

# WEEKLY EPIDEMIOLOGICAL REPORT

# A publication of the Epidemiology Unit Ministry of Healthcare and Nutrition

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## Reintroduction of Combined Pentavalent (DTP-Hep B – Hib) Vaccine into the EPI Programme

General Circular No: 01-23/2009 issued on 15 July 2009.

Ministry of Health has decided to reintroduce combined Pentavalent (DTP-Hep B – Hib) Vaccine into the National Immunization Programme commencing from 1<sup>st</sup> of September 2009.

National Immunization Programme of Sri Lanka is a success story which has gained national and international recognition. High immunization coverage, commitment of the public health staff together with the trust of people has contributed in achieving this success and are already reaching the envisaged goals of the immunization programme.

As further expansion to the immunization programme Hib vaccine was introduced in early 2008 aiming at reducing the morbidity, mortality and complications that arise from Haemophilus Influenzae infection based on data on the disease burden in the country.

Hib vaccine was introduced into the EPI programme in the form of combined pentavlent (DTP-Hep B-Hib) liquid vaccine which was a WHO pre qualified vaccine and has been found to be safe. This vaccine has been in use in over 34 other countries at the time of commencement of the programme and no serious adverse events have been reported from these countries. These are countries continually using the same vaccine without interruption up to now.

However in Sri Lanka use of this vaccine had to

be suspended temporarily due to the occurrence of a previously unfamiliar adverse event, Hypotonic Hyporesponsive Episodes (HHE) and a few deaths temporally associated with the administration of the newly introduced pentavalent vaccine.

Epidemiological Unit has carried out detailed investigations to ascertain the causality of all such deaths and HHE cases with the assistance of Regional Epidemiologists, Judicial Medical Officers and other experts.

In addition, the WHO, Head Quarters, Geneva appointed an international expert panel to examine and report whether the reported adverse events and deaths following administration of Pentavalent vaccine in Sri Lanka have occurred due to any safety issues related to the vaccine used.

Following a thorough investigation, it was the opinion of the international expert panel that there was no evidence to establish a causal relationship between Pentavalent (Quinvaxem®) vaccine and any of the deaths reported following its administration and also concluded that there is no increase in other AEFI including HHE following Pentavalent (Quinvaxem®) vaccine when compared to expected rates of AEFI

The National Advisory Committee on Adverse Events Following Immunization, which consists of key Paediatricians, Pharmacologists, Virolo-

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gists, Epidemiologists, Forensic Pathologists and other relevant officials after reviewing all available case reports and WHO expert panel report were in agreement with the WHO expert panel recommendations.

The committee as well as the WHO expert panel further noted that there were similar deaths temporally associated with other vaccines continued to be reported even after withdrawal of pentavalent vaccine. Hence it was the view of the committee that the deaths reported temporally associated with vaccination may be a part of post the neonatal mortality which were reported more due to the intensification of the AEFI surveillance system with the introduction of the new vaccine.

Accordingly the National Advisory Committee on Adverse Events Following Immunization recommended the reintroduction of the suspended Pentavalent (Quinvaxem®) vaccine into the national immunization programme.

The National Advisory committee on Communicable Diseases which met on 2<sup>nd</sup> march 2008, on scrutiny of the findings and recommendations of the National Advisory Committee on Adverse Events Following Immunization also recommended the reintroduction of the suspended Pentavalent (Quinvaxem®) vaccine into the national immunization programme

The committee further noted that a majority of the reported deaths were following the administration of first dose of pentavalent vaccine at two months with the pre-existence of certain risk conditions during the neonatal period.

