

Eradication of Poliomyelitis

A comprehensive guide for Medical Officers

Second Edition 2005

EPIDEMIOLOGY UNIT
Ministry of Healthcare & Nutrition
Colombo



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Information in this manual has been predominantly extracted from national reports on the Expanded Programme on Immunization (EPI) and poliomyelitis eradication and other technical papers of the WHO and PAHO.

The contributions made by Dr (Mrs) M. Senanayake Senior Lecturer in Paediatrics, Faculty of Medicine University of Colombo, Dr Sudath Gunasekera, Consultant Neurophysiologist, National Hospital of Sri Lanka and Dr Sunethra Gunasena Consultant Virologist Medical Research Institute (MRI), for this publication are greatly appreciated.

This manual was originally compiled in 1997 by Dr (Mrs) S I Weeraman formerly of Epidemiological Unit, and it has now been revised and updated by her on the recommendations made at the International AFP Surveillance Review held in Colombo in 2003.

The inputs to this manual by Dr T A Kulatilaka, former Epidemiologist of the Epidemiological Unit are much valued and appreciated.

FOREWORD

A resolution calling for the global eradication of poliomyelitis by the year 2000 was adopted by the World Health Assembly in 1988. During the past seventeen years the eradication initiative has spread from one to all of the six WHO Regions. Poliomyelitis eradication has become one of the primary goals of the WHO and all its Member States. The goal of achieving global poliomyelitis eradication is a matter of concern for all countries as no country is safe until every country in the world is free of poliomyelitis.

In the South East Asian Region, poliomyelitis eradication activities have progressed well and there are only a few foci of infection. Sri Lanka has not reported a single case of poliomyelitis since 1993 and the Acute Flaccid Paralysis (AFP) surveillance programme in our national poliomyelitis eradication initiative has been well recognized by regional authorities as successful. However, extreme vigilance and further strengthening of the surveillance activities are necessary till we finally achieve the polio-free certification and thereafter reach the ultimate target of poliomyelitis eradication.

The primary objective of this manual is to update the knowledge of all Medical Officers on the rapidly evolving poliomyelitis eradication activities. Paediatricians and Physicians play a major role in poliomyelitis eradication activities by notifying cases of acute flaccid paralysis. Notification of such a case from an institution initiates all the field activities conducted by the Divisional Directors of Health Services (DDHS) / Medical Officers of Health (MOOH). All health personnel could continue to contribute to the poliomyelitis eradication initiative by ensuring that all children under 5 years seen by them are fully immunized with Oral Polio Vaccine according to the national immunization schedule.

The manual will provide practical information on activities included in AFP surveillance programme including epidemiological investigation, outbreak control, laboratory confirmation and information on national immunization days and “mopping up” activities for poliomyelitis eradication. Further, it includes practical information on laboratory containment of wild poliovirus and the process of certification of a country as poliomyelitis free.

This manual also makes an effort to provide practical guidelines to supervisors to assist DDHS/MOOH to carry out eradication strategies in a timely and comprehensive manner.

I thank Dr S I Weeraman, formerly of the Epidemiological Unit for revising this manual. I also wish to take this opportunity to thank all experts who contributed to this Second Edition as well as the First Edition. I am grateful to Dr Paba Palihawadana Deputy Epidemiologist of the Unit for her untiring efforts in making this manual a reality.

I am pleased to have the opportunity to write this foreword for this revised edition of the manual and I trust that it will fulfill its intended task.

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INTRODUCTION

1.1 BACKGROUND

Sri Lanka is an island nation near the South Eastern coast of India, and covers an area approximately 65,610 square kilometers. Like many developed countries, Sri Lanka has a rapidly aging population and a high literacy rate (90.5% for men and 82.4% for women). The Sinhalese constitute the largest ethnic group (81.9%) and are mainly Buddhist. The Tamils, the second largest group (9.5%) are mainly Hindu and speak Tamil. There are two distinct groups of Tamils in Sri Lanka. The Tamils concentrated in the North of the country had migrated primarily from South India. The other group of Tamils resident primarily in the “hill country” had been brought from India during the colonial period by the British to work in the tea plantations. Muslims the third largest ethnic group is concentrated mainly in the Eastern Province.

The island has experienced severe conflict between the two main ethnic groups namely Sinhalese and Tamil, for the past 20 years in the North Eastern Province. This has resulted in periodic displacement of large sections of the population from conflict areas. Large-scale migrations have taken place from North East predominantly to Southern India and to Tamil Nadu in particular. In times of peace, these populations have moved back to their residential areas in Sri Lanka. According to the 2001 census, the population estimate for Sri Lanka was 19.65 million. Approximately 25.8% of the population is less than 15 years of age (1) and 7.9% is less than 5 years. Virtually all childbirths take place in hospitals with the Public Health Midwife (PHM) conducting home visits within the first 10 postnatal days. Newborns are registered for child health services, including immunizations, by the PHM. Health care is provided free of cost in government health facilities.

A pilot project to immunize children against poliomyelitis using Trivalent Oral Polio Vaccine (TOPV) was carried out in one health unit area in September 1961 in the Kalutara District in Sri Lanka. This was in anticipation of introducing vaccination against poliomyelitis. The administration of TOPV was introduced island wide; when the worst outbreak of poliomyelitis occurred in 1962. All children in the age group of 3 months to 15 years were immunized. The first mass immunization programme for children under 8 years of age covering the entire country was conducted in 1963, as the coverage achieved in 1962 was inadequate. Thereafter routine immunization was carried out in all child welfare clinics in the country, but the coverage achieved was low. Mass campaigns were conducted annually from 1968 to 1973. Between this period mass campaigns were restricted to those health divisions that showed an increase in the incidence of poliomyelitis during the year. With the implementation of the Expanded Programme on Immunization (EPI) in 1978, all aspects of the programme improved, specially the “cold chain” which is of vital importance in maintaining the potency of the Polio vaccine.

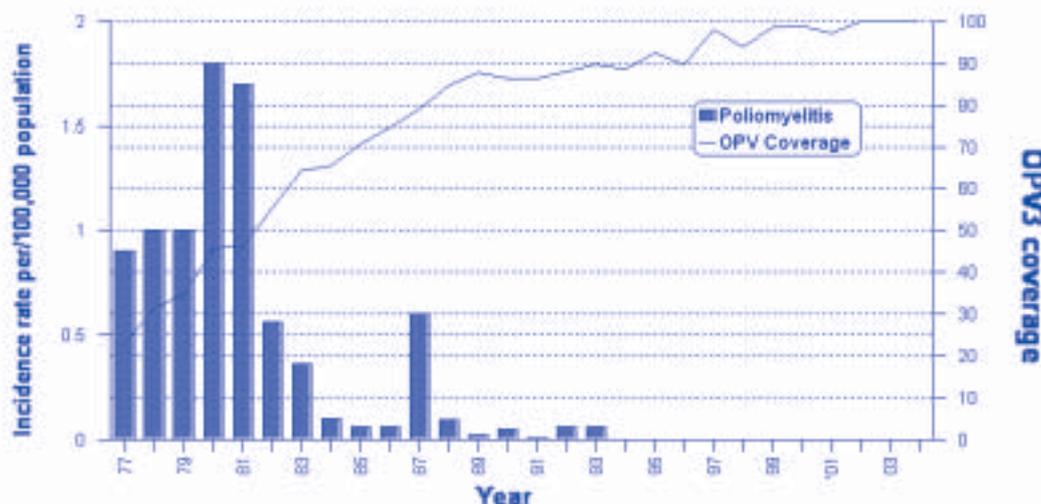
From the inception of immunization to date, OPV is given free of charge like all other vaccines. Earlier, Polio vaccine was donated to Sri Lanka by UNICEF and Rotary International–Sri Lanka. Since 1995 all requirements of polio vaccine is provided by the Government of Sri Lanka. The financial sustainability for successful implementation will be ensured by the Sri Lankan Government. In order to reduce the financial burden on governments through out the world, WHO has endorsed a policy for the use of opened multi dose vials of liquid vaccines in subsequent immunization sessions without compromising the quality and safety of the vaccine. This has been practiced in many other countries for the last few years. After considering all relevant factors the National Advisory Committee on Communicable Diseases decided to introduce the open vial policy for OPV in Sri Lanka from February 2005.

HISTORY OF POLIOMYELITIS, ITS CONTROL AND ERADICATION ACTIVITIES IN SRI LANKA

- 1944 - Poliomyelitis was made a notifiable disease
- 1961 - Pilot project to immunize children using Trivalent Oral Polio Vaccine (TOPV) – Kalutara Health Unit
- 1962 - Introduction of TOPV in Colombo and suburbs for children in the age group of 3 months to 15 years
- 1963 - Mass immunization programme island wide for children under 8 years
- 1964 - Routine immunization of the infant population commenced in all child welfare clinics
- 1964 -67 - Mass immunization campaigns in selected areas
- 1968 -73 - Annual mass immunization campaigns island wide
- 1978 - Expanded Programme on Immunization (EPI) implemented
- 1988 - Commitment to eradicate poliomyelitis
- 1990 - Acute Flaccid Paralysis (AFP) was made notifiable as suspect poliomyelitis
- 1991 - 5th dose of TOPV at school entry introduced
Case based investigation of AFP cases commenced
- 1993 - Immunization campaign for all children under 5 years of age in DPDHS Division Puttalam
- 1994 - Immunization campaign for all children under 5 years of age in DPDHS Division Trincomalee
- 1995 - Moved from clinical to virological classification of AFP cases
1st National Immunization Days (NIDs) [04.11.95 and 09.12.95]
- 1996 - 2nd National Immunization Days (NIDs) [07.09.96 and 12.10.96]
- 1997 - 3rd National Immunization Days (NIDs) [06.06.97 and 11.10.97]
- 1998 - 4th National Immunization Days (NIDs) [19.09.98 and 24.10.98]
- 1999 - 5th National Immunization Days (NIDs) [11.09.99 and 16.10.99]
National Committee for Certification of Polio Eradication (NCCPE) convened
- 2000 - 1st Sub National Immunization Days (SNIDs) and mop-up campaign for children under 5 yrs in the North and East Province [11.09.2000 and 16.10.2000]
- 2001 - 2nd Sub National Immunization Days (SNIDs) and mop-up campaign for children under 5 yrs in the North and East Province [22.09.01 and 20.10.01]
Laboratory containment of wild polio virus commenced
- 2002 - 3rd Sub National Immunization Day (SNID) and mop-up campaign for children under 5 yrs in the North and East Province [28.09.02 and 29.10.02]
- 2003 - 4th Sub National Immunization Days (SNID) and mop-up campaign for children under 10yrs in the North and East Province [20.09.03 and 19.10.03]
- 2005 - Acute Flaccid Paralysis (AFP) gazetted as a notifiable disease.

An increasing immunization coverage with a continued decline in the incidence of the disease as shown in Figure 1 indicated the prospects of eradicating poliomyelitis from Sri Lanka. At the 41st World Health Assembly held on the 13th of May 1988, Sri Lanka along with 31 other countries pledged to eradicate poliomyelitis by the year 2000.

Figure 1 INCIDENCE RATE OF POLIOMYELITIS CASES AND OPV3 COVERAGE SRI LANKA 1977 TO 2004



The short-term cost of achieving the goal, poliomyelitis eradication outweighs the long-term financial and humanitarian benefits. The long-term benefits are the savings that could be made from treatment and rehabilitation costs of poliomyelitis victims and the savings from the reduced purchases and delivery of vaccine stocks. More importantly no child will any longer be crippled by poliomyelitis. In the highly competitive society of today, the poliomyelitis disabled child is at a disadvantage physically socially and educationally. The affected child is often unable to become an active and a productive member of society.

1.2 POLIOMYELITIS ERADICATION

Most poliovirus infections are sub clinical. Therefore eradication of poliomyelitis is not mere absence of clinical cases caused by the naturally occurring (wild) poliovirus but that of ending wild poliovirus transmissions so that no wild poliovirus can be found despite intensive efforts to do so.

POLIOMYELITIS ERADICATION

- **No wild polio virus transmission**
- **No wild poliovirus found despite intensive efforts**

Eradication of poliomyelitis is possible as poliovirus infects only humans and there is no long-term carrier state after infection. Further, there is no evidence of an animal or insect reservoir. The inability of the virus to survive for long outside the human body and the availability of a very effective and a safe vaccine are positive factors that contribute to the eradication of this disease.

ERADICATION OF POLIOMYELITIS IS POSSIBLE BECAUSE:

- **Poliovirus infects only humans**
- **There is no long-term carrier state after infection**
- **There is no evidence of an animal or insect reservoir**
- **Virus is unable to survive outside the human body for long**
- **A very effective and a safe vaccine is available**

1.3 OBJECTIVES OF POLIOMYELITIS ERADICATION

The objective of polio eradication is to interrupt the transmission of the wild poliovirus; and to implement the polio endgame programme of work. This includes containment of wild poliovirus, global polio-free certification, development of a post-eradication immunization policy; and certification of global polio eradication.

As a result of this eradication initiative, there are many direct and indirect benefits. Once polio has been eradicated, the world will reap substantial financial, as well as humanitarian dividends due to foregone polio treatment and rehabilitation costs. Besides there are many other indirect benefits. To achieve eradication, facilities like cold chain and other equipment, including laboratory equipment are provided and/or improved. Disease and laboratory surveillance are markedly improved and these could be made use of in control/elimination of other diseases. Improvements in vaccine quality etc. are also made and this was of benefit to other vaccine preventable diseases. Conduct of supplementary immunization activities contribute experience to organize and conduct such activities for other diseases e.g. measles immunization campaigns. Health education activities and organization of community participation for mass field activities are also benefited. Challenges to get high-level political and non-governmental participation could also be overcome. There will be improvement in human resources aspect too; like long term and short term recruitment of staff and training. There will also be greater interaction between curative, laboratory and preventive institutions.

Inaccessibility to children in conflict areas has been recognized as a threat to global poliomyelitis eradication. Certification cannot be achieved until there is confidence that transmission of wild poliovirus in these areas has ceased. However there has been a rapid increase in the quality of polio eradication activities in many conflict affected areas. Cross regional working groups are to be established to ensure that the lessons learned and strategic approaches in these areas are shared. These will be a major focus in future plans for eradication. Neighbouring countries affected by conflict should put special emphasis on cross-border coordination of eradication activities.

EPIDEMIOLOGY OF POLIOMYELITIS

2.1 INFECTIOUS AGENT

Poliomyelitis is an infectious disease caused by poliovirus. The disease, which causes paralysis, can strike at any age but mainly affects children under three years of age. Polio virus (wild) is an enterovirus. There are three antigenic types, (type 1, type 2, type 3) and all three types can cause paralysis. Most cases of paralysis are due to type 1, while paralysis caused by type 3 is less frequent. Paralysis due to type 2 is uncommon. Most epidemics are due to type 1.

The virus usually enters through the mouth and thereafter multiplies inside the throat and intestines. Once established, the poliovirus can enter the blood stream and invade the central nervous system spreading along the nerve fibres. As it multiplies, the virus destroys the motor neurons that activate muscles. These nerve cells cannot be regenerated and the affected muscles can no longer function. Muscle pain and spasms, and fever are associated with the rapid onset of acute flaccid paralysis. Paralysis due to poliomyelitis is almost irreversible.

INFECTIOUS AGENT OF POLIOMYELITIS

- **Polio Virus (wild)**
- **An enterovirus**
- **Antigenic types 1,2, and 3**

Oral Polio Vaccine (OPV) is a stabilized preparation of live attenuated poliomyelitis viruses of the Sabin strains type 1, 2, and 3 propagated in MRC5 human diploid cells. Poliomyelitis could rarely occur due to vaccine virus. These vaccine associated paralytic cases are usually due to type 2 and 3.

During routine immunization, the rate of vaccine associated paralytic cases reported has been 1 case per every 2.4 million doses of OPV administered. During mass immunization campaigns such as National Immunization Days (NIDs), the rate of vaccine associated paralytic cases (2) in general is as follows:

- 1 case per 3,300,000 doses distributed or administered
- 1 case per 700,000 first doses distributed or administered
- 1 case per 6,900,000 subsequent doses distributed or administered

2.2. OCCURANCE WORLD WIDE

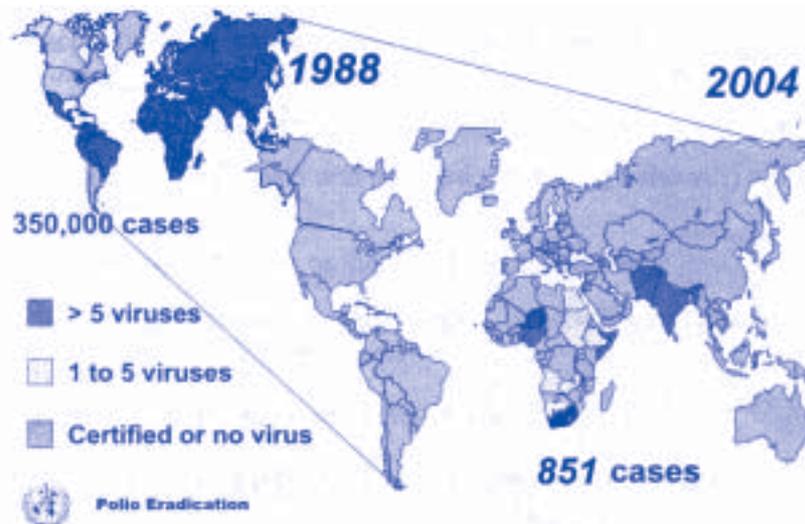
Poliomyelitis is a disease that does not respect national borders or continental boundaries, and in that sense is truly a problem of global concern. Genetically related polioviruses however cluster geographically. Poliomyelitis produces a significant amount of illness, death and disability. All persons infected with the wild poliovirus do not develop paralysis and generally for each case of paralytic poliomyelitis there may be more than 100 persons with minor or in-apparent illness. There is no long-term carrier state.

Poliomyelitis occurred worldwide in epidemic form in the first half of the 19th century. The incidence of poliomyelitis declined dramatically, once a safe and effective vaccine was available and was widely distributed at the end of Nineteen Fifties and early Sixties.

In 1988 at the 41st World Health Assembly (WHA), the annual meeting of the ministers of health of all Member States of the World Health Organization, voted to launch a global initiative

to eradicate polio. Between 1988 and the mid 1990s, there was a limited reduction in the number of endemic countries as the partnership was developed, broader political commitment secured and operational feasibility of strategies was established. From the mid 1990s, it was possible to rapidly scale-up eradication activities, so that by the end of the decade over 575 million children were regularly being reached with oral polio vaccine. During the last 14 years since the Global Polio Eradication Initiative was launched, the number of cases has fallen by 99% from an estimated 350,000 cases in 1988 to 1919 reported cases in 2002 (3). Polio cases were then at the lowest in history, and by the end of 2001 there were approximately 483 reported polio cases (Figure 2). In the year 2003, 784 wild virus confirmed cases have been reported, and by late 2003 polio had been eliminated from all but six countries. An outbreak of poliomyelitis was reported in March 2005 from Indonesia, which had been free of polio since 1995, and now the world count of wild polio virus confirmed cases stands at 1004 by August 2005. However more notably, nearly five million children are able to walk who would otherwise have been paralyzed by poliomyelitis (4).

Figure 2 GLOBAL PROGRESS IN POLIO ERADICATION 1988- 2004



Today the technical feasibility of polio eradication has been demonstrated through the elimination of the disease from 210 countries, territories, areas and large geographic areas of the six remaining endemic countries. By late 2003, the remaining chains of wild poliovirus transmission, concentrated primarily in the five states or provinces of Nigeria (2), India (5), and Pakistan (5) were the result of substantial numbers of children missing out their vaccinations during both routine and supplementary polio immunization activities during the preceding years.

Due to a marked increase in frequency and quality of supplementary immunization campaigns, geographic distribution of polio transmission in India, Pakistan and Afghanistan is decreasing and just 96 cases were reported by Autumn 2004 compared with 213 at the same time in 2003. In West and Central Africa 709 polio cases were reported in the year 2004, including 92 cases in 10 previously polio- free countries. This area accounts for 90% of all new polio cases in the world today (4).

2.3 TRANSMISSION

Transmission is primarily person to person and by the faeco-oral route. One week after the onset few viruses remain in the throat and they continue to be excreted in the stools. The faeco-oral route is the most common route of transmission. The time between the infection and onset of paralysis is 10 to 21 days. The virus spreads rapidly to non-immune persons and

transmission is usually widespread by the time of onset of paralysis. The virus is shed intermittently for one month or more after infection and is excreted with the faeces. The heavy shedding occurs just prior to the onset of paralysis and during the first two weeks after initial symptoms occur.

2.4 RESERVOIR

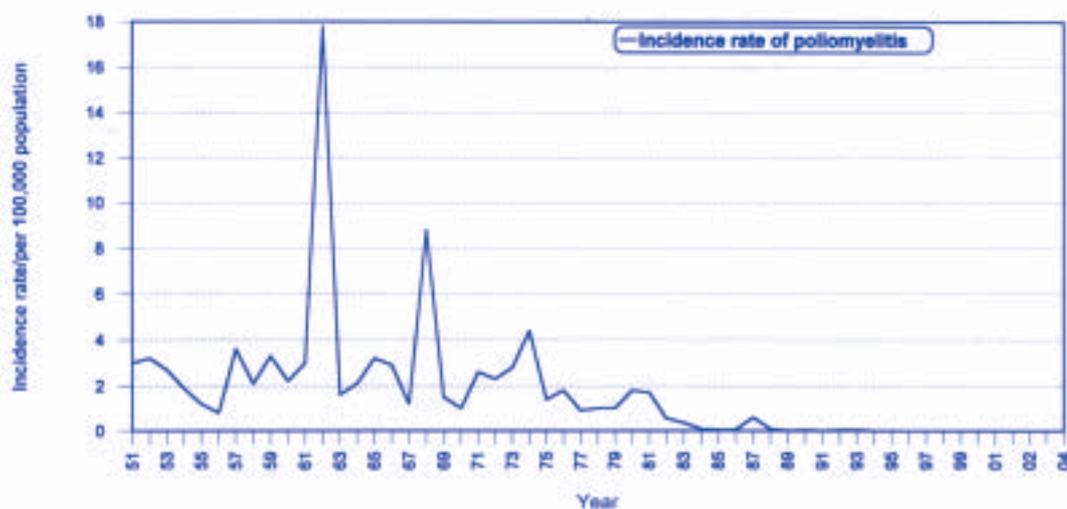
Poliovirus infects only humans and causes acute non-persistent infections. The virus does not survive long in the environment outside the human body.

2.5 OCCURANCE IN SRI LANKA

In Sri Lanka poliomyelitis was made a notifiable disease in 1944. During this year, 4 cases were reported and the number of cases gradually increased to an average of about 100 to 200 cases per year (from 1951 to 1986 the average number of cases was 277). In 1962, Sri Lanka experienced the first major epidemic with 1810 cases and 180 deaths. With this outbreak Oral Polio Vaccine (OPV) was introduced on a mass scale in March 1962. Since then the disease assumed epidemic proportions every six years as shown in Figure 3. Thus epidemics occurred in 1968, 1974, and 1980. Though 1986 was the next anticipated epidemic year, only 9 cases were reported.

This raised an expectation of being able to eradicate this disease from Sri Lanka. However in 1987, an unexpectedly large number of cases were reported during July to October from the Jaffna health division. There were no cases reported in the first six months of the year. No cases were reported from any other part of the country. In the northern part of the country where Jaffna was located, there was considerable disruption of the EPI activities prior to and during this period. There was frequent movement of adults and children to India and back due to the prevailing unsettled conditions. Moreover during this period there was an outbreak of poliomyelitis in South India. A total of 97 cases were reported from Jaffna district and 87.25% of these cases were under 5 years of age while 24.4 % were below 1 year. Sixty seven percent (67.2%) of the children affected had not received even a single dose of OPV, while another 19% had been only partially immunized.

Figure 3 INCIDENCE RATE OF POLIOMYELITIS - SRI LANKA 1951 - 2004



Virological confirmation of poliomyelitis cases had been carried out over the years. According to the virological pattern of the cases detected, it was evident that the ratio of the types 1 2 and 3 in the vaccine formulation of the OPV in use, was not effective. In accordance with this finding, an OPV with a vaccine formulation suitable for use in Sri Lanka was introduced.

A decision was taken to eradicate poliomyelitis from Sri Lanka in 1988 and the surveillance of acute flaccid paralysis (AFP) cases was initiated. In 1990 under the strategy of enhanced surveillance, a case of AFP was made notifiable as a suspect case of poliomyelitis, and during this year 81 cases of AFP were reported and 9 were confirmed as poliomyelitis. In 1991, 1992, and 1993 the number of AFP cases reported were 85, 84, and 96 respectively. Of these 1, 12, and 15 cases were confirmed as poliomyelitis. Of the 15 cases of poliomyelitis confirmed in 1993, 7 were virologically confirmed. Poliovirus type I (wild) was isolated from 5 cases and poliovirus type 2 (wild) and poliovirus type 3 (wild) was isolated from one case each. The others were clinically confirmed. The date of onset of paralysis of the last virologically confirmed (P1 wild) case in 1993 was 9th of November and the patient was from Moneragala DPDHS division.

HISTORY OF POLIOMYELITIS IN SRI LANKA

1944 – Poliomyelitis was made a notifiable disease

1962 – First major epidemic with 1810 cases and 180 deaths

1968 – Epidemic – 1009 cases

1974 - Epidemic – 608 cases

1980 - Epidemic – 264 cases

1986 – Anticipated epidemic year but only 9 cases reported

1993 – November – last virologically confirmed case reported

2.5.1 SEASONAL DISTRIBUTION

In Sri Lanka a definite seasonality was not observed over the years, but it has been observed that most number of cases tend to be reported in the first half of the year in epidemic years while the reverse was observed during the inter-epidemic years. However this pattern has not been consistent and during the last few years a seasonal pattern has not been observed.

2.5.2. AGE DISTRIBUTION

An analysis by age of 7,613 cases of polio identified between 1962 and 1993 (Figure 4) showed that 17.2% of cases (1308) occurred in children under 1 year, 68.8% of cases (5239) in 1 to 4 year olds, 10.6% of cases (807) in 5 to 9 year olds and 34% of cases (259) occurred in children 10 years and over.

2.5.3 SEX DISTRIBUTION

Over the years there has been a male preponderance. An analysis by sex of 7,638 cases identified between 1962 and 1993 (Figure 5) showed that 56.7% of cases (4331) were males while 43.3% (3,307) were females.

