WEEKLY EPIDEMIOLOGICAL REPORT

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Ministry of Healthcare and Nutrition

231, de Saram Place, Colombo 01000, Sri Lanka
Tele: + 94 11 2695112, Fax: +94 11 2696583, E mail: epidunit@sltnet.lk
Epidemiologist: +94 11 2681548, E mail: chepid@sltnet.lk
Web: http://www.epid.gov.lk

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Revised Guidelines on Introduction of live Attenuated JE Vaccine SA14-14-2 (LJEV) to the National Immunization Programme

Immunization against Japanese Encephalitis (JE) was commenced in Sri Lanka in 1988. This was following the epidemics of JE experienced in the period of 1985 – 1988 in the North Central Province. The decision to introduce a vaccine was based on the successful use of inactivated JE vaccine in other JE endemic countries in the Far East to control epidemics and reduce the disease burden..The Sri Lankan programme was initiated with the introduction of the mouse brain derived killed JE vaccine of the Nakayama strain. Based on the Epidemiology of JE in Sri Lanka, initially it was limited to a few high endemic areas targeting children in the age group 1-10 years. In 1992, the National Program of Immunization switched over to the Beijing strain of the mouse brain derived killed JE vaccine.

Over the years, vaccine uptake was on the upward trajectory. As a result, the disease incidence was drastically reduced. However, outbreaks occurred in other endemic areas where the vaccine was not being used. Therefore, immunization against JE was gradually extended to 18 endemic districts based on disease surveillance data. Though incidence was brought down with increased and extensive use of the killed JE vaccine, it was noted that the concern on the AEFI caused by JE vaccine was on the rise. JE was the second antigen after DTP for which the highest number of AEFI was reported. High numbers of immunized children leading to an increase in absolute numbers of AEFI and incessantly expanding AEFI surveillance system also partly contributed to the increase in AEFI. Irrespective of reasons for increased AEFI, mounting concerns of AEFI had an impact on the acceptance of the killed JE vaccine in Sri Lanka.

Against this background, a wealth of information appeared on more safe and effective alternative JE vaccine. This vaccine was the Live Attenuated Japanese Encephalitis SA 14-14-2 (LJEV) which had been used in China for well over a decade. After pioneering work of the Program of Appropriate Technology of Health (PATH), USA, in particular, safety and efficacy trials in Nepal and Philipines, this vaccine was seen as an appropriate candidate to replace the existing killed vaccine which was already in short supply due to manufacturing difficulties. It appeared in WHO position papers on JE vaccine as a safe and efficacious alternative to the killed vaccine. Having taken into consideration the existing concerns on AEFI, short supply of vaccine and rising cost of the killed JE vaccine, LJEV was proposed as a viable alternative for use in Sri Lanka. However, the National Advisory Committee on Communicable Diseases (NACCD) recommended conducting a safety and efficacy study in Sri Lankan children before making a decision to eplace the killed vaccine with the LJEV, Based on convincing results, NACCD approved use of LJEV in Sri Lanka from the 1st July 2009.

Though there were convincing safety and efficacy data at clinical trial levels, Post Marketing Surveillance data were relatively inadequate. In addition to that there were many concerns related to the safety of EPI vaccines adversely affecting the acceptance of EPI vaccines at the time of introduction of the LJEV. Therefore, considering that this vaccine was a relatively new vaccine to the National program of Immunization and any untoward effect temporally related to vaccine will have severe repercussions on the JE immunization in Sri Lanka, 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 some of the listed contraindications were untypical for childhood vaccination, it caused some operational problems for the NPI. There were some concerns from the medical paternity in particular Pediatricians. As a result of the created confusion, some potential vaccine recipients were not offered the vaccine. Nor were they unnecessarily referred to consultants. Considering the gravity of the unfolding issues, the Epidemiology Unit initiated a dialogue with the manufacturer and the World Health Organization. In the process, it was revealed that the manufacturer had listed controversial contraindications namely "Renal, hepatic, cardiac diseases and epilepsy/convulsions based on local precautionary measures and not on any clinical evidence. In the absence of clinical evidence, WHO was of the opinion that there was no point for them to have a discussion at the Global Advisory Committee on Vaccine Safety (GACVS). Sri Lankan authorities were requested to determine the contraindication for their program while emphasizing the fact that there was no documented risk of immunizing children with above conditions.

