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A Prospective Observational Study on Adverse Event Following Immunizationin Warangal Region

Dr. S.Satish Kumar MD[1], K.Anusha[2], V.MounaReddy[2],Kirankumar[2], Waseema Khatoon[2], Mohammad Abdul Mubeen[2], G.Sruthi[2]

[1](Department of Gynecology & Pediatrics, Kalyani Hospital, Hanamkonda, Warangal-506001, Telangana, India.

2. Department of Clinical Pharmacy, Vaagdevi Institute of Pharmaceutical sciences, Bollikunta, Warangal-506005, Telangana, INDIA.

**Corresponding author:Dr. S.Satish KumarMD[1]*

Abstract:*Immunization currently prevents an estimated 2 to 3 million deaths every year. If proper vaccine administration covers globally, an additional 1.5 million deaths could be avoided. This study aims to document and need to detect and assess the adverse events for improving quality of life (QOL) of children on immunization.*

Methods: *A prospective observational study was carried out over 1465doses. The data was collected using a data collection form and the standard AEFI form prescribed by the WHO. The patients were also followed up on phone. Causality assessment was done by Causality assessment of an adverse event following immunization (AEFI).*

Results:*Total no. of adverse events detected was 1100 doses among 1465 doses. Generalized adverse events outnumbered other AEs (69.08%) by a wide margin it was followed up by Application site disorders (23.66%), Respiratorysystem (3.36%), Gastrointestinal system (2.24%), Skinappendages (0.98) %, Neurological disorders (0.26%) Musculoskeletal disorder (0.26%), Ocular and optic disorder (0.06%) Urinary tract infection (0.06%).*

Conclusion: *Developing and maintaining electronic documentation of patient's medical records may serve as a valuable tool to detect adverse events. In addition, creating internet facilities within a hospitals or immunization centers may help in easy access for healthcare professionals to update patient's medical records resulting in possible detection and assessment and reporting of adverse event.*

Keywords: *Vaccination, Adverse event(s) following immunization, Quality of Life, WHO Causality Assessment Scale for AEFI.*

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I. Introduction

Immunization is one of the most effective public health interventions for protecting the individual and the public from vaccine-preventable diseases (VPDs). Itis a process where a person is made immune (or) resistant to an infectious disease, by the administration of a vaccine. Vaccines stimulate the body's own immune system to protect the person against subsequent infectious disease. [1] Immunization currently prevents an estimated 2 to 3 million deaths every year. If proper vaccine administration covers globally, an additional 1.5 million deaths could be avoided. According to World Health Organization (WHO), an adverse event following immunizations (AEFI) as a medical incident that takes place after administration of vaccine, which causes concern and is believed to be caused by immunization. [2]. AEFI may be caused by a vaccine(s) or occur coincidentally. Vaccines rarely cause serious adverse reactions, andcommon reactions are minor and self-limited. We monitorthe safety of vaccines by looking for adverse eventsfollowing immunizations (AEFI).An AEFI may be caused by a vaccine reaction but often, particularly if the event is serious, the event is coincidental to vaccination. Other events may be caused by an error in administration or handling of the vaccine.Vaccines are given to children for development of immunization for diseases, the adverse event for vaccination have been detected and assessed by many developed countries but in India proper detection and assessment of adverse events following immunization is at budding stage which has to be progressed in government sector .There will be many minor adverse events which are very common / possible through immunization and also less major events too so , there is a need to detect and assess the adverse events for improving quality of life (QOL) of children on immunization .

II. Material and Methods

It is a prospective observational study conducted in various Pediatric Hospitals and Vaccination Centers in and around Warangal (Kalyani Hospital, CKM Hospital, Mission Hospital and in Primary Health Care centers). A total of 1783 infants were involved in study and 1465 were followed. This study was conducted for a period of 6 months (February-August 2017) after obtaining the requisite clearances from the human ethical committee. People who visited the study site for vaccination and ready to give inform consent were recruited in the study. Data of all the subjects who received vaccine were collected by systematically designed data collection form which includes Subject's demographics, Immunization records, past medical history and follow up details. A post vaccination follow-up was done to detect AEFI (if any) and the information given by parent during ward rounds and through phone calls collected and added to the data which is previously collected by data collection form. The reactions, events, inputs given by parent or guardian during follow up was collected and considered in detection of AEFI.