Figure 4

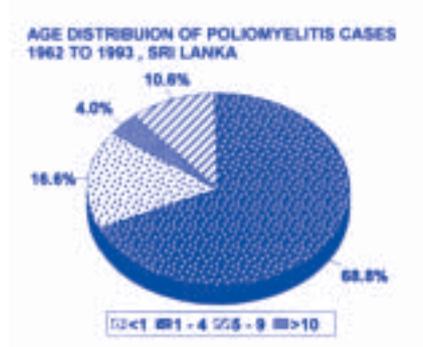
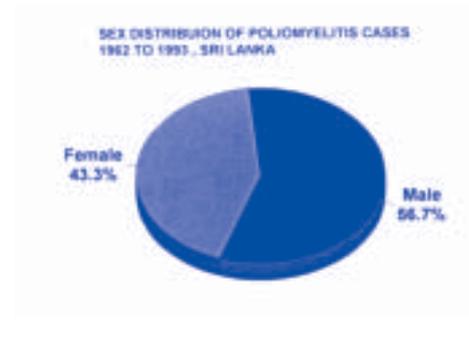


Figure 5



2.6 POLIOMYELITIS ERADICATION STRATEGIES IN SRI LANKA

In 1988 Sri Lanka committed itself to the goal of eradication of poliomyelitis. In accordance with guidelines of the World Health Organization (WHO) strategies were developed and implemented to achieve this goal. These strategies were reviewed and modified according to the experience of other countries and the epidemiology of the disease in Sri Lanka. These strategies focused on immunization, surveillance, out-break control and prevention.

The strategies adopted to eradicate poliomyelitis from Sri Lanka are maintenance of a high immunization coverage among infants with three doses of OPV in the first year of life, enhanced surveillance for wild poliovirus through reporting and laboratory testing of all cases of acute flaccid paralysis (AFP) among children under fifteen years of age, supplementary doses of OPV to all children under five years of age during national immunization days and targeted 'mop-up' immunization campaigns once wild polio transmission is limited to a specific focal area.

POLIOMYELITIS ERADICATION STRATEGIES IN SRI LANKA

- Maintenance of a high immunization coverage among infants with three doses of OPV before the 1st birthday
- Enhanced surveillance
- National immunization days
- 'Mop - Up' immunization campaigns

Chapter 2

CLINICAL ASPECTS OF POLIOMYELITIS

When a susceptible person becomes infected with a poliovirus, the virus multiplies in the pharynx and intestines. During the next several days, the virus spreads to the regional lymph system and may also enter the blood stream. The virus spreads to the spinal cord and brain through the blood, or by travelling through the nerve fibres. Once the virus enters the nervous system, it selectively invades the motor neurons of the spinal cord and/or brain stem. As these cells are damaged and destroyed, the denervated muscles become paralyzed and eventually atrophy.

3.1 CLINICAL MANIFESTATIONS

The clinical response to poliovirus infection is extremely variable. In more than 90% of infected persons, poliovirus infection is sub-clinical. An additional 4 to 8% of infections will result in a minor illness also known as abortive poliomyelitis and about 1% of cases will present as aseptic meningitis. Between 1 and 10 of every 1000 susceptible persons infected with a poliovirus will develop paralytic disease.

Non - paralytic poliomyelitis may escape detection due to non-specificity of symptoms. A high degree of suspicion is necessary to detect poliomyelitis in this situation.

CLINICAL RESPONSE TO POLIOVIRUS INFECTION

- **Clinical response is extremely variable**
- **In more than 90% of cases infection is sub-clinical**
- **In 4 to 8% of cases infections result in minor illness**
- **About 1% of cases will present as aseptic meningitis**
- **Between 1 to 10 of every 1000 infected persons will develop paralytic disease**

3.1.1 SUB-CLINICAL INFECTIONS

In sub-clinical infections the infected person has no signs of illness, but is capable of spreading the virus to others.

3.1.2 ABORTIVE POLIOMYELITIS

Abortive poliomyelitis is a mild illness, characterized by low-grade fever, sore throat, vomiting, abdominal pain, loss of appetite and malaise. Because these symptoms are non-specific, this form of poliovirus infection cannot be distinguished from other mild viral infections. There is no paralysis and recovery is rapid and complete.

3.1.3 ASEPTIC MENINGITIS

Aseptic meningitis caused by a poliovirus cannot be distinguished on clinical grounds from aseptic meningitis caused by other viruses. The symptoms include malaise, fever, headache, muscle aches, hyperaesthesias and paraesthesias. Nausea, vomiting, diarrhoea, constipation or loss of appetite may also be present. Physical examination may reveal stiffness of the neck,

particularly in the early stages of the illness. A lumbar puncture will demonstrate a moderate increase (less than 1500 per mm³) in the number of white blood cells in the cerebrospinal fluid (CSF). Early in the course of the illness, these cells may be polymorph nuclear leucocytes, but later lymphocytes will predominate. The CSF protein may be either normal or slightly elevated and CSF glucose is normal.

3.1.4 SPINAL PARALYTIC POLIOMYELITIS

The typical course of spinal paralytic poliomyelitis occurs in two phases, minor and major, sometimes separated by several days without symptoms. The minor phase of poliomyelitis consists of fever, upper respiratory and gastrointestinal symptoms typical of abortive poliomyelitis after a short symptom free interval and the major phase of the illness begins with muscle pain and spasms and return of fever. The second phase of central nervous system manifestations may include muscle tenderness, neck stiffness, spinal rigidity and changes in deep and superficial reflexes. This is followed by the rapid onset of flaccid paralysis in one or more muscle groups, skeletal or cranial. The progression some times takes only a few hours, but it is always complete almost within 48 hours and does not progress after 5 days. Tendon reflexes may disappear before muscle weakness is obvious. Paralysis affects the legs more often than the arms and is usually asymmetric. The large proximal muscles are affected more often than the small distal muscles. In severe cases, quadriplegia may develop with involvement of the trunk, abdominal and thoracic muscles. The paralysis of poliomyelitis is flaccid; the muscles are floppy and without tone. Reflexes are absent in the affected muscles. The sensory nerves are not usually affected; the sense of pain and touch are normal. Spinal paralytic poliomyelitis, affecting the muscles of the legs, arms or trunks is the most common form of paralytic poliomyelitis.

TYPICAL COURSE OF PARALYTIC POLIOMYELITIS

- **Phase 1 – Minor illness**
- **Phase 2 – Major illness**
- **Phase 1 & 2 could be separated by several days without symptoms**
- **Major phase begins with muscle pain & spasms & return of fever**
- **Rapid onset of flaccid paralysis follows**
- **Paralysis never progresses beyond 5 days**
- **Paralysis is usually asymmetric**

3.1.5 BULBAR PARALYTIC POLIOMYELITIS

Bulbar paralytic poliomyelitis is less common. In this case, the motor neurons of the cranial nerves originating in the brain stem are affected. Bulbar poliomyelitis without simultaneous spinal poliomyelitis is rare. In bulbar poliomyelitis, there may be severe respiratory insufficiency, difficulty in swallowing, eating and speaking. The risk of death from respiratory insufficiency is high in bulbar poliomyelitis.

Encephalitis is an infrequent manifestation of poliomyelitis. Poliomyelitis encephalitis affects infants and children more often than adults and cannot be distinguished clinically from other forms of viral encephalitis.

It is not known why only a small percentage of infections with poliovirus lead to paralysis while the rest do not. But several key factors have been identified which increase the likelihood of paralysis. They include immune deficiency and injury. Also pregnant women are more likely to become paralyzed when infected with a poliovirus. Strenuous exercise, tonsillectomy and intramuscular injections during poliovirus infection increase the risk of developing paralysis. Paralysis is more likely to occur in the limb receiving the injection. Tonsillectomy increases the risk of bulbar poliomyelitis during the postoperative period. Because of the increased risk of paralysis, elective surgery should be postponed during known poliomyelitis outbreaks and only the most essential injections should be given.

**KEY RISK FACTORS WHICH INCREASE THE
LIKELIHOOD OF PARALYSIS.**

- **Immune deficiency**
- **Tonsillectomy**
- **Intramuscular injections**
- **Strenuous exercise**
- **Injury**
- **Pregnancy**

3.2 CLINICAL DIAGNOSIS OF POLIOMYELITIS

Poliomyelitis should be considered in the differential diagnosis of any case of flaccid paralysis. A THOROUGH history and a physical examination should be performed with appropriate laboratory investigations. Accurate neurological evaluation is of particular importance. The initial clinical evaluation will usually enable the clinician to exclude other causes of paralysis, particularly injuries and cerebral palsy. Traumatic myelitis with injury to the sciatic nerve following a gluteal injection requires a careful history to differentiate it from provocation poliomyelitis.

In paralytic poliomyelitis, presence of fever at the onset of weakness, presence of muscle spasms in the limbs or back and asymmetry of the weakness are distinguishing features of poliomyelitis. Bladder involvement is usually absent in children. Muscle pain is a prominent feature but this can occur in other conditions.

Absence of fever at the onset of weakness, symmetry of the weakness, progression of weakness beyond five days, presence of bilateral facial weakness, presence of paraesthesia with or without sensory impairment and prominent bladder involvement are features against the diagnosis of poliomyelitis.

FEATURES IN FAVOUR OF POLIO

1. Fever at onset of weakness
2. Asymmetry of weakness
3. Muscle pain & spasms
4. Signs of meningeal irritation

FEATURES AGAINST POLIO

1. Progression of weakness >5 days
2. Absence of fever
3. Symmetrical weakness
4. Bladder involvement
5. Sensory loss

Poliovirus infection is only one out of a number of causes for acute flaccid paralysis in children and young adults. The possibility of poliomyelitis should be considered for any case of acute flaccid paralysis, even in countries where poliomyelitis is thought to be absent.

In countries with low poliomyelitis incidence, the diagnosis of paralytic poliomyelitis should be discarded only after appropriate viral studies have proved negative and another diagnosis has been established.

This is essential to achieve total eradication of poliomyelitis.

3.2.1 DIFFERENTIAL DIAGNOSIS OF POLIOMYELITIS

The diagnoses that are most often confused with paralytic poliomyelitis are Guillain Barre' Syndrome (GBS) and transverse myelitis. The presentation of these conditions is shown in Table 1. Experienced clinicians will often be able to distinguish these conditions by CAREFUL HISTORY TAKING and OBSERVATION of the patient. However, many cases of poliomyelitis have been diagnosed initially as GBS even by experts; hence it is recommended by the WHO that specimens of stools be tested for poliovirus on all patients with GBS who are less than 15 years of age.

Table 1 SIGNS AND SYMPTOMS OF POLIOMYELITIS, GUILLAIN BARRE SYNDROME AND TRANSVERSE MYELITIS

SIGNS AND SYMPTOMS	POLIOMYELITIS	GUILLAIN BARRE SYNDROME	TRANSVERSE MYELITIS
Fever at onset	Present	Absent	May be present or absent
Meningeal irritation	Usually present	Usually absent	Absent
Pain in muscles	Severe	Variable	Absent
Paralysis	Usually asymmetric (unequal)	Symmetric & ascending from the legs up	Symmetrical & stationary
Progression of paralysis	3-4 days	2 weeks	Rapid usually few hours
Residual paralysis	Usually present	Usually absent	Variable
Paraesthesia	Rare	Frequent	Frequent
Sensation	Normal	May be diminished	Diminished
Deep tendon reflexes	Diminished or absent	Diminished. May return in several days	Absent. May return in 2-3 weeks
Cerebrospinal fluid	High leukocyte count, Normal or high protein (up to 25% over normal)	Normal leukocyte count, <10 white cells/mm; Protein twice the upper limit of normal	Normal or high leukocyte count; Moderate or high protein

Wild polioviruses are not the only cause of paralytic poliomyelitis. Rarely, poliomyelitis is caused by the poliovirus used in live oral polio vaccine. In vaccine-associated poliomyelitis, there is a history of administration of oral polio vaccine to the patient 4 to 30 days before paralysis or to a close contact within 4 to 75 days prior to onset of paralysis. The virus isolated from the stool of a patient with vaccine-associated poliomyelitis can be distinguished from the wild virus by laboratory techniques that are available at the Medical Research Institute, Colombo. There are also other enteroviruses that could cause flaccid paralysis and cases of this nature could only be distinguished from poliomyelitis by isolating the causative virus from the stools of such patients.

DISCARD THE DIAGNOSIS OF POLIOMYELITIS ONLY AFTER

- **Viral studies have proved negative**

AND

- **Another diagnosis has been established**

3.2.2 LABORATORY DIAGNOSIS OF POLIOMYELITIS

As a country approaches poliomyelitis eradication and the number of cases becomes less and less, each case must be confirmed in the laboratory. Virological studies will allow identification of cases of paralytic poliomyelitis caused by the vaccine.

In poliomyelitis, examination of CSF is not diagnostic and can only be used to support a diagnosis of poliomyelitis.

The characteristic changes found on electromyography do not distinguish paralytic poliomyelitis from the paralysis caused by other enteroviruses.

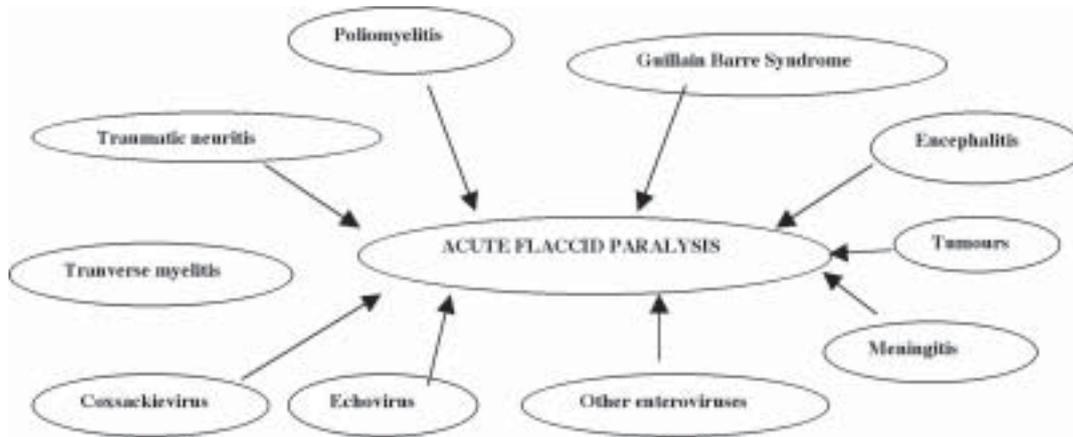
Serological studies demonstrating the development of serum antibodies to poliovirus may help to confirm the diagnosis of acute poliovirus infection. However the interpretation of the results of these may be difficult. In addition, the commonly available serological tests do not distinguish wild poliovirus infection from the normal response to polio immunization.

Isolation and identification of the poliovirus in the stools using cell culture techniques is the recommended test for laboratory diagnosis of poliomyelitis. Because the excretion of the virus in stools is variable, **two specimens of stools should be collected 24 - 48 hours apart**. Stool specimens should be collected **as soon as possible** once the diagnosis of acute flaccid paralysis is considered, **ideally within 2 weeks of onset of paralysis** when the highest quantity of virus is in the stool.

3.2.3 DIFFERENTIAL DIAGNOSIS OF ACUTE FLACCID PARALYSIS

Neurophysiological investigations (nerve conduction tests and electromyography) are very useful in the evaluation of AFP. This is particularly of value in the differentiation between causes of AFP. This investigation should be performed as early as possible in the course of the illness and repeated as necessary to obtain the maximum benefit. It often gives a clue to the final diagnosis. Having this knowledge at an early stage of the illness is a great advantage in the management. These facilities are available at National Hospital Sri Lanka and a few other teaching hospitals. The disease conditions that should be considered are shown in Figure 6 below.

Figure 6 DIFFERENTIAL DIAGNOSIS OF ACUTE FLACCID PARALYSIS (AFP)



3.3 ROLE OF THE CLINICIAN IN SURVEILLANCE OF ACUTE FLACCID PARALYSIS (AFP)/ SUSPECTED POLIOMYELITIS

The surveillance of acute flaccid paralysis is **primarily the responsibility of the doctors engaged in clinical work**. For effective surveillance, sensitive reporting of cases acute flaccid paralysis is essential. This section deals with the action that should be taken by the clinician when confronted with a patient with acute flaccid paralysis. The common pit falls that should be avoided are also detailed.

The duties of the clinician regarding surveillance of AFP are:

- Notification
- Dispatch of stools for virologic diagnosis
- Clear and accurate documentation of clinical notes
- Confirmation of diagnosis

3.4 PATIENTS WHO SHOULD BE INCLUDED IN THE SURVEILLANCE

3.4.1 AGE LIMIT

All patients under the age of 15 years with acute flaccid paralysis should be included in the surveillance. **However any adult in whom the diagnosis of poliomyelitis is suspected should also be included.**

3.4.2. CLINICAL CHARACTERISTICS

All patients with acute flaccid paralysis due to any cause other than trauma should be included in the surveillance programme.

Paralytic poliomyelitis is a brief febrile illness with clinical manifestations of malaise, abdominal symptoms and upper respiratory tract symptoms followed by a short symptom free interval and a second phase of central nervous system manifestations. These are muscle tenderness, neck stiffness, spinal rigidity and changes in superficial and deep reflexes. In paralytic poliomyelitis, weakness in one or more muscle groups (skeletal or cranial) will occur. Flaccid paralysis is the most obvious clinical sign. Respiratory muscle involvement and autonomic nerve involvement may also be seen. The distribution of paralysis is characteristically asymmetrical. The clinical picture could take the spinal form, bulbar form or the encephalitic form.

It is important to remember that patients with acute flaccid paralysis in whom the diagnosis of poliomyelitis is unlikely should also be included in the surveillance programme. This is important since many diseases can be confused with poliomyelitis. Guillain-Barre Syndrome and transverse myelitis are two such diseases.

The following categories of patients should also be included.

- Patients in whom the diagnosis of Guillain-Barre Syndrome is suspected or confirmed
- Patients in whom an encephalitic illness is the predominant feature but is associated with acute flaccid paralysis
- **Patients in whom isolated or multiple cranial nerve palsies is/are the only clinical manifestation**
- Patients in whom acute flaccid paralysis is suspected to be due to other enteroviruses or the polio vaccine virus

To reiterate, this surveillance should include patients in whom poliomyelitis is likely as well as those in whom poliomyelitis is unlikely (on clinical grounds) to be the cause of flaccid paralysis.

3.4.3 EXCEPTIONS

Those patients in whom the paralysis is clearly due to trauma need not be notified,

SURVEILLANCE INCLUDES AFP CASES

- **In whom poliomyelitis is likely**
AND
- **In whom poliomyelitis is unlikely**
EXCEPTIONS
- **In whom AFP is due to trauma**

3.5 PROCESS OF NOTIFICATION

It is imperative that all the above categories of patients should be notified to the Epidemiologist, Epidemiological Unit, Colombo and the Regional Epidemiologist by telephone, telegram, fax or email. This should be done immediately or at least within 24 hours of examining the patient.

In addition, on receipt of the special notification form (EPID/37/1/R2004 - pink), it should be filled and forwarded to the Epidemiologist, Epidemiological Unit, Colombo immediately or as soon as possible. Care should be taken to fill this form as completely as possible giving all the required particulars of the patient.

3.6 DETAILED DOCUMENTATION OF CLINICAL DATA AND INVESTIGATIONS

Clear documentation of clinical and laboratory findings in the case notes by the attending doctors are essential for the success of the poliomyelitis eradication programme.

All clinical findings and daily status of patients with acute flaccid paralysis should be dated and clearly recorded in the patient's hospital ticket (Bed Head Ticket) or clinical notes.

The documentation is important because the entire Bed Head Ticket is scrutinized by the Polio Expert Committee when deciding on the final diagnosis for inclusion in epidemiological records. Clear records maintained by all attending clinicians become very useful in reaching a conclusive diagnosis prior to entering in epidemiological records.

Data such as the presence or absence of fever, history of recent administration of OPV, the presence of meningeal irritation, the timing of the onset of paralysis, when ventilatory support was required, the presence or absence of sensory loss and the degree and progress of paralysis should be entered by the resident staff in the BHT together with the consultant's findings and diagnosis.

Complete investigations inclusive of cerebrospinal fluid (CSF) examination should be carried out whenever possible to reach a definitive diagnosis. The timing of the CSF examination should be clearly stated. The results of investigations should be written in the clinical notes. This would help to avoid situations where results of investigations cannot be traced in the BHT. This is a common occurrence due to the poor keeping quality of documents and storage facilities available.

3.7 DISPATCH OF SPECIMENS FOR VIROLOGICAL DIAGNOSIS

Surveillance is essential for eradication of poliomyelitis. Samples of stools for virological examination should be dispatched to the Medical Research Institute Colombo.

Two samples of stools should be sent. Stools should be collected in the **early acute phase of the illness**, when maximum shedding of the virus occurs. This should be as early as possible within the first two weeks of onset of paralysis. Due to the intermittent nature of shedding of virus the two samples are best collected **24-48 hours apart**.

Even if the patient presents late, the two samples should be dispatched since the virus may continue to be shed until 6-8 weeks after the onset of the illness.

In the presence of constipation, glycerine suppositories could be used to obtain stools. Rectal swabs are not suitable. The quantity of stools required is 8-10 grams (approximately the size of two tamarind seeds or two adult thumb nails) and it should be transported in a clean, dry, leak proof, wide mouthed, screw capped bottle or in the container provided for this purpose by the Epidemiological Unit.

The specimens should be accompanied by a detailed request form with details of the date of onset of paralysis, dates of collection of the two samples and the date of dispatch of the samples in addition to personal identification information of the patient.

The specimen should be dispatched packed in ice or in a reverse cold chain box with frozen ice packs to maintain the cold chain. Transport should be via a messenger (i.e. should be hand carried).

Results of stools examination are invaluable for virological classification of AFP patients and help eliminate poliomyelitis. Results of virological investigations are especially important in situations when death occurs in the acute phase of the illness or when patients are lost to follow up.

DOCUMENTATION OF AFP CASES IN THE BHT

- **All clinical findings daily**
- **Timing of the onset of paralysis**
- **Progress of paralysis**
- **Degree of paralysis**
- **When ventilatory support was required**
- **Presence or absence of fever**
- **Presence or absence of meningeal irritation**
- **Presence or absence of sensory loss**

3.8 CONFIRMATION OF DIAGNOSIS

The Sri Lankan experience has been that GBS may show residual paralysis lasting longer than 60 days. Therefore residual paralysis by itself is not adequate to conclude that poliomyelitis was its cause.

All patients with residual paralysis are reviewed at 60, 90, 180 days by an epidemiologist. Nerve conduction studies and electromyography are helpful in differentiating GBS from poliomyelitis. However at present such investigations are restricted to those patients in whom a residual paralysis is found and to whom the Polio Expert Committee decides to carry out to help decide on a final diagnosis. These investigations and follow up are conducted by the Institute of Neurology, Colombo and are co-ordinated by the Epidemiological Unit, Colombo.

The Polio Expert Committee recommends that if a patient has a likelihood of being lost to follow up (e.g. on the basis of being resident in a remote or conflict area) such investigations should be undertaken at an earlier stage. This is important because in the poliomyelitis eradication programme, any patient who is “**lost to follow up**” is considered as a “**poliomyelitis compatible case**” if poliomyelitis has not been eliminated. Referral to a consultant Neurologist to obtain these investigations is recommended in such cases.

As the target date for a “poliomyelitis free Sri Lanka” approaches, it would be ideal if nerve conduction studies and electromyography could be carried out on all cases of acute flaccid paralysis in whom a virological investigation have not yielded a positive result. Non-availability of such services and facilities in some provinces would be a limiting factor in implementing this recommendation. However it is preferable if referral to a neurologist could take place wherever possible, to obtain nerve conduction studies and electromyography on patients included in the AFP surveillance.

Chapter 3

LABORATORY DIAGNOSIS

4.1 CAUSATIVE AGENT

Paralytic poliomyelitis is caused by a virus that belongs to the enterovirus genus of the family Picornaviridae. As the family name suggests, the poliovirus is a small virus of approximately 27nm in diameter, with a genome made up of a single strand of positive sense RNA. The poliovirus has 3 serotypes; polio type 1, type 2 and type 3. These types were earlier known as Brunhild, Lansing and Leon respectively.

4.2 PHYSICAL & CHEMICAL PROPERTIES OF THE POLIO VIRUS

Polioviruses, like other enteroviruses are stable at acid pH for 1-3 hours and as such are able to withstand gastric acidity. The virion is non-enveloped; as it has no lipid-containing envelope, it is not affected by lipid solvents such as ether and chloroform. This fact is made use of in the processing of stool samples for virus isolation. The stool samples are mixed with phosphate buffered saline (PBS), and chloroform is added to a final concentration of 10%. The chloroform will destroy all organisms having a lipid envelope; the enteroviruses that are naked RNA viruses will not be destroyed in the process.

The virus activity is completely inactivated when heated at 56° C for 30 minutes. Procedures such as pasteurization of milk will also inactivate the virus. In the presence of 1 molar magnesium chloride however, this virus is partially protected from inactivation. Therefore 1 molar magnesium chloride is used as a stabilizing agent for oral polio vaccine (OPV). 50% glycerol saline also exhibits this stabilizing property. In the past when stool samples were dispatched to the laboratory by post, both 1 molar magnesium chloride and 50 % saline were used as stool transport mediums.

4.3 VIRUS GROWTH

Poliovirus grows only in primary or continuous cell cultures obtained from various human or monkey tissue, the reason being that these viruses will infect only cells that have a specific membrane receptor (human poliovirus receptor) on the cell surface. However, mouse cells that were not susceptible to poliovirus infection under normal circumstances, had been made susceptible by the introduction of human poliovirus receptor. These genetically engineered mouse cells (L20 B cells) are highly specific to poliovirus and are able to pick up poliovirus, even from mixtures of enteroviruses. L20B cells and RD cells (derived from human rhabdomyosarcoma) are used in the polio laboratory network, for the laboratory diagnosis of poliomyelitis.

The replication of the poliovirus takes place in the cytoplasm of the infected cell and the infective cycle takes approximately 6 hours. The infected cell lyses and liberates mature virions that in turn infect other susceptible cells.

4.4 VIROLOGICAL INVESTIGATION

Poliovirus infection is only one of a number of causes of Acute Flaccid Paralysis (AFP) and therefore laboratory investigation of all cases of AFP becomes necessary in order to help in the differentiation of poliomyelitis cases from patients with AFP due to other causes. As the number of poliomyelitis cases has rapidly decreased and Sri Lanka has not had any confirmed poliomyelitis cases since 1994, it is extremely important that all suspected cases are investigated not only clinically and epidemiologically but virologically as well. These virological

investigations are carried out ONLY at the Department of Virology of the Medical Research Institute (MRI), Colombo.

