WEEKLY EPIDEMIOLOGICAL REPORT

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Ministry of Health

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Adverse Events Following Immunization (Part II)

This is the second in a series of two articles on Adverse Events Following Immunization (AEFI). The previous article was on the types of AEFI and this article is on the prevention of AEFI.

Prevention of vaccine reactions

Vaccines are very rarely contraindicated. However, it is important to check for contraindications to avoid serious reactions. For example, vaccines are contraindicated if there is;

- Serious allergy to the vaccine (anaphylaxis) or its components (excipients)
- Progressive neurological illness
- Immunodeficiency (in the case of live vaccines)

Immunization error–related reactions

"Immunization" as used here means the usage of a vaccine for the purpose of immunizing individuals. "Usage" includes all processes that occur after a vaccine product has left the manufacturing/ packaging site, i.e. handling, prescribing and administration of the vaccine.

Earlier, this AEFI type was categorised as "Programme errors" (Syn; Programmatic error or Programme operation errors) result from errors and mistakes in vaccine preparation, handling, or administration.

Immunization errors (previously classified as Programme errors) are preventable and controlled. They reduce the overall benefit of the immunization programme. Identification and correction of these errors are of great importance.

An immunization error (Programme error) may lead to a cluster of events associated with immunization. These clusters are usually associated with a particular provider or health facility or even a single vial of vaccine that has been inappropriately prepared or contaminated. Immunization errors can also affect a stock of vaccines (e.g. by freezing vaccines during transport leading to an increase in local reactions in recipients).

The most common Immunization errors reported in Sri Lanka are sterile abscesses and nodules due to incorrect technique used in vaccine administration. Infection resulting in non sterile injections was dominant before introducing Auto disable (AD) syringes in many parts of the world. Infection can manifest as a local reaction (e.g. suppuration, abscess), systemic effect (e.g. sepsis or toxic shock syndrome) or blood borne virus infection (e.g. HIV, Hepatitis B, or Hepatitis C). Immunization errors may also result in AEFIs when another chemical or drug, other than the intended vaccine or diluent, is inadvertently used in the reconstitution of freeze dried vaccines (e.g. muscle relaxant given instead of relevant diluent for measles vaccine) or administered directly in place of liquid vaccines. Immunization error can occur if wrong vaccine is administered to a person or a vaccine was given where it was not indicated (e.g. JE vaccine given instead of DPT vaccine). These also occur if the contraindications were ignored.

Also, need a clear understanding of contraindications and precautions. Precautions are not contraindications, but decision on vaccination requires a case base assessment. Use of vaccines in pregnancy is limited or mostly not recommended. The vaccines which are recommended in pregnancy would benefit and protect both mother and the newborn. However, the limited use of vaccine in pregnancy is largely due to the potential risk and harm to the foetus. The risk is mostly theoretical and limited to live attenuated vaccines which have demonstrated evidence of potential risk and harm, particularly in animal models. Vaccine manufacturers instruct pregnancy as a contraindication not due to proven evidence, but as a precautionary measure against litigation.

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Immunization errors (Programme errors) can be avoided by adhering to following:

- Vaccine must only be reconstituted with the diluent supplied by the manufacturer.
- Reconstituted vaccine should not be used for more than six hours after reconstitution.
- Reconstituted vaccine must be discarded at the end of each immunization session and never retained.
- No other drugs or substances should be stored in the same refrigerator where vaccines are stored.
- Immunization staff must be adequately trained and closely supervised to ensure that proper procedures are being followed.
- Careful epidemiological investigation of an AEFI is needed to ascertain the cause and to correct the wrong immunization practices

Coincidental Events

Children are usually given vaccines at an age when they are susceptible to many diseases. Thus, situations may arise when an adverse medical event is falsely attributed to the vaccine. In other words a chance temporal association (ie, an event occurs after immunization) is falsely considered to be caused by immunization.

These are purely temporal associations which are inevitable when large number of vaccine doses administered, especially in mass campaigns. Vaccines are normally scheduled early in life, when infections and other illnesses are common, including manifestations of an underlying congenital or neurological condition. It is therefore, possible for many events including deaths, to be falsely attributed to vaccine through chance association. For example, Sudden Infant Death Syndrome (SIDS or cot death) incidence peaks around the age of early childhood immunization. Many SIDS cases will be in children who have been recently immunized. Controlled studies have shown that the association of SIDS and immunization is purely coincidental and not causal. Knowledge of Infant mortality rates and rates of SIDS are helpful when investigating and in causality assessment to make valid conclusions and to rule out vaccine reactions.

