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சுகாதாரம் மற்றும் சுதேசவைத்தியஅமைச்சு
Ministry of Health & Indigenous Medicine

Provincial /Regional Directors of Health Services,
Heads/ Directors of Health Institutions,
Directors of National Hospital/Teaching Hospitals/
Provincial & District General Hospitals, Base Hospitals,
Medical Superintendentss of other Hospitals,
Heads of Decentralized units.
Provincial Consultant Community Physicians,
Regional Epidemiologists/ Medical Officers (Maternal and Child Health),
Medical Officers of Health,

Revised guidelines on Introduction of injectable Inactivated Polio Vaccine (IPV) to the National Immunization Programme

Injectable Inactivated Polio Vaccine (IPV) will be introduced into the National Expanded Programme on Immunization (EPI) from1st July 2015, in liaised with the recommended Global Poliomyelitis eradication endgame strategies.Despite the declaration of the certification of South-East Asia as polio-free in March 2014, the risk persists until the disease is eradicated globally.

Universally identified the requirement of shifting over from trivalent Oral Polio Vaccine (tOPV) to bivalent Oral Polio Vaccine (bOPV) (with Polio Virus type 2 withdrawal plans) during 2016. Wild Polio Virus type 2 (WPV type 2) has been eliminated globally since 1999 but some countries still experiencing symptomatic cases due to Vaccine Derived Polio Virus type 2 and Vaccine Associated Paralytic Polio type 2 ($VDPV_2$ & VAPP type 2). In fact ensuring the maintenance of immunity to polio virus type 2 (PV), after withdrawal of PV type 2 from tOPV, introduction of at least one dose of IPV in to the National EPI schedule as an additional dose before shifting over from tOPV to bOPV, is a requirement.

Introduction of IPV will supplement the immunity to polio virus and is recommended in addition to OPV but does not replace OPV. Inactivated Polio Vaccine has been proven to be an extremely safe and effective vaccine but does not produce adequate gut immunity which OPV would provide.

1. Introduction of injectable Inactivated Polio Vaccine (IPV) into the National EPI schedule

One dose of IPV should be given to infants from 1st of July 2015 on completion of 4 months of age , together with the 2nd dose of Pentavalent vaccine and OPV vaccine. IPV is a vaccine suspension given as an injection.

a. Dose,route and site of administration

IPV is liquid suspension, which does not require reconstitution. A single dose of 0.5 ml of IPV should be administered by intramuscular route (IM) into the right thigh of the baby.
Sequence of vaccination of infant at 4 months of age at the visit of vaccination

- Step 1: Give OPV first
- Step 2: Give IPV to Right thigh
- Step 3: Give Pentavalent vaccine to Left thigh

b. Contraindications

Should not vaccinate if:

- Known or documented allergy to vaccine components, including: Streptomycin, Neomycin, Polymyxin B
- History of an allergic reaction following a previous IPV injection
- Thrombocytopenia (insufficient blood platelets, which play an important role in coagulation)
- Other bleeding disorders
- Anyone with a fever over 38.5° C (101° F)
- But IPV can be administered on schedule to immune deficient infants (such as HIV) or infants born prematurely (on completion of 2 months)

Vaccination is better postponed if

- The recipient is under temporary treatment that suppresses the immune response in which the treatment could reduce immune response to the vaccine

c. Side effects

Side effects are rare, the most common side effects of the vaccine are

- Redness, swelling and pain at the injection site, fever and discomfort
- Allergic reactions are extremely rare
-

d. Storage

IPV in 5-dose (multi-dose) vial

- IPV should be stored in the upper compartment in the Ice lined Refrigerator and middle compartment in the Domestic refrigerator
- IPV should be transported and stored at $+2^0$ C to $+8^0$ C temperature (should not expose to heat)
- The vaccine should be kept in the clinic in a container with cool water or inside the form pad of the vaccine carrier to maintain the cold chain ($+2^0$ C to $+8^0$ C) and should be protected from direct sunlight.
- IPV should not be stored in the freezer compartment since it is freeze sensitive (unlike OPV which can be frozen)
- It is important to ensure that the vaccine is not frozen. If vaccines are frozen (as indicated by "X" in the freeze tag or any electronic monitor), potency will be lost and will not provide adequate protection against the disease. The "shake test" is ineffective in determining whether IPV has been frozen since it does not contain aluminum adjuvant. If there is any suspicion that IPV was frozen, the vial must be discarded.
- IPV 5-dose vial can be used under Multi-dose Vial Policy (MDVP)
- Opened IPV 5-dose vial can be used upto 28 days after opening if the following criteria defined are fully met.
    - The expiry date of the vaccine has not passed
    - The vaccine vial has been, and will continue to be stored at $+2^0$-8^0C and the Vaccine Vial Monitor (VVM) has not passed its discard point
- Further information on MDVP as with circular no:01-06/2015 dated on 11/02/2005

e. Injection safety:

