



WEEKLY EPIDEMIOLOGICAL REPORT

A publication of the Epidemiology Unit
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AEFI in Sri Lanka: is it real or a perceived risk? (part 2)

According to AEFI rates in 2008, all Sri Lankan figures were well below the expected AEFI rates of the WHO. Nevertheless, in interpretation of this data, it is necessary to bear in mind that the AEFI reporting rate is not 100% due to various reasons.

Are all AEFI caused by the vaccines ?

When an AEFI is reported, one decision that the EPI managers have to make is if the reported event has been caused by the vaccine or not. Usually a temporal association is ascertained between the vaccination and the development of a medical event. Naturally, it tends to be attributable to the vaccine. However, It is really not so in many instances. These events could be due to many other factors coinciding with the vaccination. For example, a child may be incubating a viral infection at the time of receiving a dose of vaccine and the health care worker, the parents or caretakers see an apparently normal child. Onset of fever due to the incubating infection is naturally attributed to the vaccine which was given a few hours before the onset of fever. Therefore, the causality assessment is important to assign the likelihood of the event to the incriminated vaccine. This causal association of the AEFI and the vaccine should be established after a thorough investigation with the involvement of relevant stakeholders. However, It is not cost effective to conduct detailed analysis of each and every AEFI for causality assessment. Therefore, the most feasible option for the National Programme of Immunization is routine collection of all data on events following vaccination procedure through the AEFI notification system. As a means to ensure cost effectiveness, detailed investigations are being carried out in serious events only. Therefore, the limitation of such a move is that AEFI figures reported through the national AEFI surveillance system represent various temporally associated events with the vaccination rather than those events caused by the vaccine itself.

Are there vaccines without risk ?

All manmade medicines including vaccines contain many chemical substances. These chemicals are quite capable of giving rise to unwanted side effects at anytime. Therefore, like many medicines, the currently available vaccines are not 100% risk free.

What harm can this perceived, increased risk of AEFI inflict on the vaccination program ?

No parent wants to see their healthy children being ill after vaccination especially with severe events like vaccine derived poliomyelitis, anaphylaxis and death. Therefore the fear of untoward events due to vaccination can create a situation where children will be kept away from age appropriate EPI vaccines by their parents. This situation gives rise to an opportunity to pool a non vaccinated cohort of children with increased vulnerability to the disease. If this non immune cohort is exposed to the pathogen, on set of an outbreak of the disease will be imminent as has been demonstrated in many countries.

Are we ready to react timely to an AEFI ?

One hundred and twenty years have passed since the enactment of the Ordinance of quarantine and prevention of diseases in Sri Lanka in 1886 parallel to the vaccination of smallpox. Vaccination clinics are conducted in each and every village in Sri Lanka. Continuity of the function of these clinics was not disturbed in the war affected north and eastern provinces of the country even with the ongoing war. These clinics are conducted with minimal resources in order to achieving the highest vaccination coverage. But with the present concern with AEFI and its management Epidemiology Unit with the help of Family Health Bureau, College of Paediatricians, College of Anaesthesiologists is in the process of upgrading the basic emergency care at the field level, screening and referral process of the child prior to vaccination as a means of ensuring safety of the vaccine recipient.

Is there any difference of quality of products used for vaccination in the private and government sectors and the programme ?

Service provision in the private sector is based on a fee and usually focuses on individuals. Its main concern is institutional profit margin obtainable by providing the service that an individual seeks for a fee in contrast to the social responsibility of public institutions. On the other hand, the government sector has to cater to all the people in the country in line with the national health and other government policies. Since the government policy is to provide services free of charge, the tax payer has to bear the cost of vaccination unless international or local external donor support is provided. Another obligation of national Program managers of immunization

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is to concentrate on the provision of the best available vaccines with high quality. However, there is a trade off of quality vs cost to a certain degree. The best example would be the DTP whole cell vaccine use in the government sector. The probability of the onset of fever as an AEFI due to this vaccine is 50% and can be managed effectively with paracetamol within the home setting. The other available vaccine is acellular DTP used in the private sector. The probability of onset of fever as an AEFI due to this was very much less than that due to the DTP whole cell vaccine. If one were to compare the prices of the two vaccines per dose government spends Rupees 513/- (pentavalent form) per dose while private sector spends Rupees 3600/- (hexavalent form) per dose.

An area where the government sector is in the fore front is the cold chain maintenance. Vaccine quality, more or less, depends on the temperature they are exposed to. Exposure to higher or lower temperatures than the recommended range by the manufacturer detrimentally lowers the efficacy of the vaccine. Government sector has a well established and supervised cold chain monitoring system to ensure that the recommended range of temperature by manufacturer is maintained from production until up to the administration of the vaccine to recipients in the field. Can any private vaccine marketing company give a 100% assurance that the cold chain is maintained effectively for their products till it reaches the vaccine recipients as in the government sector?

The liquid vaccines which can be administered directly to the recipients without reconstituting are technologically more advanced than the lyophilized vaccines which are to be reconstituted before the administration giving more chance for contamination. Thus, recipients accrue additional benefits by the practice of the government sector using more liquid vaccines than the lyophilized vaccines.

