Ministry of Health

Government of the Democratic Socialist Republic of Sri Lanka

Polio Eradication-Endgame strategies
Polio Type 2 withdrawal

National tOPV-bOPV switch plan

Epidemiology Unit

October 2015

Table of contents

List of Acronyms

DSC	District Switch Committee
ILR	Ice Lined Refrigerator
MOH	Medical Officer of Health
MO/MCH	Medical Officer (Maternal and Child Health)
NCCPE&MRCE	National Certification Committee for Polio Eradication &Measles,Rubella,CRS Elimination
NIP	National Immunization Programme
NMRA	National Medicinal Drug Regulatory Authority
NOC	National Operating Centre
NSCC	National Switch Coordination Committee
NSVC	National Switch Validation Committee
MSD	Medical Supplies Division
RDHS	Regional Director of Health Services
OIC	Officer In-Charge
PV	Polio Virus
RE	Regional Epidemiologist
RMSD	Regional Medical Supplies Division
PDHS	Provincial Director of Health Services
WPV	Wild Polio Virus

National tOPV-bOPV switch plan

Executive summary:

Sri Lanka is comprised of 9 provinces and 25 districts with a population of 20,277,597 (estimated 2015 = 20,355,439) based on the population census data 2012. The public health service is provided by the Ministry of health through well-established public health infra-structure facilities. Central level coordinated public health services reach to field level through 26 Regional Directors of Health Service areas and 337 Medical Officer of Health (MOH) areas. Each Medical Officer of Health area is having a public health field staff that provides community level services. Immunization services are provided by these public health staff at community level at Maternal and Child Health clinics and also at health facility (hospital) level immunization clinics.

Main vaccine stores are located at the Epidemiology Unit walk-in cold rooms and 2 monthly stocks of vaccinerequirements are stored each at 26 regional level walk-in cold rooms at Regional Medical Supplies Divisions. They distribute to each Medical Officer of Heath office and for hospital immunization clinics on monthly basis where Ice Lined Refrigerators are available for vaccine storage. From MOH offices, vaccines are carried to fixed immunization clinics on daily basis on the scheduled clinic days.

A plan is developed for the switch from tOPV to bOPVin par with the Global and Regional strategies of Polio Virus type 2 withdrawal plans. The plan is developed considering the procedures and activities essentially required to be attended during the rest of the 2015 and during 2016 until validation procedure of withdrawal of Sabin type 2 in OPV vaccine used in NIP.

National Switch Coordination Committee (NSCC) will be established by identifying resources from the National Polio Eradication programme for the planning, preparation and implementation of the switch and theNational Certification Committee for Polio Eradication (NCCPE) will be functioned as the National Switch Validation Committee (NSVC) for the validation procedure.

The country has already done the first detailed tOPV inventory in August 2015 and plans are underway for the 2nd detailed inventory to be conducted on 31st December 2015. Based on the country tOPV stock situation, the last tOPV stock adjustments have been done and already received the last consignment in October 2015. Until the switch day the country plans to use the tOPV stocks by re-distribution plans among districts / divisions (MOH level) if required.

The bOPV registration has already been done by National Medicine Regulatory Authority (NMRA). The stock forecasting and ordering of bOPV requirements has been submitted to the Medical Supply Division (MSD) in March 2015 and the purchasing procedures are underway.

Relevant guidelines will be developed for the switch procedure, monitoring of the switch plan, advocacy, awareness, communications, and remaining tOPV withdrawal after the switch.

Training materials will be developed and training will be carried out for relevant health care staff on the procedures of the switch. Other relevant health categories such as Paediatricians, Microbiologists, academic staff , staff of private sector health institutions, General Practitioners, Professional Colleges will be made aware on the switch procedures to get the fullest support in the Polio Virus type 2 withdrawal procedures.

The switch day will be on 30th April 2015 which is selected from the last optional period proposed by WHO, starting from April 24th 2016 -8th May 2016 and the "push mechanism" of exchange (of tOPV to bOPV) at the time of delivery will be carried out. The delivery ofbOPV and collection of remaining tOPV will be done within a week period, and the collection of tOPV will be done by visiting the centers twice during the period, per center.

The collected tOPV will be destroyed by incineration accordance to the procedures of the government vaccine waste destruction policy. The NCCPE who will function for the switch validation procedure,after total withdrawal of tOPV,will identify relevant switch monitors at National and Regional levels. The switch monitors will be adequately trained for the validation procedure for effective and reliable functioning.

Switch validation will be carried out after 2 weeks of the switch date and the report will be submitted to the Ministry of Health for relevant regional communication procedures.

