cases of the disease were reported, with an incidence of 27.6 per 100,000 population.

The outbreak occurred from September 1999 to May 2000, peaking in February 2000, with 1378 cases being notified during the 2nd week of February. The initial increase of cases was noted from the Colombo district, which then spread to the rest of the country. The highest rate of notifications was received from the Moneragala district (227 per 100,000 total population). Of the clinically confirmed cases, nearly 54% were 15 years of age and above, while the highest age specific morbidity rate was seen in the under 1 year age group. Forty percent of the cases were vaccinated. The cumulative percentage of children and adolescents without immunization was seen to increase over several years, and approximated a birth cohort in 1999.

10.3. Vaccine

Measles vaccine, live, attenuated freeze dried is prepared from the Edmonston Strain measles virus which has been further attenuated by twenty two passages on human diploid cell (HDC) and is known as the Edmonston-Zagreb strain. This strain of vaccine is used in the EPI programme at present in Sri Lanka.

10.4. Indications

For active immunization against measles. A single dose of measles is sufficient to provide prolonged immunity to infection. The vaccine can also be administered to children and adolescents who have been vaccinated before or have had measles infection earlier.

All infants should be vaccinated against measles as soon as they complete 9 months.

Vaccination of contacts in an outbreak

As measles vaccine-induced measles antibody develops more rapidly than that following natural infection, measles vaccine can be used to protect susceptible contacts during a measles outbreak. To be effective, the vaccine must be administered within 3 days of exposure.

10.5. Schedule

All infants as soon as they complete 9 months.

See immunization schedule.

Two dose schedule

A two-dose immunization schedule is used in two situations:

- When the first dose must be given at an age at which sero-conversion is known to be suboptimal because the risk of early measles morbidity and mortality is high (for example, refugee camps, during outbreaks);
- In countries with measles elimination goals, this schedule is used to help achieve very high levels (approximately 98%) of herd immunity.

10.6 Dose and Administration

The vaccine should be reconstituted only with the diluent supplied using a sterile syringe and needle. After reconstitution, the vaccine should be used immediately. A single dose of 0.5 ml should be administered by deep subcutaneous injection into the upper arm. If the vaccine is not used immediately, then it should be stored in the dark at 2^{o}-8^{o}C for no longer than 8 hours.

10.7. Storage

It is important to protect both the Lyophilized and reconstituted vaccine from light. The vaccine should be stored in the dark at +2^{o}C to +8^{o}C. For long term storage, a temperature at –20^{o}C is recommended for the vaccine. The diluent should not be frozen but should be kept cool.

10.8. Cautions and contraindications

The general contraindications discussed in section 4.2, 4.3 and 4.4.

Measles virus inhibits the response to tuberculin, so tuberculin-positive individuals may become tuberculin-negative for up to a month after measles infection or immunization. As the measles virus may cause exacerbation of tuberculosis, such patients should be under treatment when immunized.

If the live measles vaccine is produced in chick embryo cell culture and contains neomycin as preservative, the vaccine is contraindicated in individuals with a history of allergy to neomycin and genuine severe egg allergy.

10.9. Adverse Events

These are few when compared with the incidence of complications of natural measles. The most common reactions are malaise and fever, with or without rash, occurring 10-15 days after vaccination; these seldom last more than 48 hours. Febrile convulsions may occur in a very small proportion of children. Encephalitis is a rare complication of measles vaccination. Allergic reactions may occur occasionally.

Reactions are generally mild. A small increase in temperature (37^{o}C) may occur in 5-6% of vaccines and a slight rash may be noticed in 1-2%.

10.10. Further Reading

1. Chin James. *Control of Communicable Disease Manual,* American Public Health Association Washington DC, 2000.

2. World Health Organization. *The Immunological Basis for Immunization Series, Module 7 – Measles,* Global Programme for Vaccines and Immunization WHO/EPI/GEN/93.17 Geneva.

3. Bhargava Indra. *Control of Measles Mumps and Rubella,* BI Churchill Livingstone Pvt. Ltd. New Delhi, 1996.

11. Rubella

11.1. Introduction

Rubella is a mild febrile viral disease with a diffuse punctate and maculopapular rash sometimes resembling that of measles or scarlet fever. Children usually present few or no constitutional symptoms, but adults may experience a 1-5 day prodromal symptoms consisting of low-grade fever, headache, malaise, mild coryza and conjunctivitis. Postauricular, occipital and posterior cervical lymphadenopathy is the most characteristic clinical feature which precedes the onset of rash by 5-10 days. Up to half the infections occur without recognized rash. Leukopenia is common and thrombocytopenia can occur, but hemorrhagic manifestations are rare. Arthralgia and less commonly, arthritis, complicate a substantial proportion of infections, particularly among adult females. Encephalitis and thrombocytopenia are rare complications in children. Encephalitis occurs more frequently in adults.

Rubella is important because of its ability to produce anomalies in the developing foetus. Congenital rubella syndrome (CRS) occurs in up to 90% of infants born to women who acquired confirmed rubella during the first trimester of pregnancy; the risk of a single congenital defect falls to approximately 10% - 20% by the 16th week, and defects are rare when the maternal infections occur after the 20th week of gestation.

Mode of transmission

The infectious agent of rubella is the rubella virus (family togaviridae: genus rubivirus) in naso-pharyngeal secretions of infected people. Infection is by droplet spread or direct contact with patients. In closed environments such as among military recruits, all exposed susceptibles may be infected. Infants with CRS shed large quantities of virus in their pharyngeal secretions and in urine, and serve as a source of infection to their contacts.

Incubation period

Sixteen to eighteen days with a range of 14-23 days.

Period of communicability

For about 1 week before and at least 4 days after onset of rash; highly communicable. Infants with CRS may shed virus for months after birth.

Susceptibility and resistance

A baby will be susceptible to rubella infection after loss of transplacentally acquired maternal antibodies. Active immunity is acquired by natural infection or by immunization; it is usually permanent after natural infection and thought to be lifelong after immunization, but this may depend on contact with endemic cases. In the USA, about 10% of the general population remains susceptible. Infants born to immune mothers are ordinarily protected for 6-9 months, depending on the amount of maternal antibodies acquired transplacentally

11.2. Situation in Sri Lanka

Incidence of rubella is given in Table I. An epidemic of rubella occurred in Sri Lanka during 1994 and 1995.

A postal survey done in 1994 among 71 paediatricians with a 69% response rate, reported that there were 275 cases of congenital rubella syndrome. A further 169 cases were reported in the first four months of 1995.

Based on available information on rubella infection and congenital rubella syndrome, the National Advisory Committee on Communicable Diseases of Sri Lanka decided to introduce rubella vaccine into the routine immunization programme. Vaccination against rubella commenced in 1996 on a phased basis and was implemented island-wide in 1997. The main objective of the rubella vaccination program is to prevent congenital rubella syndrome. The target groups for immunization are 10-15 years old school girls and women between 15-44 years who have child bearing potential.

The present objective of the rubella immunization programme is to control morbidity and mortality due to congenital rubella syndrome and morbidity due to rubella infection (in children and adults).

11.3. Vaccine

Rubella vaccine, live, attenuated (freeze dried) is prepared using Wistar RA 27/3 strain rubella vaccine virus. This vaccine is propagated on human diploid cells (HDC). The vaccine is lyophilized and is provided with a diluent.

Each single dose, when reconstituted in a volume of 0.5 ml., contains not less than 1000 CCID50 of live virus particles.

11.4. Indications

The principal aim of rubella vaccination is to prevent congenital rubella syndrome by stopping the circulation of rubella virus in the community. A history of rubella does not contraindicate vaccination. No untoward effects will be caused by vaccinating individuals who have been infected by rubella because of the unreliability of diagnosis.

All females between the ages 10-15 years. All eligible females between 15 and 44 years of age who have not been immunized earlier. Male and female completing 8 years of age (commenced as an interim measure from September 2001).

11.5. Schedule

See immunization schedule.

11.6. Dose and Administration

The vaccine should be reconstituted only with the diluent supplied using a sterile syringe and needle. After reconstitution the vaccine should be used immediately. A single dose of 0.5 ml should be administered by deep subcutaneous injection into the upper arm.

11.7. Storage

The vaccine should be stored in a dark cool place at a temperature between +2°C to +8°C. For long term storage, a temperature of +2°C to +8°C is recommended for the vaccine. The diluent should not be frozen, but should be kept cool.

11.8. Cautions and contraindications

General contraindications given in 4.2, 4.3 and 4.4.

Do not administer the vaccine during pregnancy; and advise vaccinees not to conceive for two months following vaccination.

11.9. Adverse Events

Burning and/or stinging of short duration at the injection site have been reported. Local pain, wheal and flare, induration and erythema may occur at the site of injection.

Mild local reactions such as induration, urticaria rash, malaise, sore throat, fever, headache dizziness, nausea, vomiting, diarrhoea, regional lymphadenopathy, polyneuritis and arthralgia and/or arthritis may occur. Cough and rhinitis have also been reported. Reactions are usually mild and transient. Moderate fever (101-102.9°F) occurs occasionally and high fever over 103°F occurs less commonly.

11.10.1. Measles Rubella

Given under measles and rubella.

Mode of transmission

Given under measles and rubella.

Incubation period

Given under measles and rubella.

Period of communicability

Given under measles and rubella.

Susceptibility and resistance

11.10.2. Situation in Sri Lanka

Given under measles and rubella.

11.10.3. Measles/Rubella Vaccine

Measles-Rubella (MR)virus vaccine, live, USP (freeze dried).

The vaccine is prepared from the live attenuated strains of Edmonston-Zagreb measles virus and Wistar RA 27/3 rubella virus. Both measles and rubella viruses are propergated in human diploid cells (HDC). The vaccine is lyophilized and is provided with diluent.

Each single human dose when reconstituted in a volume of 0.5 ml. contains not less than 1000 CCID50 of measles virus and 1000 CCID50 of rubella virus.

11.10.4. Indications

One dose for all children on completion of 3 years of age.

For active immunization against measles and rubella in infants, children, adolescents and young adults at risk.

11.10.5. Schedule

A single dose of measles-rubella vaccine should be administered to all children on completion of 3 years of age.

Refer immunization schedule.

11.10.6. Dose and Administration

A single dose of 0.5 ml is given by deep subcutaneous injection. The lyophilized vaccine should be reconstituted with the diluent supplied by the manufacturer and should be used immediately after reconstitution. If the vaccine is not used immediately, then it should be stored in a flask at +2^{o}C to +8^{o}C for no longer than 8 hours.

Administration with other vaccines

The vaccine can be safely and effectively given simultaneously with DPT, DT, TT, BCG and Polio (OPV and IPV) Hepatitis B and yellow fever vaccines.

11.10.7. Storage

Measles-Rubella vaccine should be stored in the dark at a temperature between +2^{o}C to +8^{o}C, for long term storage, a temperature of –20^{o}C is recommended for the vaccine. The diluent should not be frozen, but should be kept cool. It is important to protect both the lyophilised and reconstituted vaccine from light.

11.10.8. Cautions and contraindications

Given under measles and rubella.

11.10.9. Adverse events

Reactions are generally mild. An increase in temperature (average 37.9^{o}C) may occur in less than 8% of vaccinees and a slight rash may develop between 6-14 days after vaccination in 1-2%. Similarly there may also be a slight enlargement of cervical and occipital lymph nodes.

11.11. Further reading

1. Chin James. *Control of Communicable Disease Manual,* American Public Health Association Washington DC, 2000.

2. World Health Organization. *The Immunological Basis for Immunization Series, Module 7 – Measles,* Global Programme for Vaccines and Immunization WHO/EPI/GEN/93.17 Geneva.

3. World Health Organization. Rubella Vaccines WHO Position paper, *Weekly Epidemiological Record,* No.20 2000-75, 161-192.

PART IV.

OTHER VACCINES THAT CAN BE USED AS A PART OF EPI

Part IV. OTHER VACCINES THAT CAN BE USED AS A PART OF EPI

12. JAPANESE ENCEPHALITIS (J.E.)

12.1. Introduction

Japanese Encephalitis has been reported in the South-East Asia and Western Pacific regions for a long time with epidemics mainly in Japan, Korea and some provinces of Taiwan. During the last decade, outbreaks of the disease have extended to some parts of Thailand, Burma, India, Nepal and Sri Lanka. For the first time, J.E. cases were reported from Australia in 1995.

It is a disease of public health importance in many Asian countries. Approximately 50,000 cases of J.E. with 15,000 deaths are estimated to occur annually. This disease primarily occurs in children. Approximately 25 percent of cases die and 50 percent develop permanent neurologic and psychiatric sequelae. The magnitude of the problem is even greater because the disease often occurs in epidemics that are somewhat predictable and that J.E. is a vaccine preventable disease.

Mode of transmission

Japanese Encephalitis (J.E.) is an infection of the central nervous system caused by a virus transmitted to man through mosquitoes. The Japanese Encephalitis virus was first isolated in Japan in 1935 from the brain of a patient dying from encephalitis. The virus is transmitted in an enzootic cycle among mosquitoes and vertebrate amplifying hosts, chiefly domestic pigs and wading birds. Culex mosquitoes, primarily Cx. tritaeniorhynchus and Cx. gelidus are the principal vectors.

12.2. Japanese Encephalitis (J.E.) in Sri Lanka

Japanese Encephalitis virus was first isolated in Sri Lanka in 1968. The isolation was done at the Medical Research Institute, Colombo. Since then J.E. cases have been identified from various parts of the country. The disease is considered as endemic in certain parts of the country.

In the dry zone, the disease was reported mainly from areas where paddy cultivation is being done, while in the wet zone it was reported from areas where pig breeding and coir products are done as cottage industries. The vector mosquitoes were also frequently identified in these areas.

Up to 1984, there were no major outbreaks reported in Sri Lanka. The first major outbreak of J.E. was reported in 1984/85 (November 1984 to February 1985) in the Anuradhapura district in the North Central Province. In 1985, 441 cases of J.E. and 66 deaths were reported to the Epidemiological Unit, Ministry of Health. In 1987, 766 cases of J.E. and 138 deaths were reported to the Epidemiological Unit. This was the largest outbreak of J.E. that occurred in Sri Lanka. This outbreak started in the Anuradhapura district and later spread to the Polonnaruwa, Kurunegala and Puttalam districts. Before the main J.E. outbreak in 1998, control measures carried out in Sri Lanka were vector control. After the 1987 outbreak, the Ministry of Health decided to immunize children in high risk areas against J.E. during the inter epidemic periods.

In 1988, 409,888 doses of J.E. vaccine were administered to children between 1-10 years of age in Anuradhapura, Polonnaruwa, Kurunegala and Puttalam DPDHS/RDHS divisions.

The disease occurs throughout the year. It shows a marked increase with the north-east monsoonal rains (November to February) as a result of increased mosquito breeding, due to water logging of rice-fields and ground pools. Man-mosquito contact is observed to be high when adult insect densities build up to a maximum during this period.

A progressive decrease in the number of JE cases reported was seen since 1996, and 1999 recorded the lowest incidence of JE for the past 15 years. Number of cases, morbidity rates, deaths and case fatality rates of J.E. reported from 1985 to 1999 are given in Table 1.

12.3. Vaccine

1. Japanese Encephalitis vaccine – Nakayama strain.
2. Japanese Encephalitis vaccine – Beijing strain.

Both Nakayama and Beijing strain vaccines in liquid and freeze dried forms have been used in the National J.E. Immunization Programme in Sri Lanka.

Japanese Encephalitis Beijing strain liquid vaccine is now used in the National J.E. Immunization Programme in Sri Lanka.

Japanese Encephalitis Vaccine "SEIKEN" is a colourless to slightly turbid liquid preparation containing inactivated Japanese encephalitis virus.

12.4. Indications

Prevention of infections caused by Japanese Encephalitis virus.

12.5. Schedule

Given under 12.6

12.6. Dosage and Administration with Beijing strain vaccine

Primary Immunization: Two subcutaneous injections of 0.5 ml (1-3 years of age - 0.25 ml) are given at a 1-4 week interval.

Booster Immunization*:* A single subcutaneous injection of 0.5 ml (1-3 years of age - 0.25 ml) is administered about 1 year after the completion of the primary immunization. Further booster immunizations are given at the first sign of a local epidemic or every 4-5 years in order to maintain protective antibody levels.

12.7. Storage

The instructions on the product leaflet should be followed. The rule for most vaccines is that they should be refrigerated at +2°C to +8°C and NOT FROZEN.

12.8. Cautions and contraindications

General contraindications are given in sections 4.2, 4.3 and 4.4.
At the time of vaccine,

1. fever;
2. a serious illness;
3. experience of anaphylactic shock to any of the vaccine components in the past and also the reasons given below are considered as contraindications.

- Fever or allergic reaction, such as rash etc., within two days of a previous vaccination.
- A convulsion within the last one year.
- Immunodeficiency states.
- A person who is likely to experience an allergic reaction to any of the vaccine components.

Generalized urticaria may occur from several minutes to 9 days after the administration of the vaccine. It is particularly important that adrenaline is immediately available when administering Japanese Encephalitis vaccine. Individuals should be observed at the immunization facility for 30 minutes after receiving a dose. Vaccinees should be told to seek medical attention immediately upon onset of any reaction.

12.9 Adverse Events

Local induration, redness and tenderness are common. Systemic adverse reactions such as fever, headache, malaise, rash, dizziness, myalgia, nausea and vomiting have been reported in 10% of recipients. From 1989 to 1994 several countries reported adverse events characterized by urticaria, angio-oedema, hypotension and collapse. Most of these adverse reactions occurred 12 hours after the administration of a dose. They were more frequent after the 2nd or 3rd dose, and 88% occurred within 3 days of vaccination.

These reactions appear to be more common in those with a previous history of urticaria.

12.10. Further reading

1. Chin James. *Control of Communicable Disease Manual,* American Public Health Association Washington DC, 2000.

2. Vaughn David W & Hoke Charies H J. The Epidemiology of Japanese Encephalitis, *Epidemiologic Reviews* John Hopkins, University School of Hygiene and Public Health, Vol: 14, 1992, 197-221.

3. Igarashi Akira. Epidemiology and control of Japanese Encephalitis *World Health Statistics Quarter* 45 – 1992, 299-305.

4. World Health Organization. Japanese Encephalitis, *WHO intercountry symposium on prevention and control of selected communicable diseases with epidemic proportion,* SEARO New Delhi, 3-7 June 1996

5. World Health Organization. Japanese Encephalitis and Haemorrhagic Fever with Renal Syndrome *WHO Bulletin* Vol: 2, December 1987.

6. Plotkin Stanley A, Orensteiu Walter A. Vaccines for Special Risk Groups and Selected Geographical Areas *Vaccines* 3rd Edition 1999.

7. Epidemiology Unit, Sri Lanka. Adverse reactions to Japanese Encephalitis Vaccines – 1994. *Weekly Epidemiological Report Sri Lanka* Vol: 23, No. 9, 1995.