The other advantage of the immunization program in the public sector is that it is designed as a control measure to suit the vaccine preventable diseases relevant to the country. The approach of the national immunization programme is population based. In contrast to this, the private sector does not have any organized immunization program to suit the diseases relevant to the major health problems of the country. It is basically driven on profit basis and conducted in an ad hoc manner. On the other hand, it is not based on any scientific evidence. Nor does it grant any community welfare.

The other unique feature of the national immunization program is the AEFI reporting system. Government sector has a well established system to monitor AEFI. Such an infrastructure does not exist in the private sector. The very same reason makes the national programme of immunization vulnerable to unfounded criticism in an event of AEFI while non availability of information on AEFI in the private sector unreasonably places them non vulnerable to criticism. While many accusations are hurled at and drastic improvements are introduced to the National program of immunization, No individual or organization is concerned about non existence of an AEFI reporting system in the private sector in Sri Lanka. This causes ethical issues as companies importing vaccines and the private sector giving vaccines do not provide exact figures of doses sold or vaccinated and the number of AEFIs occurred in each year in the private sector to the general public to refer.

Who will benefit from none functioning of the EPI program?

As mentioned earlier, the Sri Lankan vaccination program has a proud history that dates back to around 125 years. It has demonstrated its full potential since 1978 with the launch of the EPI and achievement of the universal child immunization status. To achieve this success and sustenance of it over a long period, enthusiastic yet tedious labour of the field level community workers (Public Health Midwife and Public Health Inspectors) under the guidance of Medical Officer of Health has been proved to be very essential. It has created an environment in which parents understand the value of immunization and seek vaccination for their children voluntarily. In a reverse scenario, if an environment is created showing that being vaccinated in the government sector is not safe, parents will definitely seek the services for vaccination of their

children at the private sector. One limiting factor is the affordability. It is natural to ask the question "How many parents of this country can spend around Rs. 4500/- (including vaccine and other relevant charges) per immunization session in addition to traveling costs? On the other hand, some vaccines that are not routinely used in the national program based on low incidence of the disease are offered to children without being requested by the parents incurring them additional costs. This raises queries of ethicality. While the public program is involved in information gathering to justify introduction of new vaccines, these introductions in the private sector are ad hoc, not based on epidemiological studies in Sri Lanka. The only factor that is considered is the product availability that leads to profit maximization of the company and financial benefits to the prescriber.

What is the responsibility of Epidemiology Unit on AEFI?

Against this back ground, a historically significant role has been delegated to the Epidemiology Unit. Epidemiology Unit is the focal point for vaccine management for the National program of Immunization in Sri Lanka. It's pioneering role in AEFI surveillance has been given due recognition by making it a global training center for the AEFI under the World Health Organization. It makes participatory decisions on vaccine related matters through the national advisory committee on communicable diseases. Unit is guided by scientific evidence gathered through research conducted in collaboration with national and international partners. The choice of the relevant vaccines is based on the disease burden in the country, availability of a safe and potent vaccine, its ability to be incorporated into the EPI and financial sustainability of the introduced vaccine even with donor support. Strictly adhering to these criteria has cemented the foundation of the Sri Lankan national immunization programme which is globally recognized for its effectiveness and sustainability.

The Epidemiology Unit has undertaken capacity building of programs for the field level staff involved in EPI on AEFI and how to minimize them. This is extremely useful because quite a large number of AEFI occurs due to program errors and lack of communication with the recipients. Enhanced capacity and supervision have been instrumental in minimizing these correctable errors. The capacity thus developed will enable correct identification of AEFI by the field staff as initial feeders to the routine AEFI notification process.

The comprehensive appraisal of AEFI at the national level by the Epidemiology Unit is essential to introduce timely interventions to safeguard the recipients of the vaccines, field staff who are carrying out the vaccination activities on behalf of the Epidemiology Unit and vaccination programme itself. The data received from each the MOH area through AEFI notification system are compiled in a central database and analyzed by a consultant Epidemiologist specialized in AEFI management. Information thus generated is used for decision making. The recent spate of AEFI temporally related to the pentavalent vaccine and subsequent temporary suspension of the pentavalent vaccine was based entirely on appraisal of AEFI at the National Level. Quarterly this information is published in the quarterly epidemiological bulletin for easy reference of local and international data users.

Since of late, participatory and consensual approach in decision making with relevant stakeholders on vaccines and its safety have been adopted as a response to the developing dynamic conditions connected to the EPI. This is considered as an essentially evolutionary step to improve the quality and ensure sustainability of a program which has performed its assigned historical role and steps onto a new stage, as other mature EPI programmes did in their evolution, adaptation to which will determine the future success of the National EPI in countering emerging issues in relation to immunization.