National tOPV-bOPV switch plan

1. Introduction

Sri Lanka, officially the Democratic Socialist Republic of Sri Lanka, is an island in the Indian Ocean with a total land area of 65,610 km^2 and a population of 20,277,597 as at the last census survey (2012) (estimated 2015 = 20,355,439). The climate in Sri Lanka is tropical and warm, with mean temperatures range from 17 °C (62.6 °F) in the central highlands, to a maximum of 33 °C (91.4 °F) in other low-altitude areas. Temperature variation throughout the year is not seen and average yearly temperature range from 28 °C (82.4 °F) to nearly 31 °C (87.8 °F).

Sri Lanka is administratively divided into 9 provinces and 25 districts. In health service provision 339 divisions are functioning under Provincial Directors of Health Services (PDHS) and Regional Directors of Health Services (RDHS). Each health administrative division is named asa Medical Officer of Health area. The Medical Officer of Health (MOH) appointed to MOH area together with other categories of public health staff is responsible for the provision of grass root level public health services to the people.

1.1 Poliomyelitis situation in the country:

In line with achieving the goal of world free of Poliomyelitis the South East Asia Region hasbeen declared and certified Polio free in March 2014.

The last case of polio in Sri Lanka was reported in 1993 and the country is free of polio since then. The Epidemiology Unit of the Ministry of Health, is the central coordinating agency for the National AFP Surveillance programme under the Poliomyelitis Eradication Initiative, receiving information about AFP cases from clinicians in curative institutions. The virology laboratory in the Medical Research Institute (MRI) is the Reference Laboratory doing investigations in laboratory in exclusion of polio in all AFP cases.

Immunization against Poliomyelitis is a success story in Sri Lanka. Following first major epidemic, in 1962 Oral polio vaccine (OPV) was introduced into the country. The OPV vaccine was introduced into the National EPI in 1978 and high OPV coverage is maintained above 90% in all districts in the country for last 10 years or more. The national EPI includes 5 doses of OPV at 2,4,6, 18 months and 5 years of age till 2015. Supplementary immunization with OPV, in National Immunization Days, Sub National Immunization Days and Mopping up campaigns were conducted since 1995-2003 in achieving high population level polio immunity and maintenance of polio free status in the country.

1.2 Rationale for the Switch from tOPV to bOPV

In the attempt towards Polio Endgame in Sri Lanka, the introduction of an additional dose of injectable IPV, has been introduced further to the already given five OPV doses in the National EPI schedule. Additional IPV dose has been introduced into the National EPI schedule since 1st July 2015 with the 2nd dose of OPV at 4 months of age. Though the continuation of OPV is being done together with an additional dose of IPV, Sri Lanka has plans for shifting over to the bivalent OPV (bOPV) with Polio type 2 withdrawal plans, together with the world, in 2016.

The use of tOPV has led to the eradication of wild poliovirus type 2 (WPV2), with the last case occurred in 1999. But, circulatory Vaccine Derived Polio Virus (cVDPV) and Vaccine Associated Paralytic Polio (VAPP) caused by OPV, though rare effects, have identified a

significant impact on the use of Sabin type 2 in tOPV. It has been observed that over 90% of cVDPV cases, and approximately 40% of VAPP cases, are due to the type 2 component of tOPV. The type 2 component of tOPV also interferes with the immune response to poliovirus types 1 and 3.

The introduction of IPV will help to reduce risks associated with the withdrawal of OPV type 2, facilitate interruption of transmission with the use of monovalent OPV type 2 in the case of outbreaks and hasten eradication by boosting immunity to poliovirus types 1 and 3.

In order to ensure polio eradication , in addition to the wild polio virus (WPV), all live poliovirusesincluding vaccine viruses, have to be removed from the population as recommended. The Polio Eradication and Endgame Strategic Plan 2013-2018 highlighted the essential requirement of all countries to commit for the removal of type 2 polio virus (PV) , with the initial step of switch from trivalent OPV (tOPV) which contained Sabin vaccine viruses of type 1,2 and 3 to bivalent OPV (bOPV) which only contained Sabin vaccine viruses of type 1 and 3.

The switch refers to the replacement of all tOPV with bOPV, in routine immunization and supplemental immunization activities (SIAs) if any, in all OPV using countries in the world within a selected two week timeframe in April 2016. Once the switch is implemented, all existing tOPV stocks will be removed globally, and manufacturers will no longer produce or supply any stocks of tOPV. The switch from tOPV to bOPV has to be a globally coordinated synchronized process because any use of tOPV anywhere in the world after April 2016 could jeopardize polio eradication by generating circulating vaccine-derived polioviruses (cVDPV) from the type 2 component of the vaccine.

1.3 Polio population level immunity assessment before the switch**

Sri Lanka has achieved high population level polio immunity and is maintaining a polio free status in the country.

Polio Vaccination in the National Immunization Programme consistently reaches >90% , and no polio supplementary vaccination campaigns have been conducted since 2003.

