WEEKLY EPIDEMIOLOGICAL REPORT

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231, de Saram Place, Colombo 01000, Sri Lanka
Tele: + 94 11 2695112, Fax: +94 11 2696583, E mail: epidunit@sltnet.lk
Epidemiologist: +94 11 2681548, E mail: chepid@sltnet.lk
Web: http://www.epid.gov.lk

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Vaccine Pharmacovigilance

Vaccine pharmacovigilance: Population-based Post-licensure Safety Surveillance for Vaccines

Vaccines are among the safest innovations of modern medicine that protect against disease by inducing immunity. World over, routine immunization is a fundamental service provided by the public health system and is one of the most cost-effective methods of reducing morbidity and mortality among children. Most vaccines are administered to vulnerable groups such as children and the elderly as well as healthy adults. Therefore, stringent safety measures and supervision of vaccines are essential, as any safety concerns even unfounded rumors will undermine the public confidence in vaccination and lead to adverse consequences on immunization coverage and the incidence of vaccine-preventable diseases. Therefore, the safety of vaccines is of the utmost importance for public health. Therefore, Post-marketing surveillance is particularly critical for vaccines and surveillance systems are developed to closely monitor vaccine safety and effectiveness allowing regulatory authorities and manufacturers to take appropriate actions to protect public health, maintain trust in the healthcare system and continually improve vaccine products.

Vaccine pharmacovigilance is defined as “the science and activities relating to the detection, assessment, understanding, prevention, and communication of adverse events following immunization, or of any other vaccine- or immunization-related issues”. The World Health Organization defines an adverse event following immunization (AEFI) as "a medical incident that takes place after an immunization which causes concern and is believed to be caused by the immunization". The goals of vaccine pharmacovigilance are early detection, and timely response to AEFI, aiming to minimize negative effects on the individual while decreasing the negative impact on immunization activities in the field. Pharmacovigilance of vaccines differs from post-marketing surveillance of other medicines and medical devices. The WHO Global Vaccine Safety Initiative recommends that effective vaccine pharmacovigilance systems be established in all countries with dedicated capacity and databases with reporting forms, reporting of AEFI and established processes for monitoring and investigating AEFI, while enhancing capacity for active surveillance, epidemiological studies and hypotheses testing.

Vaccines are biological products and may contain live organisms, antigens, adjuvants, preservatives and adverse drug reactions (ADR) may occur due to any of the vaccine components, as unique safety implications are present for each, and all components need to be inquired into individually. Additionally, errors in administration could also lead to AEFI’s which has to be investigated separately. For ADRs that occur immediately or as local reactions, attribution of causality is easier compared to delayed events which are difficult to correlate. Moreover, immunological considerations must be combined with pharmacological actions when investigating causality which is an additional complication when investigating vaccine-related ADRs. Out of the Bradford Hill criteria for attribution of causality temporality, the strength of association and consistency is said to be more important when considering vaccine AEFIs, as criteria for causality assessment such as resolution of event following withdrawal of treatment or re-challenge cannot be used for the assessment.

Epidemiological studies for vaccine pharmacovigilance

Epidemiological studies play a key role in the ongoing safety assessment of vaccines as part of vaccine pharmacovigilance. These studies are designed to investigate the occurrence of adverse events following immunization (AEFIs) in large populations over time.

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Epidemiology, as a field, provides valuable tools and methodologies to assess the safety of vaccines in real-world settings including rare events and safety profiles in diverse populations. These studies are essential for making informed decisions about vaccination programs and maintaining public confidence in immunization efforts. Main epidemiological designs used to assess vaccine safety include observational studies such as cohort, case-control, case only (i.e., self-controlled case series and case cross-over) and case-cohort studies. Additionally, systematic reviews, meta-analyses and risk-benefit analyses are also done. The epidemiological design depends on the hypothesis to be tested, the availability of data sources and other factors such as the presence of confounding variables.

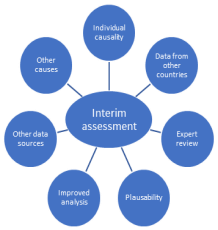

Figure 1: Signal Assessment

Figure 2: Signal Prioritization

Figure 3: Signal Refinement

As components of the vaccine surveillance systems, passive surveillance relies on spontaneous reporting of adverse events by healthcare providers, patients, or other stakeholders and is considered to be an essential component of post-marketing surveillance. Detecting signals involves assessment, prioritization and signal refinement through spontaneous reporting systems and includes activities such as case counts (frequencies, trends, spikes, etc.), clinical review of AEFI, calculating observed and expected cases and data mining for disproportionality analysis. Active surveillance involves proactive monitoring of predefined populations to actively seek and collect information on adverse events. Large linked databases, maintained for health insurance as well as general practice databases can be used for registry-based studies to utilize existing healthcare data to assess the safety of vaccines. Additionally, Hospital-based active reporting and active follow-up of cohorts (cohort event monitoring) is done in some countries. Passive surveillance is rapid and covers the whole population but bias and under-reporting are potential problems. Active surveillance is less biased, has an unvaccinated comparator but can be delayed and does not cover the whole population.

