



## Epidemiology Unit

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Provincial/Regional Directors of Health Services,  
Directors of Teaching Hospitals/Specialized Campaigns,  
MSS/DMOO of Provincial/Base Hospitals,  
Heads of Decentralized Units and,  
Medical Officers of Health.

## Introduction of live attenuated JE vaccine SA14-14-2 (LJEV) to the National Immunization Programme

It is hereby brought to your notice that the live attenuated SA14-14-2 Japanese Encephalitis vaccine will be introduced to the National Immunization Programme (NIP) in Sri Lanka with effect from 01<sup>st</sup> July 2009. This decision was made following recommendations made by the National Advisory Committee on Communicable Diseases held on 07.03.2008.

### Background

Japanese Encephalitis (JE) is caused by a zoonotic flavivirus. It is the most common arthropod borne encephalitis in the world. Further, it is considered as the leading viral cause of disability in many countries of South and South East Asia. In endemic areas, the highest attack rates occur in children with a case fatality rate of approximately 30%. Nearly a half of the survivors of JE suffer long term neuro- psychiatric sequelae. Therefore, it is obvious that the consequences of contracting the disease are drastic and invariably the impact of the disease upon the intellectual and productive capacity of a nation and economic burden is colossal.

In Sri Lanka, JE virus was first isolated in 1968. However, the first recorded major Japanese Encephalitis outbreak occurred in 1985-86 in the North Central Province where 385 cases were reported including 64 deaths accounting to a case fatality rate (CFR) of 17%. Predominantly affected in this outbreak were those who were in the age groups of 5-9 years and 20-29 years with a male: female ratio of 2:1. The disease occurred in epidemic proportions in 1986-87 and 1987-88 too. The latter outbreak was the largest outbreak reported so far with 812 cases and 192 deaths (CFR- 24%). In this outbreak, the disease already spread to three new districts adjoining the North Central Province.

Epidemiologically, incidence of JE was high in areas of rice cultivation and well developed network of irrigation canals during the rainy season. Outbreaks of JE were spreading in areas that were associated with deforestation carried out to expand agricultural areas. New areas for agricultural development were prepared with building of new canals and reconstruction of ancient remnants. Settlement drive had attracted a huge influx of non immunized people from various parts of the country encouraged by the state all these factors led to major outbreaks within the region. Pig breeding in closer proximity to residential areas providing amplifying hosts was found to be another disposing factor to the disease. Coir industry at the household level was a reason for the spread of the disease in the wet zone. These dynamic changes in conditions receptive to viral transmission have been the key in changing the pattern of JE transmission in Sri Lanka.

Although various control and preventive measures were carried out, JE was endemic in certain areas of Sri Lanka and gradually becoming prevalent in new areas or where low levels of enzootic transmission was

previously maintained. Based on experience of some countries that highlighted immunization was the main cost effective public health tool to cope with this emerging challenge, immunization against JE with mouse brain derived killed JE vaccine was introduced on phase basis in 1988 in Sri Lanka (in selected high endemic districts). The target group identified for immunization was children in the age group of 1-10 years and they were vaccinated with four doses of the Nakayama strain of the killed JE vaccine during the inter epidemic period. Immunizing with the Nakayama strain of the killed JE vaccine continued till 1992. In 1992, the Ministry of Health shifted from vaccinating with Nakayama strain of the killed JE vaccine to the Beijing strain.

As the immunization coverage increased over the years, the incidence of JE gradually started to decline in the districts where immunization was performed. Paradoxically, the disease started to emerge in other districts where immunization was not performed. The last outbreak of JE was reported in Ratnapura in 2002. Since these areas which had previously low or non-existent enzootic viral transmission reported JE in outbreak proportion, the expansion of immunization as the major means of prevention to these districts arose. Therefore, based on new epidemiological data, a decision was made to introduce the JE vaccination programme to districts such as Ratnapura and Jaffna. Subsequently, immunization against JE was carried out in altogether 18 districts in Sri Lanka.