Serological protection against polioviruses have been evaluated in 2014 among 400 children in four age groups (9-11 months, 3-4 years, 7-9 years and 15 years). Cross sectional community

based survey was performed in three districts of Sri Lanka (Colombo, Badulla and Killinochchi) among population categories living in urban slums, estate sector and resettlement areas after 2010 in the post-conflict situation. These serum samples collected were tested for poliovirus neutralizing antibodies at Polio Virology Laboratory, in CDC-Atlanta. The proportion of seropositive children for poliovirus types 1 and 2 was above 95% for all age groups; for poliovirus type 3 it was 95%, 90%, 77% and 75% in the respective age groups. The vaccination coverage in our sample based on vaccination cards or parental recall was >90% in all age groups. Most Sri Lankan children are serologically protected against polioviruses through routine immunization only. The declining seroprevalence with age for serotype 3 is an expected finding and is likely not correlated with serological protection. This seroprevalence survey provided baseline data prior to the anticipated addition of inactivated poliovirus vaccine (IPV) into the immunization programme and the switch from trivalent to bivalent OPV in Polio type 2 withdrawal plan.

** *Gamage D, Palihawadana P, Mach O, Weldon WC, Oberste SM, Sutter RW. Achieving high seroprevalence against polioviruses in Sri Lanka-Results from a serological survey, 2014.J Epidemiol Glob Health 2015. Available online at: http://www.ncbi.nlm.nih.gov/pubmed/26166424 [accessed: November 6, 2015]*

Sri Lanka expects to join with other countries through globally synchronized switch from tOPV to bOPV in the routine EPI from April 2016.

1.4 Primary objectives of the Switch plan

The National tOPV-bOPV switch plan provides the basic framework for the implementation of switch in the country. This provides the time plan for following objectives.

- To minimize the wastage of tOPV, and procurement adjustment of tOPV requirement accordingly
- To effectively recall and destroy remaining tOPV after bOPV introduction in April 2016
- To Validate that the country has successfully destroyed tOPV remaining stocks and is free of Sabin polio virus type 2 use in Immunization programmes

- To ensure procedures are followed for the validation of switch
- To facilitate monitoring and evaluation of switch and post switch continuation of bOPV
- To attend immediately for corrective measures if any unaccepted deviations from the switch plan

2. Switch Calendar

Plan	**By October 2015**
	Establish management structure Establish National coordination committee (NCC) and National Switch Validation Committee (NSVC), Conduct situation analysis & draft the national switch plan
Prepare	**July to December 2015**
	Complete detailed tOPV inventory and adjust tOPVorder & delivery Develop monitoring plan Receive last tOPV delivery to country Registration procedure and Order bOPV Develop waste management protocol Identify switch monitors
	January to March 2016
	Complete second tOPV inventory (by 31st December 2015) Re-distribute remaining tOPV stocks within the country if required Prepare training materials and implement communication strategies for switch Expect receipt of bOPV to the country and make distribution plans
Implement	**January to March 2016**
	Train health care staff and switch monitors begin distribution to districts of bOPV and divisions (MOH offices) and institutions
National Switch Day	**A day chosen during the last two weeks of April 2016**
	Stop use of tOPV and recall/remove tOPV from cold chain facility Begin use of bOPV

Validate	**Two weeks after the switch day in May 2016**
	Complete disposal of tOPV
	Validate tOPV disposal at selected sites (switch monitors)
	Collect and review data and validate switch (NSVC)

3. Management, coordination and validation mechanisms

National and District level Switch management and coordination committees are identified to plan, develop, implement and manage all activities related to the switch. These committees are identified using the existing programme delivery system of the routine EPI. The main coordinating centre is the Epidemiology Unit, Ministry of Health at national level and RDHS office at district level wheretechnical experts are identified for relevant procedures. Identified experts will frequently meet to monitor and evaluate the progress of the switch activities. The names and contact information of focal points responsible at each level will be published in the website of the Epidemiology Unit in due course.

3.1. Management and coordination Committee structure

3.1.1. National level

a) National Switch Coordination Committee (NSCC)

The NSCC will include officers from the National EPI programme and Polio Eradication programme, at the Epidemiology Unit, Family Health Bureau, Health Education Bureau, Director/Private Health Sector Development, National Medicine Drug Regulatory Authority (NMRA), Medical Supplies Division (MSD) and the State Pharmaceutical Cooperation (SPC). The Deputy Director General of the Public Health Services I (DDG/PHS I) will be the chairperson of the NSCC while Chief Epidemiologist is the Secretary to NSCC.

This NSCC will bear the whole responsibility of the managementand coordination of tOPV to bOPV switch as with the responsibility given at the Advisory Committee on Communicable Diseases (ACCD) which is the functional body for NITAG in the country.