4.5 LABORATORY DIAGNOSIS

The laboratory diagnosis of poliomyelitis involves the growth and identification of polioviruses from faecal samples using cell culture techniques and this is the most important function of the polio laboratory. In order to get meaningful results from the laboratory, timely collection, storage and proper transport of samples are of paramount importance. Delays in dispatching the sample should be avoided. If unavoidable delay occurs, the sample should be stored at + 4° C until transport, which should be within 5 days of collection. The samples should be packed in ice (with sufficient ice packs or ice cubes to maintain the temperature at + 4° C during transport) in a reverse cold chain box, thermos flask, or rigifoam box. All these precautions are necessary to ensure that no virus is lost from the specimens between the time of collection and the time of receipt in the laboratory.

Although the poliovirus replicates both in the oropharynx and the gut, the virus can be isolated from the throat only for a very short period. On the other hand as the virus is excreted in the stools in large amounts for longer periods, the emphasis should be on the collection of stools specimens. **Two stools specimens should be collected from all cases of AFP within 14 days of onset of paralysis.** As the virus concentration decreases with time, all attempts must be made to collect stools very early in the infection i.e. within 14 days of onset of paralysis. **As the excretion of virus is intermittent, a minimum of two samples, collected preferably 24 – 48 hours apart is recommended.** The quantity of the sample should be 8-10g each (size of two adult thumb nails or two tamarind seeds), as part of the original sample has to be stored as back-up samples. Stools have to be collected in a clean preferably sterile, screw capped, leak proof bottle or in a container provided for the purpose by the Epidemiological Unit. Details regarding the date of onset of paralysis, date of collection, date of dispatch and the last date of vaccination against poliomyelitis, should be given.

The specimens should be dispatched packed in ice or in a reverse cold chain box with frozen ice packs to maintain the cold chain. Transport should be via a messenger (i.e. should be hand carried).

Samples should be sent to the MRI and handed over to the medical laboratory technician at the polio laboratory or to the relief medical laboratory technician (RMLT) on duty, if it is after duty hours. Samples are received throughout the day everyday including holidays.

STOOLS SPECIMENS FROM AFP CASES

- **Two stools specimens from all AFP cases**
- **Two stools specimens within 14 days of onset of paralysis**
- **Minimum of two stools specimens collected 24-48 hours apart**
- **Quantity of sample should be adequate**
- **Stool should be collected in clean, preferably sterile, screw capped, leak proof bottle or in the plastic container provided for the purpose**

STOOLS REQUEST FORM MUST INDICATE

- **Date of onset of paralysis**
- **Date of collection of stools**
- **Date of dispatch of stools**
- **Last date of polio vaccination**

Young children are the main reservoir of infection and by the time poliomyelitis is detected in one member of the family, almost all the other family members are generally infected. It is because of this reason that stool samples are tested from three to five close contacts of all AFP cases.

All faecal samples are processed without delay but it takes a minimum of 14 – 21 days to give a negative report. Positive virus isolates have to be identified as Polio, Coxsackie or Echo viruses and polioviruses are further typed as type 1,2, or 3. Sometimes the isolates contain mixtures of enteroviruses and sorting them out takes longer.

There are intratypic differences in the wild poliovirus strains and the Sabin vaccine strains of the same serotype, which can be distinguished by a variety of methods. ELISA with polyclonal cross-absorbed antisera detects antigenic differences between wild and vaccine poliovirus strains. Nucleic acid probe hybridization and diagnostic PCR are molecular methods that detect the difference in the viral genomic RNA. All laboratories doing intratypic differentiation (ITD) testing must use two ITD methods based on different approaches for testing all polio isolates. Currently, ELISA test and RNA probe hybridization test are used in the polio regional reference laboratories at MRI for intratypic differentiation of poliovirus isolates.

Majority of strains that are derived from Sabin strains, have close sequence relationships (>99% VP1 sequence identity) to the parental Sabin strain of the same serotype. They are referred as Sabin - like or OPV- like polioviruses. ELISA test and RNA probe hybridization test are used together to categorize the isolates as Wild poliovirus or as Sabin-like poliovirus.

Rare strains that show less than or equal to 99% VP1 sequence identity to the parental Sabin strains are called “vaccine derived polioviruses (VDPVs)”. Two categories of VDPVs have been identified; immunodeficient VDPVs (iVDPVs) that have been isolated from immunodeficient patients and circulating VDPVs (cVDPVs) that have been responsible for outbreaks of poliomyelitis. VDPVs give contradictory results or inconclusive results with ITD tests based on two different approaches. Therefore, all isolates that give contradictory results or inconclusive results are referred to a global specialized laboratory for further characterization.

Further, genomic sequencing of polioviruses enables detection of imported cases and differentiation from endemic disease.

4.6 LABORATORY SURVEILLANCE

When the stool samples reach the virus laboratory of the MRI, the request (Annexure 1) form is faxed to the Epidemiological Unit of the Ministry of Health. All AFP cases are given a unique identification number, known as the EPID number. In Sri Lanka, this number is given by the Epidemiological Unit and thereafter these cases are identified by this standard number.

Results of the stool samples received from AFP cases and their contacts are faxed to the Epidemiology Unit in addition to sending them to the respective hospitals and MOH offices.

Chapter 4

IMMUNIZATION AGAINST POLIOMYELITIS

5.1 POLIO VACCINES

There are two types of vaccines against poliomyelitis: oral and injectable. Oral polio vaccine (OPV) is composed of the three types of attenuated polioviruses (types 1, 2, and 3). The injectable vaccine (IPV) is composed of inactivated or killed poliovirus. The vaccine is indicated for active immunization of infants and susceptible children and adults against infection caused by polioviruses of types 1, 2, and 3.

For infants the primary immunization course is three doses of OPV with an interval of at least one month between doses. OPV may be given at birth provided it is realized that the response is likely to be sub-optimal and that three additional doses will be required later in life to give adequate protection.

For children and adults, in order to maintain the level of protection against poliovirus infection it is recommended to give a booster dose at the time of school entry and again on leaving school and occasionally in adult life when a person is likely to be exposed to a high risk of infection, such as when traveling to endemic areas.

Because of its low cost, ease of administration, superiority in conferring intestinal immunity, and the potential to infect household and community contacts secondarily, the EPI recommends trivalent OPV as the vaccine of choice for eradication of poliomyelitis. In industrialized countries, sero-conversion rates after 3 doses of OPV have been demonstrated to be high (>90%) to all 3 types of virus. However sero-conversion rates are lower in the developing countries. These are estimated to be 73% (range 36% to 99%) for type 1, 90% (range 71% to 100%) for type 2, and 70% (range 40% to 99%) for type 3. The efficacy of three doses of OPV in preventing paralytic poliomyelitis in developing countries ranges from 72% to 98% when the cold chain is properly maintained (EPI1993c). Factors that reduce the immune response in developing countries (other than cold chain problems) include interference from other enteroviruses (that may be related to seasonal differences in response), and interference between the three vaccine viruses (that may be related to the relative doses of each virus type in the vaccine formulation). In many developing countries routine immunization alone may not be sufficient to stop transmission of wild poliovirus and supplementary immunization activities are recommended (6).

ADVANTAGES OF OPV

- **Easy administration**
- **Low Cost**
- **Produces intestinal immunity to the poliovirus**
- **Potential to infect household and community contacts secondarily with attenuated virus**
- **OPV can interrupt the wild virus transmission**

OPV is thermolabile and therefore it requires maintenance of an effective cold chain.

The disadvantage of OPV is that it could cause vaccine associated paralytic disease rarely. Vaccine associated paralytic cases may occur either in vaccinees or in their susceptible close contacts. The risk appears highest following the first dose of OPV. Approximately one case of vaccine associated paralytic disease will occur for every 2.4 million OPV doses administered (2).

DISADVANTAGES OF OPV

- **Could cause vaccine associated paralytic poliomyelitis (VAPP) rarely**
- **Disease may occur either in vaccinees or in their susceptible close contacts**
- **Could cause outbreaks of cVDPV or iVDPV cases**

Though rare, there is the risk of polio outbreaks due to circulating vaccine-derived polioviruses (cVDPV). These outbreaks are readily stopped with OPV 'mop-up' operations. Absence of indigenous wild poliovirus, low routine OPV3 coverage and the cessation of supplementary OPV immunization activities were the common factors observed in the countries where these outbreaks were reported. The consequence of failure to maintain high immunization coverage in areas of poor sanitation seems to allow VDPVs to circulate among unvaccinated children and cause disease. The implication for the global eradication initiative is that a high coverage in every area is absolutely critical both to prevent circulation of wild poliovirus and the emergence of VDPVs. The polio eradication goal should be achieved rapidly and immunization stopped as soon as it is safe to do so. The protracted use of oral polio vaccine (OPV) in routine programmes that have low coverage, risks the emergence of outbreaks of polio due to VDPVs. The other category of vaccine-derived poliovirus is immunodeficient VDPVs (iVDPV) isolated from immunodeficient patients. These individuals with primary immunodeficiency syndrome could cause outbreaks as they are long term excretors of vaccine derived poliovirus i.e. > 6-12 months) (7).

OPV is the vaccine of choice for developing countries where personal and community hygiene is poor. When OPV is ingested, the vaccine virus multiplies in the intestinal wall, produces immunity in the intestinal wall and is excreted with the faeces. If such an immunized person accidentally ingests the disease producing virus, it is unable to invade the blood stream and is therefore eliminated. This is how OPV protects the children. However immunizing with OPV once may not produce the required protection to all three types of poliovirus. There are certain situations in the bowel, which may prevent the implantation of all three types of the virus found in the vaccine. Hence the vaccine is given more than once, i.e. a minimum of three doses in infancy and two booster doses in older children. It is possible, though rare; that a child who has taken the recommended number of doses of OPV has not developed the required immunity, because the vaccine has failed to get implanted in the bowel wall. This is one way that a fully immunized child may develop the disease. However this is very rare and in such cases the disease is always mild and there is never a fatal outcome.

IPV prevents paralytic poliomyelitis by producing sufficient serum antibody to prevent the poliovirus from entering the nervous system via the blood stream. The major advantage of IPV is that there is no risk of vaccine associated paralytic poliomyelitis. The disadvantage of IPV is that it produces significantly less intestinal immunity to the poliovirus. As a result a child immunized with IPV may not develop the disease if infected, but is likely to spread the wild poliovirus to other children. Moreover IPV vaccine must be given by injection, requiring trained personnel and additional equipment. In addition IPV is more expensive than OPV. Although IPV suppresses pharyngeal excretion of wild poliovirus, this vaccine has only limited effects on intestinal excretion of poliovirus. The ability of IPV to eradicate poliovirus in developing countries where faeco-oral transmission predominates, is doubtful.

ADVANTAGE OF IPV

- **No risk of vaccine associated paralytic poliomyelitis (VAPP)**

DISADVANTAGES OF IPV

- **Produces significantly less intestinal immunity to the poliovirus**
- **Immunized children are more likely to spread wild poliovirus to other children**
- **Must be given by injection**

Both OPV and IPV can be inactivated by heat, so that the cold chain must be maintained for both during storage and transport. IPV should be kept in a refrigerator at 0 to 8 degrees centigrade. OPV may be kept in a refrigerator at **0°C to 8°C, for short periods but should be kept in the freezing compartment of a refrigerator or in a freezer if long storage periods are anticipated.**

5.1.1 COMPOSITION OF OPV USED IN SRI LANKA

Trivalent oral polio vaccine is a stabilized preparation of live attenuated poliomyelitis viruses, of the Sabin strains type 1, type 2 and type 3 (Leon) propagated in MRC5 human diploid cells. It meets the WHO requirements for biological substances and for polio vaccine. In the vaccine presently used in Sri Lanka, each immunizing dose of vaccine contains not less than 10^6 TCID₅₀ for type 1, 10^5 TCID₅₀ for type 2 and $10^{5.8}$ TCID₅₀ for type 3 (10:1:6) live attenuated Sabin strain of poliovirus. The vaccine is an oral suspension. This is the recommended composition for the Expanded Programme on Immunization. One immunizing dose is contained in two drops of the vaccine in a multi-dose container which is used in the national programme at present. The drops are delivered from a special dropper supplied with the multi-dose glass vials or directly from the multi-dose plastic tubes. OPV is for oral use only and under no circumstances should it be injected.

5.2 IMMUNIZATION SCHEDULE

The final immunization schedule (Table 2) recommended for routine immunization of children, was decided on the epidemiology of the disease, objectives of the Polio Eradication Initiative and the feasibility of implementation of the programme in Sri Lanka. On completion of two months

of age every infant should receive the first dose of OPV, followed by two more doses 6 to 8 weeks apart. Even if there is a delay between doses the child should be given the scheduled doses when he/she presents for immunization. It is very important to ensure that every child receives three doses before completion of one year of age. The interval between any two consecutive doses should not be less than 4 weeks for routine immunization. The 4th dose of OPV should be given at or on completion of 18 months of age. The 5th dose of OPV should be given at 5 years of age or at school entry. If any dose is missed by the child it is not necessary to start the schedule again. The subsequent doses should be continued at appropriate intervals. In this situation the child will receive all the scheduled doses late and will have adequate levels of immunity late.

5.2.1 DOSAGE

Recommended dose of the present vaccine is 2 drops. There is absolutely no harm even if more than two drops of vaccine are swallowed. The excess will just pass off with the faeces.

5.2.2 NUMBER OF DOSES

A minimum of 5 doses of vaccine should be administered to a child by the age of five years. However there is no harm in giving OPV many times. Every additional dose will help to increase the immunity if it is low.

OPV is recommended for epidemic control. It should be realized that the vaccine may not prevent or modify the disease in those already infected with wild poliovirus. Diarrhea and vomiting including gastro-enteritis may interfere with the replication (“take rate”) of the OPV.

OPV can be administered at the same time as Mumps, Measles and Rubella (MMR) or Bacillus Calmette Guerin (BCG) or Diphtheria Pertussis Tetanus (DPT) or Hepatitis B vaccines. Whenever extra doses of OPV are recommended by health staff they should be given to the children.

During national immunization days the extra doses of opv should be given to all children less than five years of age irrespective of the immunization status (see page 69).

Table 2 IMMUNIZATION SCHEDULE FOR OPV

Age	Vaccine	Remarks
In the 1 st year (INFANCY)		
Soon after completion of		
2 nd Month	OPV 1 st dose	
4 th Month	OPV 2 nd dose	Preferably 6-8 weeks after 1 st dose
6 th Month	OPV 3 rd dose	Preferably 6-8 weeks after 2 nd dose
In 2 nd Year	OPV 4 th dose	
At School entry	OPV 5 th dose (Booster)	

Approved by the Advisory Committee on Communicable Diseases and revised on 1/1/2001.

5.3 CONTRA-INDICATIONS FOR IMMUNIZATION

- Fever of 100^o F (38^o C) or more, at the time of immunization
- An ill child
- Presence of a progressive neurological illness

5.3.1 A CHILD WITH DIARRHOEA

A child could be immunized if the child is having diarrhea at the scheduled time of immunization. As the child may not receive the maximum benefit from that particular dose of OPV, the dose should be repeated at the next clinic, or when the diarrhea stops.

5.3.2 A CHILD WITH HUMAN IMMUNODEFICIENCY VIRUS (HIV) INFECTION

Symptomatic and asymptomatic HIV infection is not a contraindication for immunization with OPV.

5.4 COLD CHAIN

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 children who need it (8). The cold chain system is necessary because the potency of the vaccine will be diminished if they are exposed to temperatures that are too warm or too cold (freezing) depending on the type of vaccine.

A high immunization coverage alone is insufficient to prevent disease. It is very important that potent vaccines are used to immunize children.

5.4.1 COLD CHAIN EQUIPMENT

Cold chain equipment includes cold rooms, refrigerators, freezers, icepack freezers, cold boxes (igloos), vaccine carriers, flasks with cold packs, thermometers and cold chain monitors.

These items should be periodically reviewed regarding adequacy and working condition. The number of each of these items needed depends on the stock of vaccine to be handled. A thermometer should be used and a refrigerator record maintained for each refrigerator storing vaccines. (Annexure 2) Each Medical Officer of Health (MOH) should have adequate refrigerator space to store a three-month’s stock of vaccine. The cold packs provided to each cold box should be completely frozen before use. These should be frozen in the freezing compartment of the refrigerator. If possible, each MOH should also have an ice pack freezer and at least one cold box to serve as an emergency back up during any break down in the electricity supply and when defrosting the refrigerator. The duration of storage of vaccines in these boxes depends on the condition of the cold box, the number of cold packs used and the outside temperature.

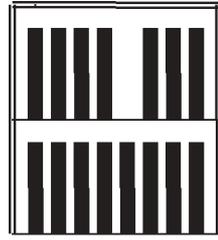
COLD CHAIN EQUIPMENT

- **Cold rooms**
- **Refrigerators**
- **Freezers**
- **Ice-pack freezers**
- **Cold boxes [igloos]**
- **Vaccine carriers**
- **Flasks**
- **Cold packs**
- **Thermometers**
- **Cold chain monitors**
- **Reverse cold chain box**

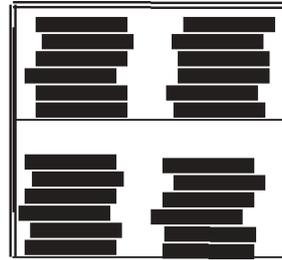
Each cold box (Igloo) / vaccine carrier/ flask must be fitted with the full set of ice packs for which it is designed, in order to properly protect the vaccines during transport. In a properly packed cold box using frozen ice packs to line the four sides and bottom of the Igloo, the cold chain of the vaccine will not be affected up to 72 hours, when the outside of the box is at room temperature. Adequate time should be given for the ice packs to get fully frozen and they should be placed in the freezer on their sides rather than stacked one on top of the other so that every ice pack is in contact with the evaporator at the base of the freezing compartment

(Figure 7). It should be noted that at least 48 hours are needed for an ice pack to freeze completely.

Figure 7 STACKING ICE PACKS IN THE FREEZER



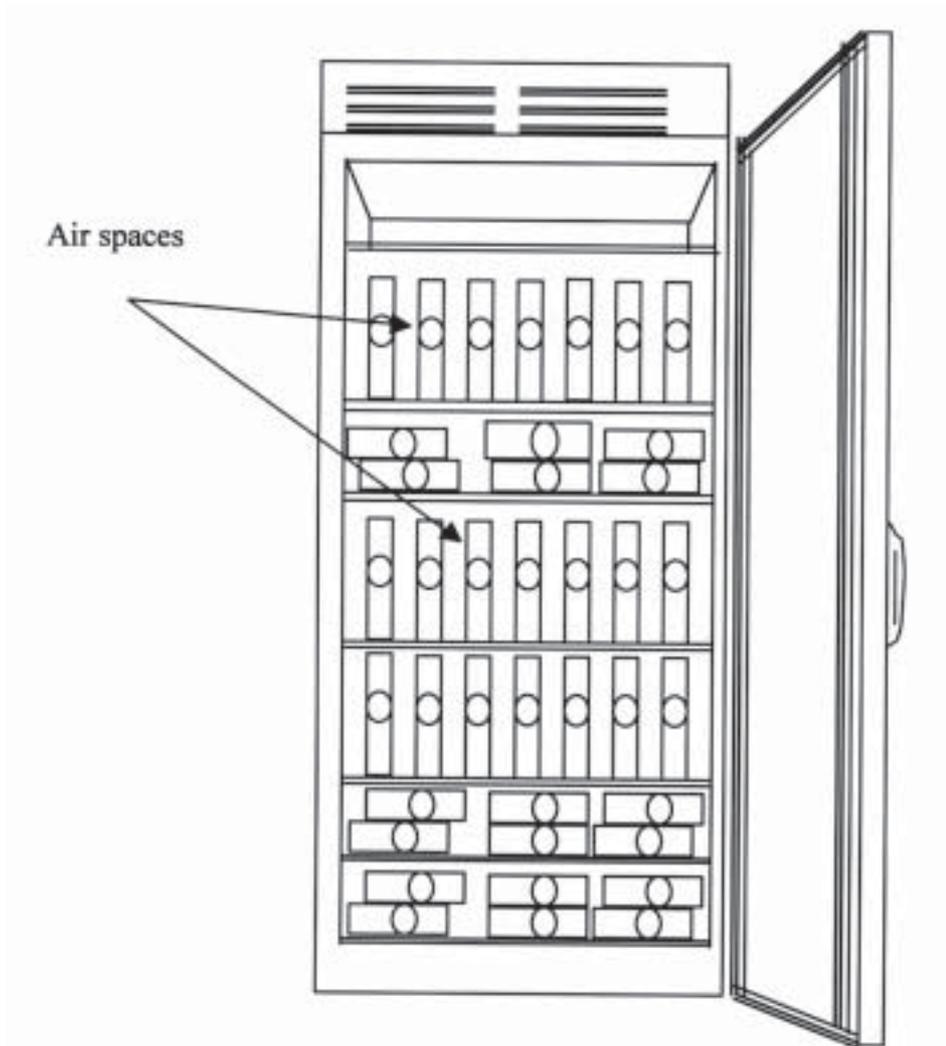
DO this



Do NOT do this

If sufficient freezing capacity is not available, an ice pack fast freezer (Figure 8) should be used.

Figure 8 ICE PACK FAST FREEZER



5.4.2 MAINTAINING THE COLD CHAIN DURING TRANSPORT OF VACCINES

The cold chain should be maintained during transport of vaccines. Cold boxes (igloos) should be used to transport vaccines from the Regional Medical Supplies Division (RMSD) to institutions in the area. Vaccine carriers / flasks should be used to transport vaccines to clinics. Even transporting vaccines through a very short distance (e.g. from one room to another) a vaccine carrier or flask should be used. The cold chain is maintained up to about 48 hours in a properly packed (using the designed number of frozen ice packs) and a properly transported vaccine carrier. If the ice in the ice packs /ice cubes used in the flask has thawed completely by the end of the journey / clinic session, the cold life in the cold box /vaccine carrier /flask is inadequate. In such a situation, make sure that the ice packs had been properly frozen and if so, the number of icepacks /amount of ice cubes should be increased during the next transport session

COLD CHAIN DURING TRANSPORT OF VACCINES

- **Use cold boxes (igloos) to transport vaccines from RMSD to institutions**
- **Use vaccine carriers / flask to transport vaccines to clinics**
- **Cold life in the cold box/vaccine carrier/flask should be maintained**

5.4.3 HOW TO PACK A VACCINE CARRIER

The specified number of ice packs for the carrier should be used. The packs should be frozen adequately. A normal size pack should be kept in a freezer for at least 48 hours to be frozen completely. If ice/frost is present on the outside of the pack, it should be kept outside till the surface frost melts before placing in the cold box /vaccine carrier/flask.

The cold box / vaccine carrier / flask should be taken close to the refrigerator and the vaccines should be packed into it immediately after taking the vaccines out of the refrigerator. The lid should be closed tightly.

WHEN TRANSPORTING VACCINES

- **Use undamaged cold box/vaccine carrier /flask**
- **Use the specified number of ice packs**
- **Use adequately frozen ice packs**
- **Ice should not be present on the outside of the packs when used**
- **The cold box/vaccine carrier/flask should be taken close to the refrigerator**
- **Vaccine should be packed immediately after taking out from the refrigerator**
- **The lid of the carrier should be closed tightly**

5.4.4 MAINTAINING THE COLD CHAIN DURING A CLINIC SESSION

The cold chain should also be maintained during the clinic session. Vials of vaccine should be kept in a vaccine carrier/flask and only one vial taken out at a time. This vial should be kept away from direct sunlight and heat and preferably kept in a container with ice.

TO MAINTAIN THE COLD CHAIN DURING A CLINIC SESSION

- Vials of vaccine should be kept in a vaccine carrier /flask
- Only one vial taken out at a time
- Vial being used to be kept away from direct sunlight and heat and kept in a container with ice

5.4.5 VACCINE COLD CHAIN MONITORS

Vaccine cold chain monitor (VCCM) is a card that has four windows for registering temperature changes (9). Before use, these windows have to be activated to register temperature changes. The combined effect of time and temperature causes the monitor to change colour gradually and irreversibly. As the temperature increases, colour change on the cold chain monitor is greater and faster. Figure 9a below shows a Vaccine Cold Chain Monitor Card.

Figure 9a FRONT OF THE VACCINE COLD CHAIN MONITOR CARD

Vaccine Cold Chain Monitor				
Date In	Index	Location	Date Out	Index
<div style="border: 1px solid black; padding: 2px; display: inline-block;"> <input type="checkbox"/> </div>		<div style="border: 1px solid black; padding: 2px; display: inline-block;"> Monitor Mark™ Indicator </div>		
<div style="border: 1px solid black; padding: 2px; display: inline-block;"> To Activate Fold up Pad </div>		<div style="border: 1px solid black; padding: 2px; display: inline-block;"> 3M </div>	<div style="border: 1px solid black; padding: 2px; display: inline-block;"> 34°C </div>	<div style="border: 1px solid black; padding: 2px; display: inline-block;"> D </div>
		A	B	C
		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	
DPT & BCG		These vaccine may be used		Use within 3 months
TT & DT				
SUPPLIER FOURNISSEUR		Name _____ Nom _____ Date of dispatch _____ Date d'expédition _____ Vaccine _____ Vaccin _____		

The instructions for interpreting the colour change readings are printed on the reverse of the card (Figure 9b)

Figure 9b BACK OF THE VACCINE COLD CHAIN MONITOR CARD

Keep the cold chain monitor with your vaccine

When the monitor arrives....
Complete the top part of the card

- fill in the date
- fill in the index (-,ABC &/or D)
- fill in the location

When the monitor leaves...
Complete the top part of the card

- fill in the date
- fill in the index (-,ABC &/or D)

if windows A,B, C, & D are all white use vaccine normally

If windows A to C are completely blue, but window D is still white it means that the vaccine has been exposed to a temperature above 10° C but below 34° C for the following number of days

	Index		
	A	AB	ABC
At temperature of 12° C	3 days	8 days	14 days
21° C	3 days	8 days	14 days

If window D is blue it means that there has been a break in the cold chain of a temperature higher than 34° C for a period of at least two hours. Check the cold chain

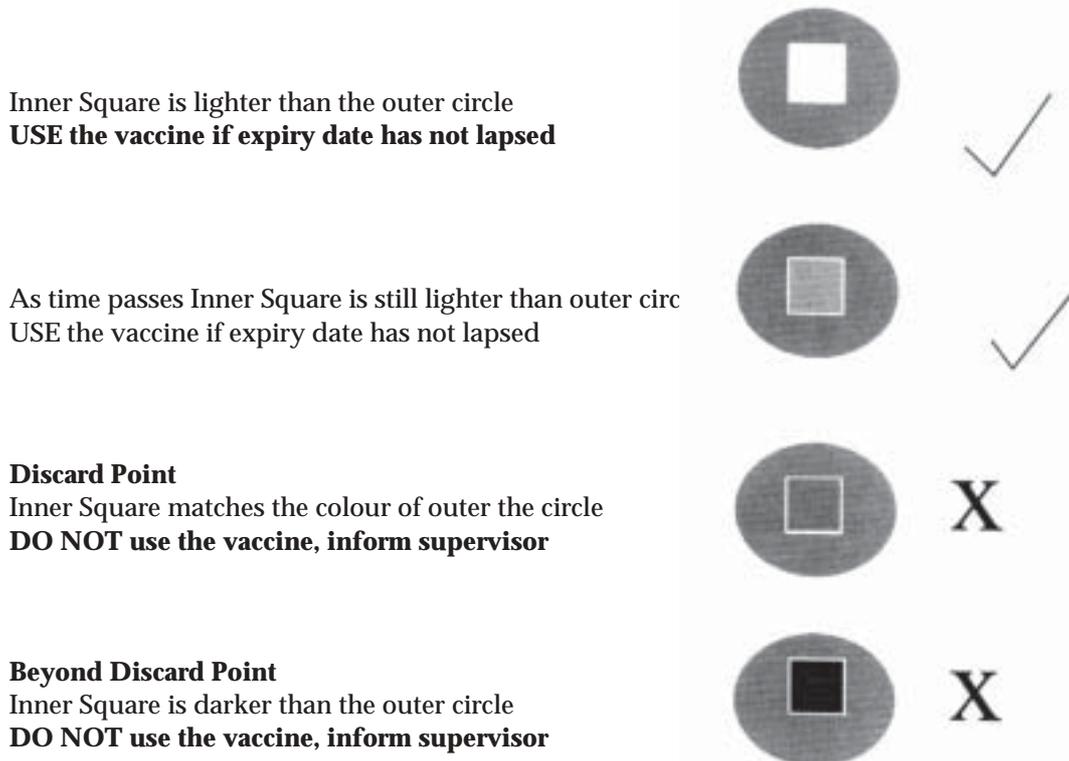
The instruction <use within 3three months> should not be followed if either the expiry date or any cold chain policy require a shorter period before use or disposal of the vaccine

Every RMSD is given cartons of vaccines to which VCCMs are attached depending on the number of MOOH in the region. These VCCMs are generally attached to cartons containing Hepatitis B vaccine and are distributed to RMSDs once in 2 months. The cold chain monitor record – EPI/CCM/R/96 (Annexure 3) records the distribution of VCCM to MOOH. This distribution to MOOH is carried out once a month. Entries made in the VCCM and in the revised VCCM form (Figure 10c) by the officer from the Epidemiological Unit, the officer in charge of the RMSD and the MOOH indicate the state of the cold chain during storage at the central cold rooms, during transport to RMSD, during storage at the RMSD, during transport to MOOH, and during storage at MOH office, These cards are subsequently collected from the refrigerators in the MOH offices after making the relevant entries, by the officer distributing vaccines. These are subsequently returned to the Epidemiologist. The receipt of these forms is monitored and any delay notified to the relevant DPDHS for action.