Though the immunization coverage took an upward trend following introduction of the JE immunization programme, the Epidemiology Unit of the Ministry of Health has observed an increasing trend of Adverse Effects Following Immunisation (AEFI) due to the vaccine. Rates of AEFI for the JE vaccine was reported to be the highest after that for the DPT. Although improved reports of AEFI in the country has attributed to the observed increase to a certain extent, reactogenicity of the killed JE vaccine previously used in the national programme also has played a major role in this regard.

Meanwhile, the WHO's Strategic Advisory Group of Experts (SAGE) had recommended the live, attenuated SA 14-14-2 JE vaccine (LJEV) as an adequately immunogenic and safer vaccine than the killed JE vaccine and an appropriate alternative for the killed JE vaccine. Recommendations were based on studies done in some countries and China's experience of using live JE vaccine for a very long period in their immunization programme.

## **Live attenuated JE vaccine (LJEV) SA 14-14-2:**

### **Introduction:**

Live JE vaccine is manufactured based on growth of genetically stable, neuro attenuated SA 14-14-2 strain of the JE virus on a mono layer of primary hamster kidney cells. After cultivation and harvest, an appropriate stabilizer is added to the virus suspension and then lyophilized. Lyophilized vaccine has to be reconstituted with the diluent provided by the manufacturer before administration. It elicits broad immunity against heterologous JE viruses with sufficient viral replication.

### **Schedule**

Children will be immunized with the LJEV at the completion of the first birthday (one year).

Though in certain other countries, a further booster dose is given one year after the primary immunization given at the completion of first birthday, many studies suggest that the immunogenicity given by a single dose is equivalent to that of when these two vaccines are given separately. Based on these data, a single dose is recommended to be used in Sri Lanka. However based on epidemiological data of JE and the effectiveness of the vaccine after being used in Sri Lanka, the necessity for a booster dose will be decided in the future.

If due to any reason, the vaccine is missed or delayed on the due date, it should be given at the next earliest available opportunity for immunization. However if another live vaccine is to be given before or after this vaccine there should be a time gap of at least four weeks between the two vaccines.

## Eligible children for live JE vaccine

There will be two groups of children eligible for immunization with LJEV

### 1. Those who complete one year on and after the commencement of immunization against JE with LJEV :

The date of commencement of the JE immunization with the LJEV is July 01<sup>st</sup> 2009. Therefore, all children who complete one year of age on and after July 01<sup>st</sup> 2009 will be eligible to receive live JE vaccine.

### 2. Those who completed one year of age in 2006, 2007, 2008 without being exposed to JE vaccination at all.

Due to non availability of vaccine, the killed JE vaccine was not provided to eligible children in 2007, 2008. Therefore, it is suggested that the backlog of children in these 3 cohorts also be cleared by offering vaccination with LJEV at the earliest point of contact based on the availability of LJEV.

For this purpose, all those children who were born in 2005, 2006 and 2007 and those who were born till July 01<sup>st</sup> 2008 should be considered for backlog clearance.

## Dose

The recommended dosage is 0.5ml of reconstituted vaccine.

## Route and site of administration

LJEV should be administered subcutaneously to the outer mid thigh or upper arm depending on the age of the child.

## Contraindications

There are only a few reasons to withhold or to postpone administration of live JE vaccine. General contraindications to vaccination specified in the Immunization Handbook issued by the Epidemiology Unit in 2002 are applicable to the LJEV as well. However, in specific instances given below, it should be avoided.

It should be avoided only for children with;

- Fever more than 38.5 °C
- Acute infectious diseases including Otitis media, and tympanitis
- Active untreated tuberculosis
- Hepatic, renal or cardiac diseases
- Subjects with an allergy to any component of the LJEV vaccine including Gelatin
- Person with a proven or suspected hypersensitivity to Kanamycin or gentamicin
- Congenital or acquired immunodeficiency states including those who were treated with any immunosuppressive therapy recently
- Pregnancy
- Past history of convulsions during the last 12 months.

Please note that subjects with a previous history of moderate to severe allergic conditions (urticaria, dyspnoea, peri-oral oedema, laryngeal oedema ) should be vaccinated in the central immunization clinic with an emergency tray and procedures for emergency care being ready.