The Committee is responsible for ensuring the registration procedures of bOPV, procurement of bOPV to the country on time, timely distribution to all districts, identify the switch day in April, effective communication with all sectors through all channels, timely collection of remaining tOPV and planned destruction of remaining tOPV.

The NSCC will frequently meet and discuss implementation of switch plan on :

1. Implementation procedure of the National switch planby attending activity plan for each procedure

2. Coordination of national and district level activities on staff awareness and training* for the synchronizedwork for the switch

3. Dissemination of information and communication including the responsible media communication

4. Implementation of the switch from tOPV to bOPV: registration, order and procurement of bOPV**

5. tOPV collection with the switch date and plan of action for destruction***

6. Regular supervisions and monitoring of the switch by identifying the Central level Epidemiology Unit as the main centre of operations forcoordination (National Operation Centre-NOC),

7. Regular monitoring of the progress using key indicators

8. Ensure availability of adequate funding for theSwitch (needs to be identified) and explore possibilities with international partners for funding support

9. Final documentation of findings and assurance of the country free of storage and usage of tOPV

** main staff categories selected for training will be health staff at National provincial and district level involved in immunization activities, Health care Institutions (government and private Hospitals) General Practitioners, officers In-charge of Regional Medical Supplies Division, Medical Officers of Health (MOOH- at the field level) and other field health staff. Sessions will be conducted for Professional Colleges (College of Paediatricians, College of Community Physicians, College of General Practitioners, College of Microbiologits)*

*** bOPV registration procedure , bOPV vaccine forecasting & ordering will be placed to get down for the introduction in April 2016,bOPV distribution, Stock inventory - based on remaining stocks of tOPV, remaining tOPV (Push mechanism) collection and distruction*

****Destruction plan, temporary store of tOPV recalled, supervision and monitoring of destruction of incineration procedure, assurance of the completion of disposal*

b) National Operations Center (NOC): The national operations centre for the NSCC is the Epidemiology Unit, Ministry of Health who will work for the preparedness of the country including district level coordination, implementation of the switch plan and monitor the progress regularly.

The NSCC Chairperson is responsible to monitor the progress of the switch plan implemented and coordinated through the NOC. Key indicators and timeline developed will be monitored on a regular basis to see the progress of the implementation plan.

3.1.2. District level

a) The **District Switch Committee (DSC)** will include the Provincial Director of Health Services, Provincial Consultant Community Physician, RDHS, Regional Epidemiologist (RE), Medical Officer/ Maternal and Child Health (MO/MCH), Medical Officer/Planning, District Supervisory Public Health Inspector (SPHI/D), Regional Supervisory Public Health Nursing Officer (RSPHNO) and OIC/RMSD. A Chairperson and a Secretary will be appointed for each DSC and are responsible to coordinate with NSCC/NOC for implementation of switch over from tOPV to bOPV procedures at district level until assuring all district are free of the use of tOPV and continue polio vaccination with bOPV.

Authority in the NOC at Epidemiology Unit, Ministry of Health will issue relevant instructions, will provide necessary training and will provide required training materials to train district level staff and the staff of the service delivery points (MOH and clinic /field level).

The DSC is also expected to follow , supervise and monitor guidelines issued by the NSCC on switch from tOPV to bOPV. The responsibility of coordination and monitoring of private sector health care institutions in order to ensure switch from tOPV to bOPV also will be held by the DSC.

The DSC will meet on monthly basis prior to the switch and more frequently during the switch implementation and validation during April-May 2016. District switch committee will frequently coordinate with NSCC/NOC and report the progress of the switch to the NSCC/NOC on a regular basis.

b) District Operations Centre: A district operations centre will be selected to monitor preparedness, implementation, supervision and monitoring of the district level, MOH level and other health care institutions(government & private) on theeffective switch over from tOPV to bOPV.

Main roles and responsibilities of the district switch committee will be as follows:

1. Implementation procedure of the National switch plan by attending activity plan for each procedure for the district

2. Close coordination with NSCC/NOC

3. Coordination of district level activities on staff awareness and training for the synchronized work for the switch as instructed by NSCC

4. Timely distribution of bOPV to each service delivery centres (MOH offices and hospital immunization clinics) for the continuation of polio vaccination from the switch day onwards

5.Dissemination of information and communication with all healthcare staff including the private sector

6. tOPV recall with the switch date from all centres involved in vaccine storage and temporarily store at RMSD until the stocks will be collected by the Central level (Epidemiology Unit)

6. Regular supervisions and monitoring of the switch

7. Regular monitoring of the progress using key indicators with timeline identified

8. Final documentation of findings and assurance of eachdistrict is free of storage and usage of tOPV

9. Provision of support for the Switch monitors who are identified from each district for the procedure of validation of the switch to assure that each district is free of the usage and storage of tOPV