5.4.6 VACCINE VIAL MONITORS (VVM)

The vaccine vial monitor is a spot placed on a vaccine vial, which is made of heat sensitive material (10). It registers cumulative heat exposure over time. The combined effect of time and temperature causes the monitor to change colour gradually and irreversibly. As the temperature rises, the colour changes greater and faster on the vaccine vial monitor. By monitoring the change in colour, the health staff can see if a vial has been exposed to unacceptably high temperatures and can decide not to use the vial. At the centre of the heat sensitive spot is a square which is of a lighter shade. (See Figure10)

Figure 10 VACCINE VIAL MONITOR (VVM)



With exposure to heat, the colour of the square becomes darker than it's surrounding. However as long as the colour is lighter than the outer ring, it indicates that the cold chain has been maintained. When the colour of the inner square matches the outer ring or its colour becomes darker than the surrounding, it means that the vaccine has become heat damaged.

VACCINE VIAL MONITOR (VVM)

- **Is a spot, made of heat sensitive material placed on a vaccine vial. Cumulative heat exposure over time is registered on this spot and its colour changes due to combined effect of time and temperature.**
- **Higher the temperature, colour will change greater and faster.**
- **Colour change is irreversible.**

These VVMs will enable health staff to reject vials of vaccines, which are heat damaged. An opened vial of OPV to which a vaccine vial monitor has been attached, and which has been used either in the MOH office clinic or in any field clinic may be reused in subsequent immunization sessions, provided the expiry date has not passed, and the vaccine is not heat damaged according to the VVM attached to the vaccine vial. However these vials should be used **within 4 weeks** of their opening. All conditions that apply for the maintenance of the cold chain for unopened vials should be maintained for these opened vials till they are completely used. However an opened vial should be discarded if sterile procedures have not been followed or if there is even a suspicion that the opened vial has been contaminated, or if there is visible evidence of contamination, such as changes in appearance or the presence of floating particles. Care should be taken to see that opened and unopened vials of vaccines are not submerged in water while being transported in the vaccine carrier and during clinic sessions because there is a possibility of contamination through the vaccine vial septum. The septum should always be dry.

5.5 VACCINE LOGISTICS

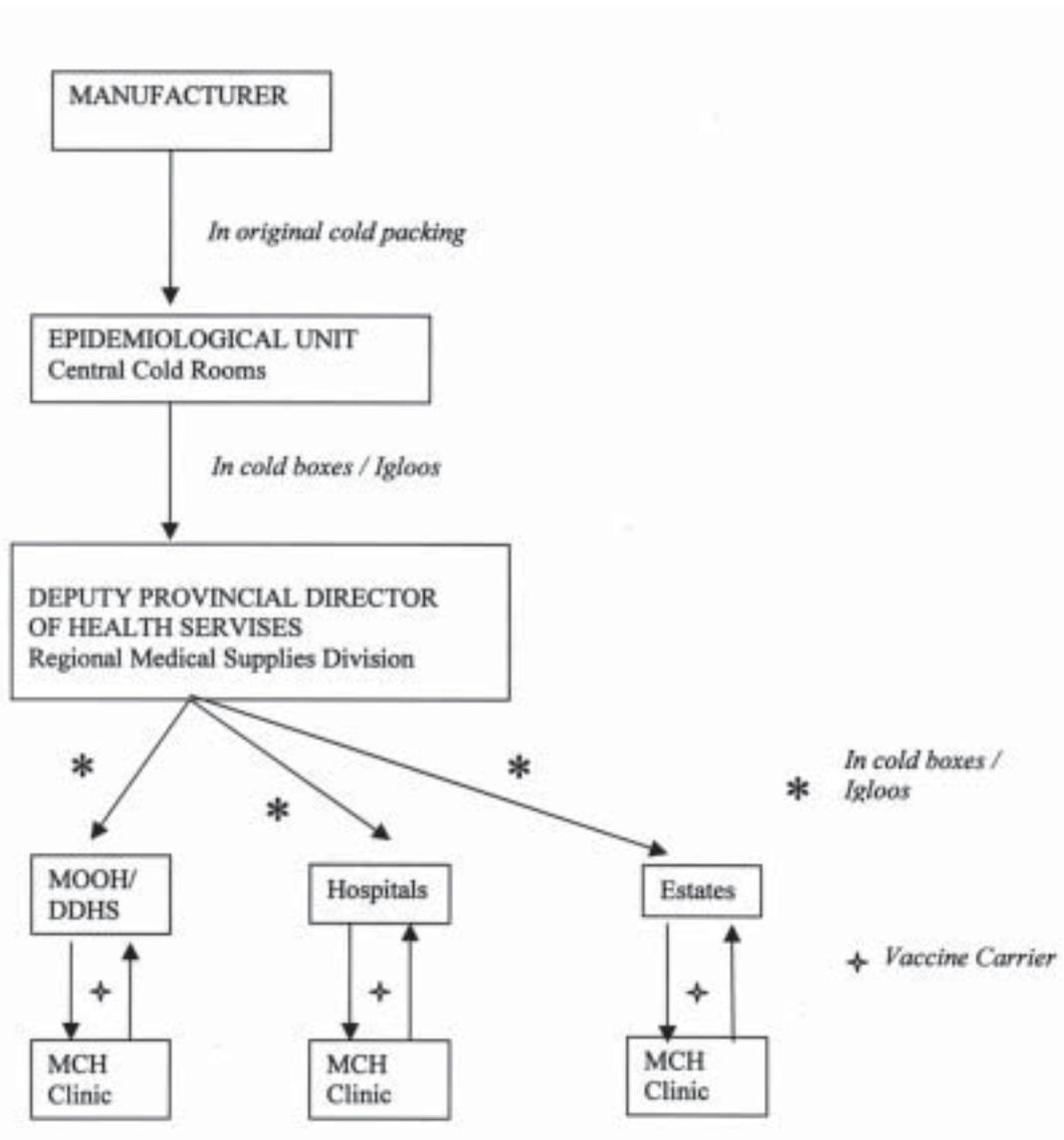
The Epidemiological Unit indents the requirement of OPV for the whole country with a buffer stock for six months. Presently the OPV requirement for immunization is funded by the Government of Sri Lanka. It is stored in the central cold rooms at the Epidemiological Unit maintaining the cold chain and is distributed to the Regional Medical Supplies Divisions (RMSD) regularly once in two months as shown in Figure 11 below. If informed of any shortage within this period at any RMSD, the requirement is sent immediately.

The vaccine is distributed to the RMSDs on requests made using the stock return form (Annexure 4). This return should be sent monthly to reach the Epidemiological Unit before the 10th of the following month whether stocks are required or not. On receipt of the vaccine stocks, they should be entered in the stock registers along with the batch numbers, dates of expiry of the stocks etc. The cold chain is maintained during transport to RMSDs.

Officer in charge of the RMSD has been identified as the person responsible for the request, receipt, storage and distribution of the vaccine. These officers have been trained on the cold chain. They transport the vaccine to all institutions in his area regularly, maintaining the cold chain. The distribution of the vaccines from the RMSD should be on the request made by the institutions using the vaccine stock return form (Annexure 4). To ensure an uninterrupted supply of vaccine it is important that all institutions send this stock return monthly to be received by the RMSD, by the 5th of the following month whether stocks are required or not. When distributing the vaccines the batch number/s of the stocks should be indicated. The stocks of vaccines that are received first should be distributed first, to ensure early distribution of stocks with a shorter expiry date before those with a longer expiry date.

At the institutions, one person should be identified and made responsible for the request, receipt, storage and distribution of the vaccines. The officer should note the batch number/s and date of expiry of the stock of vaccines received. The head of the institution is responsible to ensure that these activities are carried out.

Figure 11 DISTRIBUTION OF VACCINES



5.5.1 DISTRIBUTION OF VACCINES FROM MOH / INSTITUTION TO CLINICS

A Vaccine Movement Register should be maintained at the MOH office / Institution for the stock of vaccines distributed to the clinics conducted in the area. This should indicate the number of vials of vaccine taken to the clinic, the number vials returned unused, the number of doses in opened vials, the batch number of vials etc as shown in figure12.

Figure 12 VACCINE MOVEMENT REGISTER

Type of Vaccine.....

MOH Office / Institution.....

Month.....

Date	No. of doses in hand/ Receipts	Name of clinic	No: of doses issued	Batch number	No: of doses returned	No: of doses used	Daily Balance by	Monthly total used each clinic

A Clinic Vaccine Movement Register should also be maintained by each clinic as shown in figure 13.

Figure 13 CLINIC VACCINE MOVEMENT REGISTER

Date..... Name of Clinic.....

Type of vaccine	No. of doses issued to clinic	No.of immunizations performed	No: of doses used	No: of doses returned	No: of doses requested for the next clinic

5.5.2 STORAGE OF VACCINE

The maximum and minimum quantity of vaccines that could be stored at any point of time, at the RMSD and at an institution (Hospital/MOH office) is three month's and one month's stock respectively. The batch numbers and the expiry dates should be noted for all vaccine stocks received. Properly maintained equipment should be used to store vaccines. OPV should be stored in a deep freezer or in the freezing compartment of a refrigerator. Unused, unopened and opened vials of vaccine that had been taken to a clinic and brought back could be stored in the freezer or the main compartment of the refrigerator; but these vials should be used at the very next clinic according to the Open Vial Policy adopted by the Ministry of

Health in February 2005. The opened vials should be used within 4 weeks of being opened provided that the vaccine is within the expiry date, vaccine vial monitor changes do not indicate the discard point and that there is no evidence of contamination. Refrigerator records should be maintained for every refrigerator storing vaccines (Annexure 2).

VACCINE STOCKS

- **At the RMSD and at an institution**
- **Maximum three month's stock**
- **Minimum one month's stock**

A regular supply of electricity/Kerosene should be available to be used for all vaccine storage equipment. An emergency plan should be available and prominently displaced, to indicate the actions to be taken during a power cut, a sudden power failure and a break down in the refrigerator/freezer. This plan should be in accordance with the facilities available in and around the area.

AN EMERGENCY PLAN SHOULD BE DEVELOPED FOR THE AREA

- **Plan should indicate actions to be taken during**
 - o **A power cut**
 - o **A sudden power failure**
 - o **A break down in the refrigerator/freezer**
- **The plan should be prominently displaced**

5.6 IMMUNIZATION COVERAGE – SRI LANKA

The reported national routine immunization coverage of infants with three doses of OPV from 2000 to 2003 ranged from 99.8% to 104% (using estimated infant population). The routine immunization coverage with the 4th dose of OPV among children around 18 months of age during the same period ranged from 95% to 103%.

The target for immunization coverage is 100% for all eligible children. It is important that all infants receive 3 doses of OPV before their first birthday and that all children receive 5 doses by the age of 5 years. As the motivation among parents regarding immunization is very high this target is maintained by ensuring regularity of clinics with adequate supplies of vaccines at each clinic session. A person is identified and made responsible for this activity for each clinic. In the event of this person not being available due to being on leave or due to illness, an alternate person is identified to attend to this work. The person who has been assigned this work should ensure that vaccines are made available at the clinic, and that the clinics are conducted as scheduled. Similarly, a member/s of the health staff are identified specially for immunization activities and alternate persons identified to attend to this work in the absence of the regular officer. All these arrangements are decided by the MOH/Head of institution after discussion with the relevant staff at the beginning of the year are reviewed yearly and are made known to all staff members. In the event of any sudden changes (due to transfers

etc.) new arrangements are made and all concerned are informed of them. The immunization coverage is monitored quarterly by the Epidemiological Unit by DPDHS and MOH areas, using the quarterly EPI CDD return form. The coverage is monitored by MOH by PHM areas and special inputs are provided where necessary. It is very important to maintain the motivation of the public and health personnel, as there is a tendency for the enthusiasm to decline when the disease is no longer seen among children. Further, with the introduction of new vaccines and organization of special immunization activities with other vaccines eg. “Catch up Immunization with Measles Vaccine”, it is important to maintain the enthusiasm of the public and health personnel to immunize children at the appropriate age with OPV though this disease has not been reported in Sri Lanka since 1993. The very small percentage of unmotivated parents should be identified and motivated on an individual basis by field health personnel.

All institutions including estates conducting immunization should complete a quarterly return and forward it to the DDHS/MOH before the 10th of the following quarter. Action should be taken by the head of the institution / estates that all immunizations conducted are entered in this record by dose and age group. If all the doses had not been entered due to unavoidable circumstances they should be entered in the subsequent return/s. The DDHS/MOH should ensure that all institutions sending these returns do so on time. They should also ensure that immunization data are received from all MOH clinics, and from other places like mobile clinics, special clinics and from clinics conducted in schools. Data from late returns should be entered in subsequent returns. The consolidated return should be sent to the Epidemiologist with a copy to the RE/DPDHS, before the 20th of the month following the quarter. The RE/DPDHS should consolidate the data from all MOOH/DDHS and send the consolidated return before the 25TH OF THE MONTH following the quarter, to the Epidemiologist.

THE TARGET FOR IMMUNIZATION COVERAGE

- **100% of infants with three doses of OPV before the first birthday**

5.7 OPEN VIAL POLICY

An open vial policy has been introduced to the EPI from February 2005. This decision has been taken by the National Advisory Committee on Communicable Diseases in order to comply with the WHO endorsement to reduce the financial burden of immunization on governments throughout the world.

This policy advocates the use of balance vaccine doses left in opened multi dose vials of liquid vaccines (OPV, DPT, TT, DT, aTd, JE, Hep B) in subsequent immunization sessions.

Leftover doses of OPV can be used in subsequent immunization sessions within 4 weeks of opening the respective vial. However it is emphasized that the responsible authority should ensure that the expiry date of the vial has not been reached and that optimum cold chain conditions have been maintained. Further, the vaccine vial monitor attached to the OPV vial should not have reached the discard point.

SURVEILLANCE OF POLIOMYELITIS

6.1 SURVEILLANCE

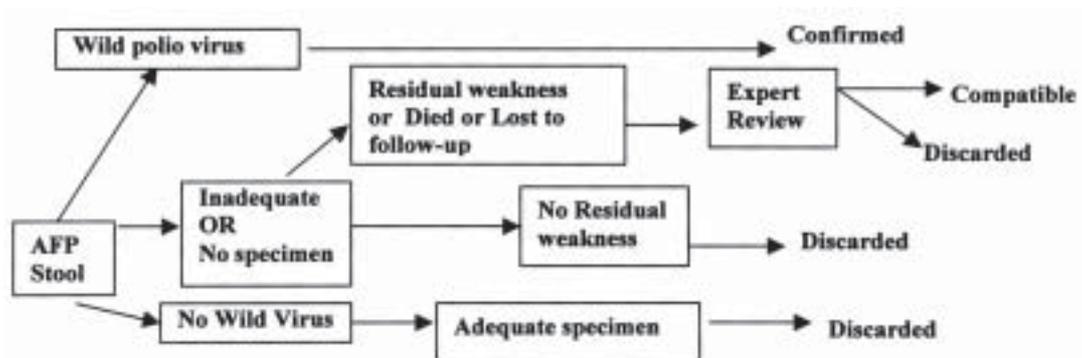
Surveillance, which is defined as the continuing scrutiny of all aspects of occurrence and spread of diseases that are pertinent to effective prevention and control, play a critical role in the implementation of the health care policy. With the present situation of poliomyelitis in Sri Lanka, it is very important to carry out enhanced surveillance to ensure that every case of poliomyelitis is detected. The purpose is to reliably identify areas where poliovirus transmission is occurring or is likely to occur and to allow supplementary immunization activities to be focused where it is necessary. As the number of poliomyelitis cases approach zero, this ability to detect and respond rapidly to every case of acute flaccid paralysis (AFP) becomes critical. Hence AFP has been identified as a notifiable disease by a government circular in 1990 and its surveillance will be carried out with special emphasis to eliminate poliomyelitis as a cause for the paralysis. Enhanced surveillance will play a major part in deciding on polio eradication status.

ENHANCED SURVEILLANCE

- **As the number of poliomyelitis cases approach zero, the ability to detect and respond rapidly to every case of AFP becomes critical.**

As Sri Lanka is identified as having a high-quality AFP surveillance programme, and stools specimens are processed in a WHO accredited laboratory, the criteria to move from clinical to virological classification was reached in 1995. Since then, the virological classification scheme (figure 14) and a standardized case definition has been adopted

Figure 14 VIROLOGIC CLASSIFICATION SCHEME



CRITERIA TO MOVE FROM CLINICAL TO VIROLOGIC SCHEME

Non poliomyelitis AFP rate >1/100,000 in children under 15 years

Two “adequate” specimens of stool collected from >60% of AFP cases

Specimens processed or results confirmed in a WHO accredited laboratory

“Adequate diagnostic specimens” = 2 specimens, 24 - 48 hours apart and within 14 days of onset of paralysis, each specimen of adequate volume [8-10 grams] and arriving in the laboratory in “good condition”

“Good condition” = no desiccation, no leakage, adequate documentation and evidence that the reverse cold chain was maintained

6.2 CASE DEFINITION

An AFP case is defined as any child less than fifteen years of age with Acute Flaccid Paralysis (including Guillain Barre Syndrome) or any person with paralytic disease at any age when poliomyelitis is strongly suspected.

6.2.1 SUSPECTED ACUTE FLACCID PARALYSIS (POLIO AND NON-POLIO) CASE

A suspected case of acute flaccid paralysis is defined as any child less than 15 years of age with acute (i.e. rapid progression of usually 1 to 3 days) flaccid (i.e. floppy) paralysis (i.e. inability to move the affected part), including those diagnosed to have Guillain Barre Syndrome or polyneuritis, or any paralytic illness at any age in whom poliomyelitis is suspected. **Each suspected case must be immediately notified to the Epidemiologist, Epidemiological Unit Colombo.** The case is recorded in the central AFP notification register and then investigated by a designated trained case investigator, within 24 to 48 hours of notification. He/She will confirm the case as AFP that was not present at birth and not caused by injury or will discard it as not being an AFP.

6.2.2 CONFIRMED CASE OF ACUTE FLACCID PARALYSIS (POLIO & NON-POLIO)

In a case of AFP, if no obvious cause of paralysis can be immediately and definitely identified on initial investigation by a designated trained investigator, the case is reclassified as a case of confirmed AFP. Investigation will be continued after recording the case in the central AFP register. If an immediate and an obvious cause, such as being present at birth or following an injury, is identified in a suspected case of AFP, the case investigator will discard the case and discontinue investigating it to rule out the cause of paralysis as poliomyelitis. If no obvious cause can be identified the case is classified as a “probable” poliomyelitis case. This is a temporary classification and the case should be re-classified as “**confirmed poliomyelitis**” or “**poliomyelitis compatible**” or discarded as a case of “**Non-Polio AFP**” using the virologic classification scheme. An alternate diagnosis is given to the non-polio AFP case.

6.2.3 CONFIRMED POLIOMYELITIS CASE

If wild poliovirus has been isolated from a stool sample of a **probable** case, it is classified as a **confirmed** case of poliomyelitis. If the case is confirmed as poliomyelitis, the case is further classified as an **indigenous** or **imported** case. An **indigenous case** is a confirmed case that has not traveled to or arrived from another country within 30 days of the onset of illness. An **imported case** is where the disease has developed in a resident who has traveled to another country within 30 days prior to the onset of the illness.

If vaccine like virus is isolated from the stools of a probable case, further tests will indicate whether it is a **vaccine associated** or **vaccine derived** case of paralytic poliomyelitis. In vaccine associated paralytic poliomyelitis (VAPP) paralysis appears within 4 – 45 days following immunization with OPV.

Vaccine derived poliovirus (VDPV) are poliovirus isolates consistent with an extensive period of virus excretion or transmission in the community, usually demonstrating 1-15% difference from parent OPV strains by full VPI sequence homology. VDPVs are classified as wild for programmatic and containment purpose(9). Two categories of VDPVs have been identified which are **immunodeficient VDPVs** (iVDPVs) and **circulating VDPVs** (cVDPVs). As VDPVs give contradictory or inconclusive results with ITD tests based on two different approaches, all such isolates detected at the MRI will be referred to a global specialized laboratory for further characterization.

CONFIRMED CASE

A confirmed case of poliomyelitis is classified as

- **Indigenous OR Imported**
- **Vaccine associated OR Vaccine derived (cVDPVs & iVDPVs)**

6.2.4 POLIOMYELITIS COMPATIBLE CASE

The case is reviewed by the National Polio Expert Committee

- **If** wild polio virus has not been isolated from an inadequate sample of stools or from a sample that has not been an “**adequate**” diagnostic specimen (i.e. two stools specimens collected at least 24 hours apart, within 14 days of onset of paralysis and received in “**good condition**”) or
- If a sample of stools has not been collected, and residual paralysis is present on follow-up examination or
- If the case has died or if the case is lost to follow-up before samples are taken for virology

The bed head ticket (BHT) including reports of special investigations are also reviewed by the committee, who will take the following information into consideration: -

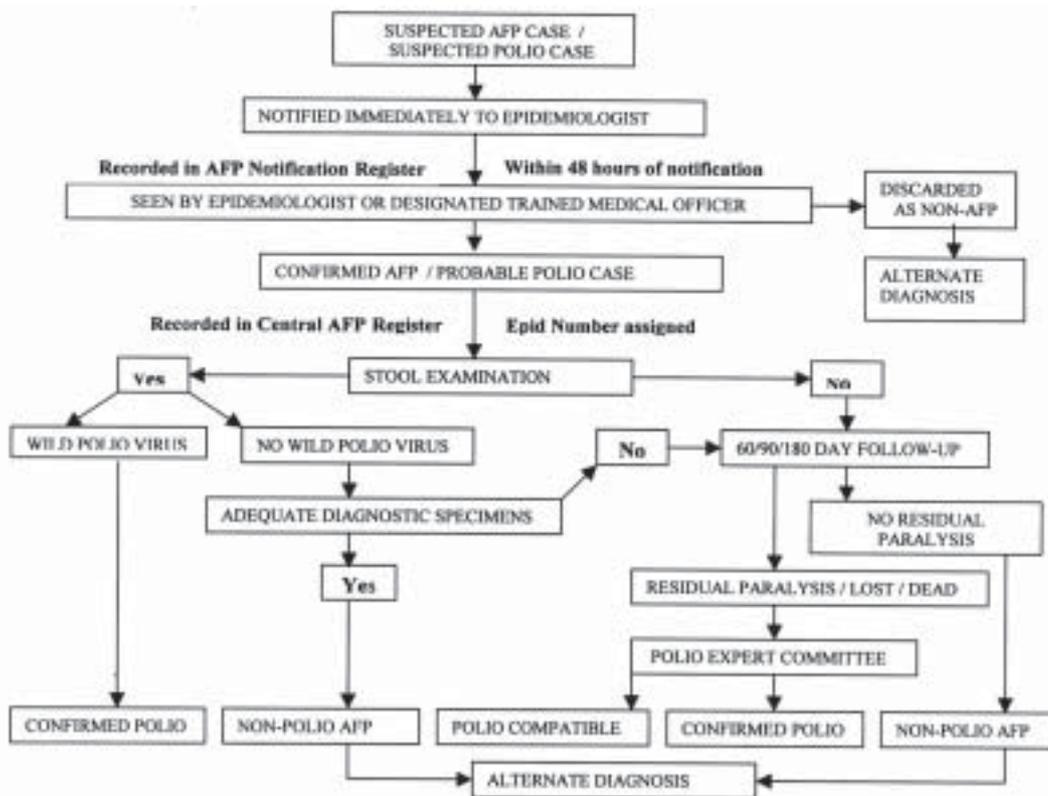
- Signs and symptoms in the early days of the illness recorded in the BHT
- Clinical progress of the patient
- Interval between time of onset of disease and collection of the stools sample for virology
- The condition of the stools sample received at the MRI
- The outcome of the illness
- The degree of residual paralysis at 60 days
- The type of residual paralysis
- OPV Immunization status of the patient
- Epidemiological linkage to any other case
- Electromyography examination results
- Cerebrospinal fluid examination results

The patient is subjected to further investigations if required by the Committee. Finally depending on the findings the case is discarded as a non-polio AFP case and an alternate diagnosis is given or the case is classified as a poliomyelitis compatible case. A poliomyelitis compatible case represents a failure of the surveillance system. Further, because poliomyelitis compatible cases can indicate areas of undetected virus transmission it is recommended that they be closely scrutinized, particularly if they cluster in time and space. Areas with such clusters may need to be included in 'mop-up' activities.

