



# WEEKLY EPIDEMIOLOGICAL REPORT

A publication of the Epidemiology Unit  
Ministry of Health

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## Reconstitution of Vaccines

### Background

Some vaccines arrive at the point of use from the manufacturer as liquids and ready to administer. Others come as frozen powders (freeze-dried) and need to have liquid (diluent) added (reconstituted) before they can be injected.

First, for each vial the process requires a sterile syringe and sterile needle to mix the powder with the diluent. Second, vaccinators need training in the process of reconstitution so that human error is kept to a minimum.

Incorrect use of diluent may occur either because stock control or shipment errors have resulted in the wrong diluent being available. Or the vaccinator may select the wrong vial through poor training, or carelessness, compounded by incorrect storage procedures.

### Shipment and storage of freeze-dried vaccine

Freeze-dried vaccines can be shipped and stored at +2° to +8°C at Medical Officer of Health office. Ship vaccines and diluents together. The diluent must be shipped and distributed at the same time and in the same quantity as the vaccine vials. It does not need to be at the same temperature, but freezing of the diluent vials must be avoided so the vial does not crack. This ensures that the correct diluent will be available for the vaccine.

Diluent must be at the correct temperature (below 8°C) at the moment of reconstitution to avoid thermal shock to the vaccine. Therefore, diluents should be kept in the refrigerator at least for 24 hours before they are used.

### Diluents

The diluent supplied with a vaccine is part of the licensed product and is specific for each vaccine. The vaccine “package” is not complete without the diluent. Diluents are specifically designed for the needs of each vaccine with respect to volume, pH (acid-alkali balance)

### Key points

- Only diluent supplied by the manufacturer, specific for the vaccine, should be used.
- No other diluent should be used.
- Diluent must be shipped and distributed together with the vaccine vials that it will be used to reconstitute. This ensures that the correct diluent will be used for the vaccine.
- Before reconstitution, diluent must be cooled to a temperature below +8°C to avoid thermal shock to the vaccine.
- Reconstituted vaccines may become contaminated with staphylococcus and other organisms from improper handling. When this happens, a toxin is produced and it may be deadly if injected. To avoid this, reconstituted vaccines should be kept between 2-8°C and must be discarded 6 hours after reconstitution/ at the end of the vaccination session, whichever occurs first.

and chemical properties of the final solution containing the immunizing agent. Using the wrong diluent may also mean a different volume of diluent is used for each vial of vaccine, so resulting in incorrect doses. It is essential that diluents for vaccines are stored, distributed and used in the proper way so that they are not the cause of damaged vaccines, adverse events or incorrect doses.

All diluents are not just sterile water for injection and diluents vary in their composition. Diluents may contain:

- Stabilizers that affect heat lability
- Bactericides to maintain the sterility of the reconstituted vaccine
- Chemicals to assist in dissolving the vaccine into a liquid
- Buffers to ensure the correct pH

In the past, the practice of supplying, transporting and storing diluents separately from the vaccine has caused confusion, and resulted in shortage of the correct diluents in the field. Poorly labelled vaccines and diluents have compounded this, as has the lack of adequate training for health workers. WHO now

WEBER SRI LANKA - 2013

### Contents

### Page

1. <i>Leading Article – Reconstitution of Vaccines</i>	1
2. <i>Surveillance of vaccine preventable diseases &amp; AFP (10<sup>th</sup>– 16<sup>th</sup> August 2013)</i>	3
3. <i>Summary of newly introduced notifiable diseases (10<sup>th</sup>– 16<sup>th</sup> August 2013)</i>	3
4. <i>Summary of selected notifiable diseases reported (10<sup>th</sup>– 16<sup>th</sup> August 2013)</i>	4

recommends that vaccines and diluents be distributed together to avoid this confusion.