III. Results and Discussions

A total of 1783 doses of vaccines were injected; 1465 doses were followed and the remaining 318 doses were not followed due to technical reasons. Among 1465 doses the 1100 doses of vaccination were found to be adverse events. The Percentage of adverse events of BCG, Hep-B, and OPV of 821 doses 537 Adverse Events was found to be 65.40%. Penta 1, 2, 3 was found to be 483 79.05% in 611 doses. Measles, Japanese encephalitis was found to be 28 26.92% in 104 doses, DPT, Measles, Japanese encephalitis, OPV, Vit-A was found to be 52 50.98%in 102 doses.

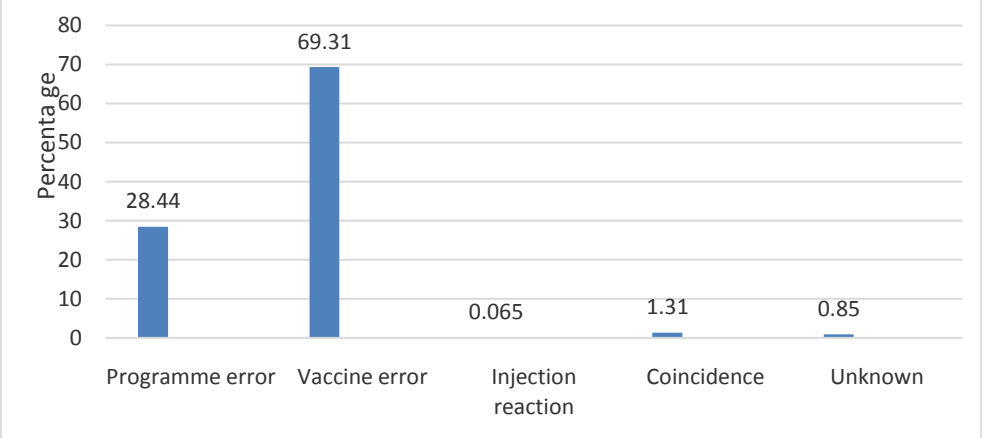
The proportion of AEFI was greater in boys (57.72%) compared to girls (42. 27%).Similar studies of AEFI were also corroborated with our results [5, 6].

Table.1: Frequency of AEFI by Gender, Vaccination Site and Type of vaccine in and around Warangal Region

Variable	Sub Group	Types of Vaccines					
		BCG Hep-B OPV	Penta			Measles J.E Vit-A	DPT OPV Vit-A Measles JE
			1st Penta	2nd Penta	3rd Penta		
Gender	Boy	310 (57.72%)	146 (56.37%)	93 (53.44 %)	25 (50%)	11 (39.28%)	28 (53.84%)
	Girl	227 (42.27%)	113 (43.62%)	81 (46.55%)	25 (50%)	17 (60.71%)	24 (46.15%)
Vaccination Site	Hospital	537 (100%)	21 (8.10 %)	06 (3.44%)	12 (24%)	23 (82.14%)	45 (86.53%)
	PHC	0	238 (91.89%)	168 (96.55%)	38 (76%)	05 (17.85%)	07 (13.46%)
Total		537	259	174	50	28	52

Most frequently reported AEFI were related to Vaccine reaction (69.31%) and Programme error (28 44%).

Table 2: Percentage of AEFI by types of Immunization errors.



Of all the errors, Vaccine errors accounts the top i.e., 69.31%, next comes Programme error i.e.,28.44%, Coincidence 1.31%, Unknown 0.85% and least accounts Injection reaction errors 0.065%.

