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Original Research Article

# Incidence and Management of Adverse Events Following Immunization in a Tertiary Care Hospital in Maharashtra: Insights from the Universal Immunization Program

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**Abstract:**

**Introduction:** Adverse events following immunization (AEFI) are a critical concern in public health, impacting vaccine safety and acceptance. The Universal Immunization Program (UIP) of India aims to provide equitable access to essential vaccines, yet monitoring and managing AEFI remains a challenge. This study investigates the incidence, types, and management of AEFI in an Immunoprophylaxis Clinic of a tertiary care hospital in Maharashtra, India.

**Methodology:** This cross-sectional study was conducted over six months, enrolling 204 children who received vaccinations under the UIP at a tertiary care hospital. AEFI data were collected using standardized reporting forms, documenting the type of vaccine administered, the occurrence of AEFI, and the management provided. The sample size was calculated to ensure a 95% confidence level with a 3% margin of error, resulting in a required sample size of 204. Descriptive statistics were used to summarize the data, and chi-square tests were applied to analyze the association between demographic factors and AEFI incidence.

**Results:** The overall incidence rate of AEFI was 6.10%, with 25 cases recorded out of 410 doses administered. The highest incidence rate was observed with the BCG vaccine (10.20%), followed by the PCV vaccine (5.90%) and the MR vaccine (5.20%). The 0-1 year age group experienced the most AEFI cases (10), indicating higher susceptibility in infants. Fever (36.00%) and local reactions (28.00%) were the most common types of AEFI, primarily managed with home care, while moderate reactions such as rash (16.00%), vomiting (12.00%), and abscess (8.00%) required medical intervention. All patients recovered successfully.

**Conclusion:** The study highlights a relatively low but significant incidence of AEFI, with variations among different vaccines and age groups. The effective management of AEFI, with all patients recovering, underscores the robustness of current protocols. Continuous AEFI surveillance, targeted education for healthcare providers, and policy improvements are essential to further enhance vaccine safety and public confidence in immunization programs.

**Keywords:** Adverse events following immunization, AEFI, Universal Immunization Program, vaccine safety, immunoprophylaxis, pediatric immunization, vaccine adverse reactions, Maharashtra, public health surveillance, immunization program effectiveness..



## Introduction

Adverse reactions following immunization (AEFI) are an important aspect of public health surveillance and patient safety in immunoprophylaxis programs. These reactions can vary from minor, such as local pain at the injection site, to severe, such as anaphylactic shock. [1] The Universal Immunization Program (UIP) of India, initiated in 1985, aims to provide equitable access to essential vaccines for all children across the country. [2] The program includes vaccines against tuberculosis, polio, diphtheria, pertussis, tetanus, hepatitis B, measles, and more recently, rotavirus

and pneumococcal conjugate vaccines. [3] Monitoring and managing AEFI are critical for maintaining public confidence in immunization programs. The World Health Organization (WHO) emphasizes the need for robust AEFI surveillance systems to detect, assess, and respond to vaccine-related adverse events. [4] In India, the AEFI surveillance system is an integral part of the UIP, involving a multi-tiered approach from local health workers to national-level experts.

In Maharashtra, one of the most populous states in India, the Immunoprophylaxis Clinic at tertiary care hospitals plays a pivotal role in implementing the UIP. These clinics are responsible for administering vaccines, monitoring for adverse events, and ensuring the overall safety of immunization practices. Despite the extensive reach and success of the UIP, concerns about AEFI remain a significant barrier to achieving higher immunization coverage rates.

This study aims to investigate the incidence, types, and management of AEFI reported at the Immunoprophylaxis Clinic in a tertiary care hospital in Maharashtra. By analyzing the patterns and outcomes of AEFI, this research seeks to contribute to the existing knowledge base, enhance vaccine safety protocols, and ultimately support the effective implementation of the UIP in India.

**Methodology**

This cross-sectional study was conducted at the Immunoprophylaxis Clinic of Shri Bhausaheb Hire Government Medical College Dhule, Maharashtra, which follows the Universal Immunization Program (UIP) of India. The study period was from August 2023 to May 2024. The study aimed to investigate the incidence, types, and management of adverse events following immunization (AEFI) in children receiving routine vaccinations. The study protocol was approved by the Institutional Ethics Committee, and written informed consent was obtained from the parents or guardians of all participating children. A sample size of 204 was determined using the formula for proportions, considering an expected prevalence of AEFI at 5%, a 95% confidence level, and a margin of error of 3%. The study enrolled 204 children who visited the clinic for immunization over a six-month period.

Data collection involved recording demographic information, medical history, and details of the vaccines administered. AEFI was monitored and documented by healthcare professionals using standardized AEFI reporting forms. The forms included information on the type of reaction, time of onset, severity, duration, and treatment provided