6.2.5 DISCARDED CASE

A **discarded case** is a case in which wild poliovirus has not been isolated from adequate diagnostic specimens and in which there is no residual paralysis on follow-up or as decided by the National Polio Expert Committee. The case is also discarded if there is no residual paralysis even if samples of stools have not been collected for virology, or if the sample collected is inadequate. If the case is discarded an alternate final diagnosis is assigned. The flow chart of AFP case classification is given in figure 15.

Figure 15 FLOW CHART OF AFP CASE CLASSIFICATION



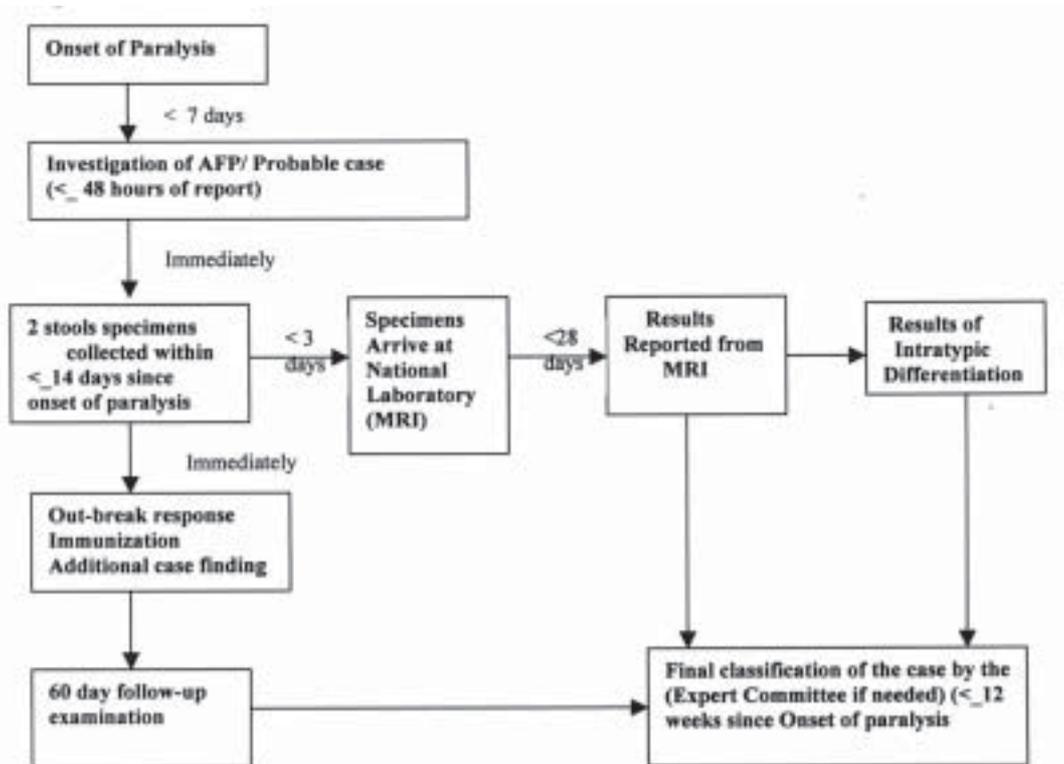
6.3 SURVEILLANCE OF ACUTE FLACCID PARALYSIS (AFP) / SUSPECTED POLIOMYELITIS CASES

The quality of surveillance is determined by noting how soon the case is notified, investigation commenced and samples of stools collected after the onset of paralysis. It is also determined by the fact that the case has been followed up for at least sixty days after onset of paralysis. It

is important to note that Acute Flaccid Paralysis (AFP) will be gazetted as a notifiable disease. Performance indicators have been developed to monitor the quality of surveillance.

To determine whether the reported case of AFP is actually poliomyelitis in the absence of isolation of wild poliovirus from stools, it is important to note the age of onset, immunization status and the progress of the disease. The presence of fever at onset, rapid progression of paralysis and asymmetry of paralysis are in favour of poliomyelitis. The presence or absence of residual paralysis sixty days after onset is also helpful to determine whether the case could be poliomyelitis. Additional tests like electromyogram and cerebrospinal fluid examination help to exclude poliomyelitis when the case is presented to the Polio Expert Committee. In the event the stools are found negative for enteroviruses, the time of collection of stools in relation to the date of onset of paralysis and the condition of the stools when it reaches the laboratory are considered before the case is discarded. That is to determine whether the sample was an adequate diagnostic specimen. The date of the last OPV immunization is important when poliovirus is isolated, to decide whether it is consistent with wild or vaccine virus. The quality of laboratory surveillance should be of good standard; for this decision certain performance indicators have been identified. Figure 16 shows the flow diagram for case investigations.

Figure 16 FLOW DIAGRAM OF CASE INVESTIGATION AND OUTBREAK RESPONSE



6.3.1 ROUTINE SURVEILLANCE OF AFP CASES

AFP has now been gazetted as a notifiable disease and is included in the list of notifiable diseases. Therefore it is a legal requirement to notify all AFP cases immediately by the medical officer treating the case. Figure 17 shows the routine and active surveillance path of AFP cases.

6.3.2.2 SENTINEL SURVEILLANCE

The major hospitals in the regions have been identified as sentinel sites for reporting AFP cases to the Epidemiologist weekly using form EPID/37/5/R2004 (Annexure 6). These major hospitals are Teaching hospitals, General hospitals, Base hospitals and District hospitals. The heads of these institutions have identified an officer to send these weekly returns including nil returns. At these institutions these officers are Infection Control Nurses (ICN), Public Health Inspectors (PHI) or Medical Records Officers (MRO) working in the institution.

The number of sites has been gradually increased over the years and by 2004, 52 sites have been identified. The completeness of reporting in 2004 was 81% and timeliness was 72 %. It has been noted over the years that reporting is better in areas where Regional Epidemiologists are present.

6.3.2.3 ACTIVE LABORATORY SURVEILLANCE OF AFP CASES AT NATIONAL LEVEL

All request forms received at the Medical Research Institute (MRI) with the stools samples for polio virology are faxed to the Epidemiological Unit by the virologist as soon as they are received (Annexure 1). If the case has not been notified earlier by the institution concerned, it is recorded in the central AFP Notification Register. The institution is contacted and the case discussed with the paediatrician treating the case and if necessary recorded in the central AFP Register. The case is then notified IMMEDIATELY to the relevant Regional Epidemiologist (RE) and Medical Officer of Health (MOH), by telephone / telegram / fax. The case is followed up till discharged from the institution to ensure that the second sample of stools is sent for virology and to follow the progress of the patient.

All polio isolates are immediately notified to the Epidemiologist.

6.3.2.4 ACTIVE SURVEILLANCE OF AFP CASES AT REGIONAL LEVEL

In the regions, where there is a Regional Epidemiologist (RE), he/she visits the major hospitals (sentinel sites) in the area at least once a week, and discusses with the Head of the Institution / Paediatrician / MOO regarding AFP cases under their care. He/she also peruses the admission register for AFP cases. If there are cases which have not been notified earlier they are discussed and if necessary, the investigation form, FORM No.1 (pink) EPID/37/1/R2004 (Annexure 7) is handed over to be completed and returned to the Epidemiological Unit. Then the case is notified IMMEDIATELY to the Epidemiologist and MOH, by telephone / telegram / fax / email. The case is recorded and followed up till discharged to ensure that samples of stools are sent for virology and to follow the progress of the patient. A monthly return including a nil return is sent to the Epidemiologist every month using the return Form: EPID/37/6/R2004 (Annexure 8). The percentage of sentinel site visits conducted in 2004 was 86%.

Each RE and MOH should maintain an AFP register with details of all AFP cases reported to them, as done at the Epidemiological Unit.

RE/MOH maintains a register of children less than 15 years of age returning from India and their immunization status is indicated there in. If there is no evidence of immunization with OPV, the children are immunized at the port of entry or at the welfare center to which they are sent. An immunization record of it is handed over to them. A return is sent monthly EPID/37/9/R2004 (Annexure 9) to the Epidemiologist.

6.4 ACTION TAKEN BY THE EPIDEMIOLOGICAL UNIT WHEN A CASE OF AFP IS NOTIFIED

The AFP case notified is recorded in the **Central AFP Notification Register**. The institution reporting the case is visited / contacted within 48 hours by an epidemiologist. If an Assistant

Epidemiologist from the Epidemiological Unit is unable to visit the institution, the Regional Epidemiologist (RE) in the DPDHS Division in which the institution is situated is informed to do so by telephone / telegram / fax/ email immediately. Where there is no RE, the MOH closest to the institution is informed by telephone / telegram /fax/ email to carry out the work; immediately. These officers are contacted again within 48 hours to find out about the outcome of the visit.

On visiting the institution, the case is investigated and discussed with the Paediatrician / MO treating the case to decide whether it is a true case of AFP which was not present at birth or not a result of an injury and is a probable case of poliomyelitis.

If the case is a probable case, either after investigation by an Epidemiologist from the Epidemiological Unit or RE or MOH, it is recorded in the **Central AFP Register**. If the case is not a probable case, it is discarded and an alternate diagnosis is given if possible. This decision is made by the Epidemiological Unit as early as possible if not within 48 hrs.

An EPID Number is assigned to the probable case when recording it in the **Central AFP Register**. This number is unique for the case and is for identification of the case at the Epidemiological Unit, Laboratory (MRI), hospital managing the patient and in the field at the DDHS/MOH level. All relevant data are also assigned this number. This number is also used for identification of each case internationally. The number is assigned taking the Country / Province / District /Year / Serial Number – SRL / 1-9 / 1-23 / 05 / 001. For example the first case occurring in Sri Lanka in the Western Province (coded as 01) in the District of Gampaha (coded as 02) in 2005, will have the Epid No. SRL / 1/ 2 / 05 / 001. A file is opened for each case and all relevant data / documents are filed there in.

The investigation form FORM No.1 (pink) EPID/37/1/2004 (Annexure 7) is sent immediately to the Medical Officer treating / reporting the case. The available identification data are entered in the form including the EPID number assigned to the case. This form should be returned to the Epidemiologist after completion.

Regional Epidemiologist (RE) in the DPDHS division in which the patient resides is informed of the case by telephone / telegram / fax / email immediately. This is followed by sending FORM No.4 (Blue) EPID/37/4/R2004 (Annexure12) to the RE with a copy to the MOH.

The MOH in whose area the patient resides is informed of the case by telephone / telegram / fax immediately. The investigation form FORM No.2 (yellow) EPID/37/2/R2004 (Annexure 10) is sent to the MOH in duplicate, after filling in all available data regarding the patient including the EPID number assigned to it. The EPID number assigned to the case is faxed to the Virologist at MRI along with available other identification data using a special form.

Once the case is discharged, RE in the area of residence of the patient is informed and the investigation Form No. 3 (Green) – Form EPID/37/3/R2004 (Annexure 11) is sent to be completed after examination of the patient at 60 days after the onset of paralysis. RE should complete this and forward it to the Epidemiologist. Where an RE is not available, this activity is carried out by an Assistant Epidemiologist from the Epidemiological Unit or MOH of the area. If the patient has not been discharged, RE or Assistant Epidemiologist from the Epidemiological Unit examines the patient at the institution and completes the form.

If a diagnosis of the case has not been established as polio or not polio from stools virology examination and if residual paralysis is present, all institutional records and investigation results are collected and the Polio Expert Committee is convened. All relevant data are discussed by the committee and a diagnosis is assigned. If a diagnosis cannot be assigned to the case, it is followed up and re-examined at 90 and/or 180 days after onset of paralysis, another form Form No. 3 (Green)– Form EPID/37/3/R2004 is completed, and the findings are discussed by the Expert Committee and a diagnosis assigned.

If residual paralysis is present at 60 / 90 / 180 days after onset of paralysis, and it is not possible to arrive at a diagnosis from the available data, the Expert committee will request a neurologist's /neuro-physician's examination and opinion, and /or further tests to be carried out, and will assign a final diagnosis. If poliomyelitis still cannot be ruled out as a cause of the acute flaccid paralysis, it is categorized as a case of **polio compatible**.

Soon after a final diagnosis is made for the case of AFP, the paediatrician / medical officer who notified the case is sent a feed back, using the Form EPID/37/7/R2004 with a copy to the relevant RE and MOH (Annexure 13)

ACTIVITY SCHEDULE FOR AFP SURVEILLANCE DISCIPLINE

DAILY

- **Update AFP Notification Register**
- **Update AFP Register**
- **On notification of a case of AFP**
 - **Send Investigation Form 1 to Hospital**
 - **Send Investigation Form 2 (2 copies) to MOH.**
 - **Send Investigation Form 3 to Regional Epidemiologist**
 - **Send Investigation Form 4 to Regional Epidemiologist**
 - **Fax information regarding AFP case to MRI**
 - **Open a file for each investigated case of AFP**
 - **File all relevant data of each AFP case in the relevant file**

ACTIVITY SCHEDULE AFP SURVEILLANCE DISCIPLINE

WEEKLY

- **Three visits per week to LRH for active surveillance activities**
- **Monitor weekly AFP reporting from sentinel hospitals**
- **Send AFP data files to WHO**
- **Send feed back to Paediatricians (Annexure 13)**
- **Monitor data entry in the AFP register and entry of weekly reporting of lab data**
- **Monitor submission of Notification Register and AFP register to Epidemiologist**

ACTIVITY SCHEDULE AFP SURVEILLANCE DISCIPLINE

MONTHLY

- **Arrange meeting with relevant staff of MRI & Epidemiological Unit**
- **Monitor monthly reporting of AFP by REE**
- **Monitor performance indicators of AFP surveillance**
- **Monitor data on returnees from India in the North & East**

ACTIVITY SCHEDULE AFP SURVEILLANCE DISCIPLINE**QUARTERLY**

- **Co-ordinate meetings between Expert Polio Committee and NCCPE**
- **Co-ordinate AFP consultative meetings with Paediatricians**
- **Co-ordinate AFP surveillance reviews in districts**
- **Co-ordinate NCCPE meetings**
- **Review of AFP cases from each region with respective RE at RE Conferences**

6.5 ENVIRONMENTAL SURVEILLANCE

The detection of AFP cases and laboratory testing of stools specimens is the surveillance standard for global polio eradication. However years of experience with environmental sampling in several industrialized countries with well developed sewage systems and qualified laboratories have demonstrated that such surveillance can detect circulation of wild polioviruses. Environmental surveillance has been suggested as a method to detect unrecognized poliovirus circulation in high risk or reservoir populations. However it has been recognized that the considerable logistic problems involved could compromise AFP surveillance. Targeted environmental sampling may become more important in the final stages of eradication.

If wild poliovirus is detected through environmental sampling (sources include sewage, water, stools survey, etc) the following steps should be taken

- Notification to WHO and to reporting sites in the country within 48 hours, with instructions to enhance AFP surveillance.
- Confirmation of the isolate in a WHO accredited laboratory.
- Re-sampling of the area where the isolate has originated.
- Determination of the virus origin through genomic sequence analysis within 21 days of confirmation of wild virus isolation. This is to help to determine whether the wild virus was imported or indigenous

WILD POLIOVIRUS IS DETECTED FROM ENVIRONMENTAL SAMPLE

- Notify WHO and reporting sites within 48 hours
 - Confirm the isolate in a WHO accredited laboratory
 - Re-sample the area where the isolate originated
 - Determine whether imported or indigenous within 21 days

The following actions have been suggested as an immunization response when wild poliovirus has been isolated from environment sampling.

- In endemic countries continue NIDs with special focus on the area sampled
- In high-risk countries if virus proves to be indigenous, large scale supplementary immunization Activities are needed. If virus is imported mopping -up is needed
- specially if routine coverage is low and surveillance performance is inadequate
- In Polio - free countries (>3 yrs) mop-up may be needed with the extent depending on routine coverage and surveillance performance

IMMUNIZATION RESPONSE TO WILD POLIOVIRUS ISOLATION FROM ENVIRONMENT SAMPLE

- **ENDEMIC COUNTRIES** - continue NIDs with special focus on the area sampled
- **HIGH-RISK COUNTRIES** if virus is *indigenous* - large scale supplementary Immunization
- **If imported** - 'mopping -up' specially if routine coverage is low and surveillance performance is inadequate
- **POLIO - FREE COUNTRIES (>3 YRS)** - 'mop-up' the extent depending on routine coverage and surveillance performance

Chapter 6

AGGRESSIVE OUTBREAK CONTROL

7.1 ACTION TO BE TAKEN BY INSTITUTIONAL STAFF

Besides investigating the case with a view to establishing a definite aetiological diagnosis of AFP, the Medical Officer (MO) treating a case of AFP, should initiate action to prevent an outbreak, in the event that this case is a case of poliomyelitis. The first action is notification of the case to relevant officers. Action should also be taken to collect and dispatch samples of stools from the case to the MRI for virology, and INVESTIGATION FORM No 1 (Pink), EPID/37/1/R2004 (Annexure 7) should be completed and returned to the Epidemiological Unit

ACTION TO BE TAKEN BY INSTITUTIONAL STAFF

- **Notify the case of AFP immediately to relevant officers**
- **Collect and dispatch stools for virology**
- **Complete INVESTIGATION FORM No 1 EPID/37/1/R2004**
- **Return INVESTIGATION FORM No 1 EPID/37/1/R2004 to the Epidemiological Unit**

7.1.1 NOTIFICATION

Any child under 15 years of age with acute flaccid paralysis (including Guillain Barre syndrome) or any person with acute paralytic illness at any age when poliomyelitis is suspected should be notified immediately by the Medical Officer treating the case. The case should be notified to the Epidemiologist at the Epidemiological Unit, Colombo. The relevant MOH and RE where the patient is resident should also be notified, immediately. The notification should be by telephone / telegram / fax / email or a messenger, and should be immediate or within 24 hours of examining the patient, even if the patient is to be transferred. On arrival of a patient from another institution, the case should be notified, if there is no evidence, in the transfer form to show that it has been notified by the institution transferring the case. There is no danger of duplication or over reporting as particulars of all cases are recorded in a central AFP notification register and these particulars are such that duplication would be detected before an EPID No. is assigned to the case and taken over to the central AFP register. It is the responsibility of the head of the institution to ensure that all cases of AFP are notified to all the relevant authorities and that this is done timely.

7.1.2 INVESTIGATION

Poliomyelitis should be considered in the differential diagnosis of any case of flaccid paralysis of acute onset. A thorough history should be taken and a thorough physical examination should be performed. The progress of paralysis if recorded daily would be of great help to reach a diagnosis. Studies have shown that in confirmed cases of poliomyelitis about 81% have fever at onset, in about 90% it takes less than 4 days for paralysis to develop and in about 87% sequelae is present and in about 75% atrophy is seen. Every effort should be made to obtain stools specimens to confirm the case by virology. Additional tests like Electromyogram (EMG) and Cerebrospinal Fluid (CSF) examination help to exclude poliomyelitis when a case is presented to the Polio Expert Committee.

7.1.3 COLLECTION AND DISPATCH OF SAMPLES OF STOOLS FROM A CASE OF AFP

Two adequate diagnostic specimens of stools should be collected. That is, the quantity of each sample should be 8 to 10 grams or the size of two thumbnails or two tamarind seeds. The two samples should be collected at least 24-48 hours apart preferably. Both samples should be collected within two weeks of onset of paralysis or as early as possible. Two stool samples should be collected the same way even when cases present to hospitals more than 14 days after the onset of paralysis. This would facilitate the classification of these cases by the National Polio Expert Committee.

The samples should be collected in the plastic containers provided for this purpose by the Epidemiological Unit (see Figure 18) or in clean dry screw capped bottles. These bottles should be free of soap and detergents. The samples should be correctly labeled, indicating name and age of the AFP case, hospital and ward number and BHT number, a short clinical history including immunization history, date of collection of the sample and the date of dispatch of the sample/s.

THE LABEL ON SAMPLES BOTTLES SHOULD INDICATE THE FOLLOWING

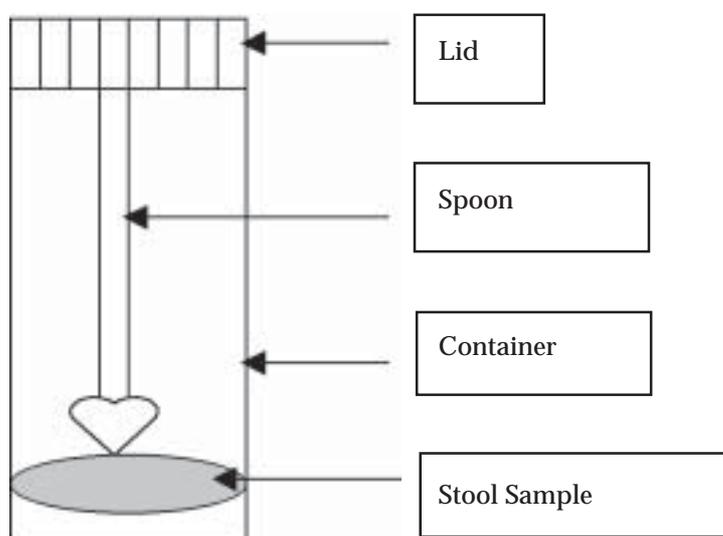
- **Name of AFP case**
- **Age of AFP case**
- **Hospital reporting the case**
- **Ward number reporting the case**
- **BHT number of AFP case**
- **A short clinical history including immunization history**
- **Dates of collection of the samples**
- **Date of dispatch of the sample/s.**

These samples should be transported to the MRI as early as possible preferably within 72 hours of collection. The samples should be transported in a flask with ice or ice-packs or it should be packed in ice, in a container eg rigifoam box. The quantity of ice should be such that at least some pieces of ice are present on arrival at the MRI. The lid of the sample bottles should be tightly closed to prevent leaking and drying of the stools. If there is a delay in dispatching, the samples should be kept at 0 to 8 degrees Centigrade, till they are ready for dispatch i.e. in the main compartment / door of a refrigerator. If a “reverse cold chain box” is available it should be used with frozen ice packs to transport the samples. It should be noted that 48 to 72 hours are needed to freeze an ice pack. The samples should be sent by the fastest and most reliable mode of transport. A special messenger should transport the samples and he/she should be made responsible to ensure that the samples are handed over to a responsible person at the MRI. The samples should be sent with a request for polio virology. The special request form made available by the MRI should be used if available. Whenever possible, MRI should be informed of the expected date and time of arrival of the samples.

By taking these precautions adequate diagnostic specimens of stool could be sent to the laboratory in “good condition”. “Good Condition is defined as presence of ice in the transport container upon arrival or a temperature indicator showing that the temperature was

maintained at $< 8^{\circ}\text{C}$, adequate volume of sample 8-10g), no evidence of leakage or desiccation and with appropriate documentation accompanying the sample.

Figure 18 SPECIAL PLASTIC CONTAINER FOR COLLECTION OF STOOL SAMPLES



COLLECTION AND DISPATCH OF STOOLS FROM AN AFP CASE

- **Two samples of stools collected 24 – 48 hours apart**
- **Both samples collected within 2 weeks of onset of paralysis**
- **Samples collected in the container provided/ dry clean screw capped bottle**
- **Correctly labeled**
- **Each sample weighing 8 to 10 grams/size of 2 thumb nails or 2 tamarind seeds**
- **Lid of container tightly closed to prevent leakage and drying of sample**
- **The container packed in ice**
- **Samples to reach MRI within 72 hours of collection in “good condition” with a request form for polio virology or special form provided by the MRI**

7.2 ACTION TO BE TAKEN BY THE MEDICAL OFFICER OF HEALTH (MOH)

7.2.1 INVESTIGATION

On receipt of notification of an AFP case from any institution and / or from the Epidemiological Unit and / or Regional Epidemiologist (RE) the MOH should record the case in the AFP register and should investigate PERSONALLY within 72 hours of notification. On receipt of INVESTIGATION FORM No 2 (Yellow) EPID/37/2/R2004 (Annexure 10) in duplicate from the Epidemiological Unit, the forms must be completed and one should be returned to the Epidemiologist with a copy to the Regional Epidemiologist early and the duplicate should be retained and filed at the MOH office.

During investigation of the case, the following activities should be carried out and appropriate findings entered in the INVESTIGATION FORM No 2 (Yellow) EPID/37/2/R2004:

- Visit the community where the case is resident.
- Meet the key people and health workers in the area. Inform the parents of the case and the community that the case is an AFP case which may be due to many causes one of which being poliomyelitis. Explain the importance of investigating such cases to specially eliminate poliomyelitis as the cause.
- Meet the parents of the case and inquire whether the patient has had contact with another AFP/polio patient within 60 days of onset of paralysis or whether he/she has traveled out of the area within 28 days before the onset of paralysis. Inform the relevant MOH/MOOH of the areas to which the patient had traveled for further investigation. Also inquire whether the patient or near relatives had traveled out of the country within 28 days before the onset of paralysis.
- Inquire from the parents about the polio immunization history of the patient including any extra doses received.
- Inquire from the parents whether anyone in the house including the patient, had received OPV during the 28 days before onset of paralysis. Enter any positive findings under immunization history.
- Inquire whether there are any other children in the family or in the vicinity with paralysis of recent onset.
- Make house-to-house visits in the immediate neighbourhood of the patient to detect any other cases.
- Request parents of at least 3 - 5 immediate contacts to make available samples of stools for collection the following day. Immediate contacts are siblings, playmates and classmates of the patient. The parents should be informed of the method of proper collection of the stools samples.
- If samples of stools have not been collected the following day, they should be collected as early as possible.

Parents should be instructed to collect the stools in a clean container (a clean, dry, wide mouthed bottle with a lid). The container should be free of soap or detergent. The container should be tightly closed to prevent leaking and drying of the stools sample and kept in a cool place away from sunlight till it is collected by a field health officer (Public health Inspector (PHI) or Public health Midwife (PHM)). Action should be taken by the PHI/PHM to help the parents to obtain suitable containers where necessary. The special stool collection bottle provided by the Epidemiological Unit could be used if available.