8. Centers for Disease Control and Prevention. Inactivated Japanese Encephalitis Vaccine *Recommendations of the Advisory Committee on Immunization Practices* Vol: 42, No. RR-1, Jan. 1993. CDC Atlanta, Georgia

13. HEPATITIS B

13.1. Introduction

Hepatitis B is a major public health problem worldwide. Approximately 30% of the world's population, or about 2 billion persons, have serologic evidence of hepatitis B virus (HBV) infection (Kane, 1993). Of these, an estimated 350 million have chronic HBV infection and at least one million chronically infected persons die each year from chronic liver disease, including cirrhosis and liver cancer. HBV is second only to tobacco as a known human carcinogen.

Hepatitis B virus is a 42-nm, double-shelled deoxyribonucleic acid (DNA) virus of the class Hepadnaviridae.

Infection with HBV can cause both short-term (acute) disease and long-term (chronic) disease.

Acute Hepatitis B

The clinical course of acute hepatitis B is indistinguishable from that of other types of acute viral hepatitis and the onset of acute disease is generally insidious. Clinical symptoms and signs when they occur include anorexia, malaise, nausea, vomiting, abdominal pain, and jaundice (yellow skin or eyes). Extrahepatic manifestations can also occur including skin rashes, arthralgia, and arthritis. The case-fatality rate with acute hepatitis is approximately 1-2%.

Chronic HBV infection

Most of the serious sequelae associated with HBV infection occur in persons who develop chronic infection. Persons with chronic HBV infection are often asymptomatic for decades after infection; however, these persons are at high risk of developing chronic hepatitis. In addition, the risk of death from HBV-related liver cancer or cirrhosis (scarring of the liver) is approximately 25% for persons who become chronically infected during childhood and approximately 15% for persons who become chronically infected at an older age (Margolis, et al, 1995). HBV infections can occur at any age.

The outcome of HBV infection varies substantially depending on the age at which infection occurs. Among children under 5 years who

become infected, fewer than 10% have signs or symptoms of acute disease; however, chronic infection develops in 80%-90% of infants infected during the first year of life, and 30%-50% of children infected between 1-4 years of age (McMahon, et al, 1985). By comparison, 30%-50% of adults who become infected with HBV are symptomatic, but only 2%-6% develop chronic infection.

Mode of transmission

Hepatitis B virus can be transmitted by either percutaneous or mucosal exposure to blood or other infectious body fluids. The virus is found in highest concentrations in blood and serous exudates (as high as 10^{10} virions/ml); 10 to 1090 times lower concentrations are found in various body secretions, including saliva, semen and vaginal fluid (Margolis, et al, 1995).

The primary routes of HBV transmission are:

- Perinatal (from mother to baby at birth);
- Child to child;
- From unsafe injections and transfusions;
- Sexual contact.

Among infants, perinatal transmission from HBV-infected (HBsAg-positive) mothers is the primary route of transmission. During childhood, child-to-child transmission and transmission from unsafe injections and transfusions account for most infections. Sexual contact is the primary route of transmission among adolescents and adults. In addition, these older age groups are at risk of transmission from unsafe injections and transfusions.

Incubation period

The incubation period ranges from 45-160 days (mean, 120 days).

13.2. Situation in Sri Lanka

Morbidity and mortality data on hepatitis (all hepatitis) for the years 1996 – 1998 is given below.

Cases and deaths due to viral hepatitis from 1990 to 1999

Year	Cases	Deaths
1990	5,926	56
1991	3,227	57
1992	12,674	52
1993	9,938	53
1994	8,348	40
1995	6,370	25
1996	3,812	12
1997	5,051	10
1998	4,247	8
1999	5,016	25

Source: Medical Statistician

Hepatitis B and Hepatitis B Vaccination in Sri Lanka

Hepatitis B Disease Burden

1. Seroprevalence Surveys

Sri Lanka is considered a country of low to moderate hepatitis B disease burden, with a prevalence of HBsAg of <1% to 2.5% in the general population. Most of the seroprevalence studies were conducted in the western and southern provinces, and some data is available from the northern and eastern provinces. There are no statistics on the prevalence of HBeAg among HBsAg-positive persons.

Among more than 50,000 blood donors, the prevalence of HBsAg was 0.1%. This low prevalence is related to the rigorous pre-donation screening procedure to exclude persons at risk for being HBV-infected. In a large community-based study in Gampaha district conducted in the early 1990's, the prevalence of HBsAg was 2.5% (95% confidence intervals: 2.0% to 3.0%).

HEPATITIS B

13.3. Vaccine

Two types of hepatitis B vaccine are available:

- Plasma-derived vaccines are prepared from purified HBsAg from the plasma of persons with chronic HBV infection.

- Recombinant or genetically engineered vaccines are produced, using HBsAg synthesized in yeast (Saccharomyces cerevisae) or in mammalian cells into which the HBsAg gene has been inserted.

There are no significant differences in safety, immunogenicity, or efficacy between these types of hepatitis B vaccines.

13.3.1. Formulations

Hepatitis B vaccine is available in both monovalent formulations that protect only against hepatitis B and combination formulations that protect against hepatitis B and other diseases.

Monovalent hepatitis B vaccines:

- Can be used for any dose in the hepatitis B vaccination schedule;
- MUST BE USED for vaccination at birth.

Combination vaccines that incorporate hepatitis B vaccine:

- Can be used at any time if ALL antigens in the vaccine are indicated;
- CANNOT BE USED before 6 weeks of age (primarily because DTP and Hib immunogenicity are reduced if given before this age); thus, these vaccines CANNOT BE USED to administer the birth dose of hepatitis B vaccine.

13.3.2. Interchangability

Types and formulations of hepatitis B vaccines can be interchanged. Therefore, vaccines from different manufacturers could be used for each dose that a child receives.

13.3.3. Presentation

Hepatitis B vaccines are available in liquid single-dose and multi-dose glass vials. Multi-dose vials generally contain 2,6 or 10 doses of vaccine.

13.4. Indications

Pre-exposure immunization

Hepatitis B vaccine induces protective levels of antibody to HBsAg (anti-HBs) in >95% of vaccinated infants and children. Children who respond to hepatitis B vaccine are protected against acute hepatitis B as well as against the chronic consequences of HBV infection, including cirrhosis and liver cancer.

Post-exposure immunization

Post exposure immunization at birth is highly effective in preventing neonatal infections in infants of HBV-infected mothers. More than 90% of perinatal HBV infections can be prevented if infants of HBV-infected mothers are given the hepatitis B immunization series soon after birth. Optimum efficacy is achieved when the vaccine is administered within 24 hours after birth. There is no evidence of protection if the first dose of vaccine is given >7 days after birth. The efficacy of active immunization with recombinant hepatitis B vaccines alone and passive-active vaccination with hepatitis B immune globulin (HBIG) and hepatitis B vaccine has been found to be essentially equivalent. Thus, use of HBIG is not necessary, particularly in countries where pregnant women are not screened for HBsAg.

13.5. Schedule

Hepatitis B immunization should be introduced as an integral part of the existing childhood immunization schedule. Hepatitis B vaccine schedules are very flexible thus, there are multiple options for adding the vaccine to existing national immunization schedules without requiring additional visits for vaccination.

Hepatitis B vaccine is usually given to children as either a three-dose or a four-dose series; at least three doses are needed to ensure long-term protection. Three-dose schedules may be used with either monovalent hepatitis B vaccines or combination vaccines. A four-dose schedule is acceptable in countries where a birth dose of monovalent hepatitis B vaccine is given, followed by three doses of a combination vaccine.

Long term protection and booster doses

A number of cohort studies have shown that persons vaccinated as infants, children, or adults, with a 3-dose immunization series retain protection from HBV infection for as long as 15 years (Hadler et al, 1992; Harpaz et al, 2000). Immunized persons remain protected from acute disease and chronic infection, even if they lose detectable anti-HBs, and booster doses of vaccine are not recommended.

13.6. Dosage and Administration

The standard paediatric dose is 0.5 ml. (However the dose can vary with the manufacturer).

Hepatitis B vaccine is administered by intramuscular injection in the anterolateral aspect of the thigh (infants) or deltoid muscle (older children). It can safely be given at the same time as other vaccines, such as DTP, polio, Hib, measles, BCG, and yellow fever vaccines. If hepatitis B vaccine is given on the same day as another vaccine, it should not be given on the same limb to avoid overlapping local reactions.

The injection equipment for hepatitis B vaccine is the same type as that for DTP:

- 1.0 or 0.5 ml. syringe;
- 25 mm, 22 or 23 gauge needle.

13.7. Storage

The storage temperature for hepatitis B vaccine is the same as for DTP vaccine, between +2°C to +8°C.

HEPATITIS B VACCINE SHOULD NEVER BE FROZEN. Freezing hepatitis B vaccine causes the HBsAg protein to disassociate from the alum adjuvent and thus lose its immunogenicity/potency.

Shelf life

The shelf life of hepatitis B vaccine should be a minimum of 3 years from the date of manufacture if stored between +2°C and +8°C. The package insert should be consulted for the manufacturer's recommended shelf life for each specific vaccine.

13.8. Cautions and contraindications

There are very few reasons to withhold or postpone administration of hepatitis B vaccine. Too often immunizations are delayed or denied because of conditions falsely believed by health care workers to be contraindications for administering the vaccine.

Contraindications to hepatitis B vaccine administration include the following:

- **Severe allergic reaction to a previous dose of hepatitis B vaccine**. A child with a history of a severe allergic reaction (e.g. generalized urticaria, difficulty in breathing, swelling of the mouth and throat, hypotension, shock) to a prior dose of hepatitis B vaccine should not receive another dose (from the same manufacturer).

- Severe allergic reaction to baker's yeast (the kind used in making bread). Children with a history of a severe allergic reaction to baker's yeast should not receive formulations of hepatitis B vaccine prepared in yeast cells. These children may receive plasma-derived hepatitis B vaccine.

The following are NOT contraindications for administering hepatitis B vaccine.

- Any minor illness such as respiratory tract infection or diarrhoea with temperature below 38.5^{o}C.
- Allergy or asthma
- Family history of convulsions
- Treatment with antibiotics
- Infection with human immunodeficiency virus (HIV)
- Breastfeeding
- History of seizures (convulsions, fits)
- Chronic illnesses such as chronic diseases of the heart, lung, kidney or liver
- Stable neurological condition such as cerebral palsy and Down's Syndrome
- Prematurity or low birthweight
- History of jaundice at birth

Hepatitis B vaccine will only protect against hepatitis B, and will not protect against other types of hepatitis.

More than 95% of children develop protective antibody after three doses of hepatitis B vaccine. However, a small percentage of children will not be protected after vaccination.

Limitations

Hepatits B vaccine will only protect against Hepatitis B and will not protect other types of Hepatitis.

More than 95% of children develop protective antibody after three doses of hepatitis B vaccine. However, a small percentage of children will not be protected after vaccination.

13.9. Adverse events

Hepatitis B vaccine is very safe

The most common side effects that may occur after vaccination are soreness at the injection site, which has been reported in 3%-9% of children. Mild transient systemic symptoms including fatigue, headache, and irritability have also been reported in 8%-18% of children, and low-grade fever (>37.7oC) has been reported in 0.4%-8% of children. These transient signs/symptoms usually occur within 1 day after the vaccine is given and lasts for 1 to 3 days. When given at the same time as DTP vaccine, the rate of fever and/or irritability is no higher than when DTP vaccine alone is given.

Administration of hepatitis B vaccine soon after birth has not been associated with an increased rate of elevated temperatures that require extensive medical evaluation.

Serious allergic reactions to the vaccine (hives, difficulty in breathing, shock) are rare (about one in 600,000 children vaccinated) (Institute of Medicine).

There is no confirmed scientific evidence that hepatitis B vaccine causes chronic illness, including multiple sclerosis, chronic fatigue syndrome, diabetes, rheumatoid arthritis or autoimmune disorders.

There is no risk of HBV infection from the vaccine.

13.10. Further reading

1. Chin James. *Control of Communicable Disease Manual,* American Public Health Association Washington DC, 2000.

2. Global Alliance for Vaccines and Immunization (GAVI) Vaccines and Immunization Products *Guideline for Countries Eligible for Support from the Global fund for Children's Vaccines,* Copenhegan, Denmark,2000

3. Epidemiological Unit. *EPI Five Year Plan,* Ministry of Health 2001.

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14. MUMPS

14.1. Introduction

An acute viral disease characterized by fever, swelling and tenderness of one or more salivary glands, usually the parotid and sometimes, the sublingual or submaxillary glands. Orchitis, usually unilateral, occurs in 20%-30% of postpubertal males and oophoritis in about 5% of postpubertal females; sterility is an extremely rare sequel. The CNS is frequently involved, either early or late in the disease, usually as an aseptic meningitis, almost always without sequelae. Encephalitis is rare (1-2/10,000 cases); pancreatitis, usually mild, occurs in 4% of cases but a suggested association with diabetes remains unproven. Overall, mortality from mumps is approximately 1/10,000 cases.

Mode of transmission

The infectious agent of mumps is the mumps virus, a member of the family *Paramyxoviridae*, genus *Paramyxovirus*, is antigenically related to the parainfluenza viruses.

Infection is by droplet spread and by direct contact with the saliva of an infected person.

Incubation period

About 12-25 days, commonly 18 days.

Period of Communicability

The virus has been isolated from saliva 6-7 days before overt parotitis, to 9 days after; exposed nonimmune people should be considered infectious from the 12th through the 25th day after exposure while a maximum infectivity occurs about 48 hours before onset of illness. Urine may be positive for virus as long as 14 days after onset of illness. Inapparent infections can be communicable.

Susceptibility and resistance

Immunity is generally lifelong and develops after inapparent as well as clinical infections. Most adults are likely to have been infected naturally and may be considered to be immune, even if they did not have the apparent illness.

14.2. Situation in Sri Lanka

In the year 2001 a survey was conducted among family physicians and specialists through a questionnaire sent out from the Epidemiological Unit. They had reported 2279 cases of mumps. This may not be the true situation as mumps is considered a mild disease and only complicated cases seek medical attention.

14.3. Vaccine

A live attenuated mumps virus vaccine is available either as a single vaccine or in combination with rubella and measles live virus vaccines (MMR). Different strains of mumps virus are used to produce mumps vaccines and MMR vaccines. These vaccines should be stored in the dark at a temperature between +2^{o}C to +8^{o}C.

14.4. Indication

Immunization against mumps infection.

14.5. Schedule

Extracted from the Weekly Epidemiological Record No. 45, 9 November 2001.

General vaccine characteristics and schedule

Mumps vaccines are recommended for use in a 1-dose schedule, given at the age of 12-18 months. This is because persistent maternal antibodies to mumps virus from previous infection or vaccination interferes with the response to mumps vaccines in young infants. Preparations of the Urabe vaccine have generally been found to be immunogenic among children as young as 9 months, but data is limited in this age group for other strains.

Mumps vaccines are available as monovalent, bivalent measles-mumps (MM) and trivalent measles-mumps-rubella (MMR) vaccines. WHO requirements do not specify the minimum amount of vaccine virus that 1 human dose should contain. This is determined by the national regulatory authority of the country where the vaccine is produced. Most of these vaccines contain more than 1000 cell-$CCID_{50}$ of attenuated mumps virus per dose. Depending on the manufacturer, hydrolysed gelatin and/or sorbitol are used as stabilizers and neomycin is added as a preservative to the mumps vaccines. The vaccines are cold chain dependent, and should be protected from light both before and after reconstitution. Reconstituted vaccine must be discarded if not used within 6 hours.

Adverse reactions

In general, adverse reactions to mumps vaccination are rare and mild. The most common adverse reactions following mumps vaccination are parotitis and low-grade fever. However, moderate fever occurs rarely and aseptic meningitis has been reported at widely varying frequencies. The difference in frequency of aseptic meningitis noted above is not only a reflection of differences in strains and preparation of strains, but also of variation in study design and clinical practice. Onset of aseptic meningitis is delayed (median interval from vaccination to onset was 23 days, range 18-34 days, in a study from the United Kingdom), which may limit the ability to detect these cases by passive surveillance. Vaccine-associated meningitis resolves spontaneously in less than 1 week without any sequelae. Orchitis and sensory-neural deafness have been reported following mumps vaccination. The available data suggests that strain-specific differences in the profiles of adverse events exist, but this data is not strong enough to form the basis of a recommendation not to use specific strains. More data is needed to establish precise estimates of aseptic meningitis in recipients of various mumps vaccines.

Contraindications

There are few contraindications to mumps vaccination. As with all live attenuated vaccines, mumps vaccine should not be administered to individuals with advanced immune deficiency or immunosuppression. Foetal damage has not been documented when mumps vaccines was given to pregnant women. Allergy to vaccine components such as neomycin is a contraindication to administration of the vaccine.

14.6. Further reading

1. Chin James. *Control of Communicable Disease Manual,* American Public Health Association, Washington DC, 2000.

2. World Health Organization. *The Immunological Basis for Immunization Series, Module 7 – Measles,* Global Programme for Vaccines and Immunization WHO/EPI/GEN/93.17 Geneva.

3. Bhargava Indra . *Control of Measles Mumps and Rubella*, BI Churchill Livingstone Pvt. Ltd. New Delhi, 1996.

4. World Health Organization. Mumps virus vaccines WHO Position Paper *Weekly Epidemiological Record* No. 45, 9 November 2001, 346-355.

15. MENINGOCOCCAL VACCINE

Neisseria meningitidis is unique among major causes of bacterial meningitis for its ability to cause endemic and epidemic disease. Meningococcal disease is a major cause of morbidity and mortality worldwide. Most are caused by serogroups A, B and C. Serogroup A is the commonest cause of large epidemics but it also causes endemic disease. Group C mostly causes endemic disease.

Types of vaccine

Monovalent - Group A, Group C
Bivalent - Groups A and C } available in
Quadrivalent - A, C, Y and W-135 } Sri Lanka

Vaccination is recommended only for persons with specific high risk conditions including complement deficiency, anatomic or functional asplenia or for those who have had contacts with infected patients.

Vaccination may also be recommended for travellers visiting areas which are recognized as having epidemic meningococcal disease (e.g. Pilgrims to Mecca during Hadji season).

It is a polysaccharide vaccine 0.5 ml. administered intramuscularly as a single dose.

Post vaccinal immunity lasts for 3 years.
Vaccine should be stored at +2^{o}C to +8^{o}C.

16. HAEMOPHILUS INFLUENZAE TYPE B VACCINE

Haemophilus influenzae is a respiratory pathogen of humans and the infections it causes range from asymptomatic colonization of the upper respiratory tract to serious invasive disease such as meningitis, pneumonia, epiglotitis and septicaemia in infants and children.

Indications

To prevent haemophilus influenzae type B infection in infants and children up to 5 years.

Vaccine

Vaccine is used in combination with diphtheria, pertussis, tetanus (DPT) vaccine. As the combined formula is not available in Sri Lanka, at present the two vaccines could be given simultaneously but at different sites. The two vaccines should not be mixed in the same syringe before administration if produced by two manufacturers. Conjugate Hib vaccines should be stored at +2^{o}C to +8^{o}C; they must NOT be frozen.