Immunization anxiety-related reactions

Individuals and groups can react in anticipation to an injection of any kind. This reaction may mimic an AEFI but is unrelated to the content of the vaccine. Fainting is relatively common, but usually affects children aged over five years. Fainting does not require any management beyond placing the patient in recumbent position. Hyperventilation as a result of anxiety about immunization leads to specific symptoms (light headedness, dizziness, tingling around the mouth and in the hands).

Younger children tend to react in a different way with Vomiting, a common anxiety symptom. These reactions are not related to the vaccine, but to the injection. Some individuals may be needle-phobic, aggravating such reactions. In a group situation, mass hysteria is possible, especially if a vaccinee has fainted or has had some other reaction following vaccination.

Special Issues

Serious Events

Serious AEFIs are defined as those that are life threateningand those that result in hospitalization (or prolonged hospitalization), disability (orhave the potential to result in disability) or death. In addition, it is recommended that certain types of AEFI should be considered serious enough to warrant special attention in order to ensure immediate reporting when they are detected and there by rapid and prompt response is initiated, including investigation and proper case management. These include AEFIs that may have been caused by immunization errors and occurring in cluster (e.g. bacterial abscess, severe local reaction, high fever or sepsis, BCG lymphadenitis, toxic shock syndrome, HHE), serious events of unexplained aetiology occurring within 30 days after a vaccination and events causing significant parental or community concern.

Cluster of AEFI

A cluster is defined as two or more cases of the same or similar event, which are related in time and have occurred within the same geographical unit or associated with the same vaccine, same batch number administered or same vaccinator or which had occurred during the same clinic session. For example, two or more cases of abscess occurring following one immunization session in a village; repeated cases of abscess following immunization by same vaccinator or same batch of the vaccine will be considered as clusters.

Signals

Signals are defined as possible causal relationship of a reaction/ event following a vaccine to which had been previously unknown or incompletely documented. Only a systematic causality assessment based on information/data collected through research methods can detect signals and establish causal relationships. This is important with new vaccines, particularly if introduced in a mass vaccination approach.

E.g.; Narcolepsy following Pandemic H1NI influenza vaccine (Pandemrix)reported in Finland

Maintenance of AEFI Records and Registers

Recording of AEFI is mandatory and a separate column is available in the immunization record section in the Child Health Development Record (CHDR) to record any AEFI for previous immunizations. It is necessary to record all AEFI events, including 'nil' events following each antigen. It is expected, that both parts of CHDR contain the same information on AEFI. Maintaining accurate records of AEFI in both parts of CHDR is the responsibility of PHM. Details of any reported AEFI need to be recorded in Clinic AEFI Register (which is kept in the clinic) and/or in MOH Office AEFI Register (which is kept in the MOH office). On a monthly basis, all information recorded in the Clinic AEFI Register should be transferred to the MOH AEFI Register and Information coming from any other source should be documented in the MOH AEFI Register

Source

National Guidelines on Immunization Safety Surveillance, (published by the Epidemiology Unit of Sri Lanka) available from *http://www.epid.gov.lk/web/images/pdf/Publication/AEFI_Guidelines_Sri_lanka_2012.pdf*)

Table 1: Vaccine-preventable Diseases & AFP

27th October – 02nd November 2012 (44thWeek)

Disease	No. of Cases by Province									Number of cases during current week in 2012	Number of cases during same week in 2011	Total number of cases to date in 2012	Total number of cases to date in 2011	Difference between the number of cases to date in 2012 & 2011
	W	C	S	N	E	NW	NC	U	Sab					
Acute Flaccid Paralysis	00	00	00	00	00	00	00	00	00	00	01	67	76	- 13.2 %
Diphtheria	00	00	00	00	00	00	00	00	00	-		-		-
Measles	00	00	00	00	00	00	00	00	00	00	03	58	116	- 50.0 %
Tetanus	00	00	00	00	00	00	00	00	00	00	00	11	24	- 54.2 %
Whooping Cough	00	00	00	00	00	00	02	00	00	02	01	91	49	+ 85.7 %
Tuberculosis	20	12	01	06	09	21	15	02	00	86	201	7485	7996	- 06.4 %

Table 2: Newly Introduced Notifiable Disease

27th October – 02nd November 2012 (44thWeek)