- Should explain adequately the safety of 2 injections (IPV and pentavalent vaccine)at one visit to parent/s of the child vaccinated at 4 months
- AD syringes provided in the National EPI programme should be used in vaccine administration and used AD syringes should be discarded to safety boxes provided.
- AD syringes and safety boxes will be provided for the National EPI programme by the Regional Medical Supplies Division in coordination with the Epidemiology Unit. Regional Directors of Health Services, Regional Epidemiologists, Medical Officers of Health and Heads of Medical Institutions are responsible for ensuring adequate supply, availability and use of injection safety items at all Immunization clinics in their respective areas.
- Appropriate and safe disposal of sharps should be ensured in all instances

f. Accountability of the IPV

IPV vials are presented as 5-dose vials and measures should be taken to minimize wastage. Significant wastage should be clearly documented and should be reported to both Epidemiology Unit and RDHS office. Open 5-dose multi-dose vial can be used under Multi-dose Vial Policy

2. Roles and responsibilities in IPV introduction to National Immunization Programme

a) Medical Officer of Health (MOH)

- Training of MOH staff on introduction of IPV
- Create public awareness regarding IPV by organizing public awareness sessions/ programmes
- Timely requisition and maintenance of adequate stocks of Vaccines, supervision of storage, transport of vaccines and maintenance of cold chain
- Timely requisition of adequate stocks of supplies, identifying mechanisms for disposal of AD syringes and sharp wastes and monitoring the implementation and sustenance of the activity
- Adequate screening of infants at the age of 4 months for contraindications of the vaccine and adequate communication with parents for 2 injections at a single visit
- Monitoring and reporting of Adverse Events Following Immunization (AEFI) and appropriate immediate management as instructions given in the "Guidelines on reporting and investigation of AEFI" by the Chief Epidemiologist in the Epid/75/2012 dated 01/04/2013
- Reporting of AEFI at MOH level monthly
- Prompt investigation of severe AEFI
- Monitoring and supervision of immunization coverage, vaccine wastage according to the quarterly EPI return for the area and reporting of AEFI at MOH level with regard to IPV and taking corrective measures when required
- Monitoring of record keeping at clinic level and MOH level
- Monitoring and maintenance of timeliness and accuracy of information of IPV in EPI returns sent from MOH office to RDHS/RE and Epidemiology Unit
- MOH is fully responsible for vaccine management accountability in the MOH area
- Should seek technical assistance for any issues from Regional Epidemiologist, Medical Officer –Maternal and Child Health, Provincial Consultant Community Physician, Epidemiology Unit or Family Health Bureau.

b) Public Health Nursing Sister/Supervisory Pubic Health Midwife

- Training of Public Health Midwives (PHMM) on IPV administration under the guidance of MOH
- Education/communication of the public regarding IPV introduction
- Monitoring and supervision of maintenance of cold chain at MOH office, during transport and at clinics
- Proper storage, supervisionand monitoring of vaccine stocks at MOH office
- Supervision of immunization clinics to facilitate administration of IPV
- Supervision of disposal of used AD syringes and other injection materials

- Monitoring of immunization coverage, vaccine wastage, AEFI with regard to IPV at the clinic/PHM level and MOH level
- Monitoring and supervision of record keeping at the clinic level and at MOH level
- Accurate and timely compilation of IPV related EPI data and timely submission to MOH
- Should correct any identified deficiencies under the guidance of MOH

c. Public Health Midwife

- Education/communication of the public on IPV administration
- Maintenance of cold chain during transport of vaccines to and from clinics and during clinic sessions
- Vaccine administration and monitoring for immediate AEFI at the clinic level
- Enforce vigilance and provide personal attention to prevent dropouts from immunization
- Detect and report all AEFI with regard to IPV
- Safety assurance of the sharps waste disposal activity in the immunization clinics
- Maintenance of accurate and timely records on IPV administration ; Birth and Immunization Resister, Clinic Immunization Register, Clinic AEFI Register, Portion A and B portions of CHDR, Clinic Summery, Quarterly MCH Clinic Return

d. Regional Epidemiologist/ MO-MCH

- Conduction of district training programme for MOOH and hospital staff at district level and active participation, co-ordination and supervision of training programmes at MOH level
- Estimation and maintenance of required stocks of IPV for the district
- Close supervision of vaccines and AD syringes supply in the district
- Close monitoring of requisition of IPV, vaccine storage and maintenance of cold chain at Regional Medical Supplies Division (RMSD) and at MOH level

