National Survey on Surveillance of Adverse Events Following Immunization in Sri Lanka

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Epidemiology Unit

Ministry of Health

Content

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Executive Summary

In Sri Lanka, the Expanded Programme on Immunization (EPI) was established in 1978. The country has achieved and maintaining high vaccination coverages with an impressive reduction and control of vaccine preventable diseases. A passive surveillance system of Adverse Events Following Immunization (AEFI) was started in mid 1990s to strengthen vaccine safety aspects and since then the system has improved significantly. This study was carried out to evaluate the AEFI system in the country.

Fifty two (52) Medical Officer of Health (MOH) areas, two from each district were selected into the study. Also, an immunization clinic from each selected MOH area was included in the study to describe AEFI reporting and record keeping at clinic level and, to describe AEFI related immunization service activities at the same level. AEFI registers and other relevant records too were reviewed to evaluate AEFI reporting and recording practices. Interviews of a sample of MOOH and Public Health Midwives were carried out to explore their knowledge on AEFI.

At immunization clinics, 83% children were asked for any contraindication for vaccine and 79% were asked about any AEFI following previous immunizations. Further advised on AEFI and observation for 30 miniutes for AEFI were around 90%. Only 51.1% cases have complete information in the Clinic AEFI Registers, whereas for MOH Office AEFI register it was only 40.8%. AEFI status of previous vaccinations recorded in Child Health Development Record (CHDR) part A and B were 77.5% and 73.7% respectively. Around 25% of children‘s AEFI status for previous immunizations were not entered in the CHDR. The overall AEFI reporting in the country is 3.2 adverse events/1000 antigen administered, while for investigational adverse events, it is as low as 0.8/1000 antigen administered. The highest rate of antigen specific AEFI was reported for DPwT vaccine (10.9/1000 doses administered), followed by Pentavalent vaccine (4.1/1000 doses administered). The reported AEFI rates by aged group: 8.8/1000 doses of antigen administered for infants and 5.4/1000 for children aged over one year. Immunization safety practices adopted at clinics (screening, advices, and observation for immediate AEFI following immunization) and knowledge of MOOH and PHMM on AEFI is good.

In conclusion, AEFI related activities adopted and practiced at immunization clinics and Medical Officer of Health level are good. However, further strengthening of country AEFI surveillance system is necessary.

Introduction

Despite significant progress in vaccine preventable disease control, immunization is not free of controversy and we have witnessed such challenges in Sri Lanka also. Vaccine safety is increasingly becoming important because of alleged safety issues derailing vaccine programmes worldwide. After a limited number of clinical trials done among healthy individuals in selected settings, license is granted to the vaccine and vaccine is administered to the diverse target population. Before licensure, serious and rare adverse reactions are less likely to be identified and only the post – licensure (post-marketing) surveillance can provide information on complete vaccine safety profile.

Adverse events following immunization (AEFI) is defined as 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 unfavourable or unintended sign, abnormal laboratory finding, symptom or disease. *(CIOM/WHO 2012)*

Adverse events may occur due to some inherent properties of the vaccine (**vaccine reaction**) and the new cause-specific categorization 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 thereby increased risk of adverse vaccine reactions. (Re: *Report of CIOMS/WHO Working Group on Vaccine Pharmacovigilance, 2012)*

AEFI also could be **'Immunization error–related reactions"**, resulting errors and mistakes in vaccine preparation, handling, or administration of the vaccine. Earlier, this AEFI type was categorised as "Programme errors" (*Syn; Programmatic error or Programme operation errors*). At times, the event may be unrelated to immunization, but may have a temporal association :

Coincidental event. **Anxiety-related reactions** are common resulting from fear or pain of injection rather than the vaccine. In some cases, the cause of the AEFI remains **unknown**.

A substantial number of AEFI result from immunization error-related reactions (Programme Errors) and can be avoidable through proper training and supervision. With the strengthening of AEFI surveillance, even the coincidental events are now reported, contributing to a significant proportion of adverse events reported in the country. Investigation of coincidental events will clarify the causality. A properly functioning AEFI surveillance system and laboratory supported epidemiological investigation are necessary to identify the causality of reported AEFI. This will ensure public confidence in immunization. Further, AEFI surveillance will also help to identify vaccine safety **signals**, defined as previously unknown or partially known vaccine reactions to the given antigen. Recognising these signals is more important in first years of new vaccine introduction.

AEFI surveillance in Sri Lanka was started in 1996 as a part of the National Immunization programme. It covers both vaccines used in the Expanded Programme on Immunization (EPI) and non-EPI vaccines. The objective of AEFI surveillance is to ensure vaccine safety. Components of AEFI surveillance: (i) Detection and reporting of AEFI, (ii) Investigation, (iii) Data analysis, (iv) Corrective action and (v) Evaluation. This national survey was focused on first 3 components of the national surveillance system.