Dosage and administration

Administered at 2, 4 and 6 months of age and a booster at 18 months.

If immunization is started between 6 months and 1 year of age, the child should receive two doses, 1-2 months apart and a booster at 18 months.

If immunization is started after 1 year of age, only one dose is recommended.

Freeze dried vaccine is administered intramuscularly after reconstitution.

17. PNEUMOCOCCAL VACCINE

Major clinical syndromes caused by *Streptococcus Pneumoniae* are widely recognized. Infections of the middle ear, paranasal sinuses, tracheobronchial tree and lung are the result of direct spread of the organism from the nasopharynx. Invasive pneumococcal disease is due to haematogenous spread to the central nervous system (meningitis), heart valves (endocarditis) and less commonly other sites such as joints, peritoneal cavity and fallopian tubes. It is the leading cause of pneumonia in children between 1-5 years of age causing over 1 million deaths each year.

The vaccine is poorly immunogenic in children less than 2 years of age.

Types of vaccine

This vaccine contains the capsular polysaccharides of the 23 pneumococcal types responsible for 85 – 90% bacteraemic infections due to this organism.

Indications

Pneumococcal vaccine is indicated for adults and children >2 years with underlying conditions that are associated with increased susceptibility to infection or increased risk of serious disease and its complications.

High risk individuals include those with:

- Chronic cardiac or pulmonary disease
- Anatomic or functional asplenia
- Chronic liver disease, complications of alcoholism
- Diabetes mellitus
- Chronic renal disease and renal failure
- Asymptomatic or symptomatic HIV infection and
- Recurrent otitis media [children].

Vaccine is given as a single dose of 0.5 ml. intramuscularly or subcutaneously. A booster is indicated after 3 years for children under 10 years of age and after 5 years for those who are older than 10 years.

Vaccine Storage

Vaccine should be stored at +2°C to +8°C

PART V.

ADVERSE EVENTS FOLLOWING IMMUNIZATION (AEFI)

PART V. ADVERSE EVENTS FOLLOWING IMMUNIZATION (AEFI)

18. ADVERSE EVENTS FOLLOWING IMMUNIZATION (AEFIs) AND MANAGEMENT OF AEFI

Vaccines used in the national immunization programmes are extremely safe and effective. But no vaccine is perfectly safe and adverse events can occur following immunization. In addition to the vaccines themselves, the process of immunization is a potential source of adverse events.

An adverse event following immunization (AEFI) is any adverse event that is believed to be caused by the immunization. Reported adverse events can either be true adverse events, i.e. really a result of the vaccine or the immunization process, or coincidental events that are not due to the vaccine or immunization process but are temporally, associated with immunization. For the purpose of these guidelines AEFIs are classified into five categories (see Table 2). Immunization can cause adverse events due to the inherent properties of the vaccine (**vaccine reaction**), or some error in the immunization process (**programme error**). The event may be unrelated to the immunization, but have a temporal association (**coincidental event**). Anxiety-related reactions can arise from fear or pain of the **injection** rather than the vaccine. In some cases the cause of the AEFI remains **unknown.**

Table 2: Classification of adverse events following immunization (AEFIs)

Vaccine reaction:	Event caused or precipitated by the vaccine (when given correctly), by its inherent properties.
Programme error:	Event caused by an error in vaccine preparation, handling or administration.
Coincidental:	Event that happens *after* immunization but **not** caused by the vaccine – a chance association.
Injection reaction:	Event from anxiety about, or pain from, the injection itself rather than the vaccine
Unknown:	Cause of the event cannot be determined.

Table 3: Common, minor vaccine reactions and treatment

Vaccine	Local reaction (pain, swelling, redness)	Fever >38°C	Irritability, malaise and systemic symptoms
BCG	90-95%	-	-
Hib	5-15%	2-10%	-
Hepatitis B	Adults ~ 15% Children ~ 5%	1-6%	-
Measles/MMR/MR	~ 10%	5-15%	5% (rash)
Oral Poliomyelitis (OPV)	-	<1%	<1%#
Tetanus/DT/aTd	~ 10%&	~ 10%	~ 25%
Pertussis (DTP-whole cell)	Up to 50%	Up to 50%	Up to 55%
Treatment	▪ Cold cloth at injection site ▪ Paracetamol*	▪ Give extra fluids ▪ Wear cool clothing ▪ Tepid sponge or bath ▪ Paracetamol*	▪ Give extra fluids ▪ Paracetamol*

 # Symptoms include diarrhoea, headache, and/or muscle pains

& rate of local reactions likely to increase with booster doses, from 50 to 85%

** Paracetamol dose: up to 15 mg/kg every 6 hours, maximum of 4 doses in 24 hours*

Local reactions include pain, swelling and/or redness at the injection site and can be expected in about 10% of vaccinees, except for those injected with DTP (whole cell), or tetanus boosters, where up to half can be affected. BCG causes a specific local reaction that starts as a papule (lump) two or more weeks after immunization. It then becomes ulcerated and heals after several months, leaving a scar. Keloid (thickened scar tissue) from the BCG lesion is more common among Asian and African populations.

Systematic reactions include fever and occur in about 10% or less of vaccinees, except for DTP where it is again about half. Other common systemic reactions (e.g., irritability, malaise, 'off-colour', loss of appetite) can also occur after DTP. For measles/MMR and OPV the systemic reactions arise from vaccine virus infection. Measles vaccine causes fever, rash and/or conjunctivitis, and affects 5-15% of vaccinees. It is very mild compared to 'wild' measles, but for severely immunocompromised individuals, it can be severe, even fatal. Vaccine reactions for mumps (swollen parotid gland) and rubella (joint pains and enlarged lymph nodes) affect less than 1% of children. Rubella vaccine causes symptoms more often in adults, with 15% suffering from joint pains. Systemic reactions from OPV affect less than 1% of vaccinees with diarrhoea, headache and/or muscle pain.

Rare, more serious vaccine reactions

Table 4 details the rare vaccine reactions; case definitions are in Table 4.1. Most of the rare and more serious vaccine reactions (e.g., seizures, thrombocytopaenia, hypotonic hyporesponsive episodes, persistent inconsolable screaming) do not lead to long-term problems. Anaphylaxis, while potentially fatal, is treatable without leaving any long-term effects. Although encephalopathy is included as a rare reaction to measles or DTP vaccine, it is not certain whether these vaccines in fact cause encephalopathy (brain damage).

Although other serious events have been reported following immunization, it is likely that those other events are coincidental, rather than true reactions.

Table 4: Rare vaccine reactions, onset interval, and rates

Vaccine	Reaction	Onset interval	Number of doses per reaction	Reactions per million doses
BCG	Suppurative lymphadenitis	2-6 months	1 in 1-10, 000	100-1000
	BCG osteitis	1-12 months	1 in 3,000 to 1 in 100 million	0.01-300
	Disseminated BCG infection	1-12 months	~in 1 million	0.19-1.56
Hib	None known			
Hepatitis B	Anaphylaxis	0-1 hour	1 in 6-900,000	1-2
Measles/MMR/MR#	Febrile seizures	6-12 days	1 in 3000	330
	Thrombocytopaenia (low platelets)	15-35 days	1 in 30,000	30
	Anaphylactoid (severe allergic) reaction	0-2 hours	~in 100,000	~10
	Anaphylaxis	0-1 hour	~in 1,000,000	~1
	Encephalopathy	6-12 days	<1 in 1,000,000	<1
Oral Poliomyelitis	Vaccine associated paralytic poliomyelitis	4-30 days	1 in 2.4-3 million	~0.4!
Tetanus	Brachial neuritis	2-28 days	0.5-1 in 100,000	5-10
	Anaphylaxis	0-1 hour	1 in 100,000 to 1 in 2,500,000	0.4-10

Tetanus-diphtheria	None extra to tetanus reactions			
Pertussis (DTP-whole cell)	Persistent (>3 hours) inconsolable screaming	0-24 hours	1 in 15 to 1 in 1,000	(0.1-6%) 1,000-60,000
	Seizures	0-2 days	1 in 1,750 to 1 in 12,500	80-570@
	Hypotonic, hyporesponsive episode (HHE)	0-24 hours	1 in 1,000-33,000	30-990
	Anaphylaxis	0-1 hour	1 in 50,000	20
	Encephalopathy (note: risk may be zero)	0-2 days	0-1 in 1 million	0-1

 # - Reactions (except anaphylaxis) do not occur if already immune (~90% of those receiving a second dose); children over six years unlikely to have febrile seizures.

@ Seizures mostly febrile and risk depends on age, with much lower risk in infants under the age of 4 months. VAPP risk higher for first dose (1 in 750,000 compared to 1 in 5.1 million for subsequent doses), and for adults and immunocompromised.

Programme errors leading to adverse events

Programme errors	Adverse event
Non-sterile injection: • reuse of disposable syringe or needle • Improperly sterilized syringe or needle • Contaminated vaccine or diluent • Reuse of *reconstituted* vaccine at subsequent session	Infection (e.g. local suppuration at injection site, abscess, cellulitis, systemic infection, sepsis, toxic shock syndrome, transmission of blood borne virus (HIV, hepatitis B or hepatitis C).
Vaccine prepared incorrectly: • Vaccine reconstituted with incorrect diluent	Local reaction or abscess from inadequate shaking.
• Drugs substituted for vaccine or diluent.	Effect of drug (e.g. muscle relaxant, insulin).
Immunization injected in wrong site: ▪ Subcutaneous instead of intradermal for BCG ▪ Too superficial for toxoid vaccine (DTP, DT, TT)	Local reaction or injection site abscess.
▪ Buttocks.	Sciatic nerve damage (+ ineffective vaccine-hepatitis B).
Vaccine transported/stored incorrectly.	Increased local reaction from frozen vaccine (and ineffective vaccine).
Contraindications ignored.	Avoidable severe vaccine reaction.

AEFIS TO REPORT, CASE DEFINITIONS AND TREATMENT

Events that should be reported after immunization

Occurring within 24 hours of immunization	▪ Anaphylactoid reaction (acute hypersensitivity reaction) ▪ Anaphylaxis ▪ Persistent (more than 3 hours) inconsolable screaming ▪ Hypotonic hyporesponsive episode (HHE) ▪ Toxic shock syndrome (TSS) #
Occurring within 5 days of immunization	▪ Severe local reaction # ▪ Sepsis # ▪ Injection site abscess (bacterial/sterile) #
Occurring within 15 days of immunization	▪ Seizures, including febrile seizures (6-12 days for measles/MMR; 0-2 days for DTP) ▪ Encephalopathy (6-12 days for measles/MMR; 0-2 days for DTP)
Occurring within 3 months of immunization	▪ Acute flaccid paralysis (4-30 days for OPV recipient; 4-75 days for contact) ▪ Brachial neuritis (2-28 days after tetanus containing vaccine) ▪ Thrombocytopaenia (15-35 days after measles/MMR)
Occurring between 1 and 12 months after BCG immunization	▪ Lymphadenitis # ▪ Disseminated BCG infection ▪ Osteitis/Osteomyelitis
No time limit	▪ Any death, hospitalisation, or other severe and unusual events that are thought by health workers or the public to be related to immunization #

 # limit reporting to these events, if only limited reporting capacity.

Table 4.1.
Case definitions and treatment for AEFI

Adverse event	Case definition	Treatment	Vaccines
Acute flaccid paralysis (vaccine associated paralytic poliomyelitis)	Acute onset of flaccid paralysis within 4 to 30 days of receipt of oral poliovirus vaccine (OPV), or within 4 to 75 days after contact with a vaccine recipient and neurological deficits remaining 60 days after onset, or death.	No specific treatment available, supportive care	OPV
Anaphylactoid reaction (acute hypersensitivity reaction)	Exaggerated acute allergic reaction, occurring within 2 hours after immunization, characterized by one or more of the following: ▪ Wheezing and shortness of breath due to bronchospasm ▪ Laryngospasm/laryngeal oedema ▪ One or more skin manifestations, e.g. hives, facial oedema, or generalized oedema. **Less severe allergic reactions do not need to be reported.**	Self-limiting, anti-histamines may be helpful.	All

Adverse event	Case definition	Treatment	Vaccines
Anaphylaxis	Severe immediate (within 1 hour) allergic reaction leading to circulatory failure with or without bronchospasm and/or laryngospasm/laryngeal oedema	Adrenaline injection (Given in latter part of this chapter)	All
Arthralgia	Joint pain usually including the small peripheral joints. **Persistent** if lasting longer than 10 days, **transient:** if lasting up to 10 days.	Self-limiting; analgesics	Rubella, MMR
Brachial neuritis	Dysfunction of nerves supplying the arm/shoulder without other involvement of nervous system. A deep steady, often severe aching pain in the shoulder and upper arm followed within days by weakness and wasting in arm/shoulder muscles. Sensory loss may be present, but is less prominent. May present on the same or the opposite side to the injection and sometimes affects both arms.	Symptomatic only; analgesics	Tetanus

Adverse event	Case definition	Treatment	Vaccines
Disseminated BCG infections	Widespread infection occurring within 1 to 12 months after BCG vaccination and confirmed by isolation of Mycobacterium bovis BCG strain. Usually in immunocompromised individuals.	Should be treated with anti-tuberculous regimens including isoniazid and rifampicin.	BCG
Encephalopathy	Acute onset of major illness characterized by any two of the following three conditions: Seizures Severe alteration in level of consciousness lasting for one day or more Distinct change in behaviour lasting one day or more. Needs to occur within 48 hours of DTP vaccine or from 7 to 12 days after measles or MMR vaccine, to be related to immunization	No specific treatment available; supportive care	Measles, Pertussis Measles, Pertussis

Adverse event	Case definition	Treatment	Vaccines
Fever	The fever can be classified (based on rectal temperature) as mild (38 to 38.9°C), high (39 to 40.4°C) and extreme (40.5°C or higher). Fever on its own does not need to be reported.	Symptomatic; paracetamol	All
Hypotonic, hyporesponsive episode (HHE or shock-collapse)	Event of sudden onset occurring within 48 (usually less than 12) hours of vaccination and lasting from one minute to several hours, in children younger than 10 years of age. **All** of the following must be present. ▪ Limpness (hypotonic) ▪ Reduced responsiveness (hyporesponsive) ▪ Pallor or cyanosis – or failure to observe/recall	The episode is transient and self-limiting, and does not require specific treatment. It is **not** a contraindication to further doses of the vaccine.	Mainly DTP, rarely others
Injection site abscess	Fluctuant or draining fluid-filled lesion at the site of injection. **Bacterial** if evidence of infection (e.g. purulent, inflammatory signs, fever, culture), **sterile** abscess if not.	Incise and drain; antibiotics if bacterial.	All

Adverse event	Case definition	Treatment	Vaccines
Lymphadenitis (includes suppurative lymphadenitis)	**Either** at least one lymph node enlarged to >1.5 cm in size (one adult finger width) **or** a draining sinus over a lymph node. Almost exclusively caused by BCG and then occurring within 2 to 6 months after receipt of BCG vaccine, on the same side as inoculation (mostly axillary).	Heals spontaneously (over months) and best not to treat unless lesion is sticking to skin. If so, or already draining, surgical drainage and local instillation of anti-tuberculous drug. Systemic treatment with anti-tuberculous drugs is ineffective.	BCG

Adverse event	Case definition	Treatment	Vaccines
Osteitis/Osteomyelitis	Inflammation of the bone with isolation of *Mycobacterium bovis* BCG strain.	Should be treated with anti-tuberculous regimens including isoniazid and rifampicin.	BCG
Persistent inconsolable screaming	Inconsolable continuous crying lasting 3 hours or longer accompanied by high-pitched screaming.	Settles within a day or so, analgesics may help.	DTP, Pertussis
Seizures	Occurrence of generalized convulsions that are not accompanied by focal neurological signs or symptoms. **Febrile seizures**: if temperature elevated >38^{o}C (rectal) **Afebrile seizures**: if temperature normal	Self-limiting; supportive care; paracetamol and cooling if febrile; rarely anticonvulsants.	All, especially pertussis, measles

Adverse event	Case definition	Treatment	Vaccines
Sepsis	Acute onset of severe generalized illness due to bacterial infection and confirmed (if possible) by positive blood culture. Needs to be reported as possible indicator of programme error.	Critical to recognize and treat early. Urgent transfer to hospital for parenteral antibiotics and fluids	All
Severe local reaction	Redness and/or swelling centred at the site of injection and one or more of the following: ▪ Swelling beyond the nearest joint ▪ Pain, redness, and swelling of more than 3 days duration Requires hospitalization. **Local reactions of lesser intensity occur commonly and are trivial and do not need to be reported.**	Settles spontaneously within a few days to a week. Symptomatic treatment with analgesics. Antibiotics are inappropriate.	All

Adverse event	Case definition	Treatment	Vaccines
Thrombocytopaenia	Serum platelet count of less than 50,000/ml leading to bruising and/or bleeding	Usually mild and self-limiting; occasionally may need steroid or platelets.	MMR
Toxic shock syndrome (TSS)	Abrupt onset of fever, vomiting and watery diarrhoea within a few hours of immunization. Often leading to death within 24 to 48 hours. Needs to be reported as possible indicator of programme error.	Critical to recognize and treat early. Urgent transfer to hospital for parenteral antibiotics and fluids.	All

Reference: Immunization safety surveillance guidelines for managers of immunization programmes on reporting and investigating AEFI. WHO/WPRO/EPI/99.01 Manila 1999.

Anaphylaxis

Definitions for professionals

Anaphylactic shock (anaphylaxis). Is an immediate (type 1) hypersensitivity reaction. It is acute, often explosive, allergic systemic reaction, characterized by circulatory failure (e.g. alteration of level of consciousness, low arterial blood pressure, weakness or absence of peripheral pulses, cold extremities secondary to reduced peripheral circulation, flushed face and increased perspiration) with or without bronchospasm and/or laryngospasm/laryngeal oedema leading to respiratory distress. May also include pruritis, generalized flushes, angioedema (hives), seizures, vomiting, abdominal cramps and incontinence. It occurs in previously sensitized persons who receive the sensitizing antigens again.

Definitions for Lay persons

Anaphylactic shock (anaphylaxis). A rare reaction brought on by a number of causes including administration of foreign proteins such as vaccines, usually occurring within one hour of their administration. The classical presentation is collapse. In severe cases, urgent medical treatment is needed to avert death.

Contraindications

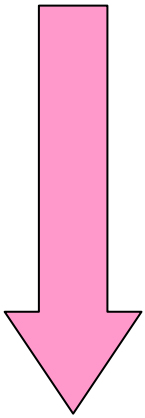
Before immunization, check for contraindications to immunization by asking about known allergies and previous adverse reactions to vaccines. In the case of a possible serious allergy, check with an appropriate supervisor before giving the vaccine. This procedure will minimize the occurrence of anaphylaxis but will not remove the risk altogether.