7.2.2 COLLECTION AND DISPATCH OF SAMPLES OF STOOLS FROM CONTACTS

ONE SAMPLE each from 3 to 5 immediate contacts should be collected. The quantity of the sample should be 8 to 10 grams or the size of two thumbnails or two tamarind seeds. The sample should be collected in clean, dry, screw capped bottles and correctly labeled. The lid of the bottles should be tightly closed to prevent leaking and drying of the stools. If the special stool collection bottle provided by the Epidemiological Unit is available they could be used. The samples of stools obtained from the contacts in the field should be collected by the field health staff and transported to the MRI as early as possible preferably within 72 hours of

collection. The containers with samples should be packed in ice. The quantity of ice should be such that at least some pieces of ice are present on arrival at the MRI. If there is a delay in transporting, the samples should be kept in a refrigerator (at 0 to 8 degrees Centigrade) till ready for transport. If a “reverse cold chain box” is available it should be used to transport the samples. The samples should be sent by the fastest and most reliable mode of transport. A special messenger should transport the samples. The samples should be sent with a request for polio virology. If possible the MRI should be informed of the expected date and time of the arrival of the samples.

The following information should be given in the request letter accompanying the samples of stools: -

- Name of the AFP case
- Epid No of the AFP case if available
- Name, age and sex of the contact.
- Date of receipt of the last dose of OPV by the contact
- Date of collection of the sample.
- Date of dispatch of the sample.
- Medical Officer of Health (MOH) area.
- Date of investigation by MOH

The date of investigation to be entered in this form is the day the MOH visited the neighbourhood of the AFP case to investigate it

COLLECTION AND DISPATCH OF STOOLS FROM CONTACTS

- **ONE SAMPLE each from 3 to 5 immediate contacts.**
- **Sample size 8 to 10 grams or the size of two thumbnails or two tamarind seeds.**
- **Sample collected in clean, dry, screw capped bottles and correctly labeled.**
- **Lid of the bottles tightly closed to prevent leaking and drying of the stools.**
- **Containers of stools packed in ice.**
- **Samples of stools transported to the MRI within 72 hours of collection**

7.2.3 LIMITED OUT BREAK RESPONSE IMMUNIZATION

As National Immunization Days have been conducted successfully from 1995 to 1999 and subsequently Sub National Immunization Days; only a LIMITED out break response immunization needs to be carried out now. The MOH team should conduct this on the day following the investigation of the AFP case. Only one dose of OPV should be given. This dose is an extra dose and should be given irrespective of the immunization status of the recipient. Even if the child had received the scheduled immunization / immunizations, this extra dose should be given. The scheduled routine OPV doses should be given on the due dates. This extra dose of OPV should be administered on a house-to-house basis for children living within

a two-kilometer radius of the AFP case and under the age of the AFP case. The number of children should be limited to about 250. Contacts from whom samples of stools have to be taken should be immunized after collecting the samples, to avoid contamination of the stools with vaccine virus making it more difficult to determine the cause of paralysis

ACTION TO BE TAKEN BY THE MOH

- Investigate the case **PERSONALLY** within 72 hours of notification
- Visit the community where the case is resident
- Note movement of patient 28 days before onset of paralysis
- Meet the key people and health workers of the area
- Explain the importance of the investigation to the parents and the community
- Make house to house visits and search for additional cases
- Request parents of contacts to make samples of stools available
- Collect and dispatch ONE sample of stools from 3 to 5 contacts
- Samples transported to the MRI within 72 hours of collection
- Complete INVESTIGATION FORM No 2 (Yellow) EPID/37/2/R2004
- Return Form no. 2 to Epidemiologist early
- Assist in follow up examination/s

7.3 FOLLOW UP OF AFP CASES

It is important to follow up the case to assist a diagnosis to be made. This is specially important in cases where poliovirus has not been isolated from stools of the patient, where the samples on arrival at the MRI has not been of “**good condition**” or when the stools have not been collected from the patient for virus isolation. If a case of AFP has residual paralysis, is dead or is lost for follow up or when poliovirus has not been isolated from an inadequate diagnostic sample of stools or a sample of stool has not been collected it is difficult to rule out poliomyelitis as the cause of paralysis. Such cases are reviewed by the **Polio Expert Committee**. This committee consists of a Neurologist, a Neuro-physician, a Paediatrician, and an Epidemiologist. The Bed Head Ticket of the patient is perused by the committee and results of investigations conducted to date such as Cerebrospinal fluid examination, and electromyogram are taken note of to arrive at a diagnosis. If necessary the patient is readmitted to hospital if he/she has been discharged and further investigations are carried out.

If the case is not diagnosed as poliomyelitis it is discarded and an alternate diagnosis given. Studies conducted in seven Latin American countries from 1989 to 1991 have shown that 60% of Guillain Barre Syndrome (GBS) cases have residual paralysis 60 days after onset and 15% of GBS cases have residual paralysis 180 days after onset and 10% of GBS cases have residual paralysis 1year after onset.

AFP cases are forwarded to the Polio Expert Committee if:

- ◆ stool samples are negative but have not been in 'good condition' on arrival at MRI
- ◆ stool samples which have been inadequate and from which polio virus is not isolated
- ◆ Stool samples have not been collected from the patient
- ◆ Residual paralysis is present at 60 days of onset of paralysis in a case with inadequate stools or stools not in 'good condition'

7.3.1 FOLLOW UP AT 60 DAYS AFTER ONSET OF PARALYSIS

If the patient has been discharged from the hospital, an Assistant Epidemiologist from the Epidemiological Unit or the relevant Regional Epidemiologist (RE), will PERSONALLY do the follow up examination of the patient, 60 days after onset of paralysis and will complete Form EPID/37/3/R2004 (green) – (Annexure 11). This form will then be returned to the Epidemiologist.

To conduct the follow up examination the Assistant Epidemiologist / RE should verify with parent/ responsible person the identity of the case. Ask the parent/responsible person if the paralysis has changed. Observe how the child moves his / her limbs or areas of the body which were paralysed. Verify presence or absence of sensation. Look for areas of muscle atrophy (wasting). Note if paralysis is present or not. Verify if paralysis is flaccid if present and examine for the degree of residual paralysis. Complete Form (green) EPID/37/3/R2004 – (Annexure 11) depending on the grade of paralysis.

Key for Grading Severity of Paralysis (Medical Research Council (MRC) Scale)

- Grade 0 = complete paralysis.
- Grade 1 = only a flicker of contraction could be detected.
- Grade 2 = contraction could be detected only after gravity has been excluded by appropriate posture adjustment.
- Grade 3 = the limb could be held against the force of gravity, but not against the examiners resistance.
- Grade 4 = there is some degree of weakness usually described as poor, fair or moderate in strength.

If the patient is still in the institution, the examination should be carried out by an Assistant Epidemiologist / RE depending on the location of the institution and the Form (green) EPID/37/3/R2004 should be completed and returned to the epidemiologist.

7.3.2 FOLLOW UP AT 90 DAYS AFTER ONSET OF PARALYSIS

If residual paralysis was present at the first examination at 60 days after onset of paralysis, and poliomyelitis could not be ruled out, the patient should be re-examined 90 days after onset of paralysis and another form, Form (green) EPID/37/3/R2004 should be completed and returned to the Epidemiologist. The same process should be adhered to as for the first examination.

7.3.3 FOLLOW UP AT 180 DAYS AFTER ONSET OF PARALYSIS

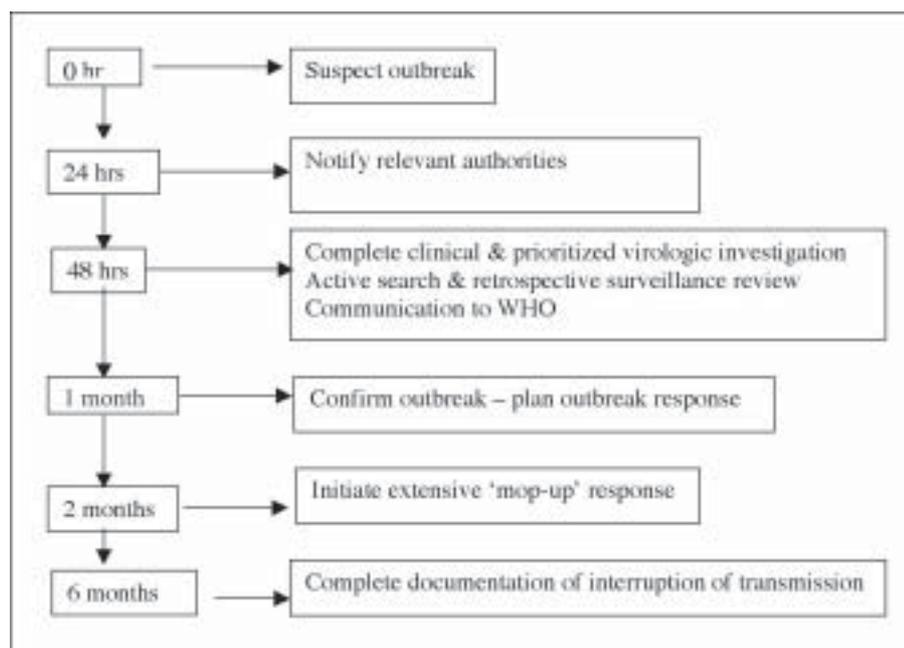
The patient should be followed up at 180 days after onset of paralysis, if residual paralysis was present at 90 days after onset, and poliomyelitis could not be ruled out, by the second examination. The same procedure as for the previous examination should be adhered to, and the appropriate form made available to the Epidemiologist.

7.4. NATIONAL PLAN OF ACTION TO RESPOND TO AN OUTBREAK OF POLIOMYELITIS

An increasing number of countries like Sri Lanka appear to have terminated transmission of wild poliovirus, yet they remain at risk for re-introduction of indigenous transmission. AFP surveillance, even when ideal, detects only a small proportion of poliovirus infections, and it is critical to rapidly detect and respond to suspected polio cases to minimize the spread of the virus. A National Plan of Action has been developed to respond in the event of importation of wild poliovirus or circulating vaccine derived poliovirus (cVDPV). For this purpose a suspected polio outbreak needing rapid investigation is defined as,

1. A cluster of polio compatible cases (two or more compatible cases as classified by an Expert Group) with onset in the same or adjacent districts within a two month period
OR
2. A cluster of AFP cases (multiple AFP cases without final classification, but which are clinically strongly suggestive of polio), with onset in the same or adjacent districts within a two-month period.
3. Within 48 hours of detection of a suspected polio outbreak, a full clinical, epidemiological, and virological investigation should be initiated; with a detailed review of surveillance quality in the area. Based on the investigation, a decision should be made on the need for, and scope of, an immunization response. Any suspected polio outbreak should be notified to WHO within 48 hours. Within one month, a suspected polio outbreak (including a cluster of AFP cases) should be confirmed as due to wild poliovirus or discarded. In polio free areas, any confirmed polio outbreak should have had an extensive 'mop-up' operation initiated within two months of onset of the index case. Exhaustive documentation of the interruption of transmission should be completed within six months of onset of the index case.

Proposed Timeline for Reacting to a Suspected Polio Outbreak



NATIONAL IMMUNIZATION DAYS

The purpose of National Immunization Days (NIDs) is to interrupt the wild poliovirus circulation by immunizing the susceptible population within a day or two, and thus interrupting the major chains of transmission by rapidly increasing systemic and intestinal immunity among all children aged less than five years. The abrupt interruption of transmission of the wild poliovirus in the community cannot be achieved by routine immunization alone; this should be combined with supplementary immunization (NIDs) and guided by high quality surveillance.

Approximately 300 million children in 62 countries received OPV during NIDs in 1995, including 150 million children in China and India alone. In the European and Eastern Mediterranean Regions 60 million children were immunized in 18 contiguous countries in the Middle East, Caucasus, and Central Asian Republic countries during co-ordinated NIDs on World Health Day. By the end of 1996 all poliomyelitis endemic countries in Europe and Asia and half of Africa had conducted at least one round of NIDs. All endemic countries had introduced NIDs by the end of 1999. Where epidemiologically appropriate, NIDs have been coordinated across national borders. House to house 'mop-up' campaigns, targeting at least one million children, were added to NIDs to interrupt the final chains of transmission. From 1999 the endemic countries increased the number of rounds of NIDs conducted each year and added sub-national immunization days (SNIDs) in particularly high risk areas and introduced house to house vaccine delivery strategy for NIDs and SNIDs. As a result, by 2003 an increasing geographic restriction of poliovirus transmission was seen.

The decision to continue NIDs should be based on the level of routine immunization and NID coverage, the performance of the AFP surveillance system and the perceived risk of introduction of wild poliovirus from endemic areas.

8.1. OBJECTIVES OF NATIONAL IMMUNIZATION DAYS (NIDS)

National immunization days or NIDs are days when EVERY child under 5 years of age residing in Sri Lanka receives TWO EXTRA doses of OPV four to six weeks apart. The additional doses are given irrespective of the prior immunization status. The two NIDs are held four to six weeks apart. During NIDs it is particularly important to immunize children who are often missed by routine immunization services.

The PRIMARY objective of NIDs is to eradicate poliomyelitis. By giving OPV at the **same time to all children over a short period of time in a large geographical area**, transmission of the poliovirus is interrupted. To be effective, very high coverage with OPV must be attained during NIDs. For those already immunized, NIDs boost both serum and intestinal immunity against the wild poliovirus.

DURING NATIONAL IMMUNIZATION DAYS (NIDS)

- Every child under 5 years of age residing in Sri Lanka receives two extra doses of OPV four to six weeks apart
- These additional doses are irrespective of prior immunization status
- The two NIDs are held four to six weeks apart
- Children missed by routine services are immunized

8.2 HOW TO CONDUCT NATIONAL IMMUNIZATION DAYS (NIDS)

The provincial and regional staff will be informed when the Ministry of Health decides on the two days on which to conduct NIDs.

All the activities for the NIDs at regional level should be planned well ahead by the Provincial Directors of Health Services (PDHS), Deputy Provincial Directors of Health Services (DPDHS), Regional Epidemiologists (RE), Medical Officers of Maternal and Child Health (MOMCH), Divisional Directors of Health Services (DDHS) and Medical Officers of Health (MOH), after discussion with the health personnel and officers of other Ministries and Non Governmental Organizations (NGO) of the area. Additional staff and vehicles should be obtained from these various sources. The regional level plans should be discussed with the National Committee. Subsequent meetings should be held to discuss the progress of the planned activities. The checklist provided by the Epidemiological Unit (Form NID/95/CL2) and Form NID/95/CL3 (Annexures 14 &15) could be used for this activity at Provincial, Regional and Divisional (MOH) level. The progress of activities at DPDHS and MOH level should be monitored by the PDHS. Immunization should be conducted at the existing MCH clinics and at temporary centres set up in schools and other public places. The number of centres should be such, that about 200 to 300 children would be immunized at each centre. Extra centres should be set up in the area depending on access and presence of hard to reach families like in low-density populations. Special centres could also be set up at welfare centres and estates. Special strategies should be adopted with the help of the armed forces and NGOO to conduct these activities in conflict areas.. The immunization centres should be identified by name and wherever possible prominently displayed banners should be used to enable the public to recognize the centre easily.

HOW TO CONDUCT NIDS

- **Plan well ahead.**
- **Discuss with health personnel, officers of other ministries & NGOO.**
- **Obtain additional staff and vehicles from various sources.**
- **Discuss progress of planned activities at regular intervals**

8.3 LOGISTICS FOR NATIONAL IMMUNIZATION DAYS (NIDS)

Requirements of vaccine, cold chain equipment, personnel, stationary including recording and reporting forms, training and social mobilization material and transport should be identified and arrangements made to obtain them by the team planning the NID in the region.

ARRANGEMENTS SHOULD BE MADE TO OBTAIN

- **Vaccine**
- **Cold chain equipment**
- **Personnel**
- **Stationary including recording and reporting forms**
- **Training and social mobilization material**
- **Transport**

8.3.1 CALCULATING VACCINE REQUIREMENTS

The following formula could be used to calculate OPV requirement for NIDs.

Number of doses required = Target population x 2 rounds x wastage multiplier

Target population is all children below the age of five years (10% of total population) in the catchment area. Wastage multiplier of 1.3 (representing about 30% wastage) could be used as was used for the first NID, to ensure that adequate stocks were available. For future NIDs the wastage multiplier could be adjusted based on experience from previous NIDs.

The number of vials required should be estimated by dividing the number of doses required by the number of doses in each OPV vial and rounding up the figure.

The No: of vials required = $\frac{\text{No: doses required}}{\text{No: of doses in each vial}}$

The required number of doses of OPV should be calculated for each center depending on the number of immunizations to be conducted at each centre. The number of doses per centre should be about 200 to 300 or less.

8.3.2. CALCULATING THE NUMBER OF IMMUNIZATION CENTRES TO BE ESTABLISHED, MANPOWER, COLD CHAIN EQUIPMENT AND OTHER REQUIREMENTS

The number of immunization centres depends on the population of the area, population density and the presence of any special population groups. One centre should be set up for every 200 to 300 target children. In addition extra centres should be organized in areas with special population groups. The requirements should be calculated depending on the number of centres. The immunization centre should be arranged in such a way to ensure easy flow of parents and children through the centre.

A health worker should be the co-coordinator of the immunization centre. Check list Form EPID/NID/95/CL4 available in Sinhalese Tamil and English could be used by the co-ordinator. In addition to the co-ordinator there should be at least one screener to screen for the correct age and one other person to immunize and to keep records. One tally sheet (Form EPID/NID/95/TS1 (Annexure16) each should be available for every 300 children expected at the center for this purpose.

Cold chain equipment requirements for storage should be calculated roughly as 1000 doses of OPV needing 1 litre of storage space. At least one vaccine carrier / flask / thermos / rigifoam box should be available at each centre to keep the OPV vials.

8.3.3 TRANSPORT OF OPV TO THE IMMUNIZATION CENTRES

The vaccine stocks should be transported to each immunization centre in a vaccine carrier / flask / thermos / rigifoam box labeled by the name of the immunization centre. These labels should also indicate the number of doses of OPV required by the centre, the identification e.g. registration number of the vehicle that would transport the vaccine and the date and time at which the vaccine should be collected from the place of storage of vaccine. The name of the officer responsible for this activity should also be indicated on the label.

One person should be made responsible to distribute the vaccine to identified centres. Vehicles should also be assigned to identified centres and the routes of distribution of OPV should be mapped out. The centres that should receive vaccine along the way should be identified on the map. The number of centres assigned to each route / vehicle should be such, that the last centre could be reached before 8am in the morning. At the end of the day the unused vaccine stocks should be collected along the same route by the same vehicle and the same officer who distributed the vaccine.

LABEL ON VACCINE CARRIER/FLASK/THRMOSE/RIGIFOAM BOX

- **Name of immunization centre**
- **Number of vials of OPV**
- **Identification of the vehicle transporting OPV**
- **Date and time OPV is to be collected**
- **Place of collection of OPV**
- **Name and designation of officer responsible**

8.3.4 STORAGE OF OPV

Where necessary vaccines should be stored at institutions including the MOH office to ensure that it is taken on time to the immunization centres on the day of the NID. The unused vaccine vials should also be returned to the place of storage from which the vaccine was taken out.

8.4 PROBLEMS ENCOUNTERED DURING NIDS

An officer should be identified to be available to handle any emergencies that could arise in different parts of the MOH area during NIDs. The MOH should be in overall charge of the activities. All planned activities should be made known to all officers carrying out these activities and to their supervising officers. The emergencies that could arise and the probable solutions should be discussed at the planning stage and subsequently at the regular meetings held to discuss the progress of the planned activities. A list of probable emergencies relevant to the MOH area and the possible solutions drawn up in a tabulated form could be of benefit to the field staff.

Some of the common emergencies are unavailability of identified personnel, inadequate number of vehicles on the scheduled dates, insufficient stocks of vaccines and stationary at a centre etc.

8.5. ANALYSIS OF DATA

The immunization should be recorded in the Child Health Development Record (CHDR) of the child immunized. If the record has not been brought to the centre, the immunization should be entered in the special record card supplied and handed over to the parent for retaining along with the CHDR.

Records of immunizations conducted at each centre should be maintained using the tally sheets. At the end of the immunization session these tally sheets with the total number of immunizations recorded should be returned to the MOH. The total number of immunizations conducted in the MOH division should then be calculated using all these returns.

8.6 IMMUNIZATION COVERAGE

The coverage for the MOH division should be calculated using the under 5-year-old population for the area as indicated in the return form NID Consolidated Report & Stock Return of Oral Polio Vaccine – Form EPID/SNID/2003/CR (Annexure 17). The final result should be forwarded to the Epidemiologist by each MOH using the same return form.

Data received from all the MOOH should be consolidated and the data presented as coverage for the under 5 years old population by DPDHS divisions. This should be done for both rounds separately.

8.7 VACCINE USAGE

Vaccine usage rate should be calculated using the information in the return Form EPID/SNID/2003/CR (Annexure 17).

8.8 ADVERSE EVENTS FOLLOWING IMMUNIZATION (AEFI)

When OPV is given on a large scale to a child population it is inevitable that some children may develop minor illnesses like fever, cough, vomiting and diarrhoea soon after. Although these maybe coincidental, parents tend to attribute the condition to the vaccine given previously. The MOOH should see such cases personally and reassure parents. Illnesses may appear to be more frequent following immunization, due to parental concern or more intense observation for illnesses following immunization.

Concerns have been raised about the safety of OPV for two reasons. Firstly, children are receiving multiple doses of OPV through routine immunization services and NIDs. Secondly as cases of poliomyelitis become rare in countries approaching eradication, any adverse event associated with the vaccine becomes less acceptable.

The only known adverse event associated with the administration of OPV is “vaccine associated paralytic poliomyelitis” (VAPP). This is extremely rare and the incidence rate is about 1 case in 2.4 million doses administered.

The working definition of VAPP is as follows (Global TCG 1997);

- i) Acute Flaccid Paralysis (AFP) with onset of paralysis 4 – 30 days following the most recent OPV dose.
- ii) The presence of neurological sequelae compatible with poliomyelitis, 60 days following onset of paralysis, when all other causes of AFP have been ruled out.
- iii) Isolation of vaccine poliovirus in adequate stool specimens (which are negative for wild poliovirus) tested in a WHO accredited polio laboratory.
- iv) No epidemiological linkage with a case of wild poliovirus or an outbreak associated polio cases.
- v) If the diagnosis is based on a review by the Expert Polio Review Committee.

The other risks of polio paralysis from continued use of OPV are due to circulating vaccine derived polio virus (cVDPV) and immuno – deficient excretors of vaccine derived polio virus (iVDPV). The risk incidence in the former was one episode per year in 1999 – 2002, and that of the latter was 19 cases since 1963 with two continuing to excrete and no secondary cases. Individuals with primary immunodeficiency syndromes are long term (i.e >6 – 12 months) excretors of vaccine-derived polioviruses.

Chapter 8

MOPPING - UP IMMUNIZATION

'Mopping-up' should be conducted when poliomyelitis has been reduced from an endemic disease to a disease occurring only in focal areas. It should be conducted usually during the low season of poliomyelitis transmission. In Sri Lanka where the poliovirus is almost eliminated, mopping-up immunization should be conducted immediately after a case is confirmed as poliomyelitis.

'Mopping-up' immunization is intensive HOUSE-TO-HOUSE immunization with OPV in high-risk districts. This consists of two rounds four to six weeks apart, and all children under 5 years of age are immunized irrespective of their immunization status. Each round should be conducted in one day and if this is not possible it should be done within a shortest possible period, not exceeding seven days.

High-risk districts are those where poliovirus is likely to circulate. These districts have been identified as those where poliomyelitis cases have been reported during the last three years and where the immunization coverage is low and the population is transient. Districts with poor access to health care and densely populated urban and/or peri-urban areas with poor sanitation are also considered as high-risk areas.

HIGH RISK DISTRICTS ARE THOSE WHERE

- **Poliomyelitis cases have been reported during the last 3 years.**
- **Immunization coverage is low.**
- **Population is transient.**
- **Access to health care is poor.**
- **Densely populated urban and/or peri-urban areas with poor sanitation**

9.1 OBJECTIVES OF MOPPING-UP IMMUNIZATION

'Mopping-up' immunization interrupts poliovirus transmission in focal areas. It is the final stage before completely eliminating the poliovirus. Even after the poliovirus is eliminated, 'mopping-up' immunization should be continued for several years in areas where the virus is likely to be imported.

9.2 HOW TO CONDUCT MOPPING-UP IMMUNIZATION

In Sri Lanka 'mopping-up' immunization was conducted following Sub-National Immunization Days conducted in high-risk areas from the year 2000 to 2003. This activity was concentrated in areas where the coverage was not satisfactory. Careful advanced planning is essential for a successful 'mopping-up' operation. Although most of the detailed planning has to be done at regional level, a national coordinator should be designated and a national mopping-up committee established. These officers should be those who were responsible for the NIDs conducted earlier.

'Mopping-up' is conducted in selected high-risk districts whereas NIDs are conducted nationwide. The provincial and regional staff will be informed when the Ministry of Health decides on the area and the dates to conduct 'mopping-up' immunization.

All activities for 'mopping-up' should be planned at regional level as for NIDs, in consultation with the National Coordinator (Epidemiologist) and the national 'mopping up' committee. It should be remembered that though immunizations were conducted at fixed centres during NIDs 'mopping-up' immunizations have to be conducted on a house-to-house basis. The duration of each round could be about one to seven days.

A district 'mopping-up' committee should be established in the district where 'mopping-up' is to be conducted and a coordinator designated. The committee should plan and implement the activities according to the national plan. Local health personnel and volunteers should be used as far as possible.

A budget should be prepared to include administrative costs, personnel, social mobilization, training and transport etc. Sources of funds should also be identified.

A detailed map of the area to be mopped-up should be obtained showing the terrain and type of roads. The district committee should decide on the number of children to be immunized per day in consultation with the field health staff. They should also decide on the number of vaccinators needed, the number of supervisors required number and type of transport to be used. Vehicles should be identified to transport the vaccinators and vaccine stocks to identified areas on the day of the mopping-up. The requirements depend on the number of households, distance between houses, terrain and the road conditions.

Supervisors should ensure that all areas and houses are visited and all target children are immunized, and that the vaccine is correctly administered. They should also ensure that the progress and problems are intimated to the district coordinator (MOH).

9.3 LOGISTICS FOR MOPPING-UP IMMUNIZATION

Requirements of vaccine, cold chain equipment, personnel, stationary including recording and reporting forms, training and social mobilization material and transport should be identified and arrangements made to obtain them

ARRANGEMENTS SHOULD BE MADE TO OBTAIN

- **Vaccine**
- **cold chain equipment**
- **Personnel**
- **Stationary including recording and reporting forms**
- **Training and social mobilization material**
- **Transport**

9.3.1 CALCULATING VACCINE REQUIREMENTS

The following formula should be used to calculate OPV requirement for mopping-up.

Number of doses required = Target population x 2 rounds x Wastage multiplier

Target population includes all children below the age of five years in the catchment area.

Wastage multiplier of 1.3 (representing about 30% wastage) could be used as was used for NIDs, to ensure adequate stocks.