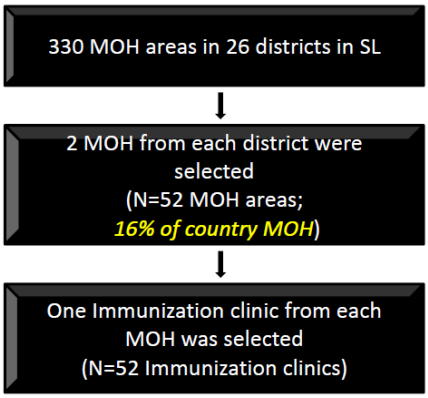
Survey objectives

- To review and evaluate case detection, reporting and recording functions of AEFI surveillance system at Medical Officer of Health (MOH) level
- To estimate AEFI reporting rates as indicators of AEFI surveillance system performances
- To evaluate impact of the AEFI training in order to achieve the objectives of AEFI surveillance.
- To identify areas to be strengthened in AEFI surveillance system in the country

Method

The study was planned to cover two MOH areas from each district and a total of 52 MOH areas were selected. Selection of MOH areas was based on AEFI reporting performance from January to May 2012. The number of AEFI reported by each MOH area was line listed in each district. Form each district, the two MOH areas which reported the highest number of AEFI for the given time period were selected. It was assumed that identifying MOH areas with high level of performance will certainly reflect the needs of improving the performance of less performing MOH areas too and also for the district, the province and the country.

Fifty two (52) immunization clinics from selected MOH areas (one immunization clinic from each MOH area) were included into the study. Selection of the immunization clinic too followed the similar process as of the selection of MOH areas. All immunization clinics in each selected MOH areas were line listed by the number of AEFI cases reported from January to May 2012. The clinic with the highest number of AEFI reported during the given time period was selected for the survey. Again, the reason for selecting the clinic with the highest number is to evaluate how well the best reporting clinic is reporting and thereby it indicates the extent of improvement necessary in the system, including the clinics with less performance.



Study components: (i) Part I: AEFI record keeping, Screening for AEFI and other AEFI related activities at immunization clinics (ii) Part II: AEFI case detection and record keeping by Public Health Midwives (PHM) and (iii) Part III: AEFI record keeping, data analysis, investigation and

reporting practices at the MOH office (iv) Part IV: Knowledge on AEFI and emergency management of AEFI by PHM and MOH.

Data collection: (i) AEFI related registers /records available at immunization clinics and MOH offices were reviewed to evaluate AEFI documentation and reporting practices and estimating reporting rates of AEFI (ii) Direct observation of PHMM was done to evaluate AEFI screening and communication practices during an immunization clinic session and (iii) Interviewer /self administered questionnaires were used to assess the knowledge and practices of PHMM and MOOH on AEFI types and an emergency management.

This study was carried out in 2012: [i] Planning (developing study method and tools, pre-testing) in Feb-April [ii] Training of research team in May [iii] Data Collection in June-August [iv] Data compilation and Analysis, Report preparation in Sep-December

Results

The AEFI surveillance in Sri lanka is guided by the national guideline on immunization safety surveillnace. All serious and non serious AEFI are required to be reported. In addition to the national guidelines, AEFI that are required to be reported and their case definitions are given on the reverse side of the AEFI notification form and the monthly AEFI return form. Presently, the programme has been expanded by developing a more detailed reporting form namely, Notification Form for Adverse Events Following Immunization (AEFI Form 1), Monthly Surveillance of Adverse Events Following Immunization (AEFI Form 2) and Adverse Events Following Immunization Case Investigation Form (AEFI Form 3). Investigation of deaths and anaphylactic reactions following immunization needs to be carried out using separate investigation forms.

Immunization clinic activities

A total of 520 children, 10 children (5 each from infants and children over 1 year of age) at each clinic centre were observed for screening for contraindication, inquiring on previous AEFI and advised given on AEFI. The observation was done by the study team (Regional Epidemiologist, Public Health Nursing Sister). Their presence would have some effect on the practice (Field staff may have more concern on above routine activities) and this is a common problem in any observational study. However, the study team members are not new to the clinic staff and often the same persons (study team members) visit and monitor clinic activities routinely.

Screening for possible contra-indications prior to the immunization is essential and important for any vaccine. This will minimize the risk of serious adverse reactions and also possible negative impact on vaccine and the immunization programme. Health care providers, particularly Public Health Midwives (PHM) and Public Health Inspectors (PHI) are expected to keep the parents aware on possible adverse events through close communication and health education. In addition, instructions are given to observe vaccinees for 30 minutes after the vaccination to make sure that acute, severe adverse reactions such as anaphylaxis would be efficently managed in a

clinic setting. This survey observed screening and communication practices of PHMM at 52 immunization clinics. (Table 1)

Overall, 83% children were asked for presence of any contraindication for the vaccine and 79% were asked about any AEFI following previous immunizations. Further advised on AEFI and observation for 30 miniutes for AEFI after vaccinnation were around 90%. However, it is expected that all these activities are to carried out 100% to ensure the highest immunization safety practices in clinic settings.

