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ANALYSIS OF SERIOUS ADVERSE EVENTS FOLLOWING IMMUNIZATION IN CHILDREN BELOW THE AGE OF 5 YEARS – A BIOVIGILANCE STUDY

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Keywords:

AEFI, Vaccine, Adverse events, Biovigilance, Under five AEFI

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ABSTRACT: Background: The WHO has defined AEFI (Adverse events following immunization) as "any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the vaccine usage". The incidence was 13.7% in our country. Vaccine safety surveillance studies are the need of the hour in developing countries to maintain public trust in vaccines since there are limited number of vaccine vigilance studies, the current study is being taken up. **Materials and Methods:** It was a retrospective observational study conducted in the Department of Pediatrics at Victoria Hospital attached to BMCRI. The study was conducted in November and December 2022. The data were collected from patient case records from the year 2018 to 2022. Totally 30 adverse events were reported in that time period. **Results:** Most of the AEFI were reported in the age group of 0-6 years (66.6%). Proportion of male was found to be more than female. Most of the AEFI were reported following Pentavalent (40%) followed by BCG (23.3%), and MR vaccine (20%). The systemic reactions were reported as a serious adverse event (56.6%) than local reactions (43.3%). **Conclusion:** Most common systemic reaction was fever with rashes followed by convulsions, and in local reactions, injection site abscess followed by lymphadenitis. The study shows some reactions are treated following AEFI. Identifying and treating these AEFIs is quite challenging. So, we have to create awareness about AEFIs so as to treat them as early as possible, and also helpful in preventing some product-related side effects.

INTRODUCTION: The WHO has defined AEFI (Adverse events following immunization) as "any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine" [1].

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In India, with approximately 26 million infants born each year, millions of doses of vaccines are administered annually. The incidence of AEFI was reported at around 13.7% in our country. Under the Universal Immunization Programme (UIP), the government of India provides vaccination free of cost against 10 vaccine-preventable diseases.

Although vaccines are proven to be extremely safe, there is a potential risk of an adverse reaction. The benefits of vaccines outweigh the risks of AEFI, hence it is considered to be safe [2]. The AEFI reactions can broadly be classified as 'serious AEFIs' (death, disability, cluster, and

hospitalization) which need to be reported immediately. The other reactions are 'severe AEFIs'. (Inconsolable screaming, Injection site abscess, lymphadenitis) requires immediate management and does not cause long-term complications, minor AEFIs' (pain, swelling at the injection site, fever, irritability, malaise) are reported through monthly reporting systems in UIP. Effective and spontaneous reporting of adverse events following immunization (AEFI) is the first step in making sure that vaccine products are safe and are being safely administered [3]. Causality assessment aims to determine the likelihood of a causal association between the event and the vaccine(s) received. According to the WHO classification, Causality assessment is categorized as consistent, indeterminate, and inconsistent [4].

Vaccine safety surveillance studies are the need of the hour in developing countries to maintain public trust in vaccines, the ultimate objective being to have vaccines with the most favorable benefit-risk profile [5]. Since, there are a limited number of vaccine vigilance studies related to adverse events following immunization, the current study is being taken up to analyze the pattern of serious AEFI in our tertiary care center.

Objective of the Study: To analyze serious adverse events following immunization in pediatric patients.

METHODOLOGY: It was a retrospective observational study conducted in the Department of Paediatrics at Victoria Hospital attached to Bangalore Medical College and Research Institute. The study was conducted in November and December 2022. The data were collected from patient case records who developed serious adverse events following immunization were reported from the year 2018 to 2022. Totally 30 adverse events were reported in that period. Under 5 age group children who have experienced adverse events following immunization were included in the study. The patients whose complete details were not available in the medical records were excluded from the study. After obtaining approval and clearance from the institutional ethics committee, patients fulfilling the eligibility criteria will be taken for the study. The details of adverse events and other information related to adverse events following immunization will be recorded in the case record form. Demographic details of the patient including age, gender, diagnosis, vaccine details, history of presenting illness, examination, and treatment details will be recorded in the predesigned case record form. According to WHO classification, Causality assessment is categorized as consistent, indeterminate, and inconsistent. The assessment tool of the study includes Patient details – age, gender, diagnosis, clinical presentation, investigation, and treatment followed by Vaccine details – type of vaccine, dose, and route of administration finally causality assessment according to WHO criteria.