**Reconstitution process**

Only the diluent supplied by the manufacturer should be used to reconstitute a freeze-dried vaccine. A sterile needle and sterile syringe must be used for each vial for adding the diluent to the powder in a single vial or ampoule of freeze-dried vaccine. Special care must be taken in opening ampoules to avoid loss of the dry vaccine. Reconstitution should be carried out as recommended, away from direct sunlight and the vaccine stored in the foam pad of a vaccine carrier or on ice. This minimizes exposure of the reconstituted vaccine to harmful ultra-violet rays.

Reconstituted vaccine should be kept on ice to preserve its potency (by maintaining the maximum possible number of live organisms in each dose). The reconstituted vaccine must be kept cool and any remaining liquid must be discarded after 6 hours or at the end of the session (which ever comes first).

**Avoiding programme errors**

Reconstituted vaccine is an ideal environment for growing a number of organisms as they do not contain preservatives.

Once the vial is contaminated with staphylococcus or other organism from improper handling, the organism grows extremely fast. As it grows, it produces a toxin. If a contaminated vial is kept (even in the refrigerator), by morning there is enough toxin in the vial to kill an infant. A number of instances are recorded when several infants have been given the remains of the reconstituted measles vaccine from the previous day. They have died due to shock several hours later. This is called “toxic shock syndrome”. If toxic shock syndrome occurs, at least two programme errors have occurred together: non-sterile reconstitution/ injection technique, and failing to discard the vaccine after 6 hours.

The practice of separate distribution of diluents and vaccines can lead to severe problems. Major adverse reactions, including a number of deaths, have resulted from the practice of mixing diluents (i.e. using diluents meant for some other vaccine).

Potentially dangerous medications such as muscle relaxant and anaesthetic agents are sometimes kept inappropriately in the same refrigerator where vaccines are stored. These medications may be packed in vials or ampoules similar to vaccines or their diluents. They may be used by mistake for reconstitution of freeze-dried vaccines.

**Vaccinators and store keepers should always**

- Include diluents in stock control and ensure adequate supplies.
- Check that the vaccines have been supplied with the right diluent. If any error is noted, the vaccine should not be used and the superior officer must be notified immediately. Use only the diluent that is indicated for each type of vaccine and manufacturer.
- Ensure the volume of diluent used is correct so that the proper number of doses per vial is obtained.
- Ensure that no other medication or substance which might be confused with the vaccine or its diluent is stored in the refrigerator of the immunization centre

Source-Vaccines and Biologicals Update-available from <https://apps.who.int/vaccines-access/vacman/reconst/properhandlingeng.pdf>

Compiled by **Dr. Madhava Gunasekera** of the Epidemiology Unit

**Invasive Bacterial Disease surveillance in Sentinel Sites- 2<sup>nd</sup> quarter 2013**

No. of suspected meningitis cases	40
No. of probable meningitis cases	5
Percentage (%) of CSF samples tested positive for organisms	0%
No. of children who met the pneumonia case definition	165
Percentage (%) of Pneumonia cases with positive blood cultures	0%
No. of sepsis cases	12
Percentage (%) of Sepsis cases with positive blood cultures	0%
Source-LRH, Epidemiology Unit	

**Rota virus surveillance in Sentinel Sites – 2<sup>nd</sup> quarter 2013**

Number of acute diarrhoea hospitalizations in children <5 years	428
Number of stool specimen collected	156
Number of stool specimen tested positive for rotavirus	35
Percentage (%) of stool specimen tested positive for rotavirus	22 %
Source-MRI, Epidemiology Unit	

**Table 3 : Water Quality Surveillance  
Number of microbiological water samples - July / 2013**

District	MOH areas	No: Expected *	No: Received
Colombo	12	72	68
Gampaha	15	90	97
Kalutara	12	72	9
Kalutara NI	2	12	14
Kandy	23	138	37
Matale	12	72	19
Nuwara Eliya	13	78	6
Galle	19	114	NR
Matara	17	102	0
Hambantota	12	72	20
Jaffna	11	66	39
Kilinochchi	4	24	24
Manner	5	30	46
Vavuniya	4	24	26
Mullatvu	4	24	26
Batticaloa	14	84	11
Ampara	7	42	4
Trincomalee	11	66	16
Kurunegala	23	138	145
Puttalam	9	84	64
Anuradhapura	19	114	53
Polonnaruwa	7	42	8
Badulla	15	90	63
Moneragala	11	66	49
Rathnapura	18	108	24
Kegalle	11	66	29
Kalmunai	13	78	0