After clarifying the WHO position on these untypical contra-

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indications for JE vaccine, Epidemiology Unit revised the list of contraindications and submitted it for the approval of the NACCD. The NACCD which was convened on 04.06.2010 approved the revised list of contraindications for LJEV. With these changes a new circular governing the administration of LJEV in Sri Lanka has been issued making the previous circular null and void. Excerpts of the new revised circular are reproduced here for the benefit of readers of the WER.

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 diluents 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 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 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°C
- Acute stage of any infectious disease
- Temporarily acquired severe immunodeficiency status due to recent immune suppressive therapy such as systemic corticosteroids, chemotherapy , irradiation etc
- History of convulsions 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 diarrhoea 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:

It is advised to review the 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 sunlight. 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.

At present Nuwaraeliya, Kandy, Badulla, Kegalle, Mulative, Mannar and Kilinochchi district are not covered with LJEV. This decision has been taken on available disease surveillance data on Japanese Encephalitis and vaccine availability. As a result of immunization, JE is no longer a public health problem though the virus is circulated in enzootic cycles. Immunized children who move from traditionally non JE area to an area where there is an enzootic cycle are at risk of JE. Therefore, all children irrespective of their resident district will be offered LJEV in the future through the EPI when the availability of adequate vaccines will be assured.

Table 1: Vaccine-preventable Diseases & AFP

01st - 07th May 2010(18th Week)

Disease	No. of Cases by Province									Number of cases during current week in 2010	Number of cases during same week in 2009	Total number of cases to date in 2010	Total number of cases to date in 2009	Difference between the number of cases to date in 2010 & 2009
	W	C	S	N	E	NW	NC	U	Sab					
Acute Flaccid Paralysis	00	00	00	00	00	00	00	00	01	01	05	30	25	+ 20.0 %
Diphtheria	00	00	00	00	00	00	00	00	00	00	00	00	00	-
Measles	00	00	01	00	00	00	02	00	01	03	01	36	46	- 21.7 %
Tetanus	00	01 KN=1	00	00	00	00	00	00	00	01	00	09	10	- 10.0 %
Whooping Cough	00	00	00	00	00	00	00	00	00	00	01	07	22	-68.2 %
Tuberculosis	57	19	13	00	12	21	00	01	07	130	312	3127	3068	+ 2.0 %

Table 2: Newly Introduced Notifiable Disease

01st - 07th May 2010(18th Week)

Disease	No. of Cases by Province									Number of cases during current week in 2010	Number of cases during same week in 2009	Total number of cases to date in 2010	Total number of cases to date in 2009	Difference between the number of cases to date in 2010 & 2009
	W	C	S	N	E	NW	NC	U	Sab					
Chickenpox	09	11	09	05	04	08	16	07	08	77	491	1445	6493	- 77.7 %
Meningitis	10 CB=4 GM=2 KL=4	00	05 GL=3 MT=2	00	00	02 KN=1 PU=1	08 PO=8	01 BD=1	05 RP=2 KG=3	31	07	553	366	+ 51.1 %
Mumps	02	04	03	06	00	02	02	00	02	21	20	314	642	- 51.1 %
Leishmaniasis	00	00	13	00	00	00	03	00	00	16	09	133	362	- 63.2 %

Key to Table 1 & 2

Provinces: W: Western, C: Central, S: Southern, N: North, E: East, NC: North Central, NW: North Western, U: Uva, Sab: Sabaragamuwa.

DPDHS Divisions: CB: Colombo, GM: Gampaha, KL: Kalutara, KD: Kandy, ML: Matale, NE: Nuwara Eliya, GL: Galle, HB: Hambantota, MT: Matara, JF: Jaffna, KN: Killinochchi, MN: Mannar, VA: Vavuniya, MU: Mullaitivu, BT: Batticaloa, AM: Ampara, TR: Trincomalee, KM: Kalmunai, KR: Kurunegala, PU: Puttalam, AP: Anuradhapura, PO: Polonnaruwa, BD: Badulla, MO: Moneragala, RP: Ratnapura, KG: Kegalle.

Data Sources:

Weekly Return of Communicable Diseases: Diphtheria, Measles, Tetanus, Whooping Cough, Chickenpox, Meningitis, Mumps.

Special Surveillance: Acute Flaccid Paralysis.

Leishmaniasis is notifiable only after the General Circular No: 02/102/2008 issued on 23 September 2008.

