

**A RETROSPECTIVE STUDY ON ADVERSE EVENTS FOLLOWING IMMUNISATION
(VACCINE VIGILANCE) AT A TERTIARY CARE TEACHING HOSPITAL**

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ABSTRACT

Background: A vaccine is a way to build our body's natural immunity to a disease before one get sick. This keeps us from getting and spreading the disease. Vaccination is an injection or a procedure or a treatment with a vaccine to produce immunity against a disease, where they make the body stronger against a particular disease. Vaccinations are an important part of family and public health, vaccines prevent the spread of contagious, dangerous, and deadly diseases. Adverse events following immunization(AEFI) main role is to observe immunization safety, detect and respond to adverse events; correct unsafe immunization practices, reduce the negative impact of the health and contribute to the quality of immunization activities. Most of them are mild and do not last for long. Some of the serious adverse reactions to vaccines are serious allergic reactions, immune thrombolytic purpura, febrile seizures, etc., Among them common ones are febrile seizures, injection site reactions and allergic reactions. **Objectives:** The main objective was to identify and evaluate the adverse reactions following vaccination. **Materials and Methods:** A retrospective study in the pediatric department of Cheluvamba Hospital, Mysore Medical College and Research Institute, Mysore from over a period of 3 months. Data collected from 2017 January to 2019 December with a sample size of 115 cases. The data obtained was analyzed by using SPSS version 20. **Result:** Among 115 patients 72(62.3%) were male and 43 (37.4%) patients were female. In this study 75 (65.2%) patients were at age group 1month-1year. The most commonly reported AEFI is febrile seizures of about 37.4% (n=75). Adverse events were related to Pentavalent (47.8%) followed DPT (19.1%) vaccines. 7 deaths were reported followed by pentavalent vaccination. **Conclusion:** The study was conducted to identify and evaluate the most common Adverse events following immunization. In the modern era of science and technology, no child should suffer from a disease which can be prevented by a vaccine. So it is very important to provide vaccination awareness among the population. All the tertiary care centres should maintain detailed information's about all vaccinated children and reports of adverse events associated with it, to overcome underreporting of AEFI.

KEYWORDS: AEFI (adverse events following immunization), seizures, health, safety, vaccination.**INTRODUCTION**

Vaccine is simply defined as a preparation containing killed or weakened microorganisms (bacteria or virus) that is given by injection to increase protection against a particular disease.^[1] Immunization describes the process whereby people are protected against illness caused by infection with microorganisms, formally called pathogens. The term vaccine refers to the material used for immunization, while vaccination refers to the act of giving a vaccine to a person.^[2] Vaccinations are an important part of family and public health, which prevent the spread of contagious and dangerous diseases. These include measles, polio, mumps, chicken pox, whooping cough, diphtheria, tuberculosis and tetanus.^[3]

Although vaccines are among the safest of pharmaceuticals, the occasional severe adverse event or cluster of adverse events associated with their use may

rapidly become a serious threat to public health. It is essential that national monitoring and reporting systems for vaccine safety are efficient and adequately coordinated with those that conventionally deal with non vaccine pharmaceuticals.^[4]

Most vaccine reactions are minor and subside on their own. Serious reactions are very rare and in general do not result in death or long term disability. The purpose of a vaccine is to induce immunity by causing the recipient's immune system to react to the vaccine antigens. Local site reaction, fever and systemic symptoms can result as a part of the immune response. In addition, some of the vaccines's components (eg: adjust stabilizers or preservatives) can lead to reactions.^[4]

MATERIALS AND METHODOLOGY

This is a hospital based retrospective observational study, was conducted at Mysore medical college and research institute and associated hospitals, (cheluvamba hospital); Mysuru. The study was carried out at paediatric department The study duration was the period of 3 months. During the study period we have collected 115 patients case reports from the year 2017 January to 2019 December. The patients who satisfy the inclusion criteria was enrolled in to the study after obtaining their consent. The pharmacist activities like participating in ward round, patient counseling, medication review

(medication chart and relevant documents), providing the drug information, monitoring and documenting of ADR will be done.

A suitably designed data collection form was used to record all the necessary data (patient demographic details, patient medication history, and reason for admission, any allergic reaction, medication details and lab investigations). The ADRs identified were documented in ADR reporting form. The obtained data was subjected for suitable study.