The number of vials required should be estimated by dividing the number of required doses by the number of doses in each vial and rounding up the figure.

$$\text{Number of vials of vaccine required} = \frac{\text{Number of doses required}}{\text{Number of doses in each vial}}$$

As the immunization has to be done on a house-to-house basis, the programme in the district should be conducted by Public Health Midwife (PHM) areas. All the villages / wards in each PHM area should be identified and the estimated population density marked, on a detailed map indicating the types of roads. A person should be assigned a certain number of houses depending on the population density and access. Each person should be given a copy of the relevant part of the map identifying the starting point and the area he/she is responsible for. The ending point should also be marked. The required number of doses of OPV should be calculated for each person depending on the number of immunizations to be carried out by him/her. Each person may need one or two day carriers.

9.3.2 CALCULATING MANPOWER, COLD CHAIN EQUIPMENT AND OTHER REQUIREMENTS

The number of immunizations that could be conducted by a vaccinator depends on the population of the area, population density, presence of any special population groups and access. One or more people could be assigned to a village / ward to conduct the immunizations. A responsible officer should be identified as a supervisor, and a few villages / wards assigned to him/her. The routes should be so assigned that there is no overlap or leaving out of any road or cluster of families. PHM / a person who knows the area should give the necessary information to the person who will be carrying out the immunizations. If possible, it is better for someone from the area to carry out the immunization or accompany the vaccinator doing the immunization. PHM should be the coordinator for her area.

Cold chain equipment and requirements for storage should be calculated roughly as 1000 doses of OPV needing 1 litre of storage space. At least one vaccine carrier / day carrier / flask / thermos / rigid foam box should be available for each person carrying out immunization. Tally sheets should be available to record the immunizations given.

9.3.3 TRANSPORT OF OPV TO VACCINATORS

The vaccine stocks should be transported to each vaccinator in a vaccine carrier / day carrier / flask / thermos / rigid foam box labeled by the name of the vaccinator and the starting point. These labels should also indicate the number of doses of OPV required by the vaccinator, the registration number of the vehicle that would transport the vaccine, and the date and time to collect the vaccine from the place of storage of vaccine. One person should be made responsible to hand over the vaccines to identified vaccinators at the identified starting point. Vehicles should be assigned to identified starting points. Routes of distribution should be mapped out and the starting points identified on the map. The number of vaccinators assigned to each route / vehicle should be such that it is possible to reach the last vaccinator before the beginning of the session. At the end of the day, unused vaccines and the tally sheets should be collected using the same route and vehicle by the same officer who distributed the vaccine.

**LABEL ON VACCINE CARRIER / DAY CARRIER / FLASK /
THERMOS / RIGIFOAM BOX**

1. **Starting Point**
2. **Name of vaccinator**
3. **Number of vials of vaccines**
4. **Reg. No. of the vehicle transporting vaccine**
5. **Place of handing over the vaccine**
6. **Place of collection of vaccine at the end of the day**

9.3.4 STORAGE OF OPV

Vaccines should be stored at institutions, including MOH offices, wherever possible to enable vaccines to be taken on time to the vaccinators on the day of 'mopping-up'. If storage is not possible at these places stocks should be taken by a separate group of distributors to identified points of distribution. These vaccines should be packed in flasks etc from the closest storage point to enable officers in charge of distribution to take the stocks on time to the vaccinators. The unused vaccines should also be returned at the end of the day to the place of storage / collection from where the vaccine was received.

9.4 PROBLEMS DURING MOPPING-UP IMMUNIZATION

An officer should be identified to be available to handle any emergencies that could arise in different parts of MOOH areas in the district. Each MOH should be in overall charge of all the activities in his/her area. All planned activities should be made known to all officers carrying out the activities and their supervising officers. The emergencies that could arise and probable solutions should be discussed at the planning stage and subsequently at the regular meetings held to discuss the progress of the planned activities. A list of probable emergencies relevant to the District/MOH/PHM area and the possible solutions drawn up and distributed in tabulated form could be of benefit to the field health staff.

MOST COMMON PROBLEMS DURING MOPPING-UP

- **Insufficient ice for vaccine transport**
- **Lack of adequate transport**
- **Poor knowledge of the area by supervisors**
- **Inadequate number of vaccinators**
- **Insufficient supplies including vaccine**
- **Poor distribution of personnel including vaccinators & supervisors**
- **Inadequate training of vaccinators & supervisors**
- **Lack of clear instructions to personnel including vaccinators & supervisors**
- **Lack of timely and sufficient social mobilization**
- **Poor community and/or volunteer support**
- **Insufficient budget**

9.5 ANALYSIS OF DATA

Immunizations conducted by each vaccinator should be reported using the tally sheets (used for NIDs). When all houses assigned to the vaccinator have been visited and all immunizations recorded in the tally sheets, these sheets should be made available to identified officers to be handed over to the relevant PHM. The tally sheets should be analyzed according to villages and a consolidated return should be compiled by the PHM for her area. A return indicating the total number of immunizations conducted should be sent to the MOH. The number of immunizations conducted in the MOH division should then be calculated using all these returns.

These immunizations should be recorded in the CHDR or in a special record such as those issued during NIDs.

9.6 IMMUNIZATION COVERAGE

Data received from all the PHMM should be consolidated by MOH and the data should be presented as coverage among less than 5 years olds for both rounds separately by PHM areas. Copies of this report should be sent to the DPDHS and Epidemiologist.

Data received from all the MOOH in the district should be consolidated by the DPDHS and coverage by MOH divisions, for the under 5 years old population for both rounds separately, should be reported with a copy to the Epidemiologist.

9.7 VACCINE USAGE

Vaccine usage rate should be calculated by MOH divisions as was done for the NIDs (refer to section 8.7).

9.8 ADVERSE EVENTS FOLLOWING MOPPING-UP IMMUNIZATION (AEFI)

MOOH should see such cases personally and reassure parents (refer to section 8.8).

Chapter 9

LABORATORY CONTAINMENT OF WILD POLIOVIRUSES

Once transmission of wild poliovirus is interrupted globally, diagnostic research and vaccine production laboratories will represent the only remaining reservoirs of wild poliovirus. The goal of laboratory containment is to minimize the risk of inadvertent reintroduction of wild poliovirus from a laboratory into human circulation. This will be accomplished through identifying laboratories worldwide that store wild poliovirus or material potentially containing wild poliovirus, and ensuring proper handling or disposal of these materials under appropriate biosafety conditions. Such material consists of stocks infectious for wild poliovirus, specimens from polio patients and products of research or potentially infectious materials defined as throat, faecal, or environmental (water and sewage) specimens collected for any purpose at a time and in a geographical location where polio was endemic. Virological laboratories are the most likely sources of infectious material, but other biomedical laboratories (such as those dealing with bacteriology, parasitology, gastroenterology, nutrition, pathology or the environment) may also have potentially infectious materials. Adequate containment of wild poliovirus is a precondition for global certification of polio eradication.

A plan of action for containment has been outlined and consists of three phases of implementation that are linked to the achievements of the polio eradication programme. These are 1) preglobal eradication 2) postglobal eradication and 3) postcessation of oral polio (OPV) immunization.

LABORATORY CONTAINMENT OF WILD POLIOVIRUS ARE LINKED TO THE THREE PHASES OF THE POLIO ERADICATION PROGRAMME

These are

- **Pre global eradication**
- **Post global eradication and**
- **Post cessation of oral polio (OPV) immunization**

10.1 PLAN OF ACTION FOR LABORATORY CONTAINMENT

10.1.1 LABORATORY CONTAINMENT IN PREGLOBAL ERADICATION PHASE

Presently the preglobal phase is being implemented. During this phase, countries in which wild poliovirus circulation has been interrupted are requested to appoint a national task force or a coordinator to develop and oversee a national plan of action for laboratory containment of wild poliovirus. The first step in the national plan is to organize a survey of biomedical laboratories. The purpose of this survey is to alert laboratories of the impending eradication of polio, to encourage the appropriate disposal of unneeded wild poliovirus or potentially infectious materials, and to establish an inventory of laboratories retaining such materials. Once transmission is interrupted, laboratories will be notified to implement biosafety requirements appropriate for the risk of working with materials infectious or potentially infectious for wild poliovirus.

Most countries are in the process of surveying laboratories to identify those of most concern and those that do not need to participate in containment activities because they do not have

the capacity to store infectious materials or do not routinely keep specimens of concern for long periods of time. Laboratories identified as having the capacity to store infectious or potentially infectious material are followed up to determine the exact nature of the materials they have in storage. Those laboratories finally identified as storing materials infectious or potentially infectious for wild poliovirus are listed in a national inventory, which serve as the foundation for all further laboratory–containment activities.

Progress is being made world wide in implementing this pre-global eradication phase of laboratory containment; some countries had established a national plan of action and a national task force for laboratory containment of wild poliovirus. Some have submitted national laboratory inventories to WHO identifying laboratories with material infectious or potentially infectious for wild poliovirus. In WHO regions that have been certified as polio free, laboratory containment activities are well under way. Parts of South-East Asia regions are still polio endemic; but many polio free countries in these regions have begun preparation for laboratory containment.

WHO is working directly with manufacturers of polio vaccine to develop a plan of action for containing the poliovirus strains used during the manufacture of inactivated polio vaccine (IPV). As facilities involved in the large scale production and testing of vaccines require different containment technologies than for those found in diagnostic and research laboratories, a collaborative effort is under way to introduce specialized guidelines for vaccine manufacturers that will provide the necessary levels of containment while ensuring the continued supply of high quality polio vaccine.

In Sri Lanka there is strong political endorsement and support for laboratory containment of wild poliovirus. A national task force with the chairperson as the coordinator has been established for laboratory containment. A national plan of action with a timeline has been developed. The first step in the national plan was to alert laboratories of the impending eradication of polio, and to inform of the need for laboratory containment of wild poliovirus and that adequate containment of wild polioviruses is a precondition for certification of polio eradication. A National Inventory together with all supporting documentation is being prepared to be handed over to the National Committee for Certification of Poliomyelitis Eradication (NCCPE) for review and approval and for submission to the International Committee for Certification of Poliomyelitis Eradication (ICCPE).

Presently a national inventory of all laboratories containing wild polio virus infectious material and/or potential wild polio virus infectious material is being prepared.

10.1.1.1 WILD POLIO VIRUS INFECTIOUS MATERIAL

Wild poliovirus infectious materials are clinical materials from confirmed wild poliovirus (including Vaccine Derived Polio Virus (VDPV) infections, environmental sewage or water samples in which such viruses are present. These also consist of replication products of such viruses, including

- cell culture isolates, reference strains, seeds for inactivated vaccines
- infected animals or samples from such animals
- derivatives produced in the laboratory that have capsid sequences from wild polioviruses
- full-length RNA or complementary DNA (cDNA) that include capsid sequences derived from wild polioviruses
- cells persistently infected with poliovirus strains whose capsid sequences are derived from wild poliovirus

WILD POLIO VIRUS INFECTIOUS MATERIAL

- **Clinical materials from confirmed wild poliovirus (including VDPV) infections,**
- **Environmental sewage or water samples in which such viruses are present**
- **Replication products of such viruses , including**
 - **cell culture isolates, reference strains, seeds for inactivated vaccines**
 - **infected animals or samples from such animals**
 - **derivatives produced in the laboratory that have capsid sequences from wild polioviruses**
 - **full-length RNA or cDNA that include capsid sequences derived from wild polioviruses**
 - **cells persistently infected with poliovirus strains whose capsid sequences are derived from wild poliovirus**

POTENTIAL WILD POLIO VIRUS INFECTIOUS MATERIAL

**faeces,
respiratory secretions
environmental sewage
untreated water samples**

Products of such materials in poliovirus- permissive cells or animals including

- **harvests untested for polioviruses and enteroviruses**
- **uncharacterized enterovirus-like cell culture isolates**
- **undifferentiated poliovirus isolates**

These materials may also include contaminated laboratory stocks of other viruses like

- **rhinovirus,**
- **enterovirus**
- **Sabin vaccine strains**

10.1.1.2 POTENTIAL WILD POLIOVIRUS INFECTIOUS MATERIAL

Potential wild polio virus infectious material are faeces, respiratory secretions, environmental sewage and untreated water samples of unknown origin or collected for any purpose at a time and in a geographic area where it was suspected that wild poliovirus (including VDPVs) were present,. They could also be products of such materials in poliovirus- permissive cells or animals including

- harvests untested for polioviruses and enteroviruses
- uncharacterized enterovirus-like cell culture isolates
- undifferentiated poliovirus isolates

These materials may also include contaminated laboratory stocks of other viruses particularly rhinovirus, enterovirus and Sabin vaccine strains in laboratories that work or have worked with wild poliovirus in the past.

In preparing this inventory, all sectors such as education, research, environment, industry and defence in addition to the health sector were taken into consideration. Data were collected through relevant government ministries, National Science Foundation, Directors of institutions, Directors of private hospitals, Medical Officers of Health, Regional Epidemiologists, Consultant pathologists, microbiologists, parasitologists and a national list of laboratories was obtained.

The types of laboratories were bacteriology, virology, parasitology, pathology, immunology, forensic medicine, molecular biology, nutrition, food and water, environment, natural products, veterinary, culture and specimen collection, industrial, and biomedical laboratories.

A survey is being conducted to contact these laboratories and to identify those with wild poliovirus infectious materials and/or potential wild poliovirus infectious material. The purpose of this survey is to organize an inventory of laboratories retaining such materials. The laboratories had also been visited. Three laboratories storing wild poliovirus infectious materials have been identified to date (2004); and these are operating at enhanced bio-safety level -2 (BSL2/Polio). Once transmission is interrupted, laboratories will be notified to implement bio-safety requirements, appropriate for the risk of working with materials infectious or potentially infectious for wild polio virus.

10.1.2 LABORATORY CONTAINMENT IN POSTGLOBAL ERADICATION PHASE

The post eradication phase is to begin soon after detection of the last wild poliovirus globally. At that time, laboratories storing or handling materials infectious or potentially infectious for wild poliovirus should prepare for global certification of polio eradication by putting in place bio-safety conditions appropriate for the levels of risk presented by the materials being worked with and the laboratory procedures being used. A further increase in bio-safety requirements is anticipated once a global decision is made to stop the use of oral polio vaccine (OPV).

Appropriate laboratory containment of wild poliovirus is a critical element of polio eradication. It is a prerequisite for both global certification of polio eradication and the eventual cessation of OPV immunization. As the eradication of wild poliovirus approaches, minimizing the risk of reintroducing the virus into a population becomes an increasing priority. The risk of accidental reintroduction of wild poliovirus into a community from a laboratory is small. Four conditions must be met for such a reintroduction to occur.

- (1) The presence of material infectious or potentially infectious for wild poliovirus in a laboratory
- (2) An event (e.g. break in standard procedure) that exposes a worker to infectious materials containing poliovirus
- (3) A susceptible worker who replicates and sheds the virus in his/her stools
- (4) Susceptible persons in the community who are directly or indirectly exposed to this worker.

Although absolute containment cannot be assured, implementation of the activities outlined in the Global Action Plan effectively minimizes the risk of encountering a situation where all of the first three conditions occur. The fourth condition is linked to eventual decisions on post-eradication immunization policies.

POLIOMYELITIS ERADICATION CERTIFICATION

Global polio eradication is defined as the complete cessation of transmission of the wild poliovirus. The plan of action endorsed by the World Health Assembly resolution in 1999 as well as by the Global Commission for the Certification of Polio Eradication has stated that “adequate containment of wild poliovirus is a pre-condition for global certification of polio eradication.

Certification of polio eradication status is the process, which verifies that a region and eventually the entire world is polio free. Certification of polio eradication will depend on the absence of circulating wild poliovirus in the country in the face of efficient and comprehensive acute flaccid paralysis surveillance, adequate polio vaccine coverage and laboratory containment of wild poliovirus. Only after a period of at least three years of continued disease certification-standard surveillance and monitoring whereby no wild polioviruses are found, can a region and eventually the world be certified polio free. For example, the last case in the Americas was found in 1991; the region was certified polio free in 1994.

11.1 GLOBAL CERTIFICATION OF POLIOMYELITIS ERADICATION

The Global Commission for the Certification of the Eradication of Poliomyelitis (GCCEP) met on 16-17 February 1995 for the first time, to discuss what criteria would be used to define and certify global eradication of poliomyelitis. Serving as a model were, the criteria established by the International Commission for the Certification of Poliomyelitis Eradication in the Americas (ICCPE), which in September 1994, certified the Region of the Americas poliomyelitis free – the first region to achieve this goal.

In 1997 GCCEP finalized the criteria for certifying whether the goal of polio eradication is achieved.

The certification should be done on a regional basis. Each of the 6 Regional Certification Commissions (RCCs) could consider certification only when all countries in that area had submitted the appropriate documentation demonstrating the absence of circulating wild poliovirus for at least three consecutive years in the presence of excellent surveillance. The guidelines for certifying poliomyelitis eradication will be based upon the assessment of documented evidence focusing on effective surveillance levels for AFP and wild poliovirus.

Effective surveillance will be of paramount importance in judging whether or not to certify a region as poliomyelitis free. Because infection with wild poliovirus does not necessarily result in clinical infection, there needs to be strict guidelines regarding AFP case surveillance and surveillance for wild poliovirus transmission.

AFP surveillance would be of “certification standard” if three performance criteria were achieved. Firstly the system should detect at least one case of non-polio AFP for every 100,000 population aged less than 15 years. Secondly two adequate diagnostic specimens (2 stools specimens collected at least 24 – 48 hours apart within 14 days of onset of paralysis and received in good condition at the laboratory) should be collected from at least 80% of AFP cases. Thirdly all specimens should be processed at a WHO accredited laboratory. Further, all facilities holding wild poliovirus infectious and potentially infectious materials must have implemented appropriate bio-containment measures.

PERFORMANCE CRITERIA OF AFP SURVEILLANCE OF “CERTIFICATION STANDARD”

- The system should detect at least one case of non-polio AFP for every 100,000 population aged less than 15 years.
- Two adequate diagnostic specimens should be collected from at least 80% of AFP cases.
- All specimens should be processed at a WHO accredited laboratory.
- All facilities holding wild poliovirus infectious and potentially infectious materials must have implemented appropriate bio-containment measures.

11.1.1 GUIDELINES FOR SURVEILLANCE OF AFP

The guidelines for surveillance of AFP are as follows;-

- a) Timely reporting of at least 80% of AFP cases (including zero reporting) and documentation of the reasons for late reporting or non-reporting.

Identification of a rate of at least 1 non-polio AFP per 100,000 children less than 15 years of age is an indicator of an adequate surveillance system.

- b) At least 80% of reported AFP cases should be investigated within 48 hours.
- c) Detailed investigation – clinical, epidemiological and virological – of suspected poliomyelitis cases; final classification should be made on the basis of examination results by a committee of experts convened for this purpose if the case has not been confirmed as not polio with or without residual paralysis.

11.1.2 GUIDELINES FOR WILD POLIOVIRUS SURVEILLANCE

The guidelines for wild poliovirus surveillance are as follows: -

- a) High levels of competency in laboratories certified as part of global / regional network
- b) Validation of specimen collection, transport and testing procedures
- c) No wild poliovirus identified from two adequate diagnostic specimens of stools from at least 80% of cases for at least three years
- d) No wild poliovirus isolated from stools samples collected from contacts of AFP cases for at least three years

11.2. LABORATORY CONTAINMENT

Further, all facilities holding wild poliovirus infectious and potentially infectious materials must have implemented appropriate bio-containment measures.

In mid -1999 the World Health Assembly (WHA) urged all Member States to begin the process leading to the laboratory containment of wild poliovirus. In phase I all biomedical laboratories had to be listed. Worldwide over 100,000 laboratories had been identified for surveying and 80 countries (37%) had finalized an inventory of laboratories storing wild poliovirus material. For IPV production facilities using wild poliovirus at these sites, consensus has been reached

on the need for BSL-3/poliolevel containment in all existing facilities, with implementation and verification activities planned for completion in 2007-2008.

11.3 INDICATORS OF DISEASE SURVEILLANCE AND LABORATORY PERFORMANCE

Indicators have been developed to assess important disease surveillance and laboratory activities, and targets have been set.

The ten Indicators of Disease Surveillance and Laboratory Performance are as follows;

1. Non - Poliomyelitis AFP rate in children <15 years of age (Target $\geq 1/100,000$)

$$\text{Non-Poliomyelitis AFP rate} = \frac{\text{Number of reported non-Poliomyelitis AFP cases} < 15 \text{ yrs of age}}{\text{Total number of children} < 15 \text{ yrs of age}}$$

2. Completeness of monthly reporting (Target $\geq 90\%$)

$$\% \text{ Complete} = \frac{\text{Number of monthly reports received}}{\text{Number of monthly reports expected}} \times 100$$

3. Timeliness of monthly reporting (Target $\geq 80\%$)

$$\% \text{ Timely} = \frac{\text{Number of reports received before specified deadline}}{\text{Number of reports expected}} \times 100$$

4. Reported AFP cases investigated ≤ 48 hours of report (Target $\geq 80\%$)

5. Reported AFP cases with 2 stools specimens collected ≤ 14 days of onset (Target $\geq 80\%$)

6. Reported AFP cases with a follow up examination at 60 days after onset of paralysis to verify presence of residual paralysis or weakness (Target $\leq 80\%$)

7. Specimens arriving at National Laboratory (MRI) ≤ 3 days of collection (Target $\geq 80\%$)

8. Specimens arriving at laboratory in "good condition" (Target $> 80\%$)

"Good condition" means that upon arrival:

- There is ice or a temperature indicator showing $< 8^{\circ}\text{C}$ in the container
- Specimen volume is adequate (> 8 grams)
- There is no evidence of leakage or desiccation
- Appropriate documentation (laboratory request / reporting form) is completed

9. **Specimen with a turn around time \leq 28 days (Target \geq 80%)**

Turn around time is the time between receipt of specimen & reporting of results

10. **Stools specimens from which non – polio entero virus was isolated (Target \geq 10%)**

This is an indicator of the quality of the reverse cold chain and how well the laboratory is able to perform in the routine isolation of enteroviruses.

11.4. COUNTRY CERTIFICATION OF POLIOMYELITIS ERADICATION

A National Certification Committee was formed in 1999 and the committee comprises of a pediatrician, a virologist and an epidemiologist.

Sri Lanka along with many other countries of the world is rapidly moving towards certification of polio eradication. Certification of polio eradication depends on the absence of circulating wild poliovirus in the country in the face of :-

- Efficient and comprehensive acute flaccid paralysis surveillance
- Adequate polio vaccine coverage and
- Laboratory containment of wild poliovirus

The National Committee will consider the situation of the above activities and will also consider active searches for AFP in areas of poor surveillance, such as those where confirmed or compatible cases occurred in the past or from which reports were not received. The Committee will also consider documentation of mass immunization in areas of risk such as those where confirmed or compatible cases have occurred or where there is conflict or unrest resulting in a migratory population.

Certifying a country poliomyelitis free requires that there are no reports of new cases of poliomyelitis caused by wild poliovirus. It also requires evidence that a country can detect a case of paralytic poliomyelitis should it occur.

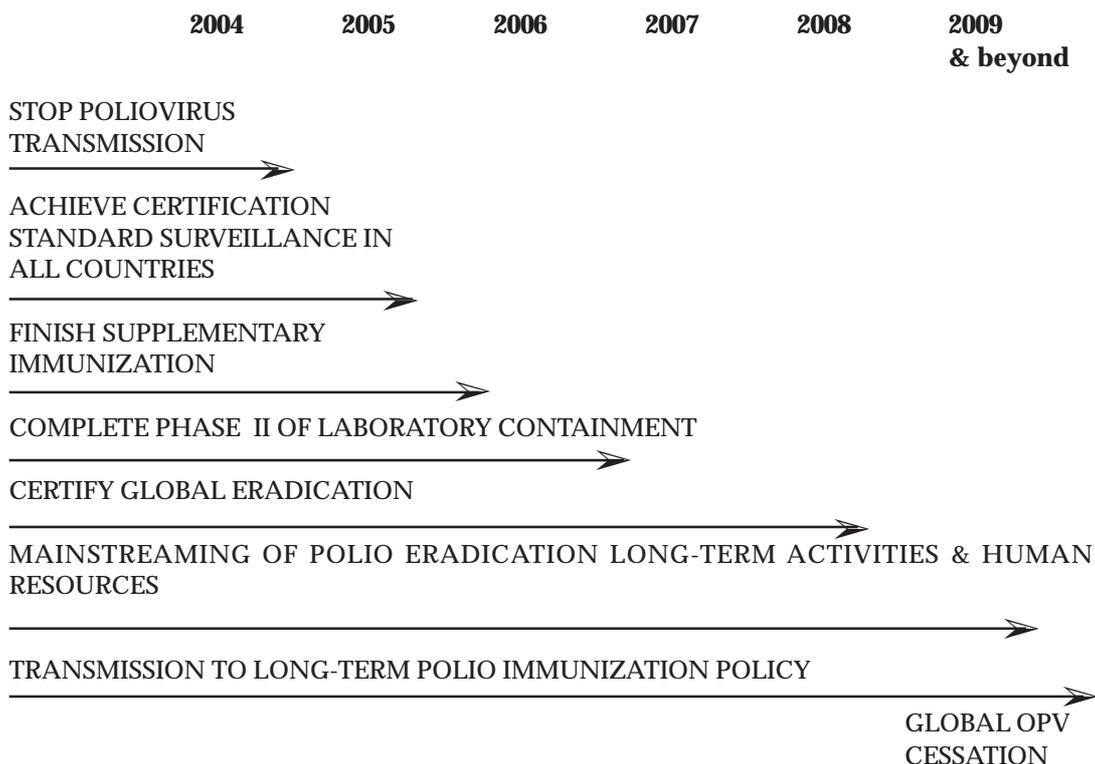
After careful documentation and review by the National Committee for Certification of Poliomyelitis Eradication, the data collected will be sent to the Regional Commissions who will have the authority to certify that polio eradication has occurred. Certification of global polio eradication will be announced only when all Regional Commissions have certified polio eradication within their respective areas. During this period it will be necessary to continue vaccination campaigns and immunization efforts, to maintain strict surveillance for all cases of AFP, and to be in readiness for possible importation of wild poliovirus.

11.5 GLOBAL POLIO ERADICATION INITIATIVE STRATEGIC PLAN 2004 – 2008

Since the Global Polio Eradication Initiative was launched, the work of the global polio partnership, including national governments, has been guided by a series of multi-year strategic plans, the last of which was published in 2000. The Global Polio Eradication Initiative strategic plan 2004-2008 replaces and updates the 2000 plan. This Plan outlines the key activities required to interrupt polio transmission (2004–2005), achieve global certification and mainstream the Global Polio Eradication Initiative (2006 – 2008) and prepares for the subsequent Global OPV Cessation Phase (2009) and beyond (Figure 19). The plan reflects the major tactical revisions of strategy which were introduced in 2003 to interrupt wild poliovirus transmission worldwide, the revised timeframe for the certification of polio eradication globally, and the substantial increase in the knowledge base for development of policies for

the period after global certification of polio eradication. This Strategic Plan serves as the basis for the annual work planning of individual partner agencies and national programmes.

