

WEEKLY EPIDEMIOLOGICAL REPORT

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AEFI Surveillance: Data analysis

All Medicines are rarely cause side effects or adverse reaction. Compared to the other pharmaceuticals, vaccine adverse reactions are rare.

Vaccines associated with risk of adverse reactions; commonly for minor and rarely for serious adverse reactions. All vaccines go through the process of testing for safety during pre licensure (clinical trails). National regulatory authorities (NRA) and World Health Organization (WHO) closely review good manufacturing process (GMP) including all the pre clinical safety data before the registration and pre-qualification for each vaccine. But yet, close monitoring for adverse reactions particularly in post licensure period is important and necessary, since not all adverse reaction are identified during the clinical trials.

Adverse reactions of vaccines are mainly

- ☑ Vaccination reaction.
- ✓ Programme errors
- ☑ Coincidental
- ☑ Injection reaction

Vaccine reaction: Due to the inherent properties of vaccine there may be minor (commonly) and severe (rarely) vaccine reaction. It may be also either local or systemic reaction.

Programme error: Mainly due to improper handling, preparation and administration errors of vaccination. Training and supportive supervision of health care workers will minimize them.

Coincidental: Events that happen after immu-

nization, but vaccine has no causative link to the event. With good awareness and an improved surveillance system, there is a strong possibility of increased number of coincidental reports. This is the challenge, particularly with severe reactions including deaths reported following vaccination. Only a proper investigation supported by good causality assessment including, clinical, laboratory, autopsy (in case of a death) and epidemiological analysis will identify the cause.

Injection reaction: Anxiety, pain or injection itself may cause this.

Surveillance of Adverse Events Following Immunization (AEFI) in Sri Lanka started in 1996 in a phased basis and gradually improved during past 15 years covering the entire country.

Components of AEFI surveillance

- ☑ Detection and reporting of AEFI
- ☑ Investigation
- ✓ Data analysis
- ☑ Corrective action

This WER report is focused on analysis of reported AEFI data at different levels of programme implementation. Analysis at both district and divisional level is important and Regional Epidemiologists and MOOH are responsible for data analysis at each level.

In analyzing data MOH plays an important part as it is the first operational level of best use of surveillance data. All reports should be analyzed to identify the type of AEFI, particularly the programe errors. This is largely to

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carry out corrective action in a timely manner. Before the analysis, MOH needs to verify and reassure the data for accuracy.

First, all reported AEFI data need to be line listed and followed by tabulating by place (PHM/PHI divisions), person and time. Secondly do analysis by antigens by type of reported adverse events (high fever, abscess). Number of doses administered for each antigen is the denominator for calculating reported AEFI rates for each antigen in a given time period (by month, quarter or year). Thirdly, analysis shall expand to the AEFI rates by first or second or third dose, when the antigen is administered more than once. For this, the number of doses administered for the given antigen by first, second or third need to be used as the denominator.

Regional Epidemiologist also need to perform the same analysis for the district. Analysis by MOH area will help to identify issues and may focus corrective action.

Available background rates for each type of AEFI for a given antigen give a guide to make a decision on act to reported AEFIs. (background rates are available in National Immunization handbook, published by the Epidemiology Unit and WHO references)

Tables 1 and 2 shows how to calculate AEFI rates by different antigens, by different doses for given adverse events by country and a selected MOH area during 2010.

Case definition & Interpretation of Data

Before any conclusion and thereby any action it is recommended to be cautious with interpretation of data. Following is an example; High fever is a known AEFI for many antigens. However, when reporting 'High Fever', what does it mean? The case definition given for high fever in AEFI surveillance system in Sri Lanka is fever >39°C. Background rates given for high fever in medical literature is varied by the different level temperature (eg; 38.5°c, 39°C or 40°c). This shows the complexity, even for a simple case definition of fever and reporting variation.