Clinical presentation

Anaphylaxis is **rare** – occurring about once in every million doses of vaccine given. Most vaccinators will go through their entire career never seeing a case. Fainting and feeling faint, however, are **common** and can easily be confused with anaphylaxis, as can anxiety, breath-holding and convulsion. Fainting has a strong emotional component, and while relatively common after immunization of adults or adolescents, is very rare in young children. Thus, sudden loss of consciousness in very young children after vaccines is much more

likely to be an anaphylactic reaction. A strong central pulse (e.g. carotid) is maintained during a faint or convulsion but not in anaphylaxis. Anaphylaxis can present at different time intervals after vaccination (but mostly within 30 minutes) and with differing degrees of severity.

Table 5: Signs and symptoms of anaphylaxis

Clinical progression	Signs and symptoms	Severity of attack
Mild, early warning signs  Life-threatening symptoms	Itching of the skin, rash and swelling around injection site. Dizziness, general feeling of warmth.	Mild
	Painless swelling in part of the body e.g. face or mouth. Flushed, itching skin, nasal congestion, sneezing, tears.	Mild to moderate
	Hoarseness, feeling sick, vomiting	Moderate to severe
	Swelling in the throat, difficulty in breathing, abdominal pain	Moderate to severe
	Wheezing, noisy, difficulty in breathing, collapse, low blood pressure, irregular or weak pulse	Severe

Important points:

- In general, the more severe the reaction, the more rapid the onset of symptoms.
- Most life-threatening reactions begin within 10 minutes of immunization.
- As a general rule, everyone receiving vaccines should remain in the vicinity of the vaccination clinic for at least 15 minutes after the administration of vaccine, and for longer if there is concern.

Symptoms limited to only one body system (e.g. skin itching) can occur, leading to a delay in diagnosis. Occasional reports have described reactions where symptoms recur 8 to 12 hours after onset of the original attack and prolonged attacks lasting up to 48 hours.

General issues of management

Having made the diagnosis, consider the patient as being in a potentially fatal condition, regardless of the severity of the current symptoms. Begin treatment immediately and, at the same time, make plans to transfer the patient swiftly to hospital (if not already in a hospital setting). All patients with anaphylaxis should be hospitalized.

Injecting adrenaline (epinephrine) as the basis of treatment

Adrenaline stimulates the heart, reverses the spasm in the blood vessels and the lung passages, and reduces swelling and skin itching. But this very potent agent can cause an irregular heart beat, heart failure, severe hypertension and tissue necrosis if used in inappropriate doses or route.

Each vaccinator who is trained in treatment of anaphylaxis should have rapid access to an emergency kit with adrenaline, and be familiar with its dosage and administration. The expiry date of the adrenaline should be written on the outside of the emergency kit and the whole kit should be checked three or four times a year. Adrenaline liquid that has a brown tinge must be discarded.

Steps in initial management

- If already unconscious, place the patient in the recovery position and ensure the airway is clear.
- Record heart rate, respiratory rate and blood pressure (if the patient has a strong carotid pulse, he is probably not suffering from anaphylaxis).
- If appropriate, begin cardiopulmonary resuscitation.
- Give 1 in 1000 *adrenaline/epinephrine* (for correct dose for age or weight, see below) *by deep intramuscular* injection into the opposite limb to that in which the vaccine was given. (Subcutaneous administration is acceptable in mild cases)*.

- **And** *give an additional half dose around the injection site* (to delay antigen absorption).

- *If the patient is conscious after the adrenaline is given, place the head lower than the feet and keep the patient warm.*

- Give oxygen by face-mask, if available.

- Call for professional assistance but never leave the patient alone. Call an ambulance (or arrange other means of transport) and a medical practitioner if necessary, after the first injection of adrenaline, or sooner if there are sufficient people available to help you. If you have made the diagnosis of anaphylaxis, do not wait for the arrival of senior staff before giving the adrenaline.

- If there is no improvement in the patient's condition within 10-20 minutes of the first injection, repeat the dose of adrenaline up to a maximum of three doses in total. Recovery from anaphylactic shock is usually rapid after adrenaline.

- Record, or get someone to record, vital signs (pulse rate, respiratory rate and blood pressure), as well as time and exact dose of any medication given. Make sure the details accompany the patient when he is transferred. Mark the immunization card clearly so that the individual **never** gets a repeat dose of the offending vaccine. At a suitable moment, explain to parents or relatives the importance of avoiding the vaccine in the future.

- Report the occurrence of anaphylaxis to the appropriate officer in the ministry of health by fax or phone when the clinical situation is dealt with.

* In a patient with severe anaphylaxis, the situation is life-threatening and requires the administration of intravenous fluids as well as possible endotracheal intubation. These are best performed in a hospital setting. A skilled physician may also use additional treatment such as hydrocortisone, anti-histamines, nebulised salbutamol (for bronchospasm) and nebulised adrenaline (for laryngeal oedema). However these treatments should not be part of primary care by those unfamiliar with them.

Adrenaline dosage

The dosage is not “one ampoule”.

1 in 1000 adrenaline (epinephrine) requires a dose of 0.01 ml/kg up to a maximum of 0.5 ml injected intramuscularly (or subcutaneously in very mild cases)

If the weight of the patient is unknown, an approximate guide is as follows:

Less than 2 years	**0.0625 ml (1/16th of a ml)**
2-5 years	**0.125 ml (1/8th of a ml)**
6-11 years	**0.25 ml (1/4 of a ml)**
11+ years	**0.5 ml (1/2 of a ml**

Further Reading

1. World Health Organization. *Immunization Safety Surveillance Guidelines for Managers of Immunization Programmes on Reporting and Investigating. Adverse Events Following Immunization,* WHO/WPRO/EPI/99.01 Manila.

2. World Health Organization. *Immunization Policy,* Global Programme for Vaccines and Immunization WHO/EPI/GEN/95.3 Geneva.

3. World Health Organization. *Supplementary Information on Vaccine Safety,* Part 1 Field issues, Department of Vaccines and Biologicals WHO/V&B/00.24 Geneva.

4. World Health Organization. *Report of Second Meeting of the Steering Committee on Immunization Safety,* Geneva 26-27 October 2000, WHO/V&B/01.17 Geneva.

5. Johns Hopkins University School of Hygiene and Public Health *Epidemiological Reviews,* Vaccines, Vol: 21, No. 1 – 1999.

PART VI.

MAINTENANCE OF THE COLD CHAIN OF E.P.I. VACCINES

PART VI. MAINTENANCE OF THE COLD CHAIN OF E.P.I. VACCINES

19. Introduction

The "cold chain" is the name given to a system of people and equipment which ensure that the correct quantity of potent vaccine reaches the women and children who need it from the point of production. The cold chain system is necessary because vaccines are delicate substances that lose potency if they are exposed to temperatures that are **too warm or too cold**. High levels of immunization coverage are useless if the vaccine that was used is not potent.

Figure 4 illustrates the entire cold chain system. There are many steps between the manufacturer of the vaccine and the woman or child in need of immunization. Vaccine must stay at the **correct temperature** throughout the entire cold chain system – when it is **transported,** when it is **stored** in a refrigerator or cold store, and when it is **used** at an immunization session

19. 1 The two essential elements of the cold chain system are:

- **People to manage vaccine distribution;**
- **Equipment to store and transport vaccine.**

People are an extremely important part of the cold chain. ***Even if the finest and most modern equipment is available, the cold chain will not be effective if people do not handle the vaccine and equipment properly.***

The basic cold chain equipment includes:

- Refrigerators, freezers and cold rooms
- Cold boxes, Vaccine carriers, Day-carriers and Thermos flasks;
- Thermometers;

- Vehicles.

Vaccine handling occurs at three levels:

- Central level
- Regional level
- Divisional level

1. Central Stores

1.1 Request for vaccine

The required stocks of vaccine is ordered from abroad the previous year. The requirement is decided by the target age group and any special immunization programmes if planned.

1.2. Receipt of vaccine

All vaccines are received from abroad. State Pharmaceutical Corporation (SPC) staff receive the stocks on arrival at the airport and transfer them to the Epidemiological Unit.

1.3. Storage of vaccine

Vaccines are stored in cold rooms maintained at $2^{o}C$ – $8^{o}C$ and $-20^{o}C$.

1.4. Distribution of vaccine

Vaccine stocks are distributed to Regional Medical Supplies Divisions (RMSDD) every other month.

2. Regional Medical Supplies Division (RMSD)

2.1. Request for vaccine

Preparation of stock return by RMSD.

Officer in charge of the RMSD should obtain the stock return forms from all the institutions to which vaccines are distributed in the DPDHS division, before the 5^{th} of the month.

These returns should be checked for the following:

- The stocks requested are within reasonable limits.
- Guidelines given to prepare the request has been followed.

The return could be adjusted in consultation with the RE/MO(MCH)/MOH/Head of the institution and the consolidated return for the RMSD prepared.

The return should be forwarded to the Epidemiologist by the 5th of the month, whether stocks are requested or not.

"Maximum stock" refers to the amount of any vaccine which should be in the store at the start of a new supply period. At the RMSD, this should be about 3 months stock of each vaccine.

The quantity of vaccine to be ordered should be calculated as follows:

The quantity of different vaccines currently in stock according to the registers should be noted. This should be checked with the actual stocks in hand (these stocks should be the same).

The formula below will determine the quantity of vaccine or supplies to be ordered for the next supply period

Maximum Stock	**-**	**Quantity in stock**	**=**	**Quantity to order**

However this should be compared with the total quantity ordered by the MOOH/institutions in the area and adjusted if necessary (e.g. vaccines for special immunization programmes).

2.2. Receipt of vaccine

Epidemiological Unit will give notice of the delivery of vaccines by letter and telephone.

The officer in charge of the RMSD should ensure that he himself receives the stocks. If not, a responsible officer should be identified to receive the stocks.

The following should be checked before accepting the stocks:

1. Vaccine has been delivered on time;
2. The stock of vaccine, diluents and supplies are correct according to the invoices;
3. Expiry date of stocks;
4. The vials of vaccine and diluents are not damaged i.e. broken vials, labels separated from the vials;
5. Vaccine has not been exposed to harmful temperatures could be detected by observing –
   - vaccine vial monitors
   - cold chain monitors accompanying the vaccine and/or
   - the ice packs are not melted completely and
   - vaccines are not frozen
6. The relevant documents are available and correctly completed i.e. cold chain monitors and relevant forms;
7. The cold chain monitors and relevant forms are completed according to instructions given by the EPID Unit/FHB.

- If no problems are detected, stocks should be accepted.
- The stocks should be taken into the relevant register.
- The invoices should be filed.
- The balance of stocks should be updated immediately.

Possible problems:

1. Short expiry date;
2. Stocks in excess/short of order;
3. Changes in cold chain.

- Any problem detected should be discussed with the superior.
- If a superior is not available, the stocks or part of the stocks of vaccine could be accepted.
- For the stocks not accepted, reasons should be indicated by a note brought to the notice of the superior as soon as possible.
- The accepted stocks should indicate the problems.

2.3. Storage of vaccine maintaining the cold chain

Vaccines should be stored in cold rooms and/or in refrigerators and deep-freezers maintained at +2°C – 8°C and –20°C – (depending on the type of vaccine).

If the temperature is maintained above +8°C:

1. Bottles of water (or ice packs filled with water) should be stored in every spare space in the refrigerator, except for one-half of the volume which is needed for air circulation. This helps to stabilize the temperature and prevent wide fluctuations during the day.
2. Ensure that the door of the refrigerator/freezer is opened as few times as possible.

The ice packs should be pre-cooled at night in the refrigerator before inserting them in the freezer (except for solar refrigerators, where ice packs should be inserted in the morning).

If the temperature is maintained below 0°C:

1. Bottles of water (or ice packs filled with water) should be stored in every spare space in the refrigerator, except for one-half of the volume which is needed for air circulation. This helps to stabilize the temperature and stops it from fluctuating widely during the day.
2. Temperature could be adjusted by turning the temperature control switch button (Thermostat) in the equipment.
3. Windows or ventilators should be kept closed at night to keep the store-room warmer if necessary.
4. If these actions do not ensure that the internal temperature is maintained correctly, the refrigerator should be replaced.

COLD CHAIN

Storage of different vaccines

1. It is best to store the different vaccines in different cold-rooms/freezers/refrigerators.
2. The maximum stock of vaccine, diluents and water bottles (if used) should only take up one-half of the total space available in the refrigerator/freezer. If more than half the space is used, air will not circulate around the vaccine to maintain the correct temperature in all parts of the refrigerator/freezer.
3. Bottles of water (or ice packs filled with water) should be stored in the refrigerator to keep the refrigerator cool specially if there is frequent interruptions to the energy/power supply.

Bottles of water will help keep the refrigerator cool if the energy/power supply fails or the refrigerator breaks down.

4. The cartons of vaccine should be stored to ensure air circulation among the piles of vaccine.
5. The cartons should be identified by date of arrival and date of expiry and the quantity in each carton.
6. The arrangement of the stocks should be such that those with a shorter expiry date are delivered before those with longer expiry dates.

Maintenance of refrigerators/freezers

At the stores, if there are more than one refrigerator/freezer it is better to house them in one room or a separate part of a room. A person should be identified to be responsible for the day to day maintenance of these.

He/she should observe the following:

1. The room is well ventilated;
2. Each refrigerator/freezer is protected from outside heat;
3. Direct rays of the sun do not fall on the refrigerator/freezer;
4. Each refrigerator/freezer has a different plug point and care should be taken to ensure that the plug is not accidentally disconnected;
5. Refrigerator/freezer doors and lids are kept firmly closed;
6. Each refrigerator/freezer is defrosted regularly and kept clean. Whenever a layer of ice measuring several millimetres (5 at most) forms on the freezer compartment, the refrigerators should be defrosted;
7. Each refrigerator/freezer has a maintenance chart - Refrigerator Record;
8. Any problems should be brought to the notice of the relevant officers immediately. A note should be prominently displayed as to whom to be contacted;
9. An alternate place to store vaccine during an emergency (an emergency plan) should be identified and prominently displayed. This place should be identified at the onset in consultation with the DPDHS/RE/MO (MCH)/MOH depending on the stores involved;
10. Inventory of equipment is checked annually.

2.4 Distribution of vaccine maintaining the cold chain

Vaccines should be delivered to the MOOH and institutions by the RMSD after prior notice by telephone or letter.

Vaccine stocks should be distributed to Medical Officers of Health (MOOH) and institutions in the DPDHS division every month.

The monthly stock return of vaccines should be received by the RMSD from all the MOOH and institutions in the division **before** the 5th of the month.

The vaccines should be distributed packed in cold boxes (igloos). The correct number of cold packs identified for each cold box (igloo) should be used to ensure the cold life of the vaccines.

Care should be taken to ensure that liquid vaccines e.g. DTP, TT, DT, aTd, Hep B and JE are not placed against the cold packs to avoid any possibility of freezing.

The igloos and cold packs should be ready and taken close to the cold room/refrigerator/freezer before taking out the vaccines for packing.

The shortest possible route should be taken to reach the MOH/institution avoiding any undue stoppages/delays en-route.

The activated cold chain monitors (CCM) should be attached to some cartons and distributed along with them packed in the igloos.

The previously distributed CCMM should be collected.

The CCM and relevant records should be completed when handling over and collecting the CCMM according to the instructions given by the Epid Unit/FHB.

Before leaving the officer from the RMSD should ensure that

- vaccines are received by a responsible officer;
- stocks are transferred to the refrigerators/freezers immediately;
- relevant forms are completed.

3. Medical Officer of Health/Institution conducting immunization

3.1. Request for vaccine

Medical Officers of Health and institutions should send the vaccine stock return to the RMSD before the 5th of the month.

The return should be sent whether stocks are requested or not.

Preparation of stock return by MOH/Institution

In general, the amount of vaccine expected to be used during the following month, should be based on what was used during the previous month. However:

- If there is a seasonal variation in vaccine demand, the quantity should be based on the experience in the previous year.
- If activities that will greatly increase immunization coverage e.g. a local immunization day is planned, a larger quantity of vaccine should be included in the stock return. This should be indicated in the return form for the benefit of the OIC/RMSD.
- If new policies which will increase the amount of vaccine are adopted, e.g. if the MOH adopts a new policy of screening women and children at every contact or special immunization campaigns such as special immunization days or Suwa Udana Programme, a larger quantity of vaccine should be included in the stock return. This should be indicated in the return form for the benefit of the OIC/RMSD.

At the MOH/Institution the maximum stock is equal to the amount of average vaccine usage for two months.

The quantity of vaccine to be ordered should be calculated as follows:

- First find out the current stocks indicated in the register and check the actual stocks physically present in the stores. Then use the formula below to determine the quantity of vaccine or supplies to order for the next supply period.

Maximum Stock	-	Quantity in stock	=	Quantity to order

- If extra stocks are needed add this amount.
- Indicate the reason for the order for extra stocks for the benefit of the OIC/RMSD.

3.2. Receipt of vaccine

Officer in charge of the institution/MOH should identify a responsible officer (who knows about vaccines and cold chain) to receive vaccines stocks and -

- to maintain the relevant registers.
- to document receipt and distribution of vaccines and supplies.

The identified officer should be personally available to receive the stocks.

Before accepting the stocks, they should be checked as given in section under RMSD.

Possible problems: Please refer to section under RMSD.

3.3 Storage of vaccine maintaining the cold chain

Refrigerators/deep freezers

Identified for vaccines storage ONLY.

For maintenance refer section in RMSD.

Temperature maintenance

Refer section in RMSD.

Storage

The cartons of vaccine should:

- be stored to ensure air circulation among the piles of vaccine;
- be identified by date of arrival and date of expiry;
- indicate the quantity in each carton.

Oral Polio vaccine should be placed in a freezer.

Small quantities of OPV brought back from clinics could be kept in the coldest part of the main compartment for a short periods of time and used as early as possible.

Rubella, Measles-Rubella (MR) and Measles vaccine should be kept in the coldest part of the main compartment of the refrigerator or in the freezer as they are not damaged by freezing.

Hepatitis B, DTP, combined Hep B/DTP, DT, aTd, TT and JE Vaccine should be:

- stored in the warmest part of the refrigerator where the temperature will most consistently stay between +2^{o}C to +8^{o}C;
- not stored in the door or vegetable compartment of the refrigerator.

The arrangement of the stocks should be such that:

1. shorter expiry date vaccines are easily accessible;
2. newly received vaccine will be used **after** those received earlier.

Stocks of vaccine that have been taken to clinics and brought back unused (unopened vials), should be stored separately from the bulk stocks. These should be taken to the very next clinic and used before using the other stocks.

Maintenance of Cold Chain

At storage point – Refer section in RMSD.

1. A responsible person should be identified to be in charge of the refrigerator/s freezer/s and to maintain all records pertaining to it/them. In the event of this person being absent, a second and a third person should be identified.
2. These persons should be made known to all relevant people.
3. Immediate action should be taken to correct any problems detected by the identified person/s.
4. Any problem should be discussed with superior officers (RE/MO (MCH) and suitable action taken.
5. Possible common problems and relevant action to be taken should be noted and prominently displayed e.g. interruption to electricity etc.