4. Work plan with expected Chronogram of tOPV-bOPV switch in OPV type 2 withdrawal plan is given as Annexure 1 asTable 1

5. Validation Mechanism

National Switch Validation Committee (NSVC): roles , responsibilities and reporting mechanism

a) NSVC

Independent validation committee will be the members of the same National Certification Committee for Polio Eradication and Measles, Rubella, CRS elimination (NCCPE& MRCE)who will get involved in the validation procedure of the tOPV recall and disposalat all levels. At the same time verification of bOPV introductionsimultaneously at all levels to ensure continuation of polio vaccination thoughout the country will be assured by the committee.

b)Roles and responsibilities

- TOR of the NCCPE&MRCE will be updated to be included thevalidation procedure of switch over from tOPV to bOPV
- During the two weeks after the National Switch Day, the NSVC will start with the responsibility and commitment of the validation procedure.
- District level validation committees will be identified independent to people directly involved in EPI implementation. (e.g.Microbiologists, Community Physicians, Paediatricians who are not directly involved in activities of vaccination programme/procedure) who work as independent switch monitors. They will involve in supervision, monitoring and evaluation of the verificationand validation procedure of switch over from tOPV to bOPV
- Data collection formats will be developed, data collection and forwarding mechanism will be identified together with data collection, analysis and presentation by switch monitors to NSVC from all levels
- Responsible switch monitor will be identified from each district for forwarding the final validation report relevant to each district

- The NSVC will attend if any corrective procedures are needed such as if any unattended remaining stocks of tOPV is identified in any of the centre during the validation in districts in assuring districts are free of tOPV storage and usage
- Central store and all district stores (main stores: Epidemiology Unit & RMSD) and 10% of facility level (MOH offices & vaccine storing hospitals) will be included for the validation procedure and recommended guidelines will be followed in the process of validation
- If any remaining tOPV is identified in any district during the validation period, an additional 10% will be reviewed in each relevant district
- The responsibility of developing the mechanism for the evaluation and validation of the private sector and procurement agencies/commercial agencies/venders will be held by the NSVC
- If any remaining tOPV stocks identified during the validation period, immediately be informed to the NSCC/ National programme of polio eradication ,Epidemiology Unitto take relevant measures to recall of remaining stocks and destroy appropriately following the same identified procedure
- Finally, the validation committee will ensure and document that the country is free of using tOPV in the process of Polio virus type 2 withdrawal

c) Reporting and documentation procedure

- The documentation procedure would first consider close evaluation of validation reports received from all districts
- The National validation committee themselves be assured by personal assessment including the central level stores, private sector facility/stores and stores of specific commercial agencies/ vendors involved in procurement procedures, if any
- Finally, assure the removal of tOPV from the country and the final report will besubmitted to the Ministry of Health, Sri Lanka and to the regional validation commission/SEAR

6. Budget

Funding for the validation procedure needs to be identified. Following areas will be considered for specific activities for the procedure

- NSCC meetings to be conducted at National level
- Trainings for National stakeholders and for district and field level healthcare staff
- Development of IEC materials for training and development of necessary switch validation guidelines and formats
- Transport for Push/pull exchange of tOPV to bOPV
- Supervision, Monitoring and evaluation of validation procedure

Financial support will seek out from partner organizations such as WHO and UNICEF in addition to the financial support received from the Ministry of Health for vaccine procurement and few other activities.

Resource personnel

Resource personel will be identified from experts within the country from the Ministry of Health, Academic staff, and experts of different specialties of health serving the country. All members in NSCC, DSCC, NCCPE & MRCE, Switch monitors at district level and all supporting staff will be the resources for the Switch over from tOPV to bOPV procedure.

7. Supply

a. Supply Assessment

The NIP in Sri Lanka is an integral component of the public health system. Immunization services are provided through well-established infra-structure with secured funding, supplies and human resources for routine immunization activities through the Ministry of Health as well as specific supports from Provincial governments. Twenty six (26) health administrative regions are functioning in 9 provinces and NIP services are provided through 337 MOH areas with supportive public health staff working at the field level. Immunization services are provided mainly through nearly 5,000 Maternal and Child Health clinics at community level and also through nearly 150 Immunization clinics functioning in Specialized Children's, Provincial General, and Base/district hospitals.

The main objective of the country's NIP is to reduce mortality and morbidity associated with 11vaccine preventable diseases and serves nearly 4 million children below 15 years of age annually. The Epidemiology Unit, Ministry of Health ensures uninterrupted supply of vaccine procurement and distribution to 26 walk-in cold room facilities in each district in every 2 monthly basis and from district cold room stores distribute on monthly basis to each MOH level vaccine stores to provide services at MCH clinics on scheduled days.