Less attention to the 'case definition' of reported AEFI is a weak point in our surveillance system. It has been observed that during reporting of AEFI, MOH staff have given less attention into the AEFI case definitions. This has led to either over reporting or under reporting of AEFI. Therefore, comparison of reported AEFI at MOH or district level with background rates need a caution.

Training and awareness of field staff on case definitions of reportable AEFI will enhance quality of AEFI surveillance. Working cases definition for most of reportable AEFI are given in "Monthly surveillance report on Adverse Events Following Immunization" (AEFI form 2). In addition, more detailed case definitions for most of AEFIs have been developed by the Brighton Collaboration and are available at www.brightoncolaboration.org

Table 1: Reported selected adverse events by antigen in Sri Lanka -2010

Antigen	Number of doses administered	Fever (>39°C)	Fever rates /1000 doses administered	Allergic reactions	Allergic reactions rates /1000 doses administered	Abscess	Abscess rates /1000 doses adminis- tered
DPT	459,892	734	734/459,892 X1000 =1.6	373	373/459,892 X1000 =0.8	215	215/459,892 X1000 =0.46
Penta	891,472	740	740/891,472 X1000 =0.8	240	240/891,472 X1000 =0.26	77	77/891,472 X1000 =0.08
Measles	344,235	54	54/344,235 X1000 =0.15	287	287/344,235 X1000 =0.8	9	9/344,235 X1000 =0.03

Table 2: Calculating adverse events rates by antigen in a defined MOH area in a define time period

Antigen	Number of doses administered	Fever (>39°C)	Fever rates /1000 doses administered	Abscess	Abscess rates /1000 doses administered
Penta 1	1681	1	1/1681x1000 =0.59	1	
Penta 2	1703	4	$4/1703 \times 1000 \\ = 2.35$	0	$0/1703 \times 1000$ = 0
Penta 3	1637	2	$ \begin{array}{r} 2/1637 \times 1000 \\ $	0	$0/1637 \times 1000$ = 0
Penta	5021	7	7/5021x1000 =1.39	1	1/5021x1000 = 0.19

Sources: www.epid.gov.lk, www.who.int,whqlibdoc.who.int

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Table 1: Vaccine-preventable Diseases & AFP

02nd - 08th April 2011(14th Week)

Disease			ı	No. of Cas	ses by P	rovince		Number of cases during current	Number of cases during same	Total number of cases to date in	Total num- ber of cases to date in	Difference between the number of cases to date		
	W	С	S	N	E	NW	NC	U	Sab	week in 2011	week in 2010	2011	2010	in 2011 & 2010
Acute Flaccid Paralysis	00	00	00	00	00	00	00	00	00	00	02	24	29	- 17.2 %
Diphtheria	00	00	00	00	00	00	00	00	00	00	00	00	00	-
Measles	00	02	02	00	00	00	00	00	00	04	01	32	30	+ 6.7 %
Tetanus	00	00	00	00	00	00	00	00	00	00	00	06	07	14.3 %
Whooping Cough	0	00	00	00	01	00	00	00	00	01	00	12	05	+ 140.0 %
Tuberculosis	124	02	13	20	04	16	00	10	02	191	117	2243	2467	- 9.1 %

Table 2: Newly Introduced Notifiable Disease

02nd - 08th April 2011(14th Week)

Disease			ı	No. of Ca	ases by	Province	e	Number of	Number of		Total num-	Difference between the			
	W	С	S	N	E	NW	NC	U	Sab	cases during current week in 2011	cases during same week in 2010	number of cases to date in 2011	ber of cases to date in 2010	number of cases to date in 2011 & 2010	
Chickenpox	13	02	10	05	03	05	08	05	11	62	29	1430	1085	+ 31.8 %	
Meningitis	02 GM=1 CB=1	01 ML=1	02 GL=1 HB=1	00	00	05 KN=5	00	00	00	10	03	278	401	- 30.6 %	
Mumps	04	05	04	02	00	07	01	02	02	27	01	568	217	+ 161.7 %	
Leishmaniasis	00	00	06 MT=6	00	00	02 KN=2	07 AP=3 PO=4	00	00	15	00	204	96	+ 112.5 %	

