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சுகாதார அமைச்சு
Ministry of Health

General Circular No. 01-20-2010

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

Revised guidelines on introduction of live attenuated JE vaccine SA14-14-2 (LJEV) to the National Immunization Programme

The live attenuated SA14-14-2 Japanese Encephalitis vaccine was introduced to the National Immunization Programme (NIP) in Sri Lanka with effect from 01st July 2009. This decision was taken following recommendations made by the National Advisory Committee on Communicable Diseases (NACCD) held on 07. 03.2008.

At the time of introduction of the LJEV, considering that this vaccine was a new vaccine to the EPI, as an interim measure, all children with conditions compatible with contraindications listed by the manufacturer, WHO and the Program for Appropriate Technology in Health (PATH) in their documents were selectively excluded from immunization. Further, the National ACCD recommended strengthening post marketing surveillance of possible AEFI due to LJEV with a view to modifying the list of contraindications prospectively. Since introduction of the LJEV, around 600000 doses have been administered and there have been no severe AEFI of concern so far.

The Epidemiology Unit in consultation with the WHO, the Vaccine manufacturer and the NACCD revised the list of contraindications for administering LJEV on 04.06.2010. Please note that the guidelines issued earlier are replaced with these new, revised guidelines with immediate effect. Therefore, it is hereby requested to adhere to contraindications listed in the present document when immunizing children in the future.

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 dilluent provided by the manufacturer before administration. It elicits broad immunity against heterologus JE viruses with sufficient viral replication.

Schedule

Children will be immunized with the LJEV at the completion of 9 months.

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 01st 2009. Therefore, all children who complete one year of age on and after July 01st 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 01st 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 contraindications for 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, It should be postponed in specific instances given below,

- Fever more than 38.5^0C
- Acute stage of any infectious disease
- Temporarily acquired severe immunodeficiency states due to recent immuno suppressive therapy such as systemic corticosteroids, chemotherapy , irradiation etc
- History of convulsion during the last 12 months

It should be avoided in

- Children with proven or suspected hypersensitivity to LJEV or its components such as Kanamycin or Gentamycin.
- Congenital or acquired severe immunodeficiency states such as impaired immunological mechanisms, malignant conditions and Acquired Immuno Deficiency Syndrome etc

Please note that subjects with a previous history of moderate to severe allergic conditions (urticarea, 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^{0}C (101^0 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:

It is advised to review child's medical history before administration of the LJEV with a view to identifying children with compromised health status. Parents/ caregivers of such children should be communicated that there may be the possibility of coincidental worsening of the health status of the vaccinated child due to the compromised health status which could be erroneously attributed to the vaccination .

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 ^{0} 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 dilluent 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 6 hours and away from light. After 6 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.

This guideline on introduction of live JE vaccine to the National Immunization Programme may be used as the training material. 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 alone 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 raw. 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)										
		Pentavalent / DTP				Hep B / OPV					Measles	JE
		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 Triple				c Polio				d Hepatitis B / Pentavalent			e Measles	f JE			
BCG													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 5th 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 1st dose, 2nd dose ,3rd dose and 4th 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 1st dose
2. Total number of Live JE immunizations performed among children who were born in 2007 should be entered in the row allocated for 2nd dose
3. Total number of Live JE immunizations performed among children who were born in 2006 should be entered in the row allocated for 3rd 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 4th dose

Triple (DPT) preschoolers	1st dose	
	2nd dose	
	3rd dose	
	4th 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.

Advesre 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	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.

Advesre 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	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 1st dose

2. Total number of Live JE immunizations performed among children who were born in 2007 should be entered in the row allocated for 2nd dose

3. Total number of Live JE immunizations performed among children who were born in 2006 should be entered in the row allocated for 3rd 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 4th dose (booster)

JE vaccine					
1st dose					
2nd dose					
3rd dose					
4th 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 revised guidelines on LJEV to the notice of all officers concerned in your Province/ District/ Institution/ Unit.

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Dr. U. A. Mendis
Director General of Health Services