In addition to the government NIP, the private sector is also involved in the provision of immunization services of 5-10% in the Colombo district and around 1-5% in a few other urban areas but they receive tOPV only through government procured vaccines for NIP.

b. Supply and distribution of OPV from Central level to the Periphery

i) tOPV

a) tOPV Stock Management and Inventories

Vaccine stock inventory is maintained at the Epidemiology Unit, Ministry of health and stock inventory check is being done at the end of each month for necessary corrective measures of stock adjustment, distribution and etc. for all vaccines.

As of the Switch plan, detailed tOPV stock inventories including all OPV remaining stocks at all facility levels have been taken already for 31st August 2015. Country has planned for the 2nd detailed all facility level stock inventories to be taken on 31st December 2015. A third inventory will be taken on 31st March 2016.

The existing stocks of tOPV will be distributed within districts and closely monitored for the maximum use thereof, to minimize the wastage and prevent stock outs until the new vaccine bOPV will be available in the country while awaiting to reach the planned switch day. In facilitating this procedure, a2nd& 3rddetailed stock inventories will be taken on 31st December 2015 and 31st March 2016, to assess the stock situation, close monitoring and to take necessary measures to ensure facilitation process for service continuation throughout the country without experiencing any stock-outs.

b) Remaining stocks of tOPV

Minimum Stocks of tOPV will be remaining by the switch date at Central level cold rooms, District level cold rooms, MOH level refrigerators and in hospital refrigerators. Private sector receives OPV only from the government and the facility level (National/district RMSD /MOH) providing tOPVwill be held responsible to collect back the remaining tOPV on exchange basis for bOPV to be returned to respective RMSD.

The remaining tOPV stocks will be collected to respective RMSD on bOPV exchange basis. Stocks collected at all RMSD will be collected at the Central level to be sent for incineration as with the planned destruction procedure in accordance with the government vaccine waste destruction guidelines.

c) tOPV Forecasting, Ordering, and Shipment Planning Process

Sri Lanka has already adjusted and received the final shipment of adjusted tOPV stocks which would be adequate until the switch date and until availability of bOPV to be used after the switch date.

ii. bOPV

bOPV Procurement and Distribution Plan

a. Licensing and regulatory approvals of bOPV

The bOPV has already been registeredin October 2015 by NMRA. In fact, licensing procedure has been completed and a regulatory approval has been received.

b. Procurement and Distribution of bOPV

Forecasting ofbOPVhas been done in March 2015 and request purchase of order for 900,000 doses has been submitted to the Medical Supplies Division (MSD) of the Ministry of Health and is being processed. First consignment of 500,000 doses, is expected to be received in the country by February, 2016 and 2nd consignment of 400,000 doses, is expected to be received by May, 2016.

Distribution of bOPV to each district will be done by the Epidemiology Unit once vaccines are available in the country. Vaccine supply from district cold rooms to MOH offices will be done by the OIC/RMSD with the support and guidance by the Regional Epidemiologist according to

the vaccine requirement in each district and to the specially prepared distribution plan for bOPV supply for each facility.

8. Private Sector

Private hospitals and General Practitioners receive tOPV only through the government system (Private sector does not procure OPV separately), if any institution is vaccinating children with OPV in the private sector. But the NSCC will re assess the situation to confirm the absence of the availability of tOPVprocurement agents for the private health institutions.

The Directorate of Private Health Sector Development in the Ministry of Health is the main link for communication with all private health institutions. The NSCC and the Epidemiology Unit will formally communicate with private health institutions through the Director/ Private Health Sector Development to make them aware in this regard and will work to get fullest support from the private health institutions for the switch.

Majority of Paediatricians involved in the private sector vaccinations are the paediatricianswho are employed in the government sector on full time basis. Almost all Paediatricians are members of their professional College (College of Paediatricians) . The NSCC will get the opportunity to make communications with the College of Paediatricians and assure the messages reach the private sector correctly to get the support.

In addition, NSCC will work to get the support of specific organizations and Forums (e.g. Vaccine Forum) who are involved in private sector health care and vaccinations for this endeavor.

All private institutions will be informed to return all remaining tOPV stocks (giving a deadline synchronized with government tOPV collection) and bOPV will be issued on request on exchange to tOPV. All MOOH are having a list of private institutions/GPs, who have received vaccines from NIP and this can use for monitoring the switch plan activities (recalled of tOPV) from private institutions.

In the switch validation procedure, the same procedures of validation will apply for the private health sector also in assuring the country free of tOPV use in PV type 2 withdrawals.

9. Implementation Preparation

a. Logistics

i. Cold Chain Capacity

Cold room capacity at Central level Epidemiology Unit,and standard walk- in cold rooms available in 26 districts are adequate to store both bOPV and remaining stocks of tOPV once stocks of bOPVare received in the country. Ice lined refrigerators (90L capacity) are available to store vaccine stocks for the current month and additional month (buffer stock) in all MOH offices and in most hospitals. These ILR for vaccine storage are adequate to store additional stocks of bOPV for a 2 month period together with minimum remaining stocks of tOPV until the switch day. Recently conducted Effective Vaccine Management (EVM) assessment is evidenced that the country has sufficient vaccine storage capacities at all levels upto 2020.