Table 1: Screening and communication on AEFI at Immunization clinics

District	% Children screened for contraindication	% Children asked for previous AEFI	% Children (parents) asked to wait for observation of AEFI	% Children observed for AEFI after vaccination	% Children (parents) advised on AEFI
Colombo	100	100	100	100	100
Gampaha	100	85	100	100	100
Kalutara	100	100	100	100	100
Kurunegala	95	70	100	90	95
Puttalam	100	100	100	100	100
Badulla	100	100	100	90	100
Monaragala	100	100	100	100	100
Kegalle	60	50	70	50	45
Ratnapura	50	50	100	100	100
Kandy	55	50	100	95	100
Matale	70	60	100	100	100
N'eliya	60	30	100	100	100
Galle	75	100	100	100	100
Hambantota	100	90	100	100	100
Matara	100	50	50	0	0
Anuradhapura	95	100	100	100	100
Polonnaruwa	100	95	100	100	100
Jaffna	10	35	55	55	30
Killinochchi	75	75	95	100	95
Mannar	100	100	100	100	100
Mullativu	65	55	60	55	45
Vavunia	100	100	100	100	100
Ampara	100	100	100	100	100
Batticaloa	90	95	90	100	95
Kalmunai	70	70	100	100	70
Trincomalee	90	95	100	100	95
SRI LANKA	**83.1**	**79.0**	**93.1**	**89.8**	**87.3**

Maintenace of AEFI Records and Registers

An effective immunization safety surveillance system involves health service providers at all levels in the immunization programme. AEFI surveillance system has three different starting points; at the community level(reporting by parents/guardians), field immunization clinics, hospitals.

Screening of all children for AEFI following previous immunizations is mandatory and a separate column is available in the immunization record section in the Child Health Development Record (CHDR) to record any adverse events which occurred following previous immunizations. The CHDR has two parts: A and B. Part A is given to parents and it contains records of all child health events. Part B is kept at the PHM office. It is necessary to record all AEFI events, including 'nil' events following each antigen. It is expected, that both parts contain the same information on AEFI. If no AEFI is reported, it must be marked in the relevant column against the particular vaccine. Details of any reported AEFI need to be recorded in *Clinic AEFI Register* and in *MOH Office AEFI Register*. Maintaining accurate records of AEFI in both parts of CHDR is the responsibility of PHM. Any discrepancies in AEFI records in two parts of CHDR suggest lack of consistency, accuracy and quality of AEFI data and also the surveillance system. This survey compared CHDR parts A and B of 520 randomly selected children (10 from each selected clinic centre) and found that recording of AEFI status for previous vaccinations in part A and B were 77.5% and 73.7% respectively. (Table 2) This indicates that around 25% of children's AEFI status for previous immunization were not entered in the CHDR, which is the only continued health record for children in Sri lanka. This is unsatisfactory, as absence of AEFI records will miss a proper evaluation of safety status at subsequent vaccinations. The lack of consistency of information in the system (disparity in ~4% of AEFI records in the two parts of CHDR) is also need an attention.

Table 2: Recording of AEFI in Child Health Development Record

District	% Children CHDR-A marked for previous AEFI	% Children CHDR-B marked for previous AEFI	Province	% Children CHDR-A marked for previous AEFI	% Children CHDR-B marked for previous AEFI
Colombo	90.0	60.0			
Gampaha	75.0	55.0	**Western**	78.3	61.7
Kalutara	70.0	70.0			
Kurunegala	70.0	60.0	**North-western**	82.5	57.5
Puttalam	95.0	55.0			
Badulla	85.0	95.0	**Uva**	92.5	97.5
Monaragala	100.0	100.0			
Kegalle	40.0	35.0	**Sabaragamuwa**	57.5	42.5
Ratnapura	75.0	50.0			
Kandy	55.0	30.0			
Matale	70.0	75.0	**Central**	46.7	60
N'eliya	15.0	75.0			
Galle	100.0	100.0			
Hambantota	75.0	75.0	**Southern**	91.7	91.7
Matara	100.0	100.0			
Anuradhapura	100.0	100.0	**North-central**	95	100
Polonnaruwa	90.0	100.0			
Jaffna	40.0	30.0			
Killinochchi	90.0	90.0			
Mannar	100.0	100.0	**Northern**	78	74
Mullativu	60.0	50.0			
Vavunia	100.0	100.0			
Ampara	100.0	100.0			
Batticaloa	90.0	90.0	**Eastern**	80	77.5
Kalmunai	30.0	20.0			
Trincomalee	100.0	100.0			
SRI LANKA	**77.5**	**73.7**		**77.5**	**73.7**

If any AEFI information reported during a clinic session should be entered in the *Clinic AEFI Register*, which is kept in the immunization clinic. On a monthly basis, all information recorded in the *Clinic AEFI Register* will be transferred to the *MOH AEFI Register*, which is kept in the MOH office. Information coming from any other source also should be documented in the *MOH AEFI Register*.