The following are NOT contraindications:

- Minor illnesses such as respiratory tract infection or diarrhea with temperature below 38.5°C ( 101° C)
- Family history of convulsions
- Treatment with topical corticosteroids or systemic use of corticosteroids at low dosages ( less than 0.5mg/kg of prednisolone or equivalent) in case of skin diseases like dermatitis, eczema or other localized skin disorders
- Stable neurological conditions e.g. cerebral palsy, down syndrome.

## **Precautions:**

Precautions should be taken to avoid undesirable reactions before administering the vaccine. These precautions include review of the child's medical history, particularly regarding hypersensitivity reactions to previous administration of any type of vaccine, past history of convulsions and the child's history of recent health problems.

There should be a gap of at least four weeks between the live JE vaccine and another live vaccine administered before or after the live JE vaccine.

## **Storage:**

LJEV should be stored and transported in a temperature between 2 and 8 °C and should be protected from sun light. Hence this vaccine should NEVER be stored in the freezer compartment and should preferably be kept in the middle shelf of the main compartment of the refrigerator with the diluent in all places storing the vaccine including MOH offices.

While transporting the vaccine, vials should NOT be kept in contact with ice in vaccine carriers / flasks and during clinic sessions vaccine vials should NOT be kept in contact with ice.

If the vaccine is not used immediately after reconstitution, it should be stored at 2°C to 8°C not longer than 2 hours and away from light. After 2 hours it should be discarded.

## **Injection safety:**

At present only auto-disable (AD) syringes are used in the National Immunization Programme in the country. Therefore, administration of live JE vaccine will be carried out using AD syringes and used syringes should be discarded to safety boxes. AD syringes and safety boxes for the National Immunization Programme will be provided by the Medical Supplies Division in coordination with the Epidemiology Unit. RDHS, MOH and head of medical institutions will be responsible for ensuring the availability and use of injection safety items at all immunization clinics in their respective areas.

Further it is emphasized that appropriate and safe disposal of sharps should be ensured in all aspects of the programme.

## **Vaccine accountability:**

LJEV vials are presented as 5 dose vials. Therefore, measures should be taken at immunization clinics whenever possible to open a vaccine vial when a group of five eligible children are identified. Each vial of vaccine is accountable and any significant wastage should be clearly documented, and reported to both Epidemiology Unit and RDHS.

## **Role of MOH in the introduction of LJEV in to the National Immunization Programme**

- Training of MOH staff on introduction of LJEV
- Creating public awareness regarding the LJEV by organizing public education programmes
- Timely requisition of adequate vaccine stocks for the area, supervision of storage, transport of vaccines and maintenance of cold chain
- Timely requisition of adequate stocks for the area, identifying mechanisms for disposal of AD syringes and sharp waste for the area and monitoring the implementation and sustenance of the activity
- Screening and excluding children for whom offering the LJEV is contra indicated
- Monitoring vaccines for immediate AEFI and initiating appropriate actions

- Monitoring and supervision of immunization coverage, vaccine wastage and reporting of AEFI at MOH level with regard to LJEV quarterly, according to the quarterly EPI return for the area and taking corrective measures when required.
- Monitoring of record keeping at clinic level and MOH level
- Monitoring timeliness of EPI returns sent from MOH office to RDHS/RE
- MOH is responsible for vaccine management accountability.

**Role of Public Health Nursing Sister/ Supervisory Public Health Midwife in the introduction of live JE vaccine to the National Immunization Programme.**

- Training of PHMM on LJEV
- Education of the public regarding the LJEV
- Monitoring and supervision of maintenance of cold chain and proper storage of vaccine stocks
- Supervision of organization of immunization clinics to facilitate administration of LJEV
- Supervision of disposal of sharps waste in the area with regard to AD syringes and other injection materials
- Monitoring of immunization coverage, vaccine wastage, AEFI with regard to LJEV at Clinic/PHM level and MOH level
- Monitoring recruitment of backlog recipients of 2007,2008 & 2009 for vaccination with LJEV by the field staff
- Monitoring and supervision of record keeping at clinic level and MOH level
- Accurate, timely compilation of EPI data at MOH level