During transport

- Vaccine stocks should be distributed to the clinic centres packed in vaccine carriers/day carriers/flasks – Figure 5 (do not take excess stocks).

- These should be used even when the clinic is held in a room adjoining the storage point.

- The correct number of cold packs or the correct amount of ice should be used to maintain the cold life of the vaccine during transport to and from the clinic and duration of the clinic.

- The vaccine carrier/day carrier/flask should be taken close to the refrigerator/deep freezer.

COLD CHAIN

- The vaccine should be packed immediately after removal from the refrigerator/deep freezer.

- The vaccine carriers/day carriers/thermos flask should be in good condition i.e.
    1. The walls are not cracked;
    2. Handles are not broken;
    3. Clasps of the lid are not broken;
    4. Lid closes tightly;
    5. Each cold box and vaccine carrier, day carrier has the full set of ice packs;
    6. They are washed, dried and kept open for complete drying after each use;
    7. Inventory is checked annually;
    8. Any problems brought to the notice of relevant officers.

Packing of vaccines in cold boxes/day carriers/thermos flasks

Health workers should:

- Remove the ice packs from the freezer;
- Wait for them to be free of frost (approximately 10-15 minutes);
- Place fully frozen ice packs around the inside walls of the the carrier;
- If pieces of ice are used they should be packed in a bag. Amount of ice should be sufficient to ensure cold life of the vaccine carrier/day carrier/thermos flask;
- Stack vaccine and diluents in the vaccine carrier/day carrier/thermos flask;
- Place two layers of frozen ice packs/pieces of ice on top;
- Take precautions to prevent vulnerable vaccines from being frozen (for example, keep them in their packaging/wrap a paper around them);
- Secure the lid tightly.

At the clinic centre

All unopened vials of vaccine should NOT be taken out of the vaccine carrier/thermos flask/day carrier till ready for use.

All opened and re-constituted vaccine vials should be placed in a cup of ice or in a special cold pack during immunization.

The vaccine should be placed away from direct sun light.

Usage of vaccine

Before taking vaccine to clinics,

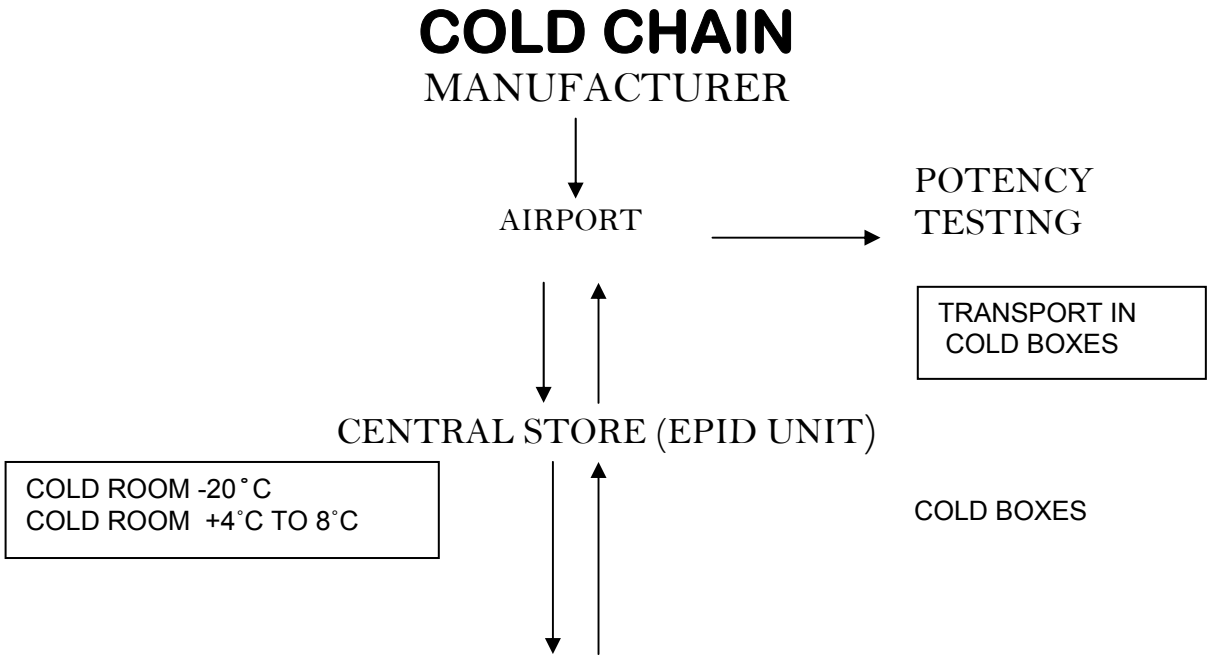
- The quantities taken to clinic should be entered in the vaccine movement register.
- unused vaccine vials should be transported back maintaining the cold chain.
- the quantities returned should be noted in the register.
- the relevant details should be used to calculate vaccine usage/wastage by clinics.

Supervision of the maintenance of the cold chain

Supervising Officer should,

1. Observe as the vaccine stocks are received at the RMSD/clinic.
2. Observe how vaccine is stored at RMSD/MOH office/institution.
3. Observe how vaccine is distributed from RMSD to MOH Office/institution.
4. Observe how vaccine is used at the clinic.
5. Observe on maintenance of records/returns at RMSD/MOH Office/institution.
6. Observe on adequacy and maintenance of cold chain equipment.

Figure 4.


COLD CHAIN
MANUFACTURER
AIRPORT
POTENCY
TESTING
TRANSPORT IN
COLD BOXES
CENTRAL STORE (EPID UNIT)
COLD ROOM -20˚C
COLD ROOM +4˚C TO 8˚C
COLD BOXES

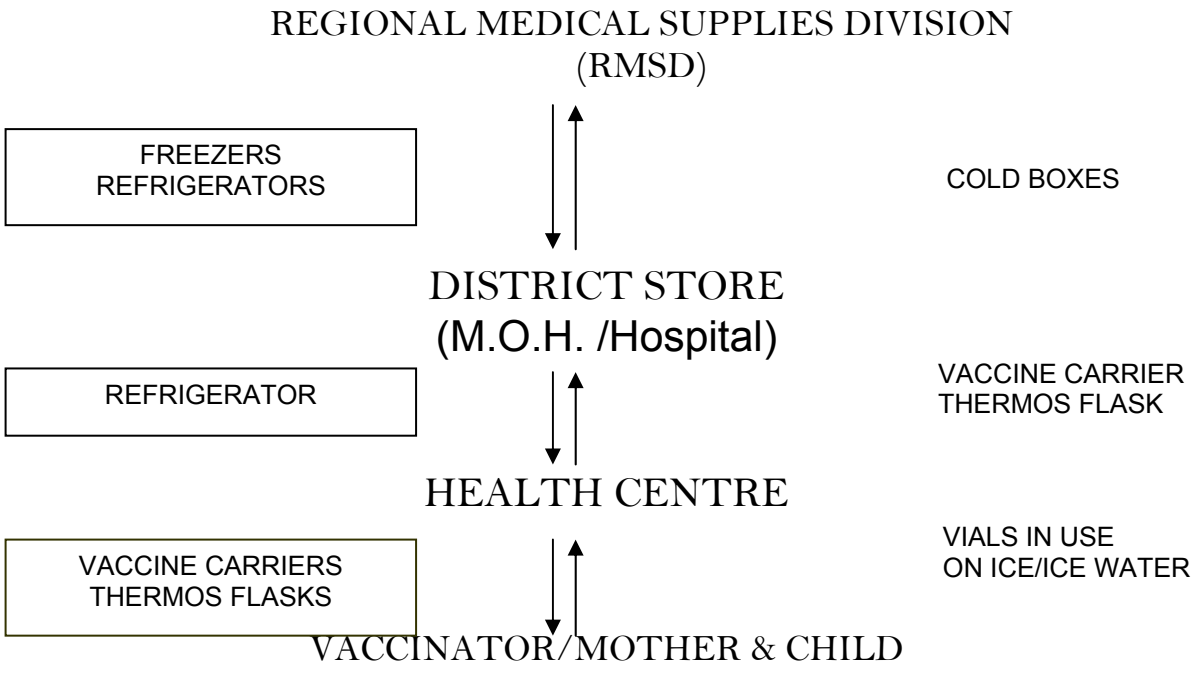

REGIONAL MEDICAL SUPPLIES DIVISION
(RMSD)
FREEZERS
REFRIGERATORS
COLD BOXES
DISTRICT STORE
(M.O.H. /Hospital)
REFRIGERATOR
VACCINE CARRIER
THERMOS FLASK
HEALTH CENTRE
VACCINE CARRIERS
THERMOS FLASKS
VIALS IN USE
ON ICE/ICE WATER
VACCINATOR/MOTHER & CHILD

Figure 5.1 Arranging icepacks in a vaccine carrier

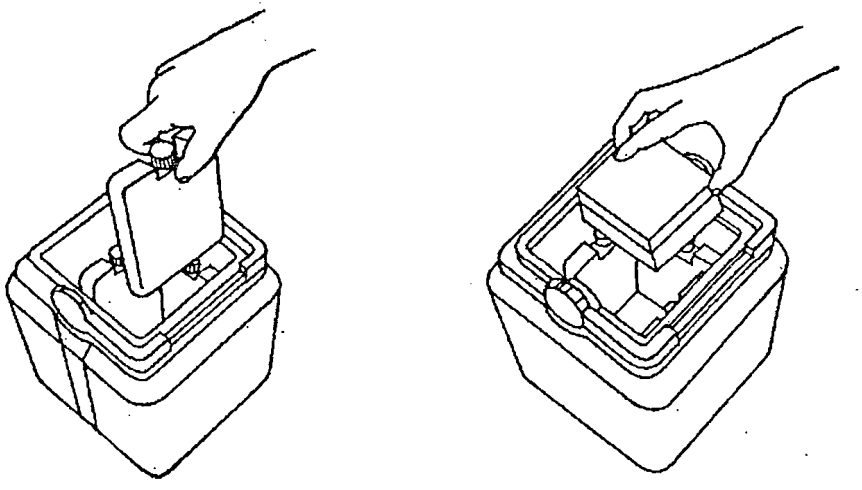
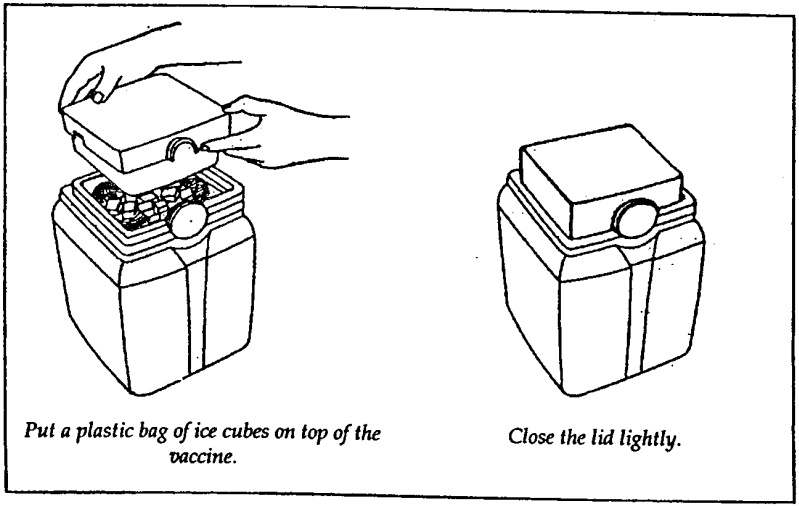


Figure 5.2



Put a plastic bag of ice cubes on top of the vaccine.

Close the lid lightly.

Note. If you use ice cubes, put one plastic bag full of cubes in the bottom of the carrier and one bag full of cubes on top of the vaccines.

19.2. The Cold Chain Monitor

The Cold Chain Monitor tells you when vaccine has been exposed to temperatures that are too high, and it helps you estimate the length of time the vaccine was exposed.

Printed on the back of the Cold Chain Monitor is a brief description of the management actions you should take for each vaccine that has been exposed to warm temperatures. There are three options:

1. Vaccine may be used freely;
2. It must be used within three months;
3. It must be tested before use.

Even if cold chain monitors are infrequently used in your health area, you should train health workers on how to interpret and use them. More information is given in EPI training materials on cold chain monitors).

Figure 6.1 Cold Chain Monitor Card

Vaccine Cold Chain Monitor

Date in	Index	Location	Date out	Index

Monitor Mark	3M INDEX / 10º C			34ºC	
Indicator	A	B		D	
	If A all blue	If B all blue	If C all blue	If A & B & C & D all blue	
Polio	Use within 3 months				
Measles		Use within 3 months	Test Vaccine Before use		
DPT & BCG			Use within 3 months		
TT, DT & Hepatitis B	**These vaccines may be used**				
SUPPLIER	Name: …… Date of dispatch: …… Vaccine: : ……				

Use of Vaccine Cold Chain Monitor Card (VCCM)

The objective of the use of vaccine cold chain monitor card is to monitor the cold chain of vaccine during;

1. Transport from the Epidemiological Unit (Central Stores) to Regional Medical Supplies Divisions (RMSDD).
2. Storage at RMSD.
3. Transport from RMSD to MOH/DDHS.
4. Storage at MOH/DDHS.

Each cold chain monitor is taken from the Epidemiological Unit to RMSD and from RMSD to MOH under cold chain conditions accompanying vaccine stocks. During the storage at each point, they are kept under cold chain in refrigerators.

Changes in the VCCM are recorded at various points of storage when they are taken out from, and taken into storage. At any point the condition of the cold chain could be noted by observing these VCCMM.

There is a system of records and returns pertaining to monitoring of cold chain using VCCM. VCCMM are collected and handed over to the Epidemiological Unit by the RMSD officers. The relevant records maintained at RMSD and MOH/DDHS office helps to identify any interruption to the cold chain.

If any changes are detected, they should be brought to the notice of relevant officers for necessary action.

Training programmes were conducted to instruct how these should be recorded and maintained. These instructions should be followed.

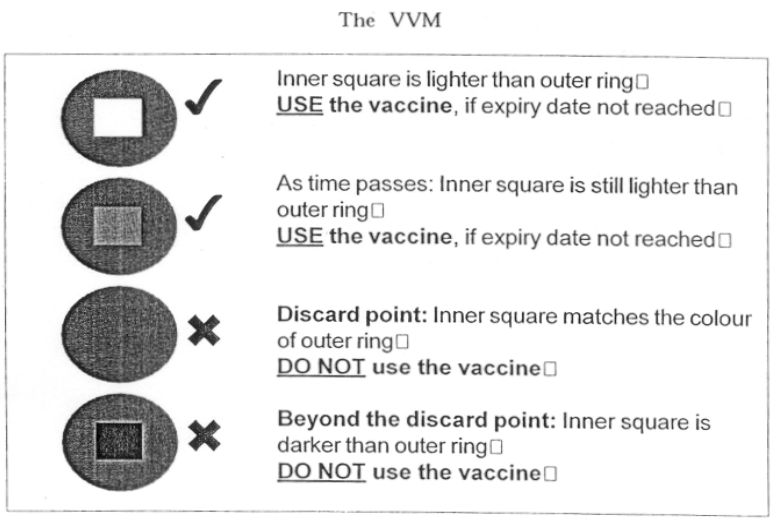
Supervising officers should note the records maintained during their supervisory visits and action should be taken when necessary.

19.3. The Vaccine vial monitor

Oral polio vaccine is the most heat sensitive of all vaccines used in the Expanded Programme on Immunization (EPI). Storage and transport have to comply with good cold chain practices. However, cumulative heat exposure can now be monitored with the help of the vaccine vial monitor (VVM), which can be found on all OPV supplied by UNICEF since 1997.

A heat sensitive square within a circle changes colour under the combined influence of heat and time. If, after exposure to heat for a certain amount of time, the square reaches the same colour of the circle or becomes darker as shown below, the vial should be discarded.

Figure 6.2 The Vaccine Vial Monitor (VVM)



At lower temperatures, the loss of potency is considerably slowed down and the time it takes for the VVM to reach the discard point increases subsequently.

The VVM allows the user to see at any time if **OPV can still be used in spite of possible cold chain interruptions.** If necessary, health staff and management can then take the required corrective measures.

Besides this important corrective management based on VVM monitoring, it is feasible and justifiable to use the **VVM to plan a more flexible, less stringent and cheaper cold chain,** which is of particular importance for NIDs.

OPV can be safely used beyond the cold chain until the **VVM reaches the discard point.** The length of time will depend on ambient temperatures and **the quality of the cold chain up to that point.**

Important VVM reminders

The VVM gives only information about the vial to which it is attached. **It can not be used as indicator of heat exposure to other vaccines,** because the cold chain history of the latter may be very different.

The **expiry date of a vial has priority over the VVM**. If the expiry date is reached, the vial should be discarded even if the VVM suggests the vial can still be used.

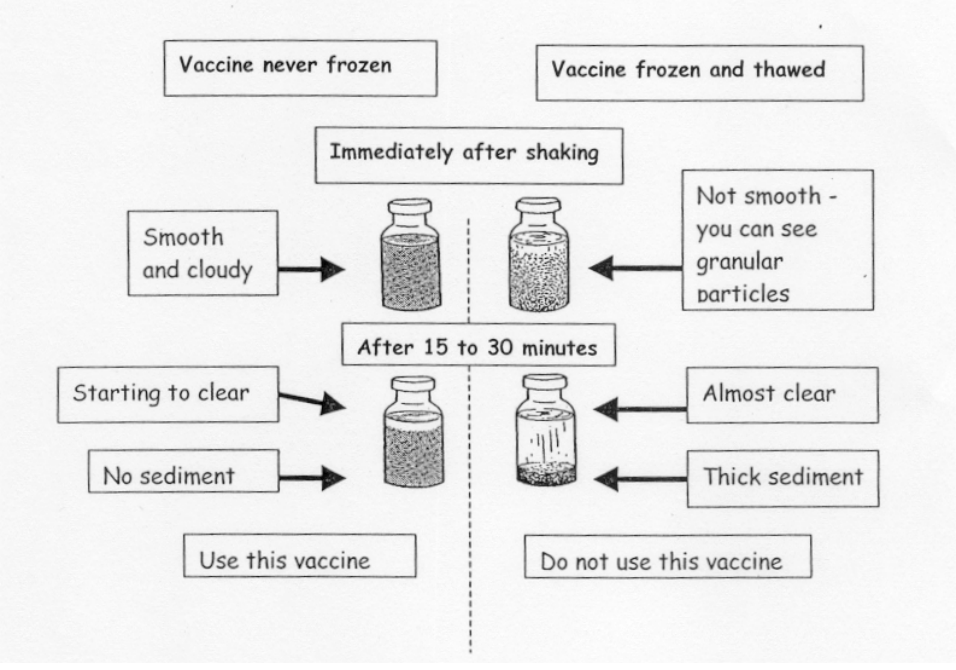
19.4. The shake test

The shake test is used to determine if vaccine has been frozen.