Table 3: Completenes of information in AEFI Registries

District	Completeness of information in Clinic AEFI Register (%)	Completeness of information in MOH AEFI Register (%)	Province	Completeness of information in Clinic AEFI Register (%)	Completeness of information in MOH AEFI Register (%)
Colombo	45.5	2.0			
Gampaha	50.0	0	**Western**	51.0	9.2
Kalutara	58.8	62.5			
Kurunegala	41.7	31.6	**North-western**	65.0	69.0
Puttalam	100.0	100.0			
Badulla	28.6	50.0	**Uva**	58.3	30.0
Monaragala	100.0	5.6			
Kegalle	75.0	45.7	**Sabaragamuwa**	66.7	42.5
Ratnapura	60.0	20.0			
Kandy	25.0	91.7			
Matale	25.0	100.0	**Central**	53.3	79.4
N'eliya	85.7	68.9			
Galle	100.0	100.0			
Hambantota	100.0	89.7	**Southern**	100.0	94.7
Matara	100.0	100.0			
Anuradhapura	100.0	97.1	**North-central**	86.4	45.3
Polonnaruwa	78.6	0			
Jaffna	15.4	0			
Killinochchi	84.6	76.9			
Mannar	100.0	100.0	**Northern**	31.4	24.4
Mullativu	0.0	100.0			
Vavunia	82.4	25.6			
Ampara	100.0	88.2			
Batticaloa	42.9	0	**Eastern**	88.4	49.5
Kalmunai	100.0	37.0			
Trincomalee	80.0	100.0			
SRI LANKA	**51.1**	**40.8**		**51.1**	**40.8**

Note: Evaluation of the documemenation in *Clinic and MOH Office AFEI Registers* are based on the following formula:

*Completeness of information in AEFI Register = $\frac{\text{Number of AEFIs with all complete information in Clinic/MOH AEFI Registers x100}}{\text{Number of AEFIs recorded in Clinic/MOH AEFI registers}}$

Completeness and accuracy of information recorded in Clinic and MOH office AEFI registers are key important factors in the AEFI surveillance system in Sri lanka as generation of all data will be based on these two registers. It was revealed that information of 51.1% of cases entered in the Clinic AEFI Register was incomplete, where as for MOH Office register, it was 40.8%. (Table 3) Missing necessary data in the registers make the surveillance system less effective.

Further, these findings indicate an important challenge in the surveillance: losing data while transfering data from clinic to MOH office. Close monitoring of transfering data from Clinic AEFI Register to MOH AEFI Register would certainly imporove the situation, in addition to making staff recognise the importance of consistency and completeness of data in both registers.

AEFI Reporting

In Sri Lanka, all AEFI needed to be reported, but not all need to be investigated. Therefore, the AEFI reporting in the surveillance system would be evaluated using two indicators: AEFI reporting rate (overall) and Investigational AEFI reporting rate. Obviously the first would be higher than the second. Under-reporting is expected as the surveillance system is passive, but sometimes even over-reporting is also possible, particularly following training and awareness activities. Therefore, setting the expected range of AEFI reporting rate would be helpful to guide and indicate programme mangers to evaluate the surveillance system in the country.

This survey found that overall AEFI reporting rate in the country is 3.2 adverse events/1000 antigen administered, while for investigational adverse events, it is as low as 0.8/1000 antigen administered. (Table 4/Annex 1) Excessive high rates of reporting were noted from a few districts in the Northern Province and it is very likely an over-reporting. The over reporting by enthusiastic staff is often observed following training programmes.

AEFI may be detected also in medical institutions when affected patients seek treatment for the said AEFI. Out Patients' Department (OPD) in these institutions, paediatric wards and surgical wards are potential places where AEFI could be detected. Therefore, it is important that relevant health workers in hospitals are made aware of AEFI and AEFI surveillance. When a patient is detected as having an AEFI in a health institution, the case should be notified in the prescribed format (AEFI Form 1) to the relevent MOH of the area where the patient resides. With retrospective review of 520 children who have received vaccination, it revealed that only 37 (0.7/1000) children developed AEFI and of which 18 (0.4/1000) had received medical care; 6 at government hospitals and 12 at the private sector. Out of 6 cases, only one was reported to the

respective MOH by government hospital and none by the private sector. This highlighted the need and attention on improving AEFI reproting from government hospitals and private sector. Despite weak reporting from hospital and private sector, community based reporting of AEFI is impressive. Out of 37 AEFI cases, 25 were either reported to the PHM by parents or detected by PHM in her routine field visits indicating that the country srveillance system is able to pick-up and report 68% (25/37*100) of all AEFI among children. As a passive surveillance system, this is a good achivement, however, it also indicates that the reporting is needed to be strengthened further.