Large linked databases and the use of artificial intelligence and big data are the future for assessing vaccine safety and effectiveness across large and diverse populations globally and over time. As medicinal products are used globally, inter-country collaborations for sharing safety information and transparent clear dialogue between healthcare professionals and the community is essential to ensure the dissemination of safety information to protect public health. Therefore, regional and global networks such as the Global Vaccine Data Network (https://www.globalvaccinedatanetwork.org/), Vaccine Monitoring Collaboration for Europe (https://vac4eu.org/), WHO Global Vaccine Safety Initiative (https://www.who.int/initiatives/the-global-vaccine-safety-initiative) have been established to support collaboration on vaccine safety and effectiveness studies using health data from around the world. A coordinated global response for vaccine effectiveness and safety is necessary to ensure the best outcomes from vaccines for the world populations.

Compiled by
Dr. Rimaza Niyas
Senior Registrar in Community Medicine
Epidemiology Unit
Ministry of Health

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Table 1 : Water Quality Surveillance
Number of microbiological water samples December 2023

District	MOH areas	No: Expected *	No: Received
Colombo	15	90	**0**
Gampaha	15	90	**NR**
Kalutara	12	72	**15**
Kalutara NIHS	2	12	**15**
Kandy	23	138	**NR**
Matale	13	78	**0**
Nuwara Eliya	13	78	**0**
Galle	20	120	**190**
Matara	17	102	**113**
Hambantota	12	72	**24**
Jaffna	12	72	**32**
Kilinochchi	4	24	**NR**
Mannar	5	30	**0**
Vavuniya	4	24	**51**
Mullatvu	5	30	**51**
Batticaloa	14	84	**0**
Ampara	7	42	**0**
Trincomalee	11	66	**0**
Kurunegala	29	174	**NR**
Puttalam	13	78	**NR**
Anuradhapura	19	114	**0**
Polonnaruwa	7	42	**154**
Badulla	16	96	**NR**
Moneragala	11	66	**0**
Rathnapura	18	108	**NR**
Kegalle	11	66	**8**
Kalmunai	13	78	**NR**

* No of samples expected (6 / MOH area / Month)
NR = Return not received

Table 1: Selected notifiable diseases reported by Medical Officers of Health 06th- 12th Jan 2024 (02nd Week)