\* No of samples expected (6 / MOH area / Month)  
NR = Return not received

Table 4: Selected notifiable diseases reported by Medical Officers of Health 10<sup>th</sup> - 16<sup>th</sup> August (33<sup>rd</sup> Week)

RDHS	Dengue Fever		Dysentery		Encephaliti		E Fever		F Poisoning		Leptospiros		T Fever		V Hepatitis		H Rabies		Chickenpox		Meningitis		Leishmaniasis		WRCD %	
	A	B	A	B	A	B	A	B	A	B	A	B	A	B	A	B	A	B	A	B	A	B	A	B	T*	C**
Colombo	144	6375	4	144	1	14	4	99	0	36	1	146	0	6	0	57	1	1	1	283	3	36	0	0	69	31
Gampaha	69	2455	10	137	0	11	3	35	1	26	9	250	0	12	0	141	0	0	0	117	1	68	0	5	80	20
Kalutara	45	1206	3	121	0	17	3	60	1	14	6	270	0	2	1	17	0	0	0	193	2	52	0	0	69	31
Kandy	45	1289	1	101	0	7	1	16	0	7	1	55	3	85	4	69	0	0	0	94	0	10	0	2	78	22
Matale	14	339	4	73	0	4	1	18	0	3	0	49	0	4	1	33	0	0	0	36	2	28	0	6	77	23
NuwaraEliya	3	178	8	119	0	2	1	9	0	4	0	21	0	54	1	19	0	0	0	76	0	11	0	0	62	38
Galle	19	611	4	78	0	12	0	3	0	79	5	155	2	37	1	10	0	1	8	226	1	41	0	0	89	11
Hambantota	9	233	2	36	0	3	1	11	1	30	3	151	0	53	1	74	0	0	0	77	5	34	2	217	75	25
Matara	5	359	0	62	0	9	1	20	0	27	3	118	5	58	2	126	0	2	6	201	0	55	2	63	100	0
Jaffna	7	530	8	171	0	7	2	281	0	83	0	7	0	326	0	14	0	1	0	122	1	46	0	0	83	17
Kilinochchi	0	45	1	15	0	0	1	10	0	5	0	9	0	16	0	0	0	0	0	2	0	7	0	6	25	75
Mannar	0	57	0	35	0	1	0	57	0	14	0	11	0	18	0	2	0	0	0	11	0	4	0	1	100	0
Vavuniya	0	57	0	35	0	11	0	8	0	13	0	48	0	2	0	2	0	2	0	20	0	26	0	7	50	50
Mullaitivu	1	98	1	12	0	1	0	7	0	34	2	36	0	6	1	1	0	2	1	8	0	4	2	12	80	20
Batticaloa	2	460	2	205	0	4	0	3	0	14	0	29	0	2	0	10	0	3	2	31	0	7	0	0	57	43
Ampara	1	119	1	82	0	0	0	4	0	6	1	29	0	1	0	2	0	0	0	60	1	12	0	1	43	57
Trincomalee	1	168	1	49	0	3	0	5	0	1	0	57	3	10	0	3	0	1	0	32	0	4	0	26	58	42
Kurunegala	21	2274	1	123	2	29	2	32	0	21	8	219	1	28	2	40	0	1	5	271	0	89	1	35	81	19
Puttalam	16	717	1	52	0	4	0	15	0	35	0	27	0	12	0	4	0	0	0	62	1	21	0	7	38	62
Anuradhapura	7	399	1	68	0	13	0	3	0	30	1	287	0	18	1	17	0	1	3	129	1	81	13	276	63	37
Polonnaruwa	17	306	0	51	0	1	0	13	0	53	0	143	0	3	0	24	0	1	0	110	0	16	4	113	86	14
Badulla	9	368	7	132	0	3	2	14	0	8	3	43	2	61	3	39	0	0	0	90	0	51	0	4	65	35
Monaragala	4	176	0	83	1	4	0	19	0	20	1	183	2	39	1	68	0	1	0	39	1	19	0	9	64	36
Ratnapura	18	1408	4	278	0	80	0	34	0	16	7	261	6	45	6	233	0	1	1	119	1	60	0	8	78	22
Kegalle	49	839	2	93	0	11	1	19	0	8	0	139	1	63	1	163	0	0	8	232	1	86	0	0	91	9
Kalmune	0	481	8	119	0	2	0	3	6	96	1	7	0	2	0	4	0	0	0	65	0	8	0	1	54	46
<b>SRI LANKA</b>	<b>506</b>	<b>21547</b>	<b>74</b>	<b>2474</b>	<b>04</b>	<b>253</b>	<b>23</b>	<b>798</b>	<b>09</b>	<b>683</b>	<b>52</b>	<b>2750</b>	<b>25</b>	<b>963</b>	<b>26</b>	<b>1172</b>	<b>01</b>	<b>18</b>	<b>48</b>	<b>2706</b>	<b>21</b>	<b>876</b>	<b>24</b>	<b>799</b>	<b>72</b>	<b>28</b>