Further, AEFI surveillance will help establishing country specific background rates for adverse reactions following immunization. *Antigen specific background rates of adverse reactions* are important to identify possible vaccine defects and susceptible populations to the given vaccines. These rates can then be compared with globally available data. (http://www.who.int/vaccine_safety/initiative/tools/vaccinfosheets/en/index.html)The knowledge on antigen specific adverse reactions rates is important, particularly to immunization programme managers in decision making.

The highest rate of antigen specific AEFI was reported for DPwT vaccine (10.9/1000 doses administered), followed by Pentavalent vaccine (4.1/1000 doses administered). Low AEFI rates were reported for BCG (0.1 /1000 doses administered), OPV (0.2/1000 doses administered), TT (0.5/1000 doses administered) and aTd (0.9/1000 doses administered). (Table 5) These reported antigen specific AEFI rates provide indicators to the programme managers to evaluate both punctuality of the AEFI surveillance system and also the antigen need more attention on responding and follow-up actions for possible AEFI.

Table 4: AEFI reporting rates per 1000 antigen

District	Number of AEFI cases reported during study period (*At the 52 MOH*)	AEFI Reporting rate /1000 antigens administered	Investigational AEFI rate/1000 antigen administered	Province	AEFI Reporting rate /1000 antigens administered	Investigational AEFI rate/1000 antigen administered
Colombo	50	9.5	0.0			
Gampaha	53	1.6	0.0	**Western**	1.8	0.2
Kalutara	16	0.6	0.4			
Kurunegala	19	3.7	2.4	**North-western**	2.4	1.6
Puttalam	23	1.9	1.1			
Badulla	22	1.6	0.0	**Uva**	1.6	0.2
Monaragala	18	1.5	0.3			
Kegalle	35	2.1	0.6	**Sabaragamuwa**	1.9	0.3
Ratnapura	5	1.2	0.2			
Kandy	12	1.2	0.0			
Matale	24	2.3	1.2	**Central**	3.2	0.2
N'eliya	61	6.5	0.0			
Galle	17	1.9	0.0			
Hambantota	29	5.6	0.0	**Southern**	2.2	0.2
Matara	11	1.0	0.3			
Anuradhapura	35	1.1	0.8	**North-central**	2	0.2
Polonnaruwa	40	7.1	0.0			
Jaffna	159	41.2	2.2			
Killinochchi	39	59.9	0.0			
Mannar	17	8.2	0.3	**Northern**	33.2	2.6
Mullativu	6	3.1	0.0			
Vavunia	86	54.3	0.0			
Ampara	17	1.2	2.4			
Batticaloa	27	6.5	3.0	**Eastern**	2.3	1.8
Kalmunai	27	1.4	1.0			
Trincomalee	20	9.1	4.0			
SRI LANKA	**868**	**3.2**	**0.8**		**3.2**	**0.8**

Note:

AEFI Reporting rate = Total number of AEFI cases reported by study sites during study period x 1000

Total number of antigen administered at study sites for given time period

Investigational AEFI Reporting Rate= Total number of investigational AEFI reported by study sites during study period x 1000

Total number of antigen administered at study sites during same period

Table 5: Antigen specific AEFI reporting rates per 1000 doses of antigen

District	BCG	DTP	Penta	OPV	MMR	LJE	TT	DT	aTd
Colombo	0	72	21.1	0	10.3	7.5	1.9	6.2	0.0
Gampaha	0.07	20	2.4	0	2.4	2.2	1.0	1.9	0.9
Kalutara	0	3	0.7	0	0.3	0.5	0.0	3.0	0.0
Kurunegala	0	20	5.7	0	4.6	1.9	0.0	0.0	20.8
Puttalam	0	7	2.2	0	2.4	4.1	1.5	4.7	1.9
Badulla	0	59	2.3	0.7	0.6	3.1	0.0	1.1	0.0
Monaragala	0	4	2.6	0.8	2.6	3.6	0.0	3.8	0.0
Kegalle	0	12	3.4	0	0.4	0.0	0.0	1.8	0.0
Ratnapura	0	43	1.6	0	1.8	0.0	0.0	0.0	30.3
Kandy	0	23	2.9	0	0.8	0.0	0.9	1.5	0.0
Matale	0	18	6.7	0	0	3.1	1.2	3.2	7.5
N'eliya	0	4	4.9	0	3.6	1.8	0.0	0.0	0.0
Galle	0	9	0.4	0	2.5	1.1	1.2	1.7	0.0
Hambantota	0	52	13.8	0	1.9	0.0	0.0	8.1	0.0
Matara	0	0	3.6	0	0	0.0	0.9	1.3	0.0
Anuradhapura	0	18.7	7.5	0	3.9	1.4	0.0	1.7	0.0
Polonnaruwa	0	14.1	4.0	0	0	3.3	0.0	0.0	0.0
Jaffna	0	50.0	9.9	0	7.8	6.9	0.0	7.9	0.0
Killinochchi	0	0	22.6	0	0	0	0	0	0
Mannar	0	22.7	14.6	0	0	0	0	0	0
Mullativu	0	0	0.0	0	0	0	0	0	0
Vavunia	0	34.5	4.7	15.1	0	7.1	0	0	0
Ampara	0	5.9	0	0	0.6	0	0	0	0
Batticaloa	0	0	16.0	1.4	3.6	3	0	8	0
Kalmunai	0	3.9	4.9	0	0	0	0	1	0
Trincomalee	0.03	0	0	0	0	0	0	0	0
SRI LANKA	**0.1**	**10.9**	**4.1**	**0.2**	**1.7**	**1.8**	**0.5**	**2.1**	**0.9**