**Role of Public Health Midwife in introduction of live JE vaccine to the National Immunization Programme.**

- Education of the public on the LJEV
- Maintenance of cold chain during transport of vaccines and during clinic sessions
- Providing immunization and monitoring vaccines for immediate AEFI at the clinics level
- Enforcing vigilance and providing personal attention to prevent dropouts from immunization and to detect AEFI with regard to live JE vaccine
- Safety assurance of the sharps waste disposal activity in the immunization clinics
- Recruitment of current and backlog recipients of 2007,2008 & 2009 for vaccination with LJEV
- Maintenance of accurate records regarding all immunization at clinic level especially on live JE vaccination: Birth and Immunization Register, Clinic Immunization Register, Clinic AEFI Register, Part A/B of CHDR, Clinic Summary, Quarterly MCH Clinic Return

**Role of Regional Epidemiologist/ MO-MCH in introduction of live JE vaccine to the National Immunization Programme.**

- Conduction of district training programmes for MOH and hospital staff at district level and active participation, co-ordination and supervision of training programmes at MOH level
- Estimation of required stocks of LJEV for the district
- Close monitoring of requisition of LJEV , vaccine storage and maintenance of cold chain at Regional Drug Stores and at MOH level
- Close supervision of vaccine and AD syringes supply in the region
- Overall supervision of mechanisms developed in the region for disposal of AD syringes and sharp waste
- Close monitoring and supervision of immunization coverage and vaccine wastage quarterly and reporting of AEFI monthly with regard to live JE vaccine

## **Role of Heads of Health Institutions in introduction of live JE vaccine to the National Immunization Programme.**

- Timely requisition of adequate vaccine stocks and AD syringes for the immunization clinic
- Close monitoring of vaccine storage and maintenance of cold chain at the institutional level
- Close supervision of vaccine and AD syringe supply to the clinic
- Overall monitoring of immunization coverage, vaccine wastage and AEFI with regard to live JE vaccination 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 . Each vial of vaccine is accountable and any significant wastage should be clearly documented, reported to both Epidemiology Unit and RDHS.

## **Role of Officer In-Charge/ Regional Medical Supply Division (RMSD) in introduction of live JE vaccine to the National Immunization Programme.**

- Timely request of adequate vaccine stocks and AD syringes for the district
- Timely distribution of vaccines and AD syringe to MOH and medical institutions
- Maintenance of cold chain for vaccine during storage at RMSD and transport
- Preparation of the correct monthly stock return for the district
- OIC RMSD is totally responsible and accountable for vaccine management at the RMSD. Each vial of vaccine is accountable and any significant wastage should be clearly documented, and reported to both Epidemiology Unit and RDHS. OIC RMSD will be held responsible for any losses due to unacceptable reasons.

## **Training of Health Staff**

Replacing currently used killed vaccine with the LJEV in the National Immunization Programme, requires training and education of field health staff to provide the knowledge and skills to sustain a successful programme. This training should include the use of AD syringes and methods adopted for safe disposal of used AD syringes and other sharp waste.

Following have been identified as important issues that should be clearly and completely addressed during all training sessions.

- Japanese Encephalitis disease, success of immunization with killed JE vaccine in prevention and control
- Live JE vaccine (contraindications, vaccine administration, storage etc)
- Use of injection safety items (AD syringes, safety boxes)
- Vaccine logistics (vaccine wastage, accountability, maintaining adequate stocks)
- Record keeping: (maintenance of records and registers, completeness, accuracy and timeliness of returns)
- Vaccine safety: (adverse events following Immunization)

At the national level, Regional Epidemiologists/ MOO(MCH) will be given an orientation and they will be the trainers for their respective health staff. They will be responsible for training MOOH and hospital staff who conduct EPI clinics in their respective districts/ medical institutions.

MOOH will be responsible for training their own staff and this activity should be assisted and monitored by RE and MO/MCH of the district.

## Schedule for training of field/ hospital health staff

Level	Target	Responsibility	Supervision	Time
National	RE /MOMCH	Epidemiology Unit		June
District	MOH, Staff of EPI clinic at TH, GH, BH	RE, MO/MCH	Epidemiology Unit	July
Divisional	PHNS, PHM, PHI, Staff of CD, PU, DH, RH	MOH	RE, MO/MCH	July

This guideline on introduction of live JE vaccine to the National Immunization Programme may be used as the training material. This will be available in all 3 official languages. Further, a guidebook will be developed and distributed to districts by the Epidemiology Unit. It is the responsibility of REE and MOO (MCH) to share this with all MOOH and hospital staff during the district level training. This document contains the disease (JE), background of the JE immunization programme, information on LJEV, its strategies of implementation and details of AD syringes.