During the process of freezing, vaccine tends to flocculate (i.e., virus particles stick together to form larger clumps). When a vial of vaccine which has been frozen and then thawed is shaken and then allowed to sediment, it will sediment more quickly than the same vaccine from the same manufacturer which has not been frozen. Figure 7 gives a comparison between the sedimentation rates of a frozen and a never frozen DTP vaccine.

The shake test is best conducted using a vial of vaccine which you have frozen solid yourself and do not intend to use. This vial can be used as a frozen "control" against which to compare vaccines in doubt. Whenever the "control" vial sediments significantly faster than the test vial, then the test vial is acceptable. If the sedimentation rates are the same, however, then the test vial should not be used. Remember, the shake test can only be conducted on "test" and "control" vials from the same manufacturer.

Figure 7: Shake test



PART VII.

INJECTION SAFETY

PART VII. INJECTION SAFETY

20. Injection Safety

Presently re-usable syringes and steam sterilizers are being used in the EPI programme. It is proposed to introduce Auto-Disable (AD) Syringes in a phased manner. Before its introduction relevant health staff will be trained.

Some information on AD syringes is given below.

20.1. Using Auto-Disable Syringes

Auto-Disable Syringes

Re-use of injection equipment is responsible for most of the infections that result from immunization. Fortunately, several new types of syringes have been designed to prevent re-use; auto-disable (AD) syringes automatically become disabled after one use. WHO and UNICEF now recommend that auto-disable syringes be used for administering vaccines – particularly in mass immunization programmes.

Auto-disable syringes are designed for use with little or no instruction. However, an initial practice session with the new syringes may help workers understand how to use them more quickly, may help them appreciate the benefits of auto-disable syringes, and may assist workers to switch between different types of syringes without wasting them.

Types of Auto-Disable Syringes

This chapter will review the following types of new AD syringes, and will discuss their use.

New types of auto-disable syringes:

Soloshot™* and Soloshot™* FX syringes from BD
KI™* syringes from Star Syringe, Ltd.
Destroject®* syringe from Bader

Univec™* syringe from Univec, Inc.
Uniject™* prefill injection device from BD.

- SoloShot and SoloShot FX, and Uniject are trademarks of BD; K1 is a trademark of Star Syringe, Ltd.; Destroject is a registered trademark of Bader and Partner Vetriebsgesellschaft mbH; Univec is a trademark of Univec, Inc.

1. BD SoloShot™ and SoloShot™ FX Auto-Disable Syringes

Syringe Description

The SoloShot and SoloShot FX syringes are single-use, disposable, auto-disable syringes with a metal clip that locks the plunger after a single use. The SoloShot syringe has a fixed needle and is packaged with plastic caps to keep the needle and plunger sterile before use. In contrast, the SoloShot FX syringe currently comes with a detachable needle that is packaged together with the syringe in a sterile paper package. **The SoloShot FX detachable needle can only be attached to the SoloShot FX syringe barrel**. This prevents the needle from being re-used with other syringes.

Change in injection technique required:

Because the plunger can go back and forward only once, health workers should NOT draw up air to inject it into the vial. In addition, the locking mechanism decreases the distance that the plunger can move if the health care workers aspirate for blood when giving an injection. It is still possible to aspirate, but the plunger will travel only a short distance.

2. Destroject® Auto-Disable Syringe

Syringe description

The Destroject syringe is the third single-use, disposable, AD syringe that is distributed by UNICEF in 2000 and 2001. The syringe comes with a fixed needle, and the sterile packaging includes a plunger cap and needle shield. The plunger locks, once it is depressed. This syringe is available in a 0.5 ml size.

Change in injection technique required:

Like the SoloShot syringes, the plunger of this syringe can be pushed in only once. Users should not draw the plunger back to inject air into the vial prior to drawing up a dose. It is not possible to aspirate for blood when using this syringe.

3. Univec™ Auto-Disable Syringe

Syringe description

The Univec syringe is a 0.5 ml syringe which comes with a fixed needle or detachable needle. The syringes are individually packed in sterile paper packaging. The plunger locks once it is depressed, but can be withdrawn a short distance to aspirate for blood when checking the needle position. A BCG syringe with a 0.05 ml dose line is available.

Change in injection technique required:

Like the SoloShot and DestroJect syringes, the plunger of this syringe can be pushed in only once. Users should not draw the plunger back to inject air into the vial prior to drawing up a dose.

20.2. Sharps and waste management

The management of sharps and waste are given in sections VIII and IX of the Infection Control Manual for Sri Lanka published by the Ministry of Health and Women's Affairs 1993. However, it is proposed to train relevant health staff and supply safety boxes to all EPI immunization clinics to collect used sharps and waste in 2003, with the assistance of WHO/Global Alliance for Vaccines and Immunization.

Comparing Different AD Syringes

Type of AD Syringe	Packaging	Requires Activation	Disabled by	Available with fixed needle (as of Oct. 2000)
SoloShot	Bulk packed with plunger caps	No	Metal clip	Yes
SoloShot FX	Individual paper package	No	Metal clip	No
K1	Individual paper or plastic package	Remove tab or twist plunger (depending on style)	Plunger breaks off	Fixed or detachable needle available
Destroject	Bulk packed with plunger caps	No	Ratchets on plunger	Yes
Univec	Individual paper package	No	Metal clip and ratchets on plunger	Fixed or detachable needle available
Uniject	Pre-filled, single dose: individual foil package	Push port into needle shield	Reservoir (bubble) can not be refilled	Yes

Further reading

1. PATH Programme for Appropriate Technology in Health *Giving safety injections.* Introducing Auto-Disable Syringes, Training Manual Washington USA – October 2000.

2. Ministry of Health and Women's Affairs. *Infection Control Manual for Sri Lanka,* 1993.

PART VIII.

RECORDS AND RETURNS

PART VIII. RECORDS AND RETURNS

21.1. Immunization records and returns

Child Health Development Record (CHDR)

The immunizations given to children according to the Expanded Programme on Immunization (EPI) are recorded in the Child Health Development Record (CHDR) of the child in the relevant section – section K in part B and section B in part A. Entries in Part A which are kept by the mother of the child are done at the place where immunization is done e.g. at the hospital, clinic or school.

For children born after 1.4.2001 a sticker is pasted on the CHDR in section K and B. Space to enter the new immunization introduced from 1.4.2001, adverse events following immunization (AEFIs) and batch number of vaccines is provided in the sticker. These particulars for children born before 1.4.2001 should be entered in the CHDR making use of the free space available in the existing CHDR.

The CHDR is issued to a new born at the hospital where the birth occurred and all immunizations given from birth up to 15 years are entered in this record. Since DT, aTd and Rubella vaccines are given in the schools, it is necessary to ensure that the CHDR is available with the child at school immunization too.

The area Public Health Midwife (PHM) should have the Part B of CHDR of all children in the area. During home visits she updates the immunization details of every child irrespective of the place of immunization.

The immunization status of pregnant mothers regarding Rubella and Tetanus at the time of registration and Tetanus Toxoid given during pregnancy are entered in **Mothers Record- H 512** and **Pregnancy Record of the mother.** Mothers Record is used by the PHM to register pregnant mothers, provide antenatal care and for follow up. It is kept with the PHM. Pregnancy Record of the mother is given by the PHM, at the time of registration to the mother to take with her whenever she seeks medical care for her pregnancy.

Rubella immunization given to school children 10-15 years and females from 16 – 44 years are recorded in the special **Rubella Immunization Record (Epid/302/96).**

At the PHM Office

The PHM registers all the children under 15 years of age in her area in the **Birth and Immunization Register** by month of birth. When immunization is given the Birth & Immunization register is updated by the PHM. This enables her to identify children who have not got the age appropriate immunizations and take necessary action to ensure that these children are promptly immunized.

PHM registers all the pregnant mothers under her care in the **pregnant mothers Register H 513.** The immunization status regarding Tetanus and Rubella are updated in this register. This helps the PHM to take action regarding immunization of pregnant mothers.

PHM maintains a **Register of Eligible Clients for Rubella in a 16-44 year age group** according to villages in a single CR register. This enables PHM to identify all eligible clients for Rubella immunization and to ensure full coverage among this group.

At post-immunization visits by the PHM, if any adverse events following immunization (AEFI) are seen, she notifies it to the Medical Officer of Health (MOH)/Deputy Director of Health Services (DDHS). Also she should note these AEFIs in the **PHMs diary- H 511** maintained by her and the total number of adverse events seen on that day are entered in the relevant cage of the **PHM Daily Statement- H 523**. These are totalled at the end of the month and the total number of AEFIs seen during the month are reported to the MOH/DDHS in the **Monthly Statement H- 524.**

In the MOH/ DDHS Office

The stocks of vaccines received at the health unit every month is entered in the **Stock Register-H 287** with batch numbers and expiry dates of vaccine. This is balanced every month and is made use of in the preparation of **Monthly Stock Return of Vaccine-FORM EPI/CDD/1/97** to order vaccines from district stores.

When vaccines are issued to a clinic from MOH office the details should be entered in the **Vaccine Movement Register** kept in the MOH/DDHS office and the respective **Clinic Vaccine Movement Register.** After the clinic session Clinic Vaccine Movement Register duly completed is sent to the storage centre with remaining unopened vials. This enables the person responsible for looking after the vaccines at the storage unit to complete the Vaccine Movement Register at the storage centre. These records enable the MOH/DDHS to monitor vaccine usage and take necessary action to reduce vaccine wastage.

At the hospital, clinic and school and estates

When a person is immunised the details are entered in a **Immunization Register** according to a standard format.

The number of immunizations done in a hospital ward or at the out-patients department are sent to the officer responsible for maintaining statistics. This information is collated and reported in the **Quarterly Immunization Return- FORM Epid/EPI/2/98** in the respective column to the MOH/DDHS office.

The number of immunizations done on a given clinic day is transferred from the **Clinic Immunization Register** to the **Clinic Summary H 518.** The number of doses given of each immunization, is totalled at the end of each month. This is taken on to the **Quarterly MCH Clinic Return H 527**, which is sent every quarter to the MOH/DDHS office.

The total number of each immunization done in a school taken from the School Immunization Register are recorded in the Monthly School Health Return- H 1014 maintained by the Public Health Inspector (PHI). Monthly totals are transferred to Quarterly School Health Return –H 797 which is sent quarterly to the MOH. At the MOH office, the number of doses given by all the PHIs in the area are totalled for every immunization on a monthly basis. This is transferred to the Quarterly School Health Return of the MOH, one copy of which is sent to the Deputy Provincial Director Health Services (DPDHS) and one copy to the Family Health Bureau.

At the MOH/DDHS office the total number of each immunization given in all clinics are totalled together with the immunizations done in schools for each month. This information is entered in the column named health unit staff in the **Quarterly Immunization Return** which

is sent every quarter to the DPDHS and to the Epidemiologist. This infomation is sent to the Family Health Bureau in **Quarterly Maternal and Child Health Return- H 509.**

21.2. E.P.I. Coverage & Vaccine Logistics

1. Quarterly EPI Return (Form: EPID/EPI/2/98)

Data on Immunization collected from immunization clinics conducted	Quarterly Immunization Return consolidated by	Copies of Quarterly Immunization Return sent to
• At Child Welfare & Ante-Natal clinics and school immunizations Programmes by MOH/DDHS Office staff at Hospitals where immunization clinics are conducted • By General Practitioners & hospitals (*who obtain vaccines from MOH/DDHS*) • At Estate clinics	MOH/DDHS	• DPDHS/RE/MO-MCH (*before the 20th of the next month*) • Epidemiologist (*before the 25th of the next month*)

2. Vaccine Logistics

1. Monthly Stock Return of Vaccines

Monthly Report on Vaccine stocks, usage and requirements from	***Monthly Stock Return of Vaccines consolidated by***	***Copies of Monthly Stock Return of Vaccines sent to***	***DPDHS/OIC(RMSD) sends copies of Monthly Stock Return of Vaccines to***
▪ Child Welfare and Ante-Natal Clinics of MOH/DDHS ▪ All medical institutions where immunizations are conducted ▪ General Practitioners (*who obtain vaccines from MOH/DDHS)* ▪ Estates (*who obtain vaccines from MOH/DDHS)*	▪ MOH/DDHS ▪ Major Hospitals ▪ Private Hospitals (*who obtain vaccines from RMSD)* ▪ Estates (*who obtain vaccines from RMSD)*	▪ DPDHS/RE/ MO(MCH) ▪ O/IC (RMSD) (Before the 5th of the month)	▪ Epidemiologist. (By the 5th of the month)

2. Refrigerator Record (EPI/2/89)

This form should be maintained for each refrigerator/freezer used for storing vaccines.

3. Vaccine Cold Chain Monitor (VCCM)

VCCM cards are sent to RMSDs from the Epidemiological Unit with vaccine stocks on the basis of one card per MOH/DDHS office per month. At the end of the month the used VCCM should be returned to Epidemiologist through OIC/RMSD by the MOH/DDHS.

4. Revised Vaccine Cold Chain Monitor (RVCCM)

This form is sent with VCCM and perfected forms should be filed and retained at the MOH/DDHS office for future reference.

5. Cold chain Monitor Record (CCMR)

This form should be prepared in duplicate by Epidemiological Unit staff; one copy is maintained by OIC/RMSD and other copy at the Epidemiological Unit.

21.3. Surveillance of Adverse Effects Following Immunizations (AEFIs)

1. Notification for AEFI (Form : AEFI – 1)

All medical officers both in government and private sector should report AEFIs through this form to the MOH/DDHS of the area where the patient resides.

2. Monthly Surveillance Report on Adverse Events Following Immunization (AEFI - 2)

Data on Adverse Events following immunization AEFI)	Monthly Surveillance Report on AEFI consolidated by	Copies of Monthly Surveillance Report on AEFI sent to
• At the immunization clinics (Field, School, and in other institutions) • Medical institutions • General Practitioners • Estates • Field health staff during home visits	MOH/DDHS	DPDHS/RE/MOMCH) *(before the 10th of the next month)* Epidemiologist (*before the 10th of the next month)*

3. Adverse Events Following Immunization Case Investigation Form (AEFI - 3)

All severe AEFIs should be investigated by MOH/DDHS using this investigation form as a guideline and the completed form/report should be sent to the Epidemiologist with a copy to DPDHS/RE/MO(MCH) within one month of report of the AEFI.

21.4. EPI Disease Surveillance

21.4.1. Notification of a Communicable Disease (H544)

All medical officers both in government and private sectors should notify all EPI target diseases (all notifiable diseases) through this form to the MOH/DDHS of the area, where the patient resides.

21.4.2. Notification Register

On receipt of a notification regarding a case of a notifiable disease (Notification card, Form: 544), MOH/DDHS should record the necessary details of the patent in the notification register.

21.4.3. Infectious Disease Register (H – 700)

On receipt of the Communicable Disease Report – Part 1 (H411) regarding a confirmed case, necessary information should be recorded in this register.

21.4.4. Weekly Return of Communicable Diseases (H399)

Notifications reported to, and investigated by MOH/DDHS during the week should be consolidated and reported to Epidemiologist with a copy to DPDHS/RE on every Saturday by using this form.

1. **Communicable Disease Report – Part 1 (H411)**

   Every notified case should be investigated and reported to MOH/DDHS using this form by the area Public Health Inspector (PHI).

2. **Communicable Disease Report – Part 1 (H411a)**

   For every confirmed case, this form should be completed and sent with H399 to the Epidemiologist.

3. **Indoor Morbidity & Mortality Register of Hospital**

   Final diagnosis of all discharges from a hospital should be corded according to the International Classification of Diseases (I.C.D.) and entered in this register.

4. **Indoor Morbidity & Mortality Report of Hospital**

   Every head of the medical Institution should send this return to the Medical statistician with a copy to DPDHS/RE before the 25th of the following month at the end of every quarter.

21.4.5. Special Surveillance of EPI Target Diseases

Special Investigation Forms

21.4.5.1. AFP/Polio

1. **Acute Flaccid Paralysis (AFP) / Suspected Poliomyelitis Form 1 (Pink Form) – Form E: 13.1/95**

   Completed by MO treating the case on suspicion of the diagnosis and sent to the Epidemiologist.

2. **Acute Flaccid Paralysis (AFP) / Suspected Poliomyelitis Form 2 (Yellow Form) - Form E: 13.2/95**

   Completed for every reported AFP case after investigation by the MOH/DDHS and sent to the Epidemiologist.

3. **Acute Flaccid Paralysis (AFP) / Suspected Poliomyelitis Form 3 (Green Form) - Form E: 13.3/95**

   Completed for every reported case of AFP by RE after 60/90/180 days of onset and sent to the Epidemiologist.

4. **Monthly Reporting Form for AFP/NNT/Measles Cases by RE**
   Form: EPID/EPI/SUR/95/7.R
   Should be sent by RE to the Epidemiologist every month after visiting sentinel stations.

5. **Weekly Reporting Form for AFP Cases From Hospitals**
   Every Head of the institution where there is a paediatric unit should send this report to the Epidemiologist weekly including a nil return.

6. **AFP Investigation Form From Regional Epidemiologist**
   Completed for every reported case of AFP by RE within 48 hours of onset and sent to the Epidemiologist.

21.4.5.2. Laboratory Investigation of AFP cases

1. Investigation of Acute flaccid Paralysis Cases

This form to be sent by every institution when sending stool samples to MRI for virological studies

21.4.5.3. Tuberculosis (TB)

1. Tuberculosis Notification Form Health 816

(Completed by MO treating the case and sent from local Anti-Tuberculosis Clinic) to Anti-Tuberculosis Campaign.

2. Treatment Defaulter Notification Form

Sent from local Anti-Tuberculosis Clinic or the Anti-Tuberculosis Campaign to MOH/DDHS to contact the treatment defaulter.

21.4.5.4. Measles

1. Special Investigation form for Measles (Epidemiological Case History of Measles Form: EPID/2/93)

Investigated by MOH/DDHS and the completed form should be sent to the Epidemiologist.

21.4.5.5. Tetanus/NNT/MNT

1. Special Investigation form for Tetanus/NNT/MNT (Epidemiological Case History of Tetanus - Form: EPID/2/89 Rev. 96)

Investigated by MOH/DDHS and the completed form to be sent to the Epidemiologist.

21.4.5.6. Whooping Cough

1. **Special Investigation form for Whooping Cough (Epidemiological Case History of Whooping Cough Form: EPID/3/94)**

   Investigated by MOH/DDHS and the completed form to be sent to the Epidemiologist.

21.4.5.7. Diphtheria

1. **Special Investigation form for Diphtheria (Epidemiological Case History of Diphtheria Form: EPID/DIPI/97)**

   Investigated by MOH/DDHS and the completed form to be sent to the Epidemiologist.

21.4.5.8. Rubella/Congenital Rubella

1. **Special Investigation form for Rubella/Congenital Rubella**

   Investigated by MOH/DDHS and the completed form to be sent to the Epidemiologist.