Note: Antigen specific AEFI Reporting rate =

$$\frac{\text{Total number of AEFI reported by study sites for given antigen during study period} \times 1000}{\text{Total number of given antigen administered at study sites during the given time period}}$$

This survey further analysed overall reported AEFI rates by age groups and found that it was 8.8/1000 doses of antigen administered for infants and 5.4/1000 for children age over one year. This may be partly due to the highest attention on younger children by parents and therefore the active reporting by them.

Table 6: Status of AEFI investigation*

District	% of AEFI investigated	Out of all investigated, the % of AEFI investigated by MOH	Province	% of AEFI investigated	Out of all investigated, the % of AEFI investigated by MOH
Colombo	100	100			
Gampaha	16.7	100	**Western**	33.3	100
Kalutara	0				
Kurunegala	33.3	0	**North-western**	50	50
Puttalam	100	100			
Badulla	75	100	**Uva**	80	100
Monaragala	100	100			
Kegalle	0		**Sabaragamuwa**	0	
Ratnapura	0				
Kandy	0				
Matale	0		**Central**	0	
N'eliya	0				
Galle	100	100			
Hambantota	33.3	0	**Southern**	71.4	80
Matara	33.3	0			
Anuradhapura	100	100	**North-central**	45.5	100
Polonnaruwa	0				
Jaffna	0				
Killinochchi	0				
Mannar	62.5	100	**Northern**	52.4	90
Mullativu	0				
Vavunia	50	0			
Ampara	100	60			
Batticaloa	100	100	**Eastern**	100	73.9
Kalmunai	100	100			
Trincomalee	100	50			
SRI LANKA	**64.1**	**83.1**		**64.1**	**83.1**

Note:

*% of AEFI Investigated = $\frac{\text{Total number of AEFI investigated at study sites}}{\text{Total number of reported investigational AEFI reported during same period at study sites}} \times 100$

Out of all investigated AEFI, the % of AEFI Investigated by MOH =

$$\frac{\text{Total number of AEFI investigated by MOH}}{\text{Total number of AEFI investigated during same period at study sites}} \times 100$$

Investigation of AEFI

It is recommended that investigation of AEFI should be done by MOH himself/herself, not by any other staff member. Only 83.1% investigations were carried out by MOOH (Table 6) and the reasons for carrying out investigations by others are given in Table 7.

Table 7: Reasons for not performing the AEFI investigations by MOH

Reason for not investigating by MOH (n=15)	%
No time	26.6%
Assumed no need	40.0%
Trust the staff can do it	33.3%

Note : One MOH may have given more than one reason.

Analysis of AEFI data

In analyzing data, MOH plays an important role as it is the first operational level and where best use of surveillance data can be obtained. All reports should be analyzed to identify the type of AEFI, particularly the immunization related (programme) errors. This will help to initiate corrective action in a timely manner. Out of 52 MOOH studied, 22 had not analyzed AEFI data and reasons given by MOOH for not performing analysis of AEFI data are listed in Table 8.

Table 8: Reasons by MOH for not performing analysis of AEFI data

Reason for not performing analysis of AEFI data (N=22)	%
No time	40.9%
No staff to do it	22.7%
Don't know how to do it	36.3%

Note : One MOH may have given more than one reason.

Public Health Midwives knowledge on AEFI and communication skill

Public Health Midwives (one randomly selected PHM from each selected clinic, n=52) were administered interviewer administered questionnaire and asked about contraindications, signs to identify anaphylaxis and use of Adrenalin in an AEFI emergency. Their knowledge on contraindications is only 42%, whereas identifying anaphylaxis was 52%. The knowledge on use of Adrenaline is impressive as of 91% of them know the correct dose, route and site of Adrenaline administration. This is largely due to the intensive training on emergency management carried out island wide in 2011.

Public Health Midwife plays an important role in communication with the public (family) in immunization as she is the centre point at majority of immunization clinics in the country. Their communication skills on immunization safety (advising on AEFI, risk-benefit of vaccines) to the parents at the clinic were evaluated. The study team observed 52 Public Health Midwives and they were rated as Good (7%), Average (87%) and Poor (6%).