RDHS	Dengue Fever		Dysentery		Encephali		Enteric		Food Poison-		Leptospirosis		Typhus		V. Hep.		H. Rabi.		Chickenpox		Meningitis		Leishmania-		WRCD	
	A	B	A	B	A	B	A	B	A	B	A	B	A	B	A	B	A	B	A	B	A	B	A	B	T*	C**
Colombo	549	848	1	1	1	1	0	1	0	3	6	15	0	0	0	0	0	0	5	14	0	0	0	0	84	100
Gampaha	111	257	0	1	0	0	1	1	0	0	5	11	0	0	1	1	0	0	5	6	2	6	1	2	79	100
Kalutara	103	180	2	2	0	0	0	0	0	0	10	25	0	0	0	0	0	0	11	23	1	4	0	0	67	100
Kandy	199	408	1	2	0	0	0	0	0	0	2	6	0	1	0	0	0	0	4	12	0	0	1	1	96	100
Matale	39	79	0	0	0	0	0	0	0	2	3	10	0	0	0	0	0	0	0	0	0	0	2	4	69	100
NuwaraEliya	28	47	3	3	0	0	0	0	1	1	10	16	0	0	0	0	0	0	3	6	1	1	0	0	92	100
Galle	84	191	0	3	1	2	0	1	3	7	17	53	3	6	0	1	0	0	9	22	3	3	0	0	78	100
Hambantota	55	93	0	0	0	0	0	0	0	0	25	56	1	1	0	0	0	0	7	11	1	1	12	21	79	100
Matara	35	81	1	2	0	1	0	0	2	2	11	21	0	0	0	0	0	0	4	11	3	22	0	1	88	100
Jaffna	805	1428	3	5	0	0	0	0	1	2	1	4	47	76	0	0	0	0	7	15	2	2	0	0	93	93%
Kilinochchi	52	81	0	0	0	0	0	0	0	1	0	1	0	0	0	0	0	0	1	1	0	1	0	0	100	100
Mannar	35	88	0	0	0	0	1	1	0	0	5	6	1	1	0	0	0	0	0	0	0	1	1	1	100	100
Vavuniya	27	47	0	0	0	0	0	0	0	0	9	15	0	0	0	0	0	0	0	1	1	2	0	0	75	100
Mullaitivu	26	51	2	2	0	0	0	0	0	1	6	12	0	0	0	0	0	0	2	2	0	0	0	0	67	100
Batticaloa	123	265	2	11	0	0	0	0	0	0	0	2	0	0	0	0	0	0	1	3	0	3	0	0	100	100
Ampara	10	21	1	1	0	1	0	0	0	0	7	23	0	0	1	1	0	0	3	10	0	1	0	0	29	100
Trincomalee	50	92	0	1	0	0	0	0	0	0	10	14	1	1	0	0	0	0	0	1	0	2	1	1	67	100
Kurunegala	127	282	1	1	0	1	0	0	1	1	19	46	1	1	0	0	0	0	8	22	4	15	13	22	79	100
Puttalam	92	182	0	0	0	0	0	0	0	0	13	29	1	1	0	0	0	0	5	7	2	3	0	1	46	100
Anuradhapur	28	56	0	0	0	0	0	0	0	0	15	38	0	3	0	1	0	0	2	5	2	3	22	35	87	100
Polonnaruwa	12	33	1	2	0	0	0	0	0	0	10	30	0	0	0	0	0	0	2	11	0	0	4	9	78	100
Badulla	78	189	0	1	0	1	0	0	0	1	17	35	0	1	1	1	0	0	6	17	0	0	0	0	94	100
Monaragala	29	71	0	0	0	0	0	0	0	0	41	89	0	0	1	1	0	0	2	3	2	6	9	10	82	100
Ratnapura	77	153	3	6	0	0	0	0	1	2	48	95	2	3	0	0	0	0	8	12	4	5	0	1	80	100
Kegalle	104	216	1	1	0	1	0	0	0	0	17	36	0	1	2	2	0	0	13	33	3	6	4	5	91	100
Kalmune	35	102	0	2	0	0	0	0	0	0	1	6	0	1	0	0	0	0	2	5	0	2	0	0	85	100
SRILANKA	**2913**	**5541**	**22**	**47**	**2**	**8**	**2**	**4**	**9**	**23**	**308**	**694**	**57**	**97**	**6**	**8**	**0**	**0**	**110**	**253**	**31**	**89**	**70**	**114**	**80**	**99**

Source: Weekly Returns of Communicable Diseases (esurvillance.epid.gov.lk). T=Timeliness refers to returns received on or before 12th Jan, 2024 Total number of reporting units 358 Number of reporting units data provided for the current week: 358 **C****-Completeness

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

Table 2: Vaccine-Preventable Diseases & AFP

06th– 12th Jan 2024 (02nd Week)

Disease	No. of Cases by Province									Number of cases during current week in 2024	Number of cases during same week in 2023	Total number of cases to date in 2024	Total number of cases to date in 2023	Difference between the number of cases to date in 2024 & 2023
	W	C	S	N	E	NW	NC	U	Sab					
AFP*	00	00	00	01	00	00	00	00	00	01	02	03	05	-40 %
Diphtheria	00	00	00	00	00	00	00	00	00	00	00	00	00	0 %
Mumps	00	00	00	00	01	00	01	00	00	02	02	07	04	75 %
Measles	02	00	22	01	01	03	00	01	02	32	00	63	00	0 %
Rubella	00	00	00	00	00	00	00	00	00	00	00	01	00	0 %
CRS**	00	00	00	00	00	00	00	00	00	00	00	00	00	0 %
Tetanus	00	00	00	00	00	00	00	00	00	00	01	00	01	-100 %
Neonatal Tetanus	00	00	00	00	00	00	00	00	00	00	00	00	00	0 %
Japanese Enceph-alitis	00	00	00	00	00	00	00	00	00	00	01	00	01	-100 %
Whooping Cough	00	00	00	00	00	00	00	00	00	00	00	00	00	0 %
Tuberculosis	88	12	08	01	17	37	04	07	05	179	55	342	171	100%

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.

RDHS 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, Neonatal Tetanus, Whooping Cough, Chickenpox, Meningitis, Mumps., Rubella, CRS,

Special Surveillance: AFP* (Acute Flaccid Paralysis), Japanese Encephalitis

CRS =**Congenital Rubella Syndrome

NA = Not Available

Take prophylaxis medications for leptospirosis during the paddy cultivation and harvesting seasons.

It is provided free by the MOH office / Public Health Inspectors.

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ON STATE SERVICE

Dr. Samitha Ginige
Actg. CHIEF EPIDEMIOLOGIST
EPIDEMIOLOGY UNIT
231, DE SARAM PLACE
COLOMBO 10