Table 3 : WhoCausality Assessment Of Aefi

S. No	Type of Vaccine	Causality Assessment(n=(1517)				
		Unrelated	Probable	Definite	Possible	Unlikely
1.	BCG, Hep-B, OPV.	23	27	577	0	0
2.	Penta 1,2,3 OPV IPV	1	12	740	0	0
3.	Measles Japanese Encephalitis Vit-A	0	2	34	0	0
4.	DPT OPV Vit-A Measles Japanese Encephalitis	0	8	93	0	0

The study showed 1517 cases. When classified by system organ the most common ADR/AE reported as a whole-generalized disorders n=1048(69.08%)including fever=956,crying=74,weakness = 1 , chills = 2 , jaundice =15; Application site disorders n=359(23.66%)including pain=51, redness=13 , lump=13 , abscess=1 , swelling=281 ; Respiratory system n=51 (3.36%) including bronchospasm = 4 , coughing = 16 , cold = 24 , sputum = 2, sneezing = 5; Gastrointestinal system n=34 (2.24%) including diarrhea = 12 , vomiting = 20 , constipation = 2 ; Skin appendages n=15(0.98%) including rash = 14 , whitespots = 1 ; Neurological disorders n=4 (0.26%) including sleeplessness =3 , sleepy = 1 ; Musculoskeletal disorder n=4 (0.26%) including dullness = 1 , tiredness = 1 , malaise = 1 ; Ocular and optic disorder n= 1 (0.06%) epiphora = 1 ; Urinary tract infection n=1 (0.06%) .

Table 4 : Data Analysis on System Organ Classification of Adverse Events Reports following Vaccination during the Study period

S.No.	SOC Disorders	AE Reported		BCG OPV HEP-B	Penta Ist,2nd,3rd IPV,OPV	Measles JE Vit-A	DPT O PV Vit-A M, JE
		Reaction	N				
1	Skin & Appendages	Rash White spots	14 1	11 0	1 1	1 0	1 0
2	Gastrointestinal System	Diarrhea Vomiting Constipation Jaundice	12 20 2 15	6 16 0 15	5 2 2 0	1 0 0 0	0 2 0 0
3	Respiratory System	Bronchospasm Coughing Cold Sputum Sneezing	4 16 24 2 5	2 7 11 0 5	2 6 8 2 0	0 1 0 0 0	0 2 5 0 0
4	Generalized Body Disorder	Fever Crying Weakness Chills	956 74 1 2	452 45 0 1	432 26 1 1	25 0 0 0	47 3 0 0
5	Application Site Disorder	Inj. Site Pain Inj. Site Redness Lump Abscess Swelling	51 13 13 1 281	7 3 0 0 42	30 7 12 1 208	3 1 0 0 4	11 2 1 0 27
6	Neurological Disorder	Sleeplessness Sleepy	3 1	2 1	1 0	0 0	0 0
7	Ocular and Optic Disorder	Epiphora	1	0	1	0	0
8	Musculoskeletal Disorder	Dullness Tiredness Malaise	1 1 2	0	1 1 2	0	0
9	Genitourinary Infection	Excess Urination	1	1	0	0	0

IV. Conclusion

This study strongly suggests that there should be a need for detection, reporting and monitoring of adverse events systems in hospital based to create awareness and to promote the reporting of adverse events after vaccination among health care professionals of the country. Measures need to be taken during administration of vaccine and to improve detection, assessment and reporting of adverse events after vaccination. The present study hints that pharmacist's involvement may not only increase the reporting rate but also helps in improving the quality of life by managing them. It is suggested that the most appropriate safety measures of vaccination administration or handling so that adverse events may be reduced. Hospital/clinical pharmacists have also a greater role to play in Immunization surveillance programme which is under pharmacovigilance, to strengthen the National Pharmacovigilance program. Developing and maintaining electronic documentation of patient's medical records may serve as a valuable tool to detect adverse events. In addition, creating internet facilities within a hospitals or immunization centers may help in easy access for healthcare professionals to updated patient's medical records resulting in possible detection and assessment and reporting of adverse event. Also, the implementation of computerized reporting system in hospital set-up may fasten reporting of adverse events and is suggested.

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