- Overall supervision of mechanisms developed in the district for disposal of AD syringes and sharp wastes
- Close monitoring , supervision and timely reporting of immunization coverage and vaccine wastage quarterly and AEFI monthly with regard to IPV integrating to existing routine system
- Should seek technical assistance for any issues from the Provincial Consultant Community Physicians, Epidemiology Unit or from Family Health Bureau

e. **Heads of Health Institutions**

- Timely acquisition of adequate vaccine stocks and AD syringes for the immunization clinic
- Close monitoring of vaccine storage and maintenance of cold chain at institutional level
- Close supervision of vaccines and AD syringes supply to clinics
- Overall monitoring of immunization coverage, vaccine wastage and AEFI with regard to IPV at hospital level
- Overall monitoring and supervision of record keeping at hospital level
- Officer in charge of the EPI clinics is responsible and accountable for vaccine management and any significant wastage should be clearly documented and reported to Epidemiology Unit and to RDHS
- Close monitoring , supervision and timely reporting of immunization coverage and vaccine wastage and AEFI with regard to IPV integrating into routine existing system

f. **Officer-In-Charge (OIC) - Regional Medical Supplies Division (RMSD)**

- Timely requisition of adequate vaccine stocks and AD syringes for the district
- Timely distribution of vaccines and AD syringes to MOH offices and medical institutions where functioning immunization clinics store vaccines
- Maintenance of cold chain for vaccines during storage at RMSD , transport and during public holidays
- Preparation of timely, accurate monthly stock return for the district
- OIC-RMSD is totally responsible and accountable for vaccine management at the RMSD and any significant wastage should be clearly documented and reported to both the Epidemiology Unit and the RDHS
- OIC-RMSD will be held responsible for any losses due to unacceptable reasons

3. Records and returns

Following the introduction of the Injectable IPV into the National Immunization Programme, it is crucial to monitor the coverage of the IPV immunization and the AEFI very closely. This could be done using the same returns and records that are being used in the EPI programme. It is very important to collect, enter, consolidate and forward accurate and quality data on time.

Registers and returns used

a. Child Health Development Record

b. Clinic Immunization Register
c. Clinic Summary
d. Birth and Immunization Register
e. Quarterly MCH clinic Return

f. Quarterly EPI Return
g. Clinic, MOH and Hospital AEFI Registers
h. Notification Form on AEFI (AEFI form 1)
i. Monthly Surveillance Report on AEFI (Form 2)
j. Adverse Events Following Immunization (AEFI) case investigation form (AEFI Form 3)
k. Monthly stock return of vaccines
l. MOH office Vaccine Movement Register
m. Clinic Vaccine Movement Register

a. Child Health Development Record(Revised 2014)

Year, month and the date of the IPV immunization along with the batch number of the IPV vaccine should be recorded in the row mentioned as '**other**' vaccines (until updated CHDR will be available) and it should be entered as 'IPV'. It is mandatory to fill both A and B portions.

b.. Clinic Immunization Registrater – H-1216

All immunizations performed in the clinic should be entered in this register. Vaccinations performed with IPV should be entered under the table heading of 'infant immunization' in the column allocated for IPV in the revised register.

Infant Immunization											
BCG	Penta 1	Penta 2	Penta 3	DT 1	DT 2	DT 3	Polio 1	Polio 2	Polio 3	IPV	LJEV

c. Clinic Summary – RH- MIS518

Entries in clinic immunization register should be added up correctly at the end of each session and totals should be recorded in the clinic summary. Total number of children who have been vaccinated with IPV should be entered in the column allocated for IPV in the revised register.

Immunization																				
Below 5 years																				
BCG		Penta			DPT		DT				OPV					IPV	Live JEV	LJEV other	MMR	
1	2	1	2	3	4	1	2	3	4	5	1	2	3	4	5				1	2

d. Birth and Immunization Register - EPI/03/79 (Revised 2014)

Date of IPV immunization should be recorded in '**column D**' in the cage allocated to enter data on IPV immunization in the revised register.

10. Date of immunization								
a	b	c			d			
BCG	Scar (Y/N)	Pentavalent			OPV			IPV
		1	2	3	1	2	3	

e. Quarterly MCH Clinic Return – RH- MIS 527

At the end of every month, entries in the clinic summary should be added up/totalled. Vaccinations performed during the whole month should be recorded in this return. This return should be sent by each PHM to the MOH office at the end of the each quarter before the 5th of the following month.