2. **Investigation and Follow-up of a Female (Form: Epid/RUB/97)**

   a. **Inadvertently vaccinated against rubella during pregnancy**
   b. **Who became pregnant within 3 months of vaccination**

   Investigated by MOH/DDHS and the completed form to be sent to the Epidemiologist.

21.4.5.9. Hepatitis

1. **Special Investigation form for Hepatitis**
   Investigated by MOH/DDHS and the completed form to be sent to the Epidemiologist.

21.4.5.10. Japanese Encephalitis

1. **Special Investigation form for Japanese Encephalitis**

   Investigated by MOH/DDHS and the completed form to be sent to the Epidemiologist with a copy to RE.

2. **Report of admissions, Notifications and Deaths of Japanese Encephalitis.**

   All Heads of the medical institutions should send this form weekly to the Epidemiologist.

3. **Record and returns regarding Japanese Encephalitis immunization programme.**

   Completed by the MOH/DDHS and RE to be sent to the epidemiologist.

PART IX.

OTHER INFORMATION ON E.P.I.

PART IX. OTHER INFORMATION ON E.P.I.

22.1. E.P.I. Disease Surveillance

E.P.I. disease surveillance is maintained by the use of available morbidity and mortality data. These data obtained from hospitals are based only on in-patient data. Epidemiological Unit is responsible for the surveillance of all EPI diseases.

22.1.1. Notifiable Diseases

There are 21 Notifiable Diseases in Sri Lanka, including the seven EPI target diseases (Polio, Whooping cough, Tetanus, Tuberculosis, Diphtheria, Measles and Rubella). Rubella was included to the list in the year 2000. Reporting of all EPI target diseases and AFP cases under 15 years of age as suspected poliomyelitis have been made mandatory in Sri Lanka. The Epidemiological Unit is the central coordinating agency for the programme, receiving information about EPI target diseases and AFP cases from the Medical Officers of Health (MOHs), as well as medical officers in curative institutions where the patients seek treatment. The physician treating a case should notify such a case on a notification card to the MOH of the area. The notification card forwarded by the hospital to the MOH is directed to the PHI of the area for investigation and report. The information flow is given in Figure 8 & 9.

Special surveillance registers are maintained at the Epidemiological Unit for Polio/AFP, Diphtheria, Tetanus, Whooping cough, Rubella and Measles. Cases are reported through the routine weekly reporting system, by a Weekly Return of Communicable Diseases sent by the MOHs on the Saturday of the week, to reach the Epidemiological Unit on the following Monday. On receiving notifications, detailed investigation forms designed for each EPI target disease mentioned above are sent to the MOH. Special investigations are carried out by the MOH using these forms and the forms are sent back to the Epidemiology Unit.

The number of Medical Officers of Health in Sri Lanka is 250. Of these, an average of 98% has been reporting regularly, and 61% on time. The percentage of units reporting even in the absence of a case is the same.

22.1.2. Mortality Data

Mortality data on EPI target diseases are collected from the Registrar General's office regularly.

22.1.3. Sentinel Surveillance

Regional Epidemiologists and some selected MOHs collect information on EPI target diseases monthly from sentinel stations (major hospitals where a majority of the population seek treatment and where specialized services are available). These stations are hospitals where specialists are available and which cater to a population representative of the area. This information is sent to the Epidemiological Unit.

22.1.4. Laboratory Surveillance

Laboratory data on EPI target diseases are regularly sent to the Epidemiological Unit from the Medical Research Institute (MRI), Colombo.

22.1.5. Active Surveillance

Epidemiologists from the central Epidemiological Unit and regional Epidemiologists actively search for EPI target diseases in large hospitals in the country.

22.1.6. Special Surveillance

There is a Special Surveillance system to monitor AFP cases in the country.

22.2. Monitoring and Evaluation of the Expanded Programme on Immunization (EPI)

22.2.1. Important areas for monitoring and evaluation of the EPI programme for strengthening routine immunization systems

1. Implementation stage of plan of action – Number of activities successfully implemented during the scheduled time.

2. Annual work plan – Number of activities successfully implemented during the year.

3. Injection safety plan – Number of activities successfully implemented on injection safety.

4. Line item in national budget for vaccines –
   (a) Amount of funds allocated in the national budget for EPI vaccines.
   (b) Percentage of government finance of vaccine for routine system allocated.

5. ICC for routine system – Number of ICC meetings held according to the schedule.

6. Cold chain review – Number of cold chain review meetings held.

7. Percentage of districts with 80% DTP_3 covered.

8. Difference between BCG, DTP_3 coverage (drop out).

9. Feedback of data to sub-national levels.

10. Immunization safety monitoring.

11. Plan for new vaccine introduction – Number of activities successfully implemented according to schedule.

12. Using Hepatitis B – Number of activities successfully implemented according to schedule.

22.2.2. Other important areas for supervision and monitoring in the EPI Programme

1. Monitoring of disease surveillance on all vaccine preventable diseases – (routine – Notification, Indoor morbidity-mortality return (IMMR},
    1. Sentinel site reporting
    2. Active surveillance
    3. Laboratory surveillance).
2. Monitoring of vaccine indenting / procurement / receipt/storage and distribution.
3. Monitoring of cold chain including break down of cold chain equipment/repair/replacement.
4. Monitoring of vaccine quality.
5. Monitoring of immunization coverage/drop out rates/vaccine wastage.
6. Monitoring of Adverse Events Following Immunization (AEFI).
7. Monitoring of injection safety/sterilization of injection equipment.
8. Monitoring of immunization quality/clinic procedures.
9. Monitoring of data quality.
10. Training – In-service training
11. Basic training
12. Health education/social mobilization
13. Feed back of information on EPI
14. How/When
    1. Routine procedures
    2. Quarterly reviews/monthly reviews.

3. Annual reviews
4. Special studies/coverage survey, vaccine quality assessment survey, zero survey.
   Supervision will be done on regular basis and quarterly and annual reviews will be carried out on all aspects of EPI.

Where

1. MOH/DDHS
2. DPDHS/Province
3. National level.

22.2.3. The EPI programme will be evaluated in the following aspects annually and in 2003 and 2005.

Evaluation of the inputs

- Buildings – Such as construction of the central cold room.
- Staff – Appointment of staff at central level and regional level – Epidemiologists, Regional Epidemiologists, Medical Officers of Maternal and Child Health.
- Finance – Allocation and availability of funds for the purchase of vaccines.
- Equipment – Steam sterilizers – cold chain equipment and safety disposable boxes.
- Supplies – Reusable syringes, auto destructive with syringes etc.

Evaluation of the process

- Training – Training of all categories of staff on EPI.
- Planning – Planning of EPI activities at central, regional and primary health care level (vaccines, supplies etc.).
- Management – Management at central, regional and field level on all aspects of EPI.
- Supervision – Supervision of staff at regional and field level such as immunization centres on EPI activities.

Evaluation of the outputs

- **Services delivery – especially at clinic level immunizations performed and coverage**
- Goods delivered – Vaccines etc.
- Staff trained – Number and category of staff trained on EPI activities.

Evaluation of the outcome

Evaluation of the more immediate and direct effects of the programme on knowledge, attitudes and behaviour of staff and community on EPI activities.

For training activities, for instance, outcome measures might be related to the achievement of learning objectives and changes in staff performance, e.g., safe immunization practices.

Evaluation of the impact

Changes in the health situation – especially the eradication, elimination and reduction of mortality and morbidity due to EPI target diseases and prevention and control of disease outbreaks.

22.3. Revised Objectives of the E.P.I. Programme

22.3.1. General

- Eradicate poliomyelitis
- Eliminate neo-natal tetanus and diphtheria
- Control other vaccine preventable diseases, childhood tuberculosis, pertussis, tetanus, measles, rubella and congenital rubella (Hepatitis B and Japanese Encephalitis).

To increase/maintain the coverage, with full series of EPI vaccines (7) in the target groups, as per current EPI schedule at minimum 80% in all the districts and minimum 90% in all the provinces and the country by end of 2001 and achieve and maintain minimum 99% coverage at national level by end of 2003.

22.3.2. Childhood Tuberculosis

To prevent childhood tuberculosis through increasing/maintaining the vaccination in the target groups with BCG at minimum 80% in all the districts and minimum 90% in all the provinces and the country as per current EPI schedule by end of 2001 and achieve and maintain minimum 99% coverage at national level by end of 2003.

22.3.3. Poliomyelitis

To maintain the interruption of wild polio virus transmission and obtain polio eradication certification by the end of 2005 through increasing/maintaining the coverage, with OPV in the target groups as per current EPI schedule at minimum 80% in all the districts and minimum 90% in all the provinces and the country by end of 2001 and achieve and maintain minimum 99% coverage at national level by end of 2003 and conducting SNID at least till 2003.

22.3.4. Maternal and Neo-natal tetanus

To maintain the status of eliminated neo natal tetanus (less than one case per 1000 live births) and achieve zero incidence of maternal and neo natal tetanus by end of 2005 through increasing/maintaining the coverage, with Tetanus vaccine (as a part of DPT, DT, aTd, TT) in the target groups as per current EPI schedule at minimum 80% in all the districts and minimum 90% in all the provinces and the country by end of 2001 and achieve and maintain minimum 99% coverage at national level by end of 2003.

22.3.5. Diphtheria

To further reduce morbidity and mortality due to diphtheria from present level and prevention of outbreaks through increasing/maintaining the coverage with diphtheria vaccine (as part of DPT, DT and aTd) in the target groups as per EPI schedule at minimum 80% in all the districts and minimum 90% in all the provinces and the country, by end of 2001 and achieve and maintain minimum 99% coverage at national level by end of 2003.

22.3.6. Whooping Cough

To further reduce morbidity and mortality due to whooping cough from the present level and prevention of outbreaks through increasing/maintaining the coverage with pertussis vaccine (as part of DPT) in the target group, as per EPI schedule at minimum 80% in all the districts and minimum 90% in all the provinces and the country, by end of 2001 and achieve and maintain minimum 99% coverage at national level by end of 2003.

22.3.7. Measles

To further reduce the incidence of measles from present levels:

- by increasing/maintaining coverage with measles vaccine (including MR) in the target groups as per EPI schedule at minimum 80% in all the districts and minimum 90% in all the provinces and the country, by end of 2001 and achieve and maintain minimum 99% coverage at national level by end of 2003.
- Prevention of outbreaks.
- Preparedness for outbreak response.

22.3.8. Rubella

To control morbidity and mortality due to congenital rubella syndrome and morbidity due to rubella infection through increasing and later maintaining the coverage with rubella vaccine (including MR) in the target groups as per EPI schedule at minimum 80% in all the districts and minimum 90% in all the provinces and the country by end of 2002.

22.3.9. Hepatitis B

Goals and objectives of Hepatitis B immunization

The ultimate goal of Hepatitis B vaccination is to reduce morbidity and mortality associated with chronic HBV infection, including cirrhosis and hepato-cellular carcinoma. However, as the long-term consequences of HBV infection occur years after infection, short-term goals and objectives have been defined. These include:

1. Introduction of hepatitis vaccine into the EPI in 2003.
2. Delivery of Hepatitis B and all other EPI vaccines according to safe injection practices.
3. Training of health care workers and sensitisation of policy makers and the community about HBV infection and hepatitis B vaccine.
4. Reduction in vaccine wastage by promoting proper indenting of vaccine and clinic management.
5. 80% coverage with 3 doses of Hepatitis B vaccine by 12 months of age by 2005 and also by district level with combined vaccine. Achieve and maintain minimum 99% coverage at national level by 2005.

22.3.10. Japanese Encephalitis

To reduce mortality and morbidity due to J.E.

APPENDICES

23.1. APPENDICES

IMPORTANT CIRCULARS AND LETTERS REGARDING EXPANDED PROGRAMME ON IMMUNIZATION (E.P.I.)

01. General Circular No. 560 of 25.06.1971 – Immunization Schedule and Supplement of 30.6.1972 – Simultaneous Administration of Several Vaccines.
02. Divisional Circular Pub. No. 103 of 11.5.1972 – Prevention of Neo-natal Tetanus.
03. Divisional Circular Pub. No. 104 of 9.6.1972 – Programme of Immunization with Triple Vaccine.
04. Divisional Circular Pub. No. 106 of 22.7.1972 – Use of Freeze Dried Vaccine in Smallpox Vaccination.
05. Divisional Circular Pub. No. 110 of 1.11.1972 – Maps and Charts at a Health Office.
06. Divisional Circular Pub. No. 118 of 6.7.1973 – Issue of Certificate of Competency in the Administration of Injections by PHII/PHMM
07. Divisional Circular Pub. No. 123 of 29.9.73 – Maintenance of Immunization Records.
08. Divisional Circular Pub. No. 127 of 31.12.1973 – Vaccination Against Smallpox.
09. Divisional Circular Pub. No. 141 of 19.3.1976 – Expansion of Immunization Programmes.
10. General Circular No. 941 of 30.8.1978 – Expanded Programme on Immunization (EPI).
11. General Circular No. 999 of 29.4.1979 – Distribution of Vaccines – Expanded Programme on Immunization (EPI).
12. General Circular No. 1250 of 12.9.1982 – Immunization Schedule
13. General Circular No. 1350 of 18.10.1984 – Immunization Against Measles.
14. General Circular No. 1480 of 10.10.1986 – Adherence to Proper Procedures during Immunization .
15. General Circular No. 1901 of 13.03.1996 – Immunization Against Rubella.
16. DDPHS Letter dated 10.06.1997 – Guidelines for Implementation of the National Rubella Immunization Programme.
17. General Circular No. 02-01-1998 of 16.06.1998 - Immunization Against Rubella.

APPENDICES

18. General Circular No. 1.08.1998 of 7.9.1998 -Issue of Rubella Vaccines to General Practitioners Register with the Sri Lanka Medical Council.
19. General Circular Letter No. 02- 142-1999 of 08.12.1999 – Measles Outbreak 1999.
20. General Circular No. 01.13/2000 of 21.8.2000 - List of Notifiable Diseases.
21. General Circular No. 01.26/2000 of 19.11.2000 – National Immunization Schedule 2001- Sri Lanka
22. DGHS Letter EPID/302/V/99 of 13.8.2001 – Rubella Immunization Coverage.
23. General Circular Letter No. 2-86/2001 of 30.8.2001 – Guidelines for Implementation of the National Rubella Immunization Programme – 2000.
24. DGHS Letter EPID/302/V/1999 of 19.9.2001 – Intensification of Rubella Immunization.

23.2. Glossary

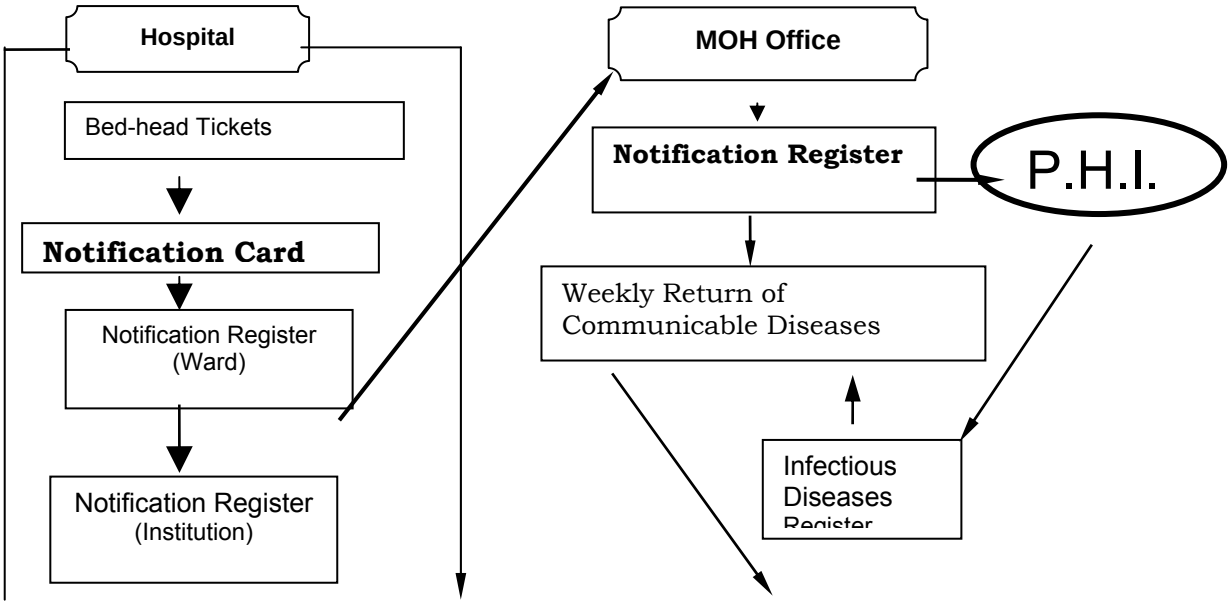
AD	Auto – disable
aTd	adult Tetanus and diphtheria vaccine
AEFI	Adverse Events Following Immunization
BCG	Bacille Calmette-Guerin, vaccine against tuberculosis
DDHS	Divisional Director of Health Services
DPT or DTP	Diphtheria-Tetanus-Pertussis vaccine
DT	Diphtheria and Tetanus vaccine
DPDHS	Deputy Provincial Director of Health Services
ELISA	Enzyme-linked immunosorbent assay
EPI	Expanded Programme on Immunization
Epid Unit	Epidemiological Unit
FHB	Family Health Bureau
GAVI	Global Alliance on Vaccines and Immunization
HA	Hemagglutination test
HB	Hepatitis B
HepB	Hepatitis B vaccine
HIB	Haemophilus Influenzae type B
ICC	Interagency Co-ordinating Committee
IU	International Unit of Potency
JE	Japanese Encephalitis
JICA	Japanese International Co-operation Agency
LD	Dose which kills 50% of test animals
LF	Flocculation value, the amount of toxoid which when mixed with one International Unit of anti-toxin produces an optimally flocculating mixture
MCH	Maternal and Child Health
MOH	Medical Officer of Health
MO (MCH)	Medical Officer (Maternal and Child Health)

MR	Measles Rubella vaccine
MRI	Medical Research Institute
NID	National Immunization Day
NGO	Non-government Organization
OPV	Oral Polio Vaccine
PDHS	Provincial Director of Health Services
PFU	Plaque forming unit; the smallest quantity of a virus suspension that will produce a plaque in monolayer cell cultures
RE	Regional Epidemiologist
SNID	Sub-national Immunization Day
TB	Tuberculosis
TCID	Tissue culture infective dose 50%; the quantity of a virus suspension that will infect 50% of cell cultures
Td	Diphtheria (reduced component) and Tetanus vaccine
TOPV	Trivalent Oral Polio Vaccine
TT	Tetanus Toxoid
UNICEF	United Nations Children's Fund
WHO	World Health Organization

