WEEKLY EPIDEMIOLOGICAL REPORT

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Adverse Events Following Immunization (Part I)

This is the first in a series of two articles on Adverse Events Following Immunization (AEFI). This article is on the types of AEFI and the next article will focus on prevention of AEFI.

Background

Vaccines used in national immunization programmes are extremely safe and effective. But, no vaccine is perfectly safe and adverse events can occur following immunization. In addition to the vaccines themselves, the process of immunizationis a potential source of adverse events. Surveillance of AEFIs is an effective means of monitoring immunization safety and contributes to the credibility of the immunization programme. It allows for proper management of AEFIs and avoids inappropriate responses to reports of AEFIs that can create a sense of crisis in the absence of immunization safety surveillance.

Irrespective of the cause, when AEFI occur, confusion is created among people to the extent that they may refuse further immunizations for their children leaving them susceptible to vaccine preventable diseases which are more disabling and life threatening. Therefore, surveillance of AEFI provides information to help plan on regaining public confidence on immunization. Timely response to public concerns about safety of vaccines as well as prompt communication will protect the public and preserve the integrity of the immunization programme as well.

Adverse Events Following Immunization

The goal of immunization is to protect the individual and the public from vaccine preventable diseases. Although modern vaccines are safe, no vaccine is entirely without risk. Some people experience adverse events following immunization (AEFI) ranging from mild side effects to life-threatening but rare, illnesses. In the majority of cases these events are mere coincidences. In others, they are caused by the vaccine or due an error in the administration of vaccine or sometimes, there is no causal relationship at all.

An adverse event following immunization (AEFI) is any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine. The adverse event may be any unfavorable or unintended sign, abnormal laboratory finding, symptom or disease.

Reported adverse events can either be true adverse events, i.e. really a result of the vaccine or immunization process or coincidental events that are not due to the vaccine or immunization process , but are associated with immunization by chance. Earlier AEFIs were classified into five categories

In 2012, Council for International Organizations of Medical Sciences (CIOMS) / WHO revised this classification concerning particularly cause-specific categorization of AEFIs and a new categorization has been introduced. (Table 1)

Vaccine Reaction

A vaccine reaction is an individual's response to the inherent properties of the vaccine, even when the vaccine has been prepared, handled and administered correctly. The new cause-specific categorization is important for decision making on a vaccine product, as it clearly differentiates the two types of possible vaccine reactions.

(i) Vaccine product related reaction; a vaccine reaction is an individual's response to the inherent properties of the vaccine, even when the vaccine has been prepared, handled and administered correctly and

(ii) Vaccine quality defect-related reaction; which is important to note that vaccine quality defect during manufacturing process has an impact on individuals response and there by increased risk of adverse vaccine reactions. (Details areavailable on the "Report of CIOMS/WHO Working Group on Vaccine Pharmacovigilance, 2012).

Vaccine reactions may be classified into common, minor reactions and rare, more serious reactions. Most vaccine reactions are minor and settle on their own. More serious reactions are very rare and in general do not result in long term problems.

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Common, minor vaccine reactions

The purpose of a vaccine is to induce immunity by causing the recipient's immune system to react to the vaccine. A quality and safe vaccine reduces these reactions to a minimum while producing the best possible immunity. The proportion of reaction occurrences likely to be expected and observed with the most commonly used vaccines. (Refer Table 2) In addition, some of the vaccine components, excipients (e.g. aluminium adjuvant, stabilizers or preservatives) can also lead to the vaccine reactions.

Fever can result as part of the immune response. Fever shall be anticipated in nearly 10% of vaccinees, except with DPT which produce fever in nearly 50% of those vaccinated. Fever is a systemic reaction that usually occur within 24-48 hours of immunization except for those produced by measles, mumps and rubella vaccines which may occurs 6 to 12 days after immunization. However, it continues only for 24 – 48 hours.

Local reactions include pain, swelling and/or redness at the injection site and can be expected in about 10% of vaccinees. BCG causes a specific local reaction which starts as a papule (lump) 2-4 weeks after immunization and may get ulcerated and healed after several months, leaving a scar. Keloid (thickened scar tissue) from the BCG lesion is more common among Asian and African populations.