RESULTS

Demographic Details in The Study Population

Table 1: Gender Distribution of the study.

Sex	Frequency	Percent
Female	43	37.4%
Male	72	62.3%
Total	115	100%

Table 2: Age Categorization in the study population.

Age group	Frequency	Percent
0-1 month	6	5.2%
1month -1 year	75	65.2%
1-3 year	21	18.3%
3-6year	8	7%
6-12year	3	2.6%
12-18years	1	0.9%
18years	1	0.9%
Total	115	100%

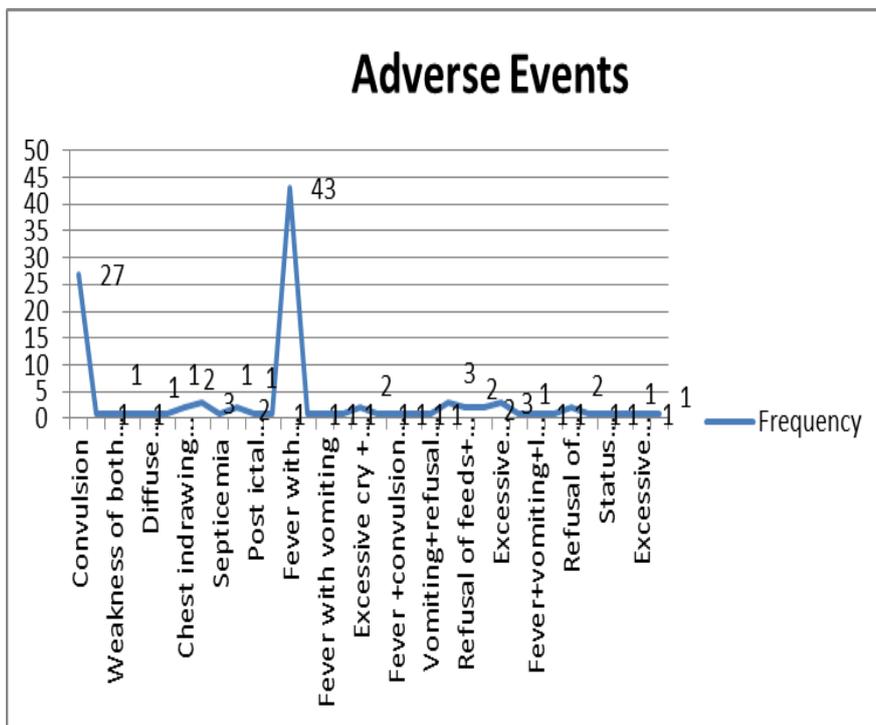


Figure 1: Suspected Adverse event in the study.

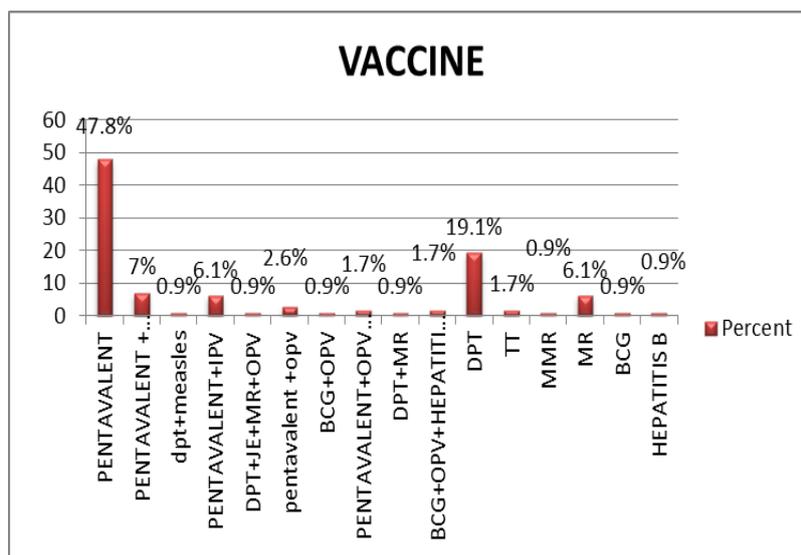


Figure 2: Suspected Vaccines in the Study Population.

Table 3: Frequency of Death by Immunization in the study population.