Disease	No. of Cases by Province									Number of cases during current week in 2012	Number of cases during same week in 2011	Total number of cases to date in 2012	Total number of cases to date in 2011	Difference between the number of cases to date in 2012 & 2011
	W	C	S	N	E	NW	NC	U	Sab					
Chickenpox	06	09	24	01	03	09	02	01	07	62	48	3886	3676	+ 05.7 %
Meningitis	02 GM=1 KL=1	00	00	01 MN=1	00	00	03 AP=3	02 MO=2	00	08	19	708	753	- 06.0 %
Mumps	03	02	02	02	05	05	01	08	04	32	73	3992	2792	+ 43.0 %
Leishmaniasis	01 GM=1	06 ML=1	08 HB=6 MT=2	00	00	02 KN=2	05 AP=4 PO=1	00	02 RP=2	24	06	979	695	+ 40.7 %

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.

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.

Dengue Prevention and Control Health Messages

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

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

27th October – 02nd November 2012 (44thWeek)

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	45	8457	0	133	0	8	2	198	0	46	0	174	0	6	0	105	0	5	**8**
Gampaha	95	6842	0	76	0	15	0	56	0	43	9	250	0	21	5	294	0	0	**80**
Kalutara	42	2426	1	97	1	5	0	45	0	28	7	239	0	4	1	33	0	2	**85**
Kandy	50	2196	3	113	2	4	0	24	0	56	2	68	4	110	2	108	0	0	**100**
Matale	11	490	2	83	0	5	0	12	7	41	0	40	0	3	0	33	0	0	**83**
Nuwara	4	303	2	172	0	3	0	26	0	8	0	32	0	60	0	18	0	1	**85**
Galle	7	1381	0	116	0	6	1	16	0	17	1	112	1	65	1	4	0	0	**79**
Hambantota	18	533	0	41	0	3	1	8	0	30	1	68	0	53	2	23	0	0	**83**
Matara	39	1616	2	80	0	8	0	19	0	28	3	166	2	75	3	129	0	0	**100**
Jaffna	27	530	5	189	0	14	3	322	0	82	0	2	0	257	0		0	1	**92**
Kilinochchi	2	81	0	31	0	2	0	32	1	45	0	4	0	31	0	18	0	1	**50**
Mannar	3	135	0	70	0	4	3	49	0	17	0	23	0	42	0	4	0	0	**60**
Vavuniya	0	84	0	38	0	21	0	12	0	20	0	18	0	3	0	2	0	0	**75**
Mullaitivu	1	23	1	22	0	1	0	12	0	3	0	3	0	5	0	1	0	0	**80**
Batticaloa	4	638	11	252	0	3	0	16	0	307	0	8	0	0	0	1	0	4	**93**
Ampara	1	132	3	84	0	3	0	6	0	12	0	27	0	0	0	8	0	0	**71**
Trincomalee	4	139	17	203	0	2	0	16	2	15	0	38	0	18	0	3	0	0	**75**
Kurunegala	56	2483	2	184	0	16	3	93	2	40	2	137	1	32	2	4	0	4	**77**
Puttalam	31	1314	0	90	0	8	0	12	0	12	1	40	0	16	0	130	0	2	**58**
Anuradhapu	2	342	1	81	0	7	0	13	0	21	0	78	0	23	0	6	0	1	**74**
Polonnaruw	3	225	2	69	0	2	0	4	0	121	0	49	0	3	1	58	0	1	**57**
Badulla	7	333	3	113	0	4	0	50	0	3	0	36	3	113	0	41	0	0	**76**
Monaragala	3	240	0	59	0	6	0	26	2	9	0	64	0	77	0	43	0	2	**82**
Ratnapura	45	3553	1	235	0	25	0	48	0	12	1	276	0	39	0	169	0	2	**61**
Kegalle	25	2411	1	56	0	9	0	25	3	14	3	161	0	61	7	113	0	0	**91**
Kalmune	1	196	4	258	0	2	1	8	0	89	0	9	0	1	0	540	0	3	**46**
SRI LANKA	**526**	**37103**	**61**	**2945**	**03**	**186**	**14**	**1148**	**17**	**1119**	**30**	**2122**	**11**	**1118**	**24**	**10**	**00**	**29**	**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 02nd November , 2012 Total number of reporting units 329. Number of reporting units data provided for the current week: 254
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.**

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