Systemic reactions: Common systemic reactions are irritability, malaise and loss of appetite. These systemic reactions are relatively common following DPwT vaccination. For measles/MMR and OPV vaccines, systemic reactions arise from vaccine virus infection. Measles vaccine may cause fever, rash, and/or conjunctivitis. It is very mild compared to "wild" measles virus, but for severely immuno—compromised individuals, it can be severe, and may be even fatal. Vaccine reactions for Mumps (parotitis ; swollen parotid gland) and Rubella (joint pains and swollen cervical lymph nodes) minimally affect the vaccinnees.

Rare serious vaccine reactions

It is important to note that there is a difference between the terms "serious" and "severe" adverse events or reactions."Serious" and 'severe' are often used as interch--angeable terms but they are not. A serious adverse event or reaction is a regulatory term. "Severe" is used to describe the intensity of a specific event (as in mild, moderate or severe); the event itself, however, may be of relatively minor medical significance. (e.g Fever is a common relatively minor medical event, but according to its severity it can be graded as mild fever or moderate fever. Anaphylaxis is always serious event and life threatening.)

As defined by the Uppsala Monitoring Centre (UMC), a serious adverse event or reaction is any untoward medical occurrence following any dose of vaccine that

- Results in death
- Requires hospitalization or prolongation of hospital stay
- Results in persistent or significant disability/ incapacity is life-threatening

Most of the rare and more serious vaccine reactions [e.g seizures, thrombocytopaenia, hypotonic hyporesponsive episodes (HHE), persistent inconsolable screaming] do not lead to long term problems. Anaphylaxis, while potentially fatal, is treatable without having any long term effects. Although encephalopathy is included as a rare reaction to measles or DPT vaccine, it is not certain whether these vaccines infact cause encephalopathy

Source

National Guidelines on Immunization Safety Surveillance, (published by the Epidemiology Unit of Sri Lanka)

available from http:// ww.epid.gov.lk/web/ images/ pdf/Publication/

Table 1: Cause –specific categorization of adverse events following immunization (CIOMS/WHO, 2012)

Cause specific Type of AEFI	Definition
Vaccine product-related reaction	An AEFI that is caused or precipitated by a vaccine due to one or more of the inherent properties of the vaccine product.
Vaccine quality defect-related reaction	An AEFI that is caused or precipitated by a vaccine that is due to one or more quality defects of the vaccine product including its administration device as provided by themanufacturer.
Immunization error-related reaction	An AEFI that is caused by inappropriate vaccine handling, prescribing or administration and thus by its nature is preventable.
Coincidental event	An AEFI caused by something other than the vaccine product, immunization error or immunization anxiety
Immunization anxiety-related reaction	An AEFI arising from anxiety about the immunization.

Note: "Immunization" as used in these definitions 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

Table 2: Frequency of common minor adverse reaction

Vaccine	Local Effects(pain, swelling, redness)	Fever (> 38^0 C)	Irritability, malaise and systemic symptoms
BCG	Common 90%-95%		
Hepatitis B	Adults up to 30% Children up to 5%	1 – 6%	
Hib	5%-15%	2%-10%	
Pertussis (DTP–whole cell)	up to 50%	up to 50%	up to 55%
Measles/MR/MMR	~ 10%	5%-15%	5% (Rash)
Tetanus/DT/aTd*	~10%	~ 10%	~ 25%
OPV	None	Less than 1%	Less than 1%

**Rate of local reactions is likely to increase with booster doses, up to 50 -85%.*

to be continued

Table 1: Vaccine-preventable Diseases & AFP

20th – 26th October 2012 (43rd Week)

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	01	00	00	00	00	00	00	00	01	02	00	67	75	- 10.7 %
Diphtheria	00	00	00	00	00	00	00	00	00	-	-	-	-	-
Measles	00	00	02	00	00	01	01	00	00	04	01	57	114	- 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	00	00	00	00	02	89	48	+ 85.4 %
Tuberculosis	17	25	07	16	08	05	09	01	08	249	268	7399	7795	- 05.1 %

Table 2: Newly Introduced Notifiable Disease

20th – 26th October 2012 (43rd Week)