Figure – 8

EPIDEMIOLOGICAL SURVEILLANCE

MECHANISM FOR COLLECTION OF DATA



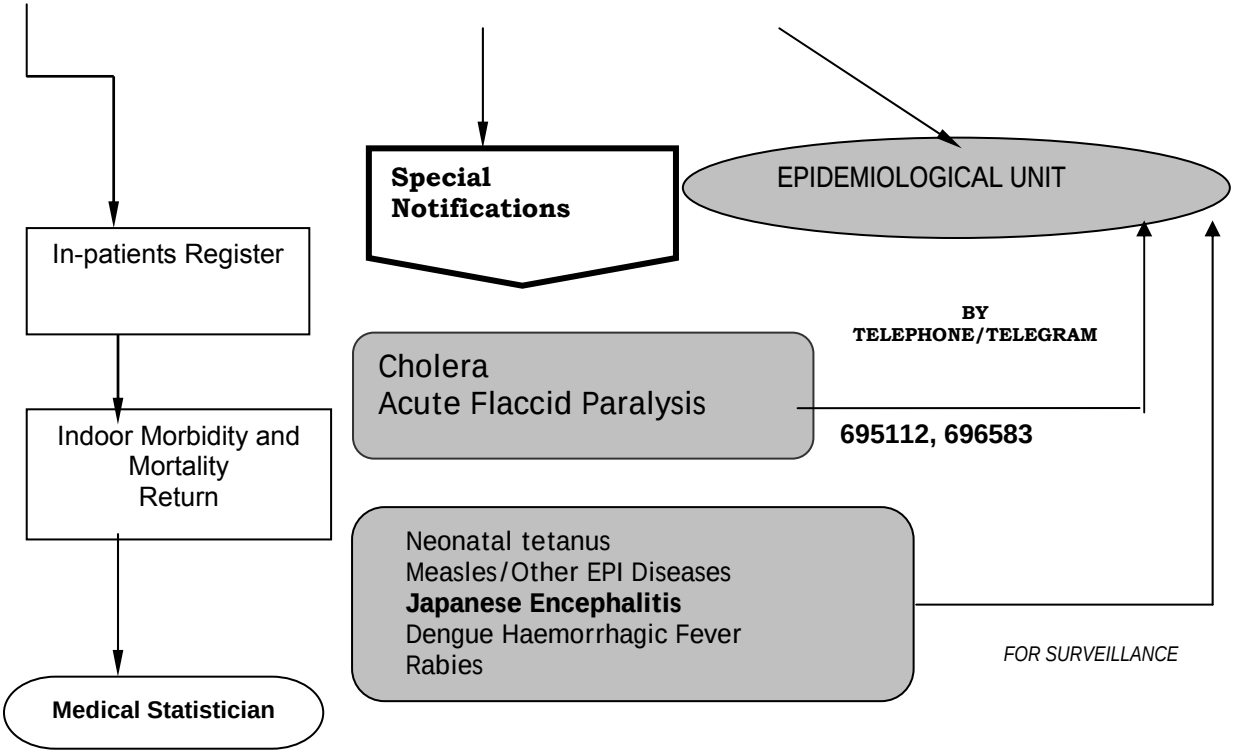
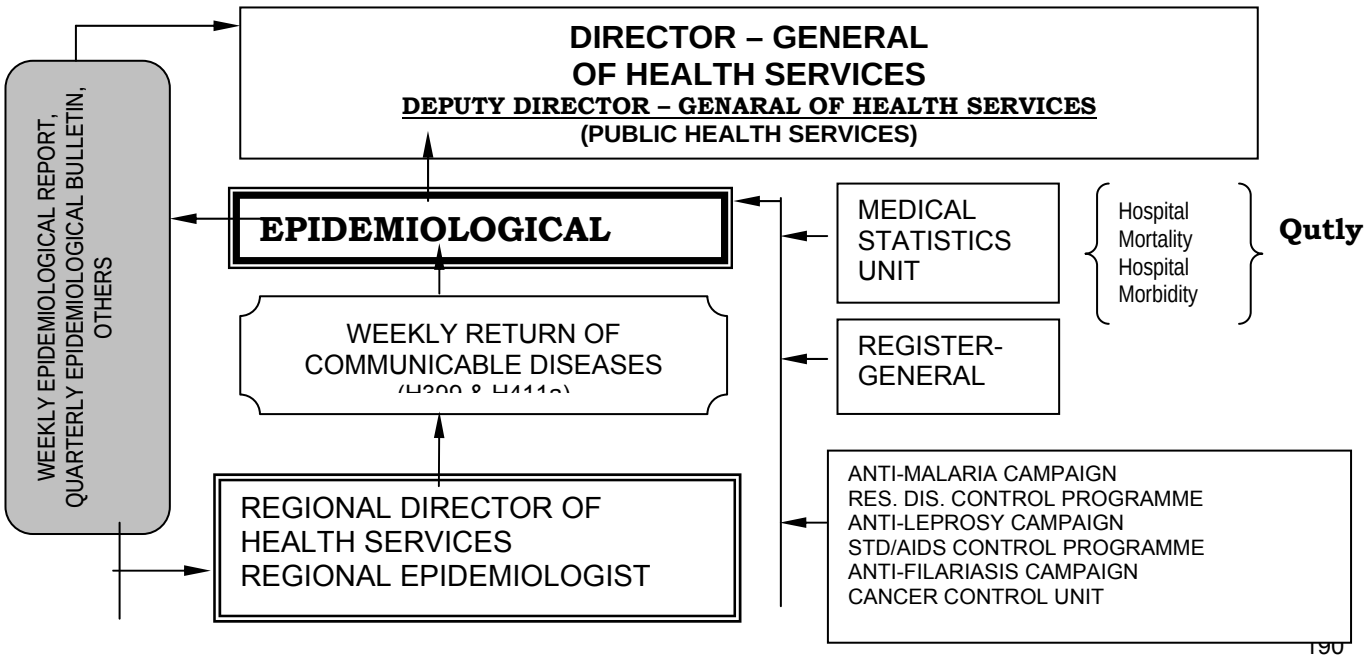
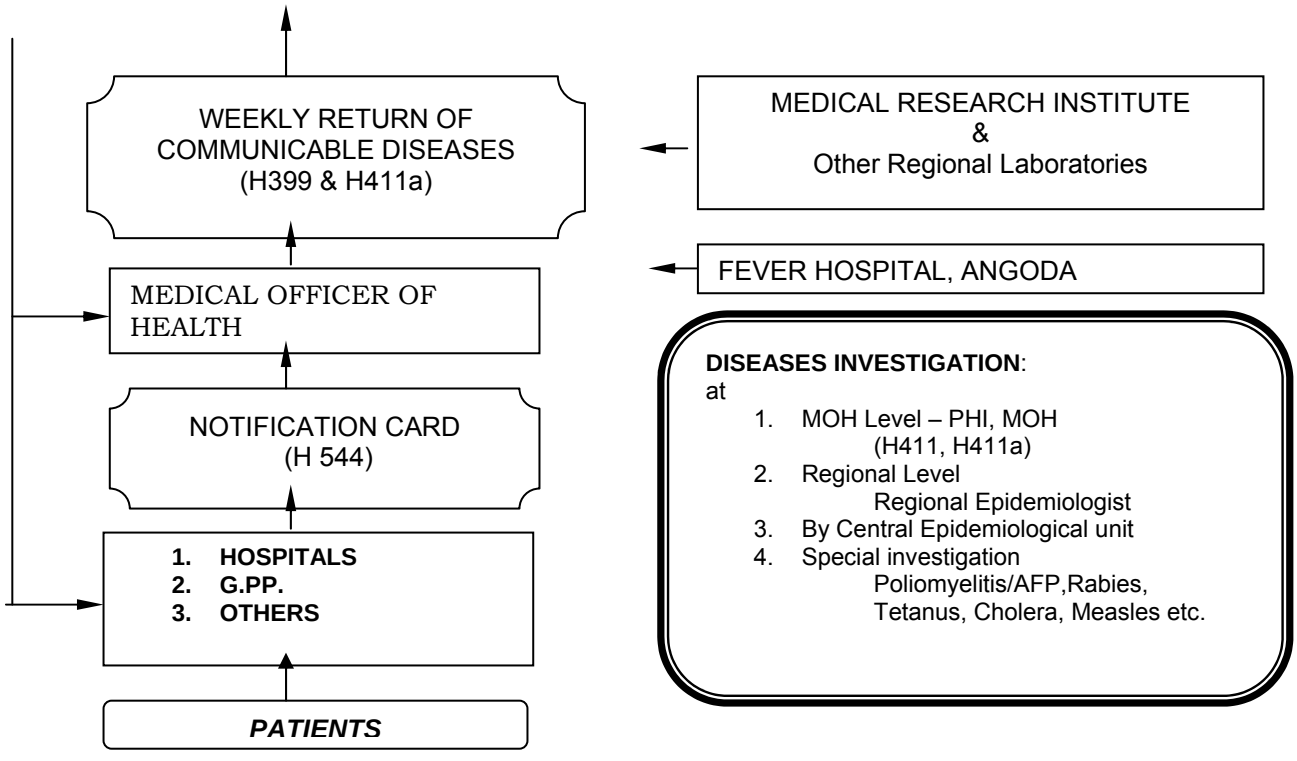

In-patients Register
Indoor Morbidity and Mortality Return
Medical Statistician
Special Notifications
EPIDEMIOLOGICAL UNIT
BY TELEPHONE/TELEGRAM
Cholera
Acute Flaccid Paralysis
695112, 696583
Neonatal tetanus
Measles/Other EPI Diseases
Japanese Encephalitis
Dengue Haemorrhagic Fever
Rabies
FOR SURVEILLANCE

Figure – 9

Disease Surveillance System




WEEKLY RETURN OF COMMUNICABLE DISEASES (H399 & H411a)
MEDICAL RESEARCH INSTITUTE & Other Regional Laboratories
FEVER HOSPITAL, ANGODA
MEDICAL OFFICER OF HEALTH
NOTIFICATION CARD (H 544)
1. HOSPITALS
2. G.PP.
3. OTHERS
PATIENTS
DISEASES INVESTIGATION:
at
1. MOH Level – PHI, MOH (H411, H411a)
2. Regional Level Regional Epidemiologist
3. By Central Epidemiological unit
4. Special investigation Poliomyelitis/AFP,Rabies, Tetanus, Cholera, Measles etc.

23.3. Incidence of E.P.I. Diseases in Sri Lanka

Table 1. 1

INCIDENCE OF EPI TARGET DISEASES – SRI LANKA

(Based on Hospital admissions 1951 – 1964 contd..... table 1.1)

	DIPHTHERIA		PERTUSSIS		TETANUS		POLIOMYELITIS		MEASLES		TUBERCULOSIS		N-TETANUS	
YEA	CAS	RATE	CAS	RATE	CAS	RATE	CASE	RATE	CASE	RAT	CAS	RATE	CA	RATE
1951	772	9.8	1236	15.7	970	12.3	239	3.0	2609	33.1				
1952	560	6.9	1146	14.2	873	10.8	255	3.2	1650	20.4				
1953	768	9.3	813	9.8	1033	12.5	226	2.7	1571	19.0				
1954	1057	12.4	1674	19.6	908	10.7	159	1.9	2424	28.5				
1955	1179	13.5	1941	22.3	873	10.0	102	1.2	3499	40.1				
1956	1823	14.8	1295	14.5	937	10.5	72	0.8	4273	47.0				
1957	929	10.1	1409	15.4	1007	11.0	334	3.6	3862	42.1	8854	96.6		
1958							201	2.1			9869	99.8		
1959	780	8.1	1955	20.3	959	10.0	321	3.3	2736	28.4	8321	86.5		
1960	1042	10.5	1786	18.0	1435	14.5	219	2.2	3060	30.9	1051	106.3		
1961	1041	10.2	1947	19.1	1621	15.9	306	3.0	3127	30.6	8411	82.7		
1962	740	7.3	1677	16.1	1181	11.3	1810	17.8	2567	24.6	9135	87.5		
1963	1040	9.9	2431	22.8	1067	10.0	166	1.6	3403	31.9	8135	76.4		
1964	953	8.9	1761	16.2	1972	18.1	223	2.1	3033	27.8	7774	71.3		

Table 1. 1

INCIDENCE OF EPI TARGET DISEASES – SRI LANKA

(Based on Hospital admissions 1965 – 1979 contd… table 1.1)

	DIPHTHERIA		PERTUSSIS		TETANUS		POLIOMYELITIS		MEASLES		TUBERCULOSIS		N-TETANUS	
YEA	CAS	RATE	CAS	RATE	CAS	RATE	CASE	RATE	CASE	RAT	CAS	RATE	CA	RATES
1965	1232	11.3	2109	18.9	1812	16.2	382	3.2	2037	18.2	6927	62.0		
1966	1436	12.6	2185	17.2	1323	11.6	332	2.9	3070	27.0	6168	54.4	280	75.0
1967	1453	12.5	1218	10.5	1994	17.2	144	1.2	2104	18.2	6304	54.5	458	123.9
1968	1148	9.7	1461	12.3	1825	15.4	1009	8.8	4544	38.4	6404	54.2	819	213.2
1969	972	8.0	2348	19.4.	2013	16.7	186	1.5	3450	28.6	6261	51.9	623	167.1
1970	986	7.9	1651	13.4	2288	18.5	121	1.0	4086	33.1	5762	46.7	847	230.3
1971	715	5.7	1696	13.4	1961	15.5	330	2.6	4549	35.9	5650	44.7	647	169.2
1972	755	5.8	1984	15.0	2137	16.5	297	2.3	2712	20.9	6441	49.7	871	226.8
1973	496	3.7	968	7.3	2138	16.1	360	2.8	4931	37.7	5970	45.0	961	262.4
1974	251	1.8	525	3.8	2012	14.8	608	4.4	1580	11.8	6074	45.7	809	221.2
1975	310	2.8	1341	9.7	1998	14.5	190	1.4	5000	37.0	7324	54.2	812	222.0
1976	152	1.1	1040	8.0	2000	14.6	258	1.8	5639	41.1	6823	49.7	642	169.4
1977	145	1.0	1078	7.6	1928	11.7	127	0.9	5814	41.7	5994	42.9	821	216.7
1978	216	1.5	703	4.9	2028	14.2	153	1.0	6128	43.9	6360	44.8	874	217.0
1979	101	0.7	803	5.5	1480	10.2	143	1.0	6126	49.0	6152	42.0	423	107.8

Table 1. 1

INCIDENCE OF EPI TARGET DISEASES – SRI LANKA

(Based on Hospital admissions 1980 – 1990 contd… table 1.1)

	DIPHTHERIA		PERTUSSIS		TETANUS		POLIOMYELITIS		MEASLES		TUBERCULOSIS		N-TETANUS	
YEA	CAS	RATE	CAS	RATE	CAS	RATE	CASE	RATE	CASE	RAT	CAS	RATE	CA	RATES
1980	37	0.3	542	3.7	1243	8.5	264	1.8	5032	34.3	6212	42.4	339	82.8
1981	36	0.2	501	3.4	949	0.3	254	1.7	6232	41.5	6288	42.4	219	54.3
1982	22	0.13	296	1.9	795	5.4	84	0.56	13273	87.3	7334	48.0	182	43.6
1983	26	0.16	244	1.6	721	4.7	57	0.36	8171	52.9	6666	43.0	70	16.3
1984	20	0.1	274	1.7	585	1.7	16	0.1	9211	59.0	6376	40.8	123	29.2
1985	10	0.04	536	3.4	481	3.0	11	0.06	8798	55.5	5889	37.8	76	19.1
1986	3	0.01	157	0.9	502	3.1	9	0.05	6235	38.7	6596	40.7	49	13.0
1987	0	0.0	31	0.2	258	1.5	96	0.6	3508	21.5	6411	38.4	37	10.1
1988	0	0.0	18	0.1	219	1.3	16	0.09	2650	15.8	6092	36.5	39	10.7
1989	0	0.0	61	0.4	295	1.7	4	0.02	780	4.6	8794	52.5	19	5..2
1990	0	0.0	271	1.6	183	1.3	9	0.05	4004	27.6	6666	39.2	5	1.5

Rate per 100,000 population except in Neo Natal Tetanus is per 100,000 live births

**Provisional data from epidemiological unit*

Table 1. 1

INCIDENCE OF EPI TARGET DISEASES – SRI LANKA

(Based on Hospital admissions 1991 – 2000 contd… table 1.1)

	DIPHTHERIA		PERTUSSIS		TETANUS		POLIOMYELITIS		MEASLES		TUBERCULOSIS		N-TETANUS	
YEAR	CASE	RATE	CASE	RATE	CASE	RATE	CASE	RATE	CASE	RATE	CASE	RATES	CASE	RATES
1991	1	0.0	25	0.1	188	1.1	1	0.0	1896	11..0	6174	35.7	10	2.8
1992	0	0.0	6	0.03	231	1.3	12	0.06	701	4.0	6802	39.1	14	4.4
1993	1	0.0	18	0.1	196	1.1	15	0.08	558	3.2	6885	38.9	11	3.5
1994	0	0.0	34	0.2	156	0.9	0	0.0	390	2.2	6121	34.2	11	1.3
1995	0	0.0	171	0.9	167	0.9	0	0.0	465	2.6	5869	32.6	2	0.6
1996	1	0.0	33	0.2	97	0.5	0	0.0	158	0.9	5366	29.3	6	1.8
1997	0	0.0	205	1.1	23	0.1	0	0.0	66	0.4	6547	35.6	4	1.2
1998	0	0.0	94	0.5	24	0.1	0	0.0	23	0.1	6925	36.9	4	1.2
1999	0	0.0	61	0.3	23	0.1	0	0.0	2341	12.5	7157	37.6	3	0.9
2000*	0	0.0	88	0.5	38	0.2	0	0.0	4096	82.5	8129	42.9	1	0.3

Rate per 100,000 population except in Neo Natal Tetanus is per 100,000 live births

**Provisional data from epidemiological unit*

Table 1. 2

INCIDENCE OF EPI TARGET DISEASES – SRI LANKA

(Based on Hospital admissions 1985 – 2000)

	Rubella		Con. Rubella		Mumps		Hepatitis		JE*	
YEAR	CASE	RATE	CASE	RATE	CASE	RATE	CASE	RATE	CASE	RATES
1990	69	0.4	-	-	756	4.4	5926	34.7	387	2.3
1991	10	0.1	-	-	2317	13.4	3227	18.7	325	2.0
1992	14	0.1	-	-	691	4.0	12674	72.5	291	1.7
1993	23	0.1	-	-	405	2.3	9938	56.4	289	1.6
1994	84	0.5	-	-	289	1.6	8348	47.6	230	1.3
1995	79	0.4	-	-	854	4.7	6370	35.3	173	1.0
1996	79	0.4	59		763	4.2	3812	21.0	307	1.7
1997	99	0.5	16		792	4.3	5051	27.5	164	1.0
1998	116	0.6	26		780	4.2	4247	22.9	122	0.7
1999	209	1.1	35		884	4.7	5016	26.7	102	0.5
2000*	N /A	N/A	N/A		901	4.8	N/A	N/A	83	0.4

** Special surveillance* *N/A – Not Available*

*Rate per 100,000 population except in Neo Natal Tetanus is per 100,000 live births * Data available from epidemiological unit*