Ethics Approval: Approved by the Ethics committee attached to Bangalore Medical College and Research Institute – Approval number - BMCRI/PS/226/22-23

RESULTS:

TABLE 1: DISTRIBUTION OF SUBJECTS ACCORDING TO AGE

Age in Months	Number of children developed AFEI (Total number of children developed AEFI - 30)
0-6 months	20 (67%)
6-12 months	04 (13%)
12-24 months	05 (17%)
>24 months	01 (03%)

TABLE 2: NUMBER OF AEFI AFTER EACH VACCINATION

S. no.	Vaccine Given	Male	Female	Total Patients
1.	Pentavalent	7	5	12
2.	BCG	4	3	7
3.	MR	3	3	6
4.	DPT	4	-	4
5.	IPV	-	1	1
	Total	18 (60%)	12 (40%)	30

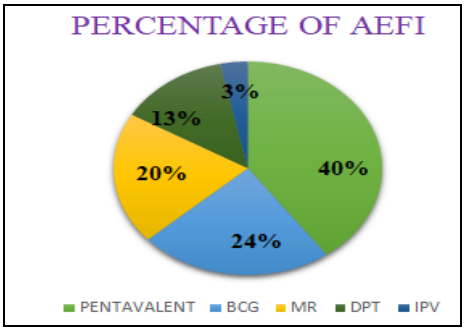

FIG. 1: FREQUENCY OF AEFI AFTER VACCINATION

TABLE 3: FREQUENCY OF LOCAL AND SYSTEMIC REACTIONS REPORTED AFTER SPECIFIC VACCINATION

S. no.	Vaccine Given	Total Patients	Frequency (%)	Number of Local and Systemic Reactions
1.	Pentavalent	12	40%	6 – Local 6 - Systemic
2.	BCG	7	23.3%	7 – Local
3.	MR	6	20%	6 – Systemic
4.	DPT	4	13.3%	4 - Systemic
5.	IPV	1	3.3%	1 - Systemic
	Total	30		13 – Local (43.3%) 17 – Systemic 56.6%)

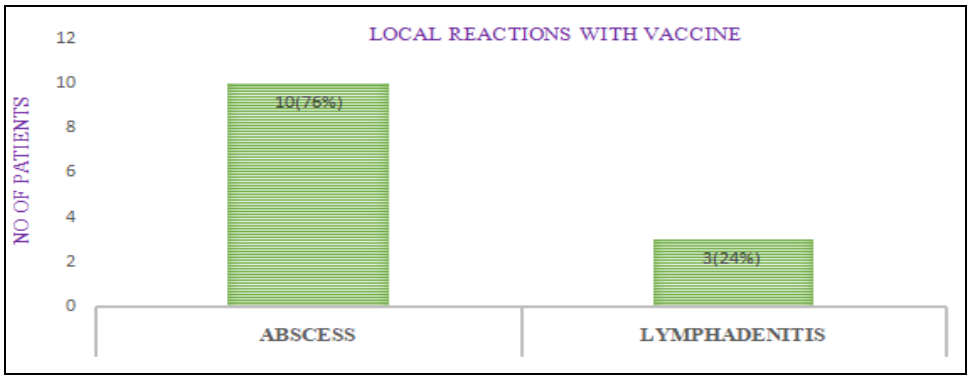

FIG. 2: FREQUENCY OF LOCAL REACTIONS OF AEFI

TABLE 4: FREQUENCY OF SYSTEMIC REACTIONS AND ASSOCIATED VACCINES

S. no.	Systemic AEFI Reactions	No. of patients (%)	Vaccine associated with AEFI
1.	Fever with rashes	7(41%)	Pentavalent, MR,
2.	Convulsions	5(29%)	Pentavalent, DPT, IPV
3.	Breathing difficulty	3(18%)	Pentavalent, DPT
4.	High grade fever with local swelling	1(6%)	Pentavalent
5.	Facial nerve palsy	1(6%)	Pentavalent