### Records and returns

With the replacement of killed JE vaccine with the LJEV in the National Immunization Programme, it is very important and vital to monitor the coverage of JE immunization and AEFI very closely. This could be done using the same returns and records use in the EPI programme. It is very important to collect, enter, consolidate and forward accurate and quality data on time.

### *Registers and returns used*

- Child Health Development Record ( CHDR)
- Clinic Immunization Register
- Clinic Summary
- Clinic AEFI Register
- Birth and Immunization Register
- Quarterly MCH clinic Return
- Quarterly EPI Return
- Monthly Surveillance Report on AEFI ( AEFI Form 2)
- Notification Form on AEFI ( AEFI Form 1)
- Adverse Events Following Immunization (AEFI)case investigation form (AEFI Form 3)
- Monthly stock return of vaccines
- Vaccine Movement Register
- Clinic Vaccine Movement Register

### *Child Health Development Record*

Year, month and the date of JE immunization along with the batch number of the LJEV should be recorded in the corresponding row given for the JE 1 vaccination. It should be renamed as "LJEV". Mark the date of administration and batch number on the same row. It is mandatory to fill the same information in both A and B parts of the CHDR.

### *Clinic Immunization Register – H1216*

- All immunizations performed in the clinic should be entered in this register. Live JE vaccinations performed should be entered under the "Childhood immunization" according to the year of birth of the child as described below. All columns meant for entering data on JE vaccine (JE 1, JE 2, JE Booster) should be renamed as LJEV.
  - JE immunizations performed for children who were born in 2008 should be recorded in the column JE1
  - JE immunizations performed for children who were born in 2007 should be recorded in the column JE2

- JE immunizations performed for children who were born in 2006 should be recorded in the column JE booster
- JE immunizations performed for children who were born in 2005 should be recorded in the column JE booster

**Clinic Summary – H 518**

Entries in the 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 immunized with live JE vaccine should be entered in the columns meant to enter data on DPT immunization among pre schoolers. Data should enter in column marked 1, 2,3,4, according to the year of birth as described below. These four columns should be marked as

LJEV.

- 1.Total number of Live JE immunizations performed among children who were born in 2008 should be entered in column marked 1
- 2.Total number of Live JE immunizations performed among children who were born in 2007 should be entered in column marked 2
- 3.Total number of Live JE immunizations performed among children who were born in 2006 should be entered in column marked 3
- 4.Total number of Live JE immunizations performed among children who were born in 2005 and any other children who doesn't belong to above three age groups should be entered in column marked 4

Date	BCG	Pre school ( 1-5 years)										JE
		Pentavalent / DTP				Hep B / OPV					Measles	
		1	2	3	4	1	2	3	4	5		

**Clinic AEFI Register**

A clinic AEFI Register should be maintained at each immunization clinic to record all adverse events reported following immunization. The date of immunization of the relevant vaccine, name of the child, the type of the adverse event and the name of the vaccine should be entered in the AEFI register.

Date	Name of the child	Address	Name of the vaccine	Date of immunization	Type of Adverse Event	Remarks

**Birth and Immunization Register EPI/03/79**

Date of JE immunization should be recorded on "column 7 " in the cage allocated to enter data on JE 1 immunization. This column should be renamed as LJEV.

7 Date of Immunization																
a	b				c				d			e	f			
BCG	Triple				Polio				Hepatitis B / Pentavalent			Measles	JE			
												1	2	3	4	

**Quarterly MCH Clinic Return- RH – MIS 527**

At the end of the every month, entries in the clinic summary should be added up (totaled). Immunizations performed during the whole month should be recorded in this return monthly. This return should be sent by each PHM to the MOH office at the end of each quarter before the 5<sup>th</sup> of the following month. It is important to note that the spaces in this return are horizontally aligned in contrast to the vertically aligned columns in the clinic registers. .