Name of vaccination	Death	N
PENTAVALENT	YES	7
PENTAVALENT +IPV+OPV	YES	1
PENTAVALENT +IPV	YES	1
BCG+OPV+HEP B	YES	1
DPT	YES	1
MR	YES	1
Total		12

Table 1 shows greater dominance of males over females in the study population. Out of 115 patients, 62.3% were males (n=72) and 37.4% were females (n=43). Table 2 indicates that 65.2 % of paediatric patients were from 1 month to 1 year (n=75) and least were in the age group of 12 to 18 years and above (n=1). Among 115 patients included in the study population, 37.4% of adverse event was febrile seizures (n=43) followed by 23.5% of convulsions (n=27). The details are depicted in the figure 1. Figure 2 shows out of 16 suspected vaccines, the most commonly reported adverse events were by pentavalent (47.8%) followed by DPT vaccine (19.1%). Table 3 shows that pentavalent (n=7) have more dominance over all other vaccines suspected in the frequency of death by immunization in the study population.

DISCUSSION

The study was carried out in the paediatric department in cheluvamba hospital of Mysore Medical college and research institute over a period of 3 month. This is a retrospective study on adverse events following immunization. In the study of 115 patients, about 72 patients (62.3%) were male and 43 (37.4%) patients were female. This can be supported by a study conducted by Hardil Patel et.al, in which 54% were male out of 637 cases reported^[5]. Most of the patients were between the age of 1 month-1years. Our results concurred with those of the study by Silvia R C et al showed that, most of the reported AEFIs occurred in children less than 1 year of

age (75%) followed by children in the age group between 1 and 4 years of age^[6]. In our study mostly reported AEFI is febrile seizures following convulsions with fever and excessive irritability. In contrast to the study Juny Sebastian et.al, reports that out of 6894 patients, 93.2% of cases were fever followed by persistent crying (n=69) and diarrhea (n=57).^[7] Figure 3 shows that 47.8% of the adverse events were caused by pentavalent vaccines followed by 19.1% of DPT vaccine. This result was comparable with the study conducted by Juny Sebastian et al, reported 84.4% (n=2220) of AEFIS with administration of the first dose of Pentavac.^[7] In our study about 7 infants have died following pentavalent immunization. But this is contradictory to the study conducted by Wang FZ et al, reported that about 10 infants have died after hepatitis B Vaccination.^[8]

CONCLUSION

The study was conducted to identify and evaluate the most common Adverse events following immunization. In the modern era of science and technology, no child should suffer from a disease which can be prevented by a vaccine. So it is very important to provide a vaccination awareness among the population. Eventhough, the merits of all the vaccine is inevitable, they should be taken with caution and care. All the tertiary care centres should maintain detailed informations about all vaccinated children and reports of adverse events associated with it, to overcome underreporting of AEFI.

REFERENCES

1. C William.Sheil, MD, FACP, FACR. Medical definition of vaccination. Medicinenet, 12-27-2018.
2. Lemon S.M, and Thomas D L Vaccine to prevent viral hepatitis.N Eng JMes, 1997; 336(3): 196-204.
3. Eserverri JL, Ranea S, Marin A. Adverse reactions to vaccines: allergol immunopathol, 2003 may-jun.
4. V. menta, J.B milstan; P Duclos. Clinical pharmacist, national adverse day event monitoring.
5. Patel H, shah S, Desai M, Kalaiselvan V, Singh G.N. Retrospective Qualitative And Quantitative Analysis Of Adverse Events Following Vaccination. Journal of young pharmacists, 2018; 10(3): 326-329.
6. RC Silvia, Perin LR, S Tainae, Maria S, Lessa C and Dorea J. Adverse events following immunization in Brazil: age of child and vaccine associated risk analysis using logistic regression. Int J Environ Res Public Health, 2018Jun; 15(6): 1149.
7. Sebastian J, Gurumurthy P, Dharti Ravi M, and Ramesh M. Active surveillance of adverse events following immunization (AEFI): a prospective 3-year vaccine safety study. Ther Adv Immunother, 2019; 7: <https://doi.org/10.1177/2515135519889000>.
8. FZ Wang, FQ Cul, DW Liu. Analysis on the adverse events following immunization of 10 infants death after hepatitis B vaccination. Europe PMC. Zhongguo yi Mian yi, 01 Feb 2009; 15(1): 52-57.