However, measures will be taken to assure segregated storage with proper labeling of tOPV and bOPVin existing cold chain capacity and adequate monitoring of cold chain through the existing system. Advices and guidelines will be given to remove tOPV from the cold chain capacity after the switch day and remove from stocks maintained in the cold chain capacity in the Vaccine Movement Register. Once tOPV is recalled by the RMSD, the stocks will be removed from the vaccine stock ledgers for adequate documentation procedure and for assurance of the accountability of proper handing over of the remaining stocks. Same procedure will be applied for RMSD in handing over remaining stocks to the Epidemiology Unit.

ii. Transport System- Reverse Logistics System to CollecttOPV

All MOH offices, hospitals and RMSDs will keep tOPV out of the cold chain until collected, back to the central level from responsible officers at each level. Guidelines will be issued for the procedure of reverse logistic system for uniform maintenance of remaining stocks throughout the country.

The staff of the RMSD is held with the responsibility to collect remaining stocks of tOPV from all MOH offices and hospitals including private sector institutions. If any other sub centres such as small private sector institutions or private practitioners are issued by any MOOH, the

responsibility will be held with the issuing authority to collect it back on the policy of exchange of vaccination information and remaining stocks to the requested quantity by bOPV.

The "push mechanism" will be used in collecting the remaining tOPV as for the policy of handing over bOPV in exchange of tOPV.

b. tOPV Disposal

1. Disposal site selection

Disposal site will be the already identified existing incinerator facility for the Ministry of Health for the destruction of vaccine waste. Same system will be used for tOPV destruction which is collected from all districts.

2. Disposal policy and monitoring

Disposal plan will be outlined and guidelines will be issued. All tOPV collected will be temporarily stored at the identified place at the Epidemiology Unit vaccine stores out of the cold chain. Focal point responsible for tOPV disposal will be the Chief Epidemiologist. The remaining tOPV will be destroyed by incineration at central level in accordance with the vaccine waste disposal procedures.

All remaining stocks of tOPV will be collected within 3-5days after the switch and destruction will take placewithin a 2-week period.

The NSCC will take relevant measures to destroy tOPV stocks within 2 weeks of the switch day. The Committee will closely monitor the accuracy of collected stocks by comparing detailed stock levels assessed on 31st December 2015 with the tOPV consumption/usage data for the period from 1st January 2016 to the switch date.

c. Update of Information Systems

The NSCC and Epidemiology Unit will ensure issuing relevant guidelines and timely communication with all relevant stakeholders. The planning on recording and reporting system will be developed and communicated at all levels.

d. Communications

All relevant information and scientific facts will be identified and will be communicated with respective authorities,stakeholders at different levels, media and general public. Relevant communications have been already started and will be continued in due course.

- National level policy makers, Professional bodies, Academic Collegesand Health professionals, provincial and district level health care staff will be communicated on tOPV-bOPV switch.
- A new Immunization Schedule with changes will be displayed
- National Guidelines will be prepared and disseminated to all relevant authorities : Professional bodies, hospitals, Academic Colleges, private institutions
- National training materials and information will be shared with the private health institutions through the Director/Private Health Sector Development
- All relevant information including guidelines will be displayed in the website, and be published in Weekly Epidemiological Report
- General public and media awareness on switch plan as a part of End Polio Game will be done as appropriately

e. Training Materials and Preparation

Training materials will be prepared as fact sheets, guidelines, circulars/ circular letters, leaflets, posters, information sheets and power point presentations.

The National programme of Polio Eradication together with the Health Education Bureau and with other relevant professional bodies will involve in preparation of the training materials. All training materials prepared will be displayed in the website for easy references for relevant stakeholders in addition to the official communications.

These communications will include the private sector stakeholders through the same existing system.

f. Switch monitoring

This will include the a) Process monitoring (switch planning, preparation, implementation, switch day activities) and b) independent validation monitoring.

Broad activity milestones are given in the Annexure 1- Table 1.

i. Process monitoring: assessing switch activities milestones

Monitoring of the procedures and activities through the switch day till destruction of remaining stocks of tOPV will be done by the NSCC together with the Epidemiology Unit.

The main responsibility of the monitoring of switch validation will be held by the NSVC. Two weeks after the switch NSVC will start the monitoring activities for the switchvalidation procedure and activities relevant to the validation procedure will be monitored till completion of the documentation.

Few process monitoring indicators will be developed and be monitored to see the adherence of procedures /activities with the time line and this will be followed up by the Epidemiology Unit.