This article was compiled by Dr.Chathura S Edirisuriya, Registrar (Community Medicine)

Epidemiology Unit website <http://www.epid.gov.lk>

Table 1: Vaccine-preventable Diseases & AFP

16th - 22nd January - 2010(03rd Week)

Disease	No. of Cases by Province									Number of cases during current week in 2010	Number of cases during same week in 2009	Total number of cases to date in 2010	Total number of cases to date in 2009	Difference between the number of cases to date in 2010 & 2009
	W	C	S	N	E	NW	NC	U	Sab					
Acute Flaccid Paralysis	01	01	00	00	00	00	00	00	00	02	00	03	03	00 %
Diphtheria	00	00	00	00	00	00	00	00	00	00	00	00	00	00 %
Measles	00	00	00	00	00	00	00	00	00	00	00	14	07	+ 100.0 %
Tetanus	00	00	00	00	00	00	00	00	01	01	02	02	04	- 50.0 %
Whooping Cough	00	00	00	00	00	00	00	00	01	01	00	01	08	- 87.5 %
Tuberculosis	143	121	04	00	12	02	02	03	67	354	72	631	477	+ 32.3 %

Table 2: Newly Introduced Notifiable Disease

16th - 22nd January - 2010(03rd Week)

Disease	No. of Cases by Province									Number of cases during current week in 2010	Number of cases during same week in 2009	Total number of cases to date in 2010	Total number of cases to date in 2009	Difference between the number of cases to date in 2010 & 2009
	W	C	S	N	E	NW	NC	U	Sab					
Chickenpox	07	01	06	03	00	09	06	05	03	42	89	169	301	- 43.9 %
Meningitis	05 CB=2 GM=2 KT=1	00	00	00	01 TR=1	01 KR=1	00	00	05 KG=1 RP=4	13	16	134	53	+152.8 %
Mumps	01	01	00	00	00	01	00	01	01	05	30	52	124	- 58.1 %
Leishmaniasis	00	00	02 HB=2	00	00	00	01 AP=1	00	00	03	04	16	21	- 23.8 %

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.

10th South East Asia Regional Scientific Meeting of the International Epidemiological Association
23rd - 26th May 2010

Colombo, Sri Lanka

Theme

"Epidemiological Methods in Evidence Based Healthcare"

Visit <http://www.episea2010.com>

Table 4: Selected notifiable diseases reported by Medical Officers of Health
16th - 22nd January - 2010(03rd 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	128	445	3	14	0	0	1	6	1	5	7	26	0	1	0	2	0	0	85
Gampaha	53	409	1	3	1	1	0	2	0	0	3	9	0	0	1	7	0	0	47
Kalutara	8	77	0	8	0	2	0	2	0	6	2	14	0	0	1	1	0	0	42
Kandy	22	143	2	31	0	0	1	2	0	0	3	9	5	12	2	8	1	1	54
Matale	7	51	6	9	0	0	0	1	0	0	3	9	0	0	0	5	0	0	42
Nuwara	3	24	0	7	0	0	9	17	0	0	0	3	3	6	1	3	0	0	62
Galle	9	28	5	11	0	1	0	0	0	0	1	1	0	0	0	1	0	0	79
Hambant	6	29	0	3	0	0	0	1	0	0	1	8	6	15	0	0	0	0	55
Matara	6	29	1	9	0	0	0	1	32	32	2	8	5	19	2	4	0	0	88
Jaffna	71	437	3	10	0	0	4	60	0	0	0	0	2	28	1	6	0	0	25
Kili-	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Mannar	12	19	2	8	0	0	1	7	0	0	0	0	0	0	1	2	0	0	60
Vavuniya	55	311	2	5	0	1	0	10	0	0	0	0	0	0	0	3	0	0	75
Mullaitivu	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Batticaloa	17	135	0	/	0	0	1	3	0	2	0	0	0	1	0	0	0	0	67
Ampara	0	6	0	7	0	0	1	1	0	2	1	9	0	0	0	3	0	0	29
Trincomal	6	117	1	12	0	0	0	0	0	0	0	6	1	2	1	4	0	0	60
Kurunega	30	145	8	24	0	2	1	4	0	0	0	9	0	3	1	6	1	1	75
Puttalam	33	161	0	15	0	1	1	7	0	0	1	4	0	0	0	0	0	0	56
Anuradha	24	132	1	9	0	0	0	2	0	0	1	3	0	1	0	1	0	0	42
Polonnar	7	18	0	11	0	0	0	0	0	0	0	5	0	0	1	3	0	0	57
Badulla	18	49	0	10	0	0	1	5	6	6	1	7	0	2	1	4	0	0	33
Monaraga	6	27	8	26	0	0	1	3	0	0	1	6	0	2	0	0	0	0	55
Ratnapur	3	44	1	18	0	2	0	3	0	6	0	24	0	8	2	13	0	1	39
Kegalle	4	60	1	3	0	1	0	3	0	0	5	14	1	1	4	10	0	0	55
Kalmunai	11	92	0	11	0	0	0	1	0	0	0	0	0	0	0	0	0	0	15
SRI LANKA	539	2988	45	272	01	11	22	139	39	59	32	174	23	101	19	86	02	03	53

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 22nd January, 2010 Total number of reporting units =311. Number of reporting units data provided for the current week: 168

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

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