Hence, the committee recommended that in future when immunizing children with the following risk conditions, adequate precautions be taken and as an interim measure where possible such children may be admitted to a suitable in-ward facility for immunization and kept under observation for 24 hours following immunization. Such conditions are;

- Prematurity less than 36 weeks of gestation and required to spend over one week in PBU
- Recent history of significant illness requiring over one week hospitalization e.g. neonatal sepsis, pneumonia etc
- Severe congenital anomalies which required prolonged hospitalization during neonatal period
- History of HHE to previous doses of pentavalent or any other pertussis containing vaccine

In addition please ensure adherence to the following directions on reintroduction:

- In addition to the precautionary conditions mentioned in my letter No. EPI/81/VII/2007 dated 15/10/2007, the above conditions also should be considered as where precautionary measures should be taken.
- All children should be screened for the presence of such conditions prior to immunization. Children receiving the first dose of pentavalent vaccine on completion of two months with such risk conditions may be admitted to a suitable in-ward facility for immunization and kept under observation for 24 hours following immunization.
- Hypotonic hyporesponsive episodes (HHE) following pentavalent or any other vaccine is not a contraindication for further immunization with the incriminated vaccine or any other vaccine used in the national immunization programme.
- The current turn of events in the history of national immunization programme highlights the importance of further strengthening of the AEFI surveillance system even encompassing private sector immunizations as well.
- To establish the causality during similar events in the future most crucial is the coordination to perform a thorough autopsy according to a standardized autopsy protocol when a death is reported temporally related to immunization. A departmental circular into this effect will be made available in due course.
- There will be no change in the dosage or schedule of the Pentavalent (DTP-HepB-Hib) vaccine which will be reintroduced into the immunization programme. Three doses of Pentavalent vaccine should be administered on completion of 2, 4, and 6 months of age. A dose of OPV also should be administered with the Pentavalent vaccine as practiced earlier. The standard dose of Pentavalent vaccine for infants and children is 0.5 ml IM given into the anterior lateral aspect of the mid thigh.
- All children presenting to the immunization clinics for 1<sup>st</sup>, 2<sup>nd</sup> or 3<sup>rd</sup> dose of DPT and Hepatitis B vaccines on or after 1<sup>st</sup> September 2009 will be eligible to receive the Pentavalent (DTP-HepB-Hib) vaccine.

Please note that instructions given in Epidemiologist's letter No. EPI/81/VII/2007 dated 15/10/2007 with regard to the introduction Pentavalent into the national immunization programme should be adhered in concurrence with instructions given in this letter.

More details is available at the Epidemiology Unit website http://www.epid.gov.lk/Immunization.htm

Table 1: Vaccine-preventable Diseases & AFP

07th - 13th November 2009 (46thWeek)

			No	o. of Cas	es by I	Provinc	e	Number of cases	Number of cases	Total	Total	Difference between the		
Disease	W C S N E		E	NW	IW NC U S		Sab	during current week in 2009	during same week in 2008	number of cases to date in 2009	number of cases to date in 2008	number of cases to date in 2009 & 2008		
Acute Flaccid Paralysis	00	00	00	01	00	00	00	01	00	02	01	66	88	25.0%
Diphtheria	00	00	00	00	00	00	00	00	00	00	00	00	01	-
Measles	00	00	00	00	00	00	01	00	00	01	03	164	105	+56.2%
Tetanus	01 GM=1	00	00	00	00	00	00	00	00	01	02	27	35	-22.8%
Whooping Cough	00	00	00	00	00	00	00	00	00	00	01	60	46	+30.4%
Tuberculosis	22	08	11	08	43	00	15	00	00	107	193	9119	7444	22.5%

Table 2: Newly Introduced Notifiable Disease

07th - 13th November 2009 (46thWeek)

			No	o. of Ca	ses by	Provinc	се							2166
Disease	W	С	S	N	E	NW	NC	U	Sab	Number of cases during current week in 2009	Number of cases during same week in 2008	Total number of cases to date in 2009	Total number of cases to date in 2008	Difference between the number of cases to date in 2009 & 2008
Chickenpox	15	07	12	07	07	09	03	02	05	67	72	13872	4874	+184.6%
Meningitis	16 CB=6 KT=4 GM=6	01 KN=1	08 GL=7 MT=1	02 VU=2	09 TR=3 KM=4 BT=2	11 KR=10 PU=1	08 AP=8	02 BD=1 MO=1	13 RP=12 KG=1	70	07	1433	1171	22.4%
Mumps	02	02	01	00	03	01	00	01	06	16	29	1599	2646	-39.5%
Leishmaniasis	00	00	02 MT=2	00	00	00	09 AP=9	00	00	11	Not available*	623	Not available*	-