Total number of children who have been immunized with live JE vaccine should be entered in the rows meant to enter data on DPT immunization among pre schoolers. Data should enter in rows marked 1<sup>st</sup> dose, 2<sup>nd</sup> dose ,3<sup>rd</sup> dose and 4<sup>th</sup> dose according to the year of birth as described below. These row should be marked as LJEV.

1. Total number of Live JE immunizations performed among children who were born in 2008 should be entered in the row allocated for 1<sup>st</sup> dose
2. Total number of Live JE immunizations performed among children who were born in 2007 should be entered in the row allocated for 2<sup>nd</sup> dose
3. Total number of Live JE immunizations performed among children who were born in 2006 should be entered in the row allocated for 3<sup>rd</sup> dose
4. Total number of Live JE immunizations performed among children who were born in 2005 and any other children who doesn't belong to above three age groups should be entered in the row allocated for 4<sup>th</sup> dose

Triple (DPT) preschoolers	1 <sup>st</sup> dose	
	2 <sup>nd</sup> dose	
	3 <sup>rd</sup> dose	
	4 <sup>th</sup> dose	

**Notification Form for Adverse Effect Following Immunization (AEFI Form 1)**

All the Adverse Effect Following immunizations which present to the hospitals should be entered in a clinic immunization register if available in the hospital. It is very important to adhere to the case definition of the Adverse Events before entering and reporting in order to improve the quality of the AEFI surveillance. Any form of AEFI which is not included in the AEFI From 1 could be entered under the "other" category. All the AEFI which has been presented to the hospital should be entered into the AEFI form one and should be forwarded monthly to the MOH in the area. Total number of particular AEFI reported should be entered in column " 1" under " JE Killed /Live". Mark "L" in the column "1" to indicate that LJEV was given.

Adverse Event	BCG	Penta/DPT				Hep B	Measles	MR	DT	aTd	Rubella	JE Killed /Live ( mark "k" for killed or "L" for live in the row against the dose )				others		
												1	2	3	4			
		1	2	3	4				1	2	3	4	1	2	3	4		

**Monthly Surveillance Report on AEFI (AEFI Form 2)**

All the AEFI reported from the MOH area following immunizations should be summarized by the MOH in the Monthly AEFI return. Copy of this return should be sent to the RE and the Epidemiology Unit. It is very important to adhere to the case definition when reporting the AEFI. Total number of AEFI should be entered under the JE column in front of the relevant row. Special attention should be given to obtain information on Adverse Events Following JE vaccination from the mothers and the guardians during the home visits, before

immunizing the next vaccine and to record them accurately. Special attention should be paid by the RE to obtain AEFI notified to the hospitals without any delay.

Total number of particular AEFI reported for LJEV should be entered in column " 1" under " JE Killed /Live". Mark "L" in the column "1" to indicate that the LJEV was given.

Adverse Event	BCG	Penta/DPT				Hep B	Measles	MR	DT	aTd	Rubella	JE Killed /Live ( mark "k" for killed or "L" for live in the row against the dose )				others	
												1	2	3	4		
		1	2	3	4				1	2	3	4					

**Monthly stock return of vaccine and ORS**

The number of JE doses required for the institutions for the month should be requested under the column "other" in the monthly stock return of vaccine and it should be re named as "LJEV"..

**Clinic Vaccine Movement Register and Vaccine Movement Register**

Clinic vaccine movement register should be maintained in each immunization clinic session held in the MOH area. Vaccine Movement Register should be maintained at the MOH office to be used when ever vaccine is transported out of the MOH office for any immunization clinic. The number of doses of vaccine used at the clinic and the number of immunization performed at the clinic should be entered for each clinic session for both registers. These registers are vital in compiling vaccine wastage.

**Quarterly EPI Return (EPID/EPI/2/98)**

Entries in all Quarterly MCH clinic returns received at the MOH office and data on immunizations performed in schools, estates and hospitals and the immunizations performed at the private institutions and by GPPs should be summarized on this return. The number of JE immunizations performed for the particular quarter should be entered under the heading JE vaccination. Until LJEV is included in newly printed **Quarterly EPI Return (EPID/EPI/2/98)**, entries for LJEV should be made against the rows indicated according to the instructions given below. The row should be renamed as "LJEV".