Figure 19 KEY TARGETS TO INTERRUPT POLIOVIRUS TRANSMISSION (2004-2005), ACHIEVE GLOBAL CERTIFICATION AND MAINSTREAM THE GLOBAL POLIO ERADICATION INITIATIVE (2006-2008) AND DURING THE GLOBAL OPV CESSATION PHASE (2009 & BEYOND)



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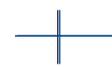
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9. Logistics and Cold Chain for Primary Health Care – How to use the Cold Chain Monitor EPI/LOG/84/27//Rev 1
10. Vaccine vial Monitor and appended vial policy
11. WHO Global Action Plan for Laboratory Containment of Wild Polioviruses 2nd Edition 2003

ABBREVIATIONS

AEFI	Adverse Effects Following Immunization
AFP	Acute Flaccid Paralysis
BCG	Bacille Calmette and Guerin
BSL	Bio Safety Level
CCMR	Cold Chain Monitor Record
CSF	Cerebro-Spinal Fluid
DDHS	Divisional Director of Health Services
DNA	Deoxyribo Nucleic Acid
DPDHS	Deputy Provincial Director of Health Services
DPT	Diphtheria Pertussis and Tetanus
EPI	Expanded Programme on Immunization
ELISA	Enzyme Linked Immuno Assay
GBS	Guillain Barre Syndrome
GCCEP	Global Commission for the Certification of Eradication of Poliomyelitis
HIV	Human Immunodeficiency Virus
ICCPE	International Commission for the Certification of Eradication of Poliomyelitis
IPV	Injectable Poliomyelitis Vaccine
ITD	Intra Typic Differentiation
LRH	Lady Ridgeway Hospital for Children
MH	Major Hospital
MMR	Measles Mumps and Rubella
MOH	Medical Officer of Health
MRI	Medical Research Institute
NCCPE	National Committee on Certification of Poliomyelitis Eradication
NID	National Immunization Day
OPV	Oral Polio Vaccine
PAHO	Pan American Health Organization
PHM	Public Health Midwife
RE	Regional Epidemiologist
RMSD	Regional Medical Supplies Division
RNA	Ribo Nucleic Acid
RVCCM	Revised Vaccine Cold Chain Monitor
TCID	Tissue Culture Infective Dose
TOPV	Tri-valent Oral Polio Vaccine
VCCM	Vaccine Cold Chain Monitor
WHA	World Health Assembly
WHO	World Health Organization
UNICEF	United Nations Children's Fund

ANNEXURES

Annexure 1	Request Form for Stools for Polio Virology
Annexure 2	Refrigerator Cold Chain Record - EPI/2/89
Annexure 3	Cold Chain Monitor Record - EPI/CCM/R/96
Annexure 4	Vaccine Stock Return Form
Annexure 5	Weekly Return of Communicable Diseases - Form Health H399
Annexure 6	Weekly Reporting Form for AFP, Measles, Rubella/CRS from Hospitals EPID/37/5/R2004
Annexure 7	Acute Flaccid Paralysis (AFP) Investigation Form No 1 (Pink) EPID/37/1/R2004
Annexure 8	Monthly Reporting Form for AFP, NNT and Measles Cases By Regional Epidemiologist
Annexure 9	Monthly Return of OPV Immunization of Returnees from South India EPID/37/9/R2004
Annexure 10	Acute Flaccid Paralysis Investigation Form (Yellow) EPID/37/2/R2004
Annexure 11	Acute Flaccid Paralysis Investigation Form (Green) EPID/37/3/R2004
Annexure 12	Notification Form for Regional Epidemiologists – EPID/37/9/R2004
Annexure 13	Feed Back to Paediatricians/Physicians on Notified cases EPID/37/7/R2004
Annexure 14	Check List for NIDs – Provincial Regional and Divisional Level EPID/ NID/95/CL2
Annexure 15	Check List for NIDs – Medical Officer of Health (MOH) Level EPID/ NID/95/CL3
Annexure 16	NID Tally Sheet – EPID/SNID/2002/TS1
Annexure 17	NID Consolidated Report and Stock Return of OPV for National Immunization Days – EPID/SNID/2003/CR



Annexure 1

**WHO Regional Reference Laboratory Medical Research
Institute Colombo Sri Lanka**

NAME:

AGE: SEX:

B.H.T.NO:.....

DATE OF ONSET of PARALYSIS:.....

FEVER:.....

PARALYSIS:.....

DATE OF COLLECTION OF STOOL SAMPLES:.....

SAMPLE 1:.....

SAMPLE 2:.....

DATE OF DISPATCH OF STOOL SAMPLES:

.....
SIGNATURE OF MEDICAL OFFICER

LABORATORY USE

DATE OF RECIPT OF STOOL SAMPLE AT THE MRI CONDITION OF STOOL

SAMPLE

ICE - PRESENT / NOT PRESENT

LAKED OUT - YES / NO

QUANTITY - ADEQUATE /NOT ADEQUATE



Annexure 3

EPI/CCM/R/96

COLD CHAIN MONITOR RECORD (CCMR)

DPDHS.....

RMSD.....

	Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
MOH Area	Date of Receipt of CCM card from Epid Unit	Date of Delivery of CCM card to MOH by OIC RMSD	Date of Collection of CCM card by OIC RMSD from MOH office	Date of Collection of CCM card by Epid Unit from RMSD	Signature of officer from Epid Unit Collecting CCM card from RMSD	CCM card Number
1						
2						
3						
4						
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22						

FORM: EPID/37/5/R2004

WEEKLY REPORTING FORM FOR AFP*, MEASLES, RUBELLA /CRS CASES FROM HOSPITALS (SENTINEL SITES)

INSTITUTION:.....

Week of reporting: (Saturday to Friday) _200 to _200

Disease	Name of the patient	Age	Sex	Ward	B.H.T. No.	** D.O.A	Date of onset	Residential address

Name :..... Designation: Signature: Date:

*AFP – Acute Flaccid Paralysis
** D.O.A – Date of admission

This form should be completed for all cases of AFP, MEASLES, and RUBELLA/CRS, after visiting medical, paediatric, EYE, ENT and neurology wards during the week. Even if no cases have been detected, please forward this return every Friday to Epidemiologist, Epidemiological Unit, 231, de Saram Place, Colombo 01000 with a copy to Regional Epidemiologist, Tel: 2695112, 2681548, Fax: 2696583, E-mail: epidunit@sltnet.lk / chepid@sltnet.lk by Head of the institution/ICN/PHI or any other identified officer.

FORM: EPID/37/5/R2004

WEEKLY REPORTING FORM FOR AFP*, MEASLES, RUBELLA/CRS CASES FROM HOSPITALS (SENTINEL SITES)

INSTITUTION:.....

Week of reporting: (Saturday to Friday) _200 to _200

Disease	Name of the patient	Age	Sex	Ward	B.H.T. No.	** D.O.A	Date of onset	Residential address

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This form should be completed for all cases of AFP, MEASLES, and RUBELLA/CRS after visiting medical, paediatric EYE, ENT, and neurology wards during the week. Even if no cases have been detected, please forward this return every Friday to Epidemiologist, Epidemiological Unit, 231, de Saram Place, Colombo 01000 with a copy to Regional Epidemiologist, Tel: 2695112, 2681548, Fax: 2696583, E-mail: chepid@sltnet.lk by Head of the institution/ICN/PHI or any other identified officer.

NEW

EPID/37/1/R2004

**EPIDEMIOLOGY UNIT
MINISTRY OF HEALTH**

Serial No.

AFP ID Code SRL/



**POLIO ERADICATION INITIATIVE
ACUTE FLACCID PARALYSIS [AFP]
INVESTIGATION FORM No. 1 (Pink)**

To be filled in by the Medical Officer treating the case, on suspicion of the diagnosis sent to the EPIDEMIOLOGICAL UNIT, 231, DE SARAM PLACE, COLOMBO 01000 (Fax: 2696583, e-mail: epidunit@sltnet.lk, chepid@sltnet.lk immediately. If appropriate, mark '✓' in the box. DO NOT WRITE IN THE SHADED AREAS.

A. GENERAL

1. Date of Notification to MOH: 1.
DD MM YYYY
2. Officer notifying the case: _____
3. Have you notified this case to the Epidemiologist by telephone (2695112) or fax (2696583) or by telegram? 1. Yes 2. No
4. If yes, when? 4.
DD MM YYYY
5. Name of Institution: _____
6. Ward No.: 6
7. Date of admission: 7.
DD MM YYYY
8. Bed Head Ticket No.: 8.

B. PARTICULARS OF THE PATIENT:

9. Name of the patient: _____
 10. Name of the Parent or Guardian: _____
 11. Residential Address (FROM THE PARENT/GUARDIAN AND NOT FROM THE B.H.T.): _____
 12. MOH area of residence: _____
 13. Date of Birth 13.
DD MM YYYY
- If Date of birth is not known go to 14. Else go to 15.
14. Age: 14.
YY MM

15. Sex: 1. Male 2. Female

C. SYMPTOMS AND SIGNS

16. Did the patient have fever 1. Yes 2. No
17. Date of onset of fever 17.
DD MM YYYY
18. Did the patient have paralysis? 1. Yes 2. No
19. Date of onset of paralysis 19.
DD MM YYYY

20. Any injections 30 days before paralysis onset: 1. Yes 2. No
21. Type of paralysis? 1. Spinal 2. Bulbar 3. Spino bulbar
- A. Asymmetric paralysis? 1. Yes 2. No
- B. Maximum Paralysis reached within 4 days 1. Yes 2. No
- After 4 days 1. Yes 2. No

20.

21.

22.

22. Site of paralysis (Fill in all the appropriate spaces below)

Site of involvement	Severity of paralysis	Sensation		Site of involvement	Severity of paralysis	Sensation	
		Yes	No			Yes	No
Left hand	Grade (Please fill in according to key)			Right hand	Grade (Please fill in according to key)		
Left forearm				Right forearm			
Left shoulder				Right shoulder			
Left hip				Right hip			
Left leg				Right leg			
Left foot				Right foot			
Left side of face				Right side of face			
Respiratory Paralysis? (Please tick)		Yes	No	Neck	Right		
					Left		
Other specify				Other specify			

Key for grading of severity of paralysis (Medical Research Council – MRC – scale):

Grade 0 = Complete paralysis

Grade 1 = A flicker of contraction only

Grade 2 = Power detectable only when gravity is excluded by appropriate postural adjustment.

Grade 3 = The limb can be held against the force of gravity, but not against the examiner's resistance

Grade 4 = There is some degree of weakness usually described as poor, fair or moderate in strength.

D. LABORATORY INVESTIGATIONS

23. 1st specimen of stools
- (i) date of collection 23b.
DD MM YYYY
- (ii) date of despatch 23c.
DD MM YYYY
24. 2nd specimen of stools
- (i) date of collection 24b.
DD MM YYYY
- (ii) date of despatch 24c.
DD MM YYYY

23a.

24a.

25.

E. IMMUNIZATION

25. The number of doses of routine OPV given, with dates

Dose	1			2			3			4			5		
Date	D	M	Y	D	M	Y	D	M	Y	D	M	Y	D	M	Y

26. Last date of OPV immunization (including NIDs): 26.
DD MM YYYY

27. Has any member of the household (including the patient) had OPV during the last 28 days?

- Yes No Unknown

28. Probable Diagnosis: _____

29. Name of Medical Officer: _____

30. Designation: _____

32. Date: _____ 32.
DD MM YYYY

33. Date of investigation by an Epidemiologist

31. Signature: _____

33.
DD MM YYYY

27.

28.

NEW

EPID/37/9/R.2004



EPIDEMIOLOGY UNIT
MINISTRY OF HEALTH

POLIO ERADICATION INITIATIVE
MONTHLY RETURN OF O.P.V. IMMUNIZATION OF RETURNEES FROM SOUTH INDIA

Information on Returnees	No.	Remarks
No. of returnees during the month		
No. of returnees (age <15 years) during the month		
No. of children (<15 years) given 1 st dose of additional OPV		
No. of children (<15 years) given 2 nd dose of additional OPV		
No. of children (<15 years) who were age appropriately vaccinated with all EPI antigens		

Port of entry:

Are facilities available at the port for O.P.V. Immunization

If facilities for OPV immunization at the port are not available how were these children vaccinated

Signature.....

Name:.....

Date.....

Designation.....

R.EE. should collect information from MOOH and prepare a consolidated return and send to the Epidemiologist, Epidemiological Unit, 231, De Saram Place, Colombo 10 before 10th of the following month (Tel: (+94-11-)2681548, (+94-11-)2695112, Fax (+94-1-)2696583, E-mail: chepid@slt.net.lk and epidunit@slt.net.lk)

NEW

EPID/37/2/R2004

**EPIDEMIOLOGY UNIT
MINISTRY OF HEALTH**

Serial No.

AFP ID Code SRL



**POLIO ERADICATION INITIATIVE
ACUTE FLACCID PARALYSIS [AFP]
INVESTIGATION FORM No. 2 (Yellow)**

This case is to be investigated personally by the Medical Officer of Health and this form returned to EPIDEMIOLOGIST, EPIDEMIOLOGICAL UNIT, 231, DE SARAM PLACE, COLOMBO 01000 (Fax: 2696583, e-mail: epidunit@sltnet.lk, chepid@sltnet.lk with a copy to Regional Epidemiologist soon after the completion of the first round of immunization. PLEASE DO NOT WRITE IN THE SHADED AREAS.

A. GENERAL

1. MOH Area: _____ 1.

2. DPDHS Area: _____ 2.

3. This case was notified to you on _____ 3.
DD MM YYYY

4. Name of patient: _____

5. Residential Address: _____

6. Date of Birth: _____ 6.
DD MM YYYY

7. Sex: 1. Male 2. Female

8. Ethnic Group: 1. Sinhala 2. Tamil 3. Moor
 4. Other 9. Unknown

9. Name of Hospital: _____

10. Date of Admission: _____ 10.
DD MM YYYY

11. Outcome: Still in hospital Discharged Died

12. Date of discharge or death _____ 12.

B. IMMUNIZATION HISTORY:

13. PHM Area: _____

14. Population of PHM Area: _____ 14.

15. Percentage immunization coverage with OPV3 in this PHM area in _____ 15.
 %

NEW

EPID/37/3/R2004

**EPIDEMIOLOGY UNIT
MINISTRY OF HEALTH**

Serial No.

AFP ID Code SRL/



**POLIO ERADICATION INITIATIVE
ACUTE FLACCID PARALYSIS [AFP]
INVESTIGATION FORM No. 3 (Green)
Follow-up after 60/90/180 days of onset**

Medical Officer of Health/Regional Epidemiologist,

This case was investigated by you on
DD MM YYYY

Please examine the child, complete the form and return it to the following address immediately. Epidemiologist, Epidemiological Unit, 231, de Saram Place, Colombo 01000. Fax: 2696583, E-mail: chepid@sltnet.lk and epidunit@sltnet.lk

PLEASE DO NOT WRITE IN THE SHADED AREAS.

Date:
DD MM YYYY

1. (a) DPDHS Division: _____
(b) MOH Area: _____ 1.

2. Name of patient: _____

3. Age of patient: 3.
YY MM

4. Sex of patient: 1. Male 2. Female

5. Name of parent/Guardian: _____

6. Residential address of patient: _____

7. Date of onset of paralysis: 7.
DD MM YYYY

8. Date of examination (by you) 8.
DD MM YYYY

9. Does the patient have residual paralysis:
 1. Yes 2. No 3. Lost 4. Dead

10. Immunization status of patient (OPV)

	DD	MM	YYYY
10.1. First dose given on:	<input type="text"/>	<input type="text"/>	<input type="text"/>
10.2. Second dose given on:	<input type="text"/>	<input type="text"/>	<input type="text"/>
10.3. Third dose given on:	<input type="text"/>	<input type="text"/>	<input type="text"/>
10.4. Fourth dose given on:	<input type="text"/>	<input type="text"/>	<input type="text"/>
10.5. Fifth dose given on:	<input type="text"/>	<input type="text"/>	<input type="text"/>
10.6. Others:	<input type="text"/>	<input type="text"/>	<input type="text"/>

11. If yes, to 9, severity of paralysis at 60/90/180 days after onset:

Site of involvement	Severity of paralysis	Wasting	Site of involvement	Severity of paralysis	Wasting
	Grade (Please fill in according to key)			Grade (Please fill in according to key)	
Left hand			Right hand		
Left forearm			Right forearm		
Left shoulder			Right shoulder		
Left leg			Right leg		
Left hip			Right hip		
Left side of face			Right side of face		
Other specify			Other specify		

Key for grading of severity of paralysis (Medical Research Council – MRC – scale):

Grade 0 = Complete paralysis
 Grade 1 = A flicker of contraction only
 Grade 2 = Power detectable only when gravity is excluded by appropriate postural adjustment.
 Grade 3 = The limb can be held against the force of gravity, but not against the examiner's resistance
 Grade 4 = There is some degree of weakness usually described as poor, fair or moderate in strength.

12. Diagnosis given on diagnosis card (if available) : _____



13. Cerebrospinal fluid analysis findings (if available) – please write the findings below:

Proteins: mg/dl Glucose: mg/dl Cells: _____

14. Electromyogram (EMG) report (if available): _____

15. Name of the MOH/ RE: _____

16. Signature of MOH/ RE: _____ 17. Designation: _____

18. Date: _____

For office use

19. Classification: _____

20. Final diagnosis: _____

21. Remarks / Expert Committee Findings.....

EPIDEMIOLOGICAL UNIT

Ministry of Health, Nutrition & Welfare

231, de Saram Place, Colombo 01000, Sri Lanka

Telephone: Epidemiologist (+94-11-) 2681548, Epid unit: (+94-11-) 2695112 Fax: (+94-11-) 2696583, E-mail: chepid@slnet.lk and epidunit@slnet.lk

EPID/37/4/R2004



My Ref.: EPID/37/X/02
.....200...

Regional Epidemiologist,
.....

POLIOMYELITIS ERADICATION INITIATIVE
ACUTE FLACCID PARALYSIS (AFP) SURVEILLANCE

Further to my telephone message on the AFP case notified to me, I would like to inform you that the following AFP case has been reported from your area on

Name :
Age :
Sex :
Address :
MOH Area :
Reporting Institution :
Ward :
B.H.T. No. :
Date of onset of paralysis :
Date of admission to hospital :

Please be good enough to see that the surveillance activities regarding this case, are carried out. Please take early action to send 2 specimens of stools at least 24 hours apart within 14 days of onset of paralysis to MRI, Colombo in a reverse cold chain box/ice with a request for polio virology.

Thank you.

Dr M R N Abeysinghe
Actg. Epidemiologist

c.c. - 1. D.P.D.H.S. -
2. MOH/DDHS
Pri/-

Checklist for NIDs – Provincial, Regional and Divisional Level

	Activity	Officer Responsible	Complete before	Date Complete	Remark
1	Establish Provincial/Regional co-ordinating committees	PDHS/DPDHS			
2	Establish Provincial/Regional social mobilization committees	PDHS/DPDHS			
3	Calculate target population and vaccine requirements	DPDHS/MOH/DDHS			
4	Allocate money for subsistence payments and incidental expenses	DDHS			
5	Prepare for receipt of vaccine, cold-chain equipments and stationery (arrange cold room, deep-freezer)	DDHS			
6	Calculate extra equipment needed	DPDHS/MOH/DDHS			
7	collect required information and logistic forms	DDHS			
8	Attend meeting of PDHS/DPDHS at central level	PDHS /DPDHS			
9	Consolidate information received from PHM	DPDHS(RE/MO/MCH)			
10	Verify availability of transport of vaccines & equipment to MOOH/DDHS	DPDHS			
11	Make supervisory visit and plane immunization centers (2-3 per PHM Area), Plane immunization centers in special areas e.g. refuge camps and estate	DPDHS			
12	Plans for supply of equipment centers (desk, chairs, vaccine, carriers, cold-pack, tally sheets, (TS1&TS2), referral forms, pens and if possible the banner for the center	MOH/DDHS			
13	Hold meeting with divisional health officials (discuss the plan of conducting NID in the region-action plan)	PDHS/DPDHS			
14	Review social mobilization /health plan by PHI, PHM, and volunteers	DPDHS/MOH/DDHS/HBO			
15	Receive vaccine at RMSD for first round of NID	DPDHS/OIC/RMSD			
16	Training / Review session for MOOH/DDHS at district level, review the plan for NID in each MOH area	DPDHS			
17	Attend review meeting with central staff	FFB/DPDHS/DDHS			
18	Distribute vaccine to MOOH (for first round of NID)				
19	Home visit by PHM and volunteer to inform mothers about NID and location of immunization centre in the area	PHM			
20	Conduct first round of NID	MOH			
21	Follow up Measles /TT immunization	MOH			
22	Receive vaccine at RMSD for the second of NID	OIC/RMSD			
23	Collect information on first round of NID	MOH			
24	Distribute vaccine to MOOH	OIC/RMSD			
25	Send information to central level	MOH			
26	Conduct intense social mobilization	HBO			
27	Conduct second round of NID	MOH			
28	Collect information on second round of NID	MOH			
29	Send information to Regional level and central level	MOH			

Checklist for NIDs - Medical Officer of Health (MOH) Level				
	Activity	Officer Responsibility	Complete Before	Date Complete
1	Establish co-ordinating committees	MCH/DDHB	10 weeks before NID/...../...
2	Establish social mobilization committees	MCH/DDHB	10 weeks before NID/...../...
3	Calculate target population and vaccine requirements	MCH/DDHB	10 weeks before NID/...../...
4	Prepare for receipt of vaccine, cold-chain equipments and stationary (arrange for deep freezer)	MCH/DDHB	10 weeks before NID/...../...
5	Calculate extra equipment needed	MCH/DDHB	10 weeks before NID/...../...
6	Meet PHM and collect required information	MCH/DDHB	10 weeks before NID/...../...
7	Consolidate information received from PHM	MCH/DDHB	10 weeks before NID/...../...
8	Meet with Regional/Division level staff and verify availability of transport of vaccine and equipment to immunization center	MCH/DDHB	10 weeks before NID/...../...
9	Make supervisory visit and plan immunization centers (2-3 per PHM Area), Plan immunization centers in special areas e.g. refuge camps and estate	MCH/DDHB	10 weeks before NID/...../...
10	Plan for supply of equipment centers (desk, chair, vaccine carriers, cold-pack, july sheets, TSI&TS2), referral forms, pens and if possible the banner for the center	MCH/DDHB	10 weeks before NID/...../...
11	Hold meeting with field health staff e.g. PHNS/PHI/SPHM/PHM and discuss the plan of conducting NID	MCH/DDHB	10 weeks before NID/...../...
12	Review social mobilization/health plan by PHB, PHM, and volunteers	MCH/DDHB/HEO/PHI	10 weeks before NID/...../...
13	Receive vaccine by at MCH office for first round of NID	MCH/DDHB/OC/RMSD	10 weeks before NID/...../...
14	Home visit by PHM and volunteers to inform mothers about NID and location of immunization centre in the area	PHM	10 weeks before NID/...../...
15	Training/Review session for coordinators and volunteers at MOH level, Review the plan for NID in each area	MCH/DDHB	10 weeks before NID/...../...
16	Distribute vaccine to storage centers for distribution to immunization centers for first round of NID	MCH/DDHB/OC/RMSD	10 weeks before NID/...../...
17	Conduct intense social mobilization	MCH/DDHB	10 weeks before NID/...../...
18	Ensure availability of OPV at immunization centre	MCH/DDHB	NID#1/...../...
19	Conduct first round of NID	MCH/DDHB	NID#1/...../...
20	Follow up Measles/TT immunization	MCH/DDHB	Day After NID/...../...
21	Collect information on first round of NID	MCH/DDHB	Day After NID/...../...
22	Receive vaccine at MOH for the second round of NID	MCH/DDHB	4week before 2 nd round of NID/...../...
23	Send information to Regional level and central level	MCH/DDHB	10 day after NID/...../...
24	Distribute vaccine to storage centers for distribution to immunization centre for second round of NID	MCH/DDHB	1week before 2 nd round of NID/...../...
25	Conduct second round of NID	MCH/DDHB	NID#1/...../...
26	Collect information on second round of NID	MCH/DDHB	Day After NID/...../...
27	Send information to Regional level and central level	MCH/DDHB	10 days after NID/...../...

Shamali/c:\mydoc\mid\fc1

පාලි : 05/05 / 2022/05 / 2022 / Day 1

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0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	100
0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
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0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	200
0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	300
0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1000
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ලැබුණු වත්තන් සෑදී ගණන

ප්‍රවීණි සංඛ්‍යා ලද සෑදී ගණන

ආපසු හැරුණු සෑදී ගණන

වෙතන් සටහනු :

වත්තන් මධ්‍යස්ථානයේ පවතින වත්තන් නිලධාරීන්ගේ නම අත්සන

(වත්තන් මධ්‍යස්ථානයේ පවතින වත්තන් නිලධාරී විසින් ජාතික ප්‍රතිපෝෂිතරණ දින අවසානයේ මෙම ආකෘති පත්‍රය පුරවා පො.වෙ.කී. වෙත හැර දිය යුතුයි)

EPID/SNID/2003/CR

**SNID CONSOLIDATED REPORT AND STOCK RETURN OF ORAL POLIO
VACCINE FOR SUB-NATIONAL IMMUNIZATION DAYS
..... round - 2003**

DDHS/MOH Area:.....

DPDHS Division:.....

	Number
(A) OPV doses received for SNIDs	
(B) OPV doses distributed to immunization centres	
(C) OPV doses returned from immunization centres	
(D) OPV doses used forround (B-C)	
(E) Estimated No. of children in the target age group (under 5 years)	
(F) Total number of children (under 5 years) immunized (Total in EPID/SNID/2002/TS1 and EPID/SNID/2002/TS2)	
(G) Estimated number of infants (under 1 year)	
(H) No. of infants immunized (Total in EPID/SNID/2002/TS1)	
(I) Coverage (Under 5 years) F/Ex100	
(J) Coverage (under 1 years) H/Gx100	
(K) OPV usage rate (F/Dx100)	
(L) Balance OPV in hand at the end of the SNID (A-D)	

.....
Name of DDHS/MOH.....
Signature.....
Date

To be completed by the DDHS/MOH and sent to the Epidemiologist/Epidemiological Unit, 231, DESaram Place, Colombo 10, with a copy to DPDHS/RE/MO(MCH), within 10 days of the completion of each round of SNID.

On receipt of returns from all the DDHS/MOH in the region, DPDHS/RE/MO(MCH) should send a consolidated return to Epidemiologist within 20 days of the completion of the SNID.