Knowledge of Medical Officers of Health on AEFI

The Medical Officers of Health (MOOH, n=50) were given a brief self-administered questionnaire on the following: Contraindication, identifying anaphylaxis and its management, classification of AEFI and describing the signal. Except for describing the signal (only 4% correctly responded), the overall knowledge on vaccine contraindications (86%), identifying anaphylaxis (96%), anaphylaxis management (93%) and AEFI classification/types (82%) were good. However, these findings clearly show that MOOH too need to be updated with new knowledge in vaccine and immunization safety to ensure that they carry out their job efficiently.

Conclusion

- Immunization safety practices adopted at clinics (screening, advices, and observation for immediate AEFI following immunization) are GOOD, but still it needs to be strengthened to ensure the highest immunization safety practices in clinic settings. Screening before immunization is an important precaution to avoid or minimise possible vaccine adverse events. Also, proper advise to the public on immunization safety will reduce negative impact of AEFI to the immunization progarmme.
- Overall reporting of AEFI at immunization clinics and Medical Officer of Health level is good. However, both over-reporting and under-reporting of AEFI are observed. Maintaining accurate information while transferring data from one document to another is a concern as it has revealed that some information is missing during the data transferring process. Despite the training, lapses in record keeping exist. MOH staff needs to be more careful in maintaining AEFI related records and registers correctly, accurately and completely. Close supportive supervision can improve the situation.
- This study has generated both overall AEFI reporting rates and antigen specific AEFI rates, which can be used to monitor system operation. These reporting rates also would help to identify both under- and over-reporting.
- Investigation of AEFI needs to be improved: Future training needs to focus on reasons given for non-investigation.
- The purpose of surveillance is *generating data for action*. MOH is the first level beneficiary of AEFI surveillance data; therefore, he/she needs to carry out data analysis to identify issues and areas which need timely and prompt action. At present, AEFI data analysis at MOH level is weak and all MOOH need to focus attention to ensure that data is analyzed regularly and continuously, enabling timely corrective follow-up action to ensure immunization safety at their level.
- Future training on immunization safety needs to be focused on findings of this survey to address areas to be strengthened in AEFI surveillance.