Source: Weekly Returns of Communicable Diseases (WRCD).

\*T= Timeliness refers to returns received on or before 16<sup>th</sup> August, 2013 Total number of reporting units 339, Number of reporting units data provided for the current week:243 C\*\* Completeness

A = Cases reported during the current week. B = Cumulative cases for the year.H Rabies\*= Human Rabies, E Fever\*=Enteric Fever, F Poison\*=Typhus Fever, V Hepatitis\*=Viral Hepatitis

**Table 1: Vaccine-Preventable Diseases & AFP**

10<sup>th</sup> – 16<sup>th</sup> August (33<sup>rd</sup> Week)

Disease	No. of Cases by Province									Number of cases during current week in 2013	Number of cases during same week in 2012	Total number of cases to date in 2013	Total number of cases to date in 2012	Difference between the number of cases to date in 2013 & 2012
	W	C	S	N	E	NW	NC	U	Sab					
AFP*	01	01	01	00	00	00	00	00	01	04	01	57	51	+ 11.5 %
Diphtheria	00	00	00	00	00	00	00	00	00	-	-	-	-	-
Mumps	03	02	04	02	04	02	06	02	02	27	77	1059	3107	- 65.9 %
Measles	30	08	37	00	06	01	03	03	53	141	01	2144	35	+ 6025.7 %
Rubella	00	00	00	00	00	00	00	00	00	00	-	21	-	-
CRS**	00	00	00	00	00	00	00	00	00	00	-	06	-	-
Tetanus	00	00	00	00	00	00	00	00	01	01	00	13	08	+ 62.5 %
Neonatal Tetanus	00	00	00	00	00	00	00	00	00	00	-	00	-	-
Japanese Encephalitis	00	00	00	00	00	00	00	00	00	00	-	64	-	-
Whooping Cough	01	00	00	00	00	00	00	00	01	10	01	57	60	+ 05.0 %
Tuberculosis	269	12	04	13	00	00	30	00	13	341	90	5547	5763	+ 03.7 %

**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.  
 RDHS 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, Neonatal Tetanus, Whooping Cough, Chickenpox, Meningitis, Mumps., Rubella, CRS,

**Special Surveillance:** AFP\* (Acute Flaccid Paralysis), Japanese Encephalitis

CRS\*\* =Congenital Rubella Syndrome

AFP and all clinically confirmed Vaccine Preventable Diseases except Tuberculosis and Mumps should be investigated by the MOH

**Dengue Prevention and Control Health Messages**

**Check the roof gutters regularly for water collection where dengue mosquitoes could breed.**

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**ON STATE SERVICE**

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