1. Total number of Live JE immunizations performed among children who were born in 2008 should be entered in the row allocated for 1<sup>st</sup> dose
2. Total number of Live JE immunizations performed among children who were born in 2007 should be entered in the row allocated for 2<sup>nd</sup> dose
3. Total number of Live JE immunizations performed among children who were born in 2006 should be entered in the row allocated for 3<sup>rd</sup> dose
4. Total number of Live JE immunizations performed among children who were born in 2005 and any other children who doesn't belong to above three age groups should be entered in the row allocated for 4<sup>th</sup> dose (booster)

JE vaccine					
1 <sup>st</sup> dose					
2 <sup>nd</sup> dose					
3 <sup>rd</sup> dose					
4 <sup>th</sup> dose ( booster)					

## Monitoring and Evaluation

Close monitoring and evaluation of the introduction of live JE vaccine in to the national immunization programme from its initiation is important for sustenance of the programme. Presently used EPI indicators: i.e. vaccine coverage, vaccine wastage and rate of AEFI will be used for this purpose.

Monitoring of live JE immunization coverage, vaccine wastage and adverse events reported following live JE immunization should be done at MOH level by MOH and PHNS and at district level by RE and MO/MCH. Epidemiology Unit will be responsible for monitoring at the national level as for other EPI antigens.

### Monitoring of live JE immunization coverage

Monitoring of live JE vaccine coverage will be incorporated in to the routine immunization monitoring mechanism, the quarterly EPI return as soon as the vaccine is introduced. Special inputs to improve coverage have to be provided by responsible monitoring authorities for areas with poor coverage of live JE immunization. It is also very important that data are recorded in the return accurately and clearly. MOH should be responsible for sending a timely, accurately recorded return and should not hesitate to take necessary action to sustain the practice. At national level, analysis of live JE immunization coverage will be dealt with to monitor the progress of the activity in its early years. This indicator will be important to assess the progress of the programme.

### Monitoring of live JE vaccine wastage

It is important to monitor the wastage and to implement strategies to minimize it at all levels concerned.

The routine immunization monitoring tool of EPI, The quarterly EPI return will be used to monitor the wastage of live JE vaccine. It is therefore important that reliable and accurate data is provided through the quarterly EPI return.

Assessment of causes for vaccine wastage at each MOH level is important as these vary widely between different settings. Strategies for reducing wastage could then be designed accordingly.

#### *Possible causes for high vaccine wastage*

- Breakdown of cold chain or inadequacy of cold chain maintenance system
- Freezing of vaccines
- Poor monitoring of proper vaccine movement between MOH office and immunization clinics

#### *Strategies that could be designed*

- Careful planning in vaccine indentation and distribution
- Strict maintenance of cold chain
- Careful planning of immunization clinic locations
- Careful planning for ensuring at least a group of five children are brought to open a 5 dose vial.
- Monitoring of proper vaccine movement at MOH level
- Maintenance of accurate records and utilization of these to minimize inadequacies of vaccine stocks at MOH level
- Improvement of safe vaccine storage

## Minimizing Vaccine Wastage at Outreach Immunization Clinics

- MOH should identify an officer at each individual outreach immunization clinic to be responsible for proper vaccine movement at individual clinic level
- Vaccine Movement Register should be rigidly maintained to monitor the flow of vaccines in each outreach immunization clinic
- Only correct amounts of vaccine stocks should be sent to the outreach clinics based on the expected and estimated number of children to be vaccinated

## Monitoring of Immunization Safety

Live JE vaccine is safe. A list of possible minor adverse events that could occur following immunization of this vaccine has been mentioned above. All adverse events associated with live JE vaccine that are reported by mothers and public should be reported by field health workers using the Monthly AEFI Return. All field health officers should specifically inquire about AEFI following the previous immunization from mothers at the next immunization session.

Please bring the contents of these guidelines to the notice of all officers concerned in your Province/ District/ Institution/ Unit.

Thanking you,

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Chief Epidemiologist.