Key to Table 1 & 2

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

02nd - 08th April 2011(14th Week)

DPDHS Division		ngue · / DHF*	Dyse	entery	-	phaliti s		teric ever	Food Poisoning		Leptospiros is		Typhus Fever			ral atitis		man bies	Returns Received Timely**
	Α	В	Α	В	Α	В	Α	В	Α	В	Α	В	Α	В	Α	В	Α	В	%
Colombo	54	1207	1	67	0	2	3	56	1	7	9	125	0	4	0	15	0	1	54
Gampaha	25	427	2	36	0	6	0	17	0	8	15	234	0	11	3	28	0	2	47
Kalutara	11	193	1	48	0	2	1	24	2	10	5	78	0	0	0	3	0	0	25
Kandy	0	98	3	124	0	4	0	11	0	23	1	40	0	32	0	18	0	0	52
Matale	3	49	1	44	0	2	0	9	0	3	3	60	0	6	0	4	0	0	67
Nuwara	5	30	11	91	0	1	0	13	0	12	1	17	1	27	2	5	0	0	69
Galle	4	69	1	27	0	2	0	2	0	5	6	43	0	13	0	7	0	0	53
Hambantota	6	62	2	14	0	3	0	1	0	7	20	189	0	20	0	0	0	0	42
Matara	13	87	1	21	0	1	0	5	0	1	7	124	1	22	3	8	0	1	41
Jaffna	2	124	0	52	0	2	0	96	0	10	0	2	3	153	0	12	0	2	18
Kilinochchi	0	19	0	5	0	2	0	5	0	1	0	1	0	4	0	1	0	0	0
Mannar	1	17	0	5	0	0	0	7	0	0	0	11	0	27	0	1	0	0	60
Vavuniya	0	34	1	12	1	9	0	5	0	3	0	31	0	2	0	0	0	0	75
Mullaitivu	0	5	0	19	0	1	0	1	0	0	0	3	0	1	0	1	0	0	0
Batticaloa	11	209	14	146	0	3	0	3	0	8	0	10	0	0	0	1	0	1	7
Ampara	3	26	0	35	0	0	0	7	0	20	3	40	0	0	0	4	0	0	0
Trincomalee	1	50	4	170	0	0	0	1	0	5	2	51	0	1	0	3	0	0	9
Kurunegala	12	162	6	88	0	5	2	40	2	26	24	1023	4	36	0	12	0	0	39
Puttalam	3	192	1	62	0	0	0	6	0	1	5	53	0	6	0	2	0	1	11
Anuradhapu	5	59	0	35	0	1	0	2	0	8	5	177	1	12	0	4	0	0	26
Polonnaruw	3	78	0	19	0	1	0	4	0	8	4	51	1	1	0	4	0	0	14
Badulla	3	63	5	44	0	3	1	18	0	3	2	22	1	10	0	16	0	0	27
Monaragala	7	67	0	21	0	1	0	13	0	4	24	79	3	30	3	26	0	0	27
Ratnapura	6	142	6	143	0	3	0	11	0	5	2	136	0	16	0	17	0	0	0
Kegalle	6	80	0	33	1	7	0	20	1	8	3	102	0	8	2	28	0	0	9
Kalmunai	0	10	10	129	0	0	0	2	0	3	0	3	0	2	1	2	0	0	23
SRI LANKA	184	3559	70	1490	02	61	07	379	06	189	141	2705	15	444	14	222	00	08	33

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 E-mail to **chepid@sltnet.lk**.

ON STATE SERVICE

^{*}Dengue Fever / DHF refers to Dengue Fever / Dengue Haemorrhagic Fever.

^{**}Timely refers to returns received on or before 08th April, 2011 Total number of reporting units =320. Number of reporting units data provided for the current week: 105

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