Final information will be communicated with the Director General of Health Services / Ministry of Health.

ii. Independentvalidation monitoring

The NSVC (same NCCPE & MRCE) will certify the validation of tOPV removal and disposal following the switch. Validation will involve evaluating data collected by independent switch monitors identified at each district.

These switch monitors will collect relevant information according to the guidelines issued for the purpose and formats prepared and given.

The purpose of information collection in switch monitoring would be to ensure the validation procedure of removal of tOPV from usage in the country, total destruction of remaining tOPV after complete recall and assess the maintenance of continuity and proper transfer of tOPV to bOPV for the usage at community level without experiencing any stock outs for bOPV.

The monitoring procedure will ensure that the validation would include all districts (main stores at RMSD) and 10% of facility level (MOH and hospitals) institutions and recommended guidelines are followed in the process of validation.

The monitoring will endure that an additional 10% of facility level institutions (MOH offices and hospitals) are included for the reviewif any remaining stocks of tOPVare identified in any district during the validation period.

The monitoring will ensure that if any remaining stocks are identified during the validation period, immediately be informed to the NSCC/Epidemiology Unit/National programme of polio eradication and relevant measures to be taken to re-collect of remaining tOPVstocks and destroy appropriately following the same identified procedures.

g. Risk Identification and Mitigation

The risks associated with the switch and validation process will be addressed by the National Polio Eradication Programme as required.

- Minimizing wastage of tOPV: Involved in adjusting the tOPV stocks, assured the minimum wastage of tOPV, possible usage of buffer stocks and the continuation of the polio vaccination for children
- Availability of bOPV: Timely registration procedure of the bOPV in the country has been done and measures have been taken for forecasting and ordering of bOPV to receive bOPVon time (expected in February) , not to experience any discontinuation of Polio vaccination and feasibility to adhere to the switch day (30^{th} April 2016)
- Recall and destruction of tOPV: ensuring 100% recall of all tOPV from both government and private sector, within 2 weeks of the Switch day and NSCC/NOC take necessary measures to destroy recalled tOPV by incineration
- The NSCC/ Epidemiology Unit take relevant measures to issue guidelines on time and follow them up till it reaches all levels and implement effectively and adhere to relevant guidelines for proper and smooth switch from tOPV to bOPV
- Adequate training and awareness of switch for all relevant health authorities including private health institutions

- Proper training of switch monitors and adequate timely data collection for the validation
- Close follow up of switch plan monitoring indicators to see the adherence to the procedures and timeline planned
- Plan for population level type 2 sero survey in 2-3 years after the switch and compare with baseline data already available for the country in 2013 before the switch

10. After the switch from tOPV to bOPV: Measures for Sabin type 2 withdrawal: laboratory containment

- Laboratory containment of the Sabin type 2 withdrawal from all potentially hazardous materials will be done
- Focal point (Chairperson) already identified and will work as an independent working group for this procedure
- A Sabin type 2 Laboratory contained plan will be developed

Annexure 1

Table 1: Chronogram of tOPV-bOPV switch in OPV type 2 withdrawal plan

	ACTIVITY	2015						2016									
		J	A	S	O	N	D	J	F	M	1 Apr	8 Apr	15 Apr	25 Apr	M	J	J
PLAN	Establish management structure	×															
	Establish National Switch Validation Committee		×														
	Conduct situation analysis		×	×	×												
	Draft national switch plan		×	×	×												

	ACTIVITY	2015						2016									
		J	A	S	O	N	D	J	F	M	1 Apr	8 Apr	15 Apr	25 Apr	M	J	J
PREPARE	Complete detailed tOPV inventory, adjust tOPV orders and/or delivery		×														
	Develop monitoring plan		×	×													
	Complete second tOPV inventory						×										
	Order bOPV				×	×											

	Develop waste management protocol				×	×	×										
	Receive last tOPV delivery to country				×												
	Redistribute remaining tOPV stock within country as required				×	×	×	×	×	×							
	Prepare training materials and implement communications strategy			×	×	×	×	×	×								
	bOPV delivery to country							×									
	Identify switch monitors								×	×							

	ACTIVITY	2015						2016									
		J	A	S	O	N	D	J	F	M	1 Apr	8 Apr	15 Apr	25 Apr	M	J	J
IMPLEMENT	Train switch monitors								×	×							
	Train health workers				×	×	×	×									
	Distribute bOPV to periphery and service points									×	×						
SWITCH DAY	Stop use of tOPV and remove tOPV from cold chain													×	×		
	Begin use of bOPV													×	×		
VALIDATE	Complete disposal of tOPV														×	×	
	Validate tOPV disposal at selected sites (switch monitors)														×	×	
	Collect and review data and validate switch (NSVC)														×	×	×