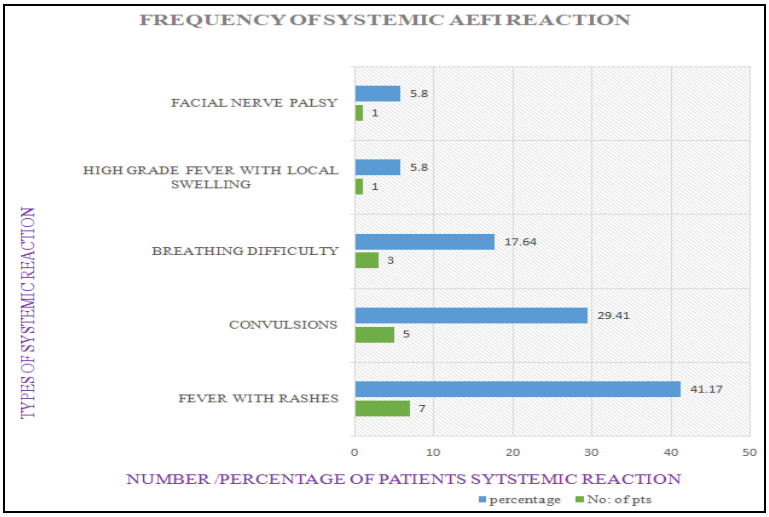

FIG. 3: FREQUENCY OF SYSTEMIC RECATIONS OF AEFI

DISCUSSION: Table 1 indicates that the highest incidence of adverse events following immunization (AEFI) was observed in infants aged 0-6 months (66.6%), a finding consistent with the results of Pagar *et al* [6]. and Cunha *et al.* [7] This increased occurrence in younger infants may be attributed to the greater number of vaccines administered during the first six months of life and their potentially higher susceptibility. According to **Table 2**, male infants comprised 60% of the 30 cases of adverse events following immunization (AEFI), a finding that aligns with observations from studies by K.C. Thoon *et al* [8] and Pagar *et al* [6].

In our study, the pentavalent vaccine exhibited the highest association with adverse events following immunization (AEFI), accounting for 40% of reported cases. Following this, BCG was implicated in 24% of AEFI, while the MR vaccine was associated with 20% of cases. The DPT vaccine contributed to 13% of reported AEFI, and IPV was linked to the smallest proportion, at 3%. This distribution highlights the pentavalent vaccine as the most frequent trigger for AEFI within our study population. Our study's finding that the pentavalent vaccine was most commonly linked to adverse events following immunization (AEFI) echoes the results reported by SA Aderibigbe [9] and Ishaku S. G *et al*.[10] Their analysis, based on WHO classification, categorized AEFI associated with BCG, HBV, and measles antigens as rare (0.01% to 0.1%), whereas the pentavalent vaccine exhibited a higher frequency of AEFI (0.01% to 1%), a pattern consistent with the increased incidence we observed.

The AEFI reactions are divided into local and systemic reactions. **Table 3** reveals that systemic reactions constituted the majority of adverse events following immunization (AEFI) observed in our study, accounting for 56.6% of cases. In contrast, local reactions were less frequent, representing 43.3% of the reported AEFI. Given that our study specifically included serious AEFI cases requiring hospitalization, the higher frequency of systemic reactions observed is likely due to the fact that these types of reactions often necessitate more intensive treatment and inpatient care compared to localized reactions. **Fig. 2** illustrates that serious local reactions were most frequently associated with the BCG vaccine, followed by the pentavalent vaccine. Specifically, abscess formation accounted for 74% of these local reactions, while lymphadenitis comprised 26%. These findings are consistent with the study by Aditi Dey et al., where 25% of patients experienced lymphadenitis as a serious AEFI.

Table 4 indicates that the pentavalent vaccine was associated with the highest number of systemic adverse events following immunization (AEFI), followed by the MR, DPT, and IPV vaccines. The systemic AEFI observed after pentavalent vaccination included convulsions, fever with rashes, facial nerve palsy, and breathing difficulty. Following MR vaccination, systemic AEFI manifested as fever with rashes and breathing difficulty. Convulsions and breathing difficulty were the systemic AEFI reported after DPT vaccination, while focal convulsions were observed after IPV administration. Our findings are consistent with the study by Aditi Dey *et al.*[11], where convulsions were the most frequent serious AEFI (52%), followed by chest discomfort (12%) and serious injection site reactions (3%). Serious local reactions were observed more frequently with BCG vaccine followed by Pentavalent vaccine, Local reactions observed were abscess 74%, lymphadenitis 26%. Similar results were observed in Aditi Dey *et al* [11], 25% patients experienced lymphadenitis as serious AEFI.

CONCLUSION: Fever with rashes was the most commonly reported systemic AFEI and abscess was the most commonly reported AEFI. Most of the AEFI were recorded following immunization with pentavalent followed by BCG and Measles-Rubella vaccine. The data reported here are consistent with an overall high level of safety for vaccines used in government setup when administered according to the clinical recommendations contained within the national immunization schedule in under five age group. Identifying and treating these AEFIs is quite challenging. So, we have to create awareness about AEFIs so as to treat them as early as possible, and also helpful in preventing some product-related side effects.

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CONFLICT OF INTEREST: Nil

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