Table 4: Selected notifiable diseases reported by Medical Officers of Health

01st - 07th May 2010(18th Week)

DPDHS Division	Dengue Fever / DHF*		Dysentery		Encephalitis		Enteric Fever		Food Poisoning		Leptospirosis		Typhus Fever		Viral Hepatitis		Human Rabies		Returns Received
	A	B	A	B	A	B	A	B	A	B	A	B	A	B	A	B	A	B	%
Colombo	58	1675	6	68	1	6	0	24	0	7	1	214	0	3	1	25	0	1	**92**
Gampaha	32	1662	3	16	1	10	0	15	0	8	0	155	2	4	1	36	0	3	**67**
Kalutara	22	497	6	57	0	8	0	7	0	24	6	135	0	0	0	15	0	1	**83**
Kandy	21	579	3	98	0	1	0	11	0	2	0	24	5	68	0	25	0	1	**78**
Matale	7	335	2	185	0	1	0	8	1	63	1	43	1	4	2	23	0	0	**92**
Nuwara	1	60	6	91	0	0	1	48	9	70	0	9	5	32	3	20	0	0	**69**
Galle	9	312	2	75	0	4	0	0	0	9	0	28	0	3	0	6	1	3	**95**
Hambant	6	304	1	15	0	2	0	1	0	3	0	21	0	42	0	4	0	0	**82**
Matara	8	154	7	46	0	1	0	1	0	39	10	133	0	66	0	9	0	0	**94**
Jaffna	13	2003	3	66	0	1	6	310	0	5	1	1	0	98	0	33	0	1	**58**
Kili-	0	1	0	1	0	0	0	1	0	0	0	0	0	0	0	0	0	0	**25**
Mannar	2	81	1	16	0	0	2	26	2	4	0	0	0	0	0	12	0	0	**100**
Vavuniya	3	484	0	15	0	1	0	25	0	7	0	0	0	0	0	10	0	1	**75**
Mullaitivu	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**0**
Batticaloa	14	981	2	46	0	2	0	15	0	25	0	5	0	1	0	1	0	1	**71**
Ampara	4	69	1	25	0	1	0	4	0	6	1	18	0	0	1	8	0	0	**57**
Trincomal	5	725	0	50	0	5	0	3	0	7	0	8	0	6	0	11	0	0	**60**
Kurunega	15	502	4	84	1	6	1	13	1	6	3	146	0	22	1	49	1	2	**90**
Puttalam	12	531	0	27	0	3	2	34	0	120	0	53	0	0	0	9	0	0	**67**
Anuradha	3	729	0	28	0	2	1	4	0	21	2	31	1	18	0	23	0	3	**84**
Polonnar	23	177	1	24	0	1	0	1	1	3	4	38	0	0	2	17	0	0	**100**
Badulla	12	246	6	65	0	1	0	46	0	13	0	28	2	35	3	38	0	0	**87**
Monaraga	15	217	3	73	1	1	1	19	0	4	6	23	2	26	0	48	0	1	**73**
Ratnapur	41	745	5	137	0	4	0	9	4	22	4	161	1	30	0	43	0	1	**50**
Kegalle	12	363	3	31	0	4	1	25	0	15	3	86	0	5	0	38	0	0	**82**
Kalmunai	2	454	3	73	1	1	0	9	0	0	0	0	0	0	0	7	0	1	**46**
SRI LANKA	**340**	**13886**	**68**	**1412**	**05**	**66**	**15**	**655**	**28**	**483**	**42**	**1360**	**19**	**463**	**17**	**510**	**02**	**20**	**76**

Source: Weekly Returns of Communicable Diseases WRCD).
*Dengue Fever / DHF refers to Dengue Fever / Dengue Haemorrhagic Fever.
**Timely refers to returns received on or before 07th May, 2010 Total number of reporting units =311. Number of reporting units data provided for the current week: 241
A = Cases reported during the current week. B = Cumulative cases for the year.

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Comments and contributions for publication in the WER Sri Lanka are welcome. However, the editor reserves the right to accept or reject items for publication. All correspondence should be mailed to The Editor, WER Sri Lanka, Epidemiological Unit, P.O. Box 1567, Colombo or sent by E-mail to chepid@sltnet.lk.

ON STATE SERVICE

Dr. P. PALIHAWADANA
CHIEF EPIDEMIOLOGIST
EPIDEMIOLOGY UNIT
231, DE SARAM PLACE
COLOMBO 10