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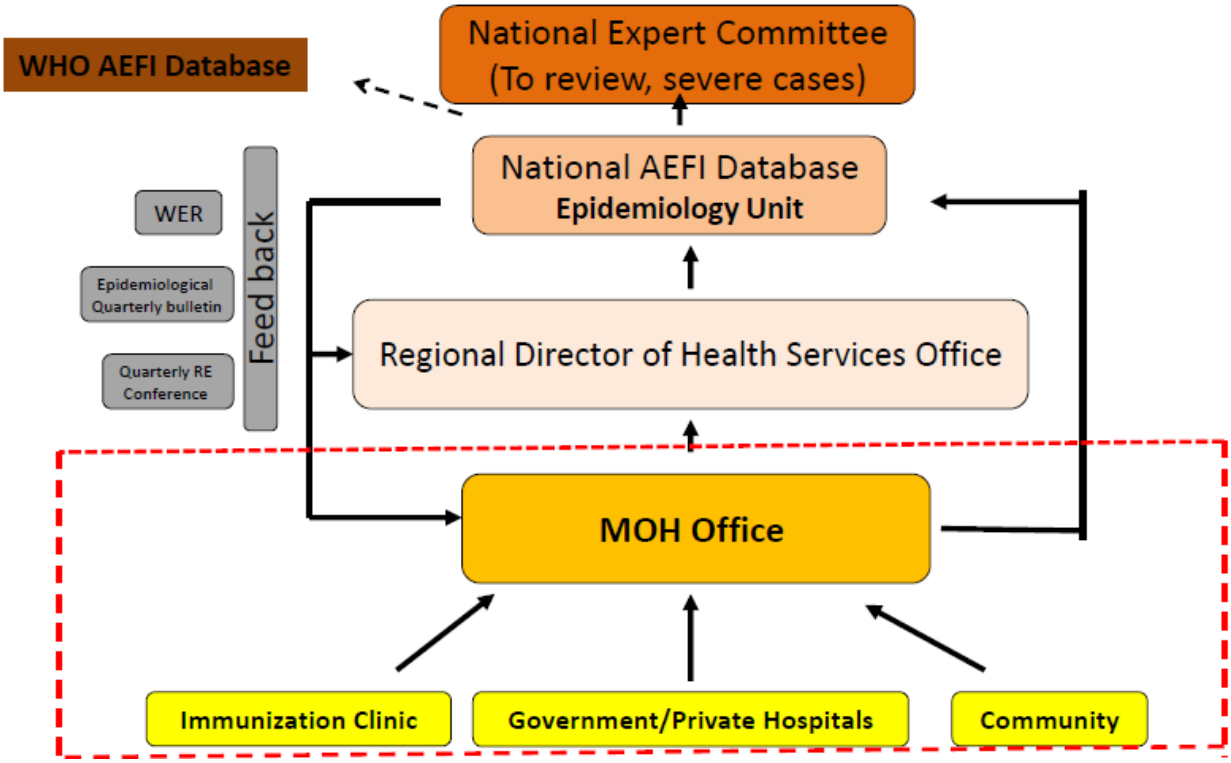
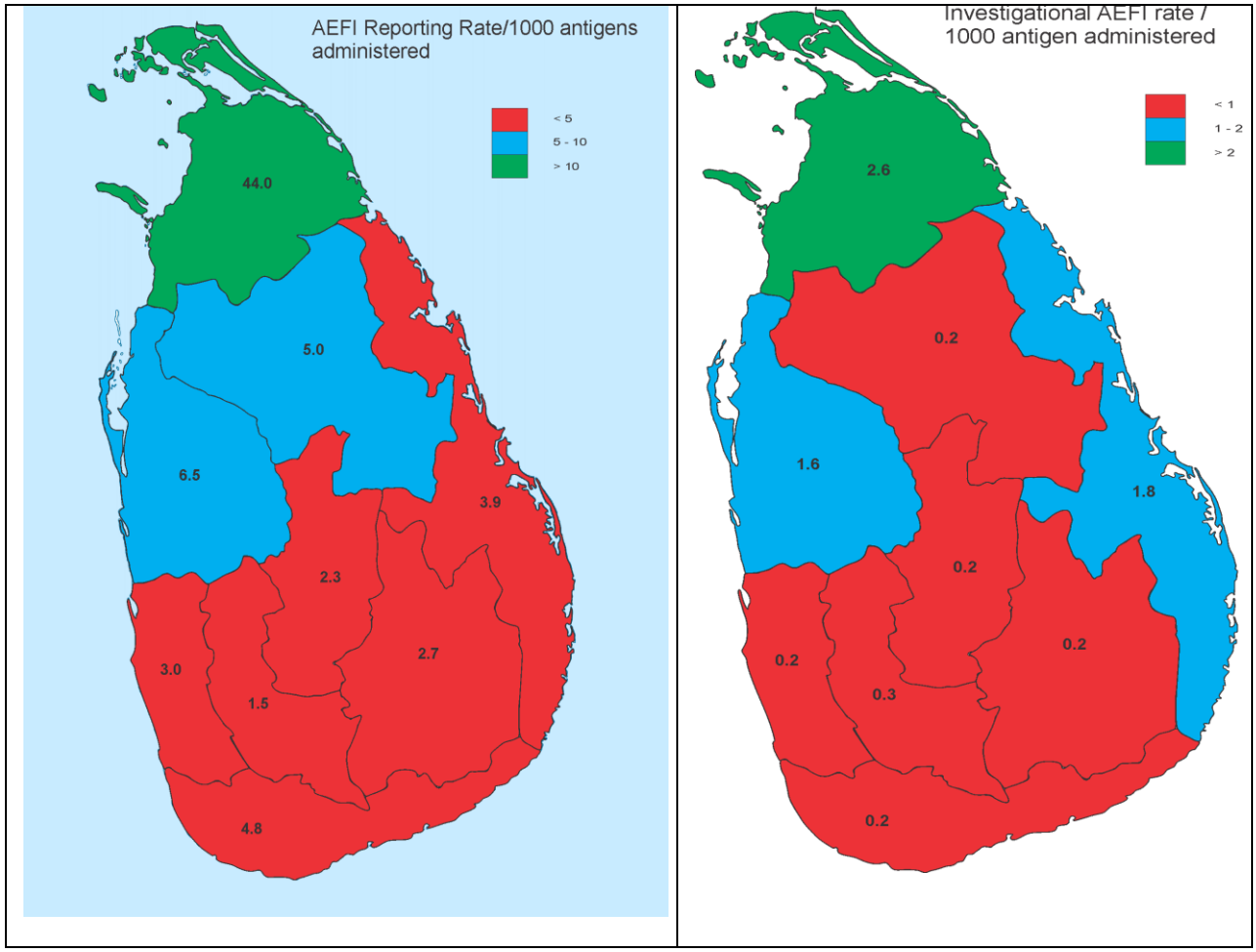
Figure 1: AEFI surveillance system in Sri Lanka



Note: This survey evaluated the AEFI surveillance at MOH office and Immunization clinic, as those two units are the AEFI data generating basis in surveillance

Annex 1


AEFI Reporting Rate/1000 antigens administered
< 5
5 - 10
> 10
44.0
5.0
6.5
3.9
2.3
2.7
3.0
1.5
4.8
Investigational AEFI rate / 1000 antigen administered
< 1
1 - 2
> 2
2.6
0.2
1.6
1.8
0.2
0.2
0.2
0.3
0.2