Total number of infants who have been immunized with IPV vaccine should be entered in the row allocated to enter data for IPV in the revised format.

f. Quarterly EPI Return (EPID/EPI/1/2013)

Entries in all Quarterly MCH clinic returns received at the MOH office and data on vaccinations performed in estates, government hospitals, private institutions and by General Practitioners should be summarized on this return. The number of vaccinations performed in relevance to IPV for the particular quarter should be entered in the row for '**Other Vaccines**' and should mention clearly specified as "IPV".

g. Clinic/MOH office/Hospital AEFI Registers

A clinic AEFI register should be maintained at each immunization clinic to record all adverse events reported following vaccination. A fresh row should be used to enter relevant information of the AEFI reported/identified including the date of vaccination of the relevant vaccine, name of child, the type of the adverse event and the name of the vaccine should be entered in the AEFI register. Same procedure of entry should be adopted in the MOH office and Hospital AEFI registers.

Serial No: (1)	Registration number of the CHDR (2)	Date of report/ Detection (3)	Adverse Event (4)	Related Vaccine (5)		Batch No: / Lots No (6)	Date of immunization (7)	Name of the Child (8)	Address	Remarks (12)
				Antigen	Dose					

All adverse events following immunizations which are entered in the Immunization Clinic AEFI Register should be transferred to the MOH office AEFI Register on the day of the monthly conference or at any convenience.

h. <u>Notification Form for Adverse Events Following Immunization (AEFI Form 1) Revised 2013</u>

All AEFI presented to the hospital should be entered in the Hospital AEFI register and each case should be reported in 'AEFI form 1' to the Epidemiology Unit and MOH office of the area where the child was given vaccination.

i. <u>Monthly Surveillance Report AEFI (AEFI Form 2) Revised 2013</u>

All AEFI reported from the MOH area following immunizations should be summarized by the MOH in the Monthly AEFI return. Copies of this return should be sent to the RE and the Epidemiology Unit. Total number of AEFI following IPV vaccination should be entered in a blank column available and should be mentioned as "IPV". Special attention should be given to obtain information on Adverse Events following IPV vaccination from mothers and the guardians during home visits, before vaccinationof 6 months OPV 3 and Pentavalent 3. Presence or absence of AEFI should be recorded accurately in both portions of CHDR and identified AEFI should be recorded and reported accurately and timely.

Adverse Events	BCG	OPV	Penta/DPT				Hep B	Measles	MMR	MR	DT	aTd	JE		Influenza		
			1	2	3	4							1	2			

k. Monthly Stock Return of Vaccine

The number of IPV doses required for the institutions for the month should be intended under the column **'other'** in the monthly stock return and should be clearly mentioned as IPV.

l. MOH office Vaccine Movement Register

MOH office Vaccine Movement Register should be maintained at the MOH office level and Clinic vaccine movement register should be maintained for each immunization clinic. In the MOH office Vaccine Movement Register, in the first page containing the 'Table of Contents', IPV should be entered in the blank row below the space given for the aTd vaccine. And in the relevant pages write the 'Name of the item' as IPV in the identified pages.

Serial No	Item	Page number		Remarks
		From	To	
	Vaccine			
	BCG			
	PVV			
	OPV			
	LJEV			
	MMR			
	DPT			
	DT			
	TT			
IPV →	aTd			

IPV →

Name of the item:								
Date (A)	No of doses/ items in hand (B)	Place of distribution (clinic/ school) (C)	No of doses/items issued (D)	Batch No: (E)	No: of vaccinations performed (F)	No: of doses /items used (G)	No: of doses/ items returned (H)	Balance in hand (I)

m. Clinic Vaccine Movement Register

In the Clinic Vaccine Movement Register, identify a (blank) row and write IPV to enter relevant data.

Type of Vaccine	No of doses/ items issued to the clinic	Batch number	No: of vaccinations performed	No: of doses/items used	No: of doses/items returned	No: of doses/ items required for the next clinic	Remarks
BCG							
PVV							
OPV							
LJEV							
MMR							
DPT							
DT							
TT							
aTD							
IPV →							
diluents							

If you need further clarification or additional information, please contact the Epidemiology Unit.

Please bring the contents of this revised guidelines to the notice of all concerned in your province/district/ institution/unit. This will replace the contents of the guidelines No. EPID/37/2015, issued on 07.05.2015.

Dr. P. G. Mahipala
Director General of Health Services
Ministry of Health and Indigenous Medicine

Cc: DDG (PHS) I & II
Chief Epidemiologist
Director MCH
Director HEB
Director/ TCS
Director MRI
Director NIHS