## 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.

Table 4:Surveillance of Communicable diseases among IDP's 07th - 13th November 2009 (46thWeek)

Area Disease	Dysentery	Enteric fever	Viral Hepatitis	Chicken Pox	Watery Diar- rhoea
Vavunia	0	4	3	5	-
Chendikulam	7	4	2	64	192
Total	7	8	5	69	192

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

07th - 13th November 2009 (46thWeek)

DPDHS Division		Dengue Fe- ver / DHF*				Dysentery		Encephal itis		Enteric Fever		Food Poisoning		Leptospiros is		Typhus Fever		Viral Hepatitis		man bies	Returns Received Timely**
	Α	В	Α	В	Α	В	Α	В	Α	В	Α	В	Α	В	Α	В	Α	В	%		
Colombo	88	4038	5	223	0	12	12	212	0	88	22	1056	0	6	5	142	0	5	92		
Gampaha	56	3972	2	154	0	21	2	45	0	38	17	429	0	9	7	244	0	5	53		
Kalutara	22	1459	6	337	1	14	3	58	0	44	27	506	0	1	3	86	0	3	92		
Kandy	23	3928	15	289	0	8	1	30	0	59	5	206	1	157	0	131	0	1	84		
Matale	37	1839	4	134	0	4	1	31	0	26	1	315	0	5	0	87	0	2	92		
Nuwara Eliya	3	246	2	393	0	2	3	173	0	801	0	43	1	73	5	85	0	0	100		
Galle	15	594	2	234	0	10	0	4	0	111	6	202	0	15	0	29	0	6	95		
Hambantota	11	899	3	89	0	8	1	8	0	15	5	90	1	83	3	52	0	0	91		
Matara	10	1115	1	257	0	8	0	9	0	20	13	207	2	141	1	64	0	1	94		
Jaffna	5	47	2	122	0	3	8	274	0	30	0	0	0	125	1	183	1	4	71		
Kilinochchi	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
Mannar	1	6	0	99	0	1	0	115	0	23	0	0	1	1	1	69	0	0	100		
Vavuniya	43	222	0	1633	0	25	5	683	0	3	0	7	0	5	3	3769	0	0	75		
Mullaitivu	0	0	0	2	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0		
Batticaloa	3	560	2	276	1	14	0	17	0	56	0	10	0	5	0	23	0	5	82		
Ampara	1	225	6	94	0	1	0	12	0	8	0	14	0	2	51	90	0	0	100		
Trincomalee	0	328	0	156	0	4	0	13	0	3	0	20	0	19	0	54	0	1	80		
Kurunegala	23	2740	9	250	0	12	2	82	0	15	4	139	5	86	5	163	0	4	90		
Puttalam	4	615	8	161	0	7	1	72	0	11	1	91	0	31	0	44	0	1	89		
Anuradhapura	8	544	2	129	0	6	1	8	0	40	2	91	1	30	4	196	0	4	74		
Polonnaruwa	6	186	2	117	0	4	0	21	0	10	1	65	0	9	0	90	0	0	100		
Badulla	8	334	18	363	0	5	2	54	0	34	0	89	2	131	3	312	0	1	87		
Monaragala	3	163	1	146	0	2	0	23	2	36	0	15	0	62	1	92	0	2	82		
Ratnapura	10	2007	4	496	0	20	0	52	1	43	6	320	0	36	11	218	0	2	67		
Kegalle	11	3696	1	176	0	9	0	54	0	7	7	294	2	37	9	258	0	1	73		
Kalmunai	7	233	1	109	0	2	0	15	0	4	0	7	0	3	0	21	0	0	62		
SRI LANKA	398	29996	96	6439	02	202	42	2066	03	1525	117	4216	16	1072	113	6502	01	48	81		

Source: Weekly Returns of Communicable Diseases WRCD).

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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 Email to chepid@sltnet.lk.

## ON STATE SERVICE

<sup>\*</sup>Dengue Fever / DHF refers to Dengue Fever / Dengue Haemorrhagic Fever.

\*\*Timely refers to returns received on or before 13th November, 2009 Total number of reporting units =311. Number of reporting units data provided for the current week: 253

A = Cases reported during the current week. B = Cumulative cases for the year.