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	07	07	29	00	01	04	08	02	06	64	75	3811	3628	+ 05.0 %
Meningitis	07 CB=2 KL=2 GM=3	00	03 MT=2 GL=1	00	00	01 KN=1	00	01 BD=1	00	12	08	698	734	- 04.9 %
Mumps	06	06	06	02	04	02	01	00	00	27	76	3941	2719	+ 44.9 %
Leishmaniasis	00	01 ML=1	04 HB=2 MT=2	00	00	00	04 AP=4	00	00	09	14	949	689	+ 37.7 %

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

You have a duty and a responsibility in preventing dengue fever. Make sure that your environment is free from water collections where the dengue mosquito could breed.

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

20th – 26th October 2012 (43rd 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	55	8351	2	133	0	8	2	196	0	46	1	174	1	6	2	105	0	5	**31**
Gampaha	139	6719	2	76	0	15	0	56	1	42	11	237	0	21	8	287	0	0	**80**
Kalutara	8	2375	0	94	0	4	1	45	0	28	0	232	0	4	0	32	0	2	**54**
Kandy	36	2136	3	110	0	2	1	23	0	56	2	66	0	106	4	101	0	0	**74**
Matale	2	473	1	81	0	5	0	12	2	34	1	40	0	3	0	33	0	0	**67**
Nuwara	2	298	1	166	0	3	0	26	0	8	0	32	0	60	0	18	0	1	**54**
Galle	9	1370	1	115	0	6	0	15	0	17	0	110	0	64	0	3	0	0	**74**
Hambantota	6	513	2	41	0	3	0	7	0	30	0	67	0	52	0	21	0	0	**67**
Matara	56	1577	3	78	0	8	0	19	0	28	2	163	3	73	1	126	0	0	**100**
Jaffna	17	486	7	181	0	14	1	319	0	82	0	2	0	257	0	18	0	1	**42**
Kilinochchi	0	78	1	28	0	2	0	32	0	43	0	4	0	30	0	4	0	1	**25**
Mannar	1	128	0	69	0	4	4	46	0	17	0	23	0	42	0	2	0	0	**40**
Vavuniya	3	84	3	38	0	21	0	12	0	20	0	18	0	3	0	1	0	0	**75**
Mullaitivu	0	22	1	21	0	1	0	12	0	3	0	3	0	5	0	1	0	0	**40**
Batticaloa	4	631	4	238	0	3	0	16	0	307	0	8	0	0	0	8	0	4	**57**
Ampara	0	130	0	80	0	3	0	6	0	12	0	27	0	0	0	3	0	0	**0**
Trincomalee	1	135	5	186	0	2	0	16	0	13	1	38	0	18	0	4	0	0	**75**
Kurunegala	37	2422	4	182	0	16	1	90	0	38	2	135	0	31	0	128	0	4	**73**
Puttalam	36	1282	1	88	0	8	0	12	2	12	1	39	0	16	0	6	0	2	**58**
Anuradhapu	4	337	3	78	0	7	0	13	0	21	0	78	0	23	0	57	0	1	**42**
Polonnaruw	1	221	0	67	0	2	0	4	0	121	0	49	0	3	0	40	0	1	**43**
Badulla	3	325	2	110	0	4	0	50	0	3	0	36	1	110	1	43	0	0	**71**
Monaragala	4	237	0	58	0	6	0	24	0	7	2	64	0	76	0	169	0	2	**36**
Ratnapura	12	3474	10	224	0	25	0	48	0	12	2	275	0	39	0	113	0	2	**39**
Kegalle	33	2384	1	55	0	9	1	25	1	11	2	158	2	61	7	533	0	0	**91**
Kalmune	0	187	1	250	0	2	0	7	0	87	0	9	0	1	0	10	0	3	**23**
SRI LANKA	**469**	**36375**	**58**	**2847**	**00**	**183**	**11**	**1131**	**06**	**1098**	**27**	**2087**	**07**	**1104**	**23**	**1866**	**00**	**29**	**59**

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 26th October , 2012 Total number of reporting units 329. Number of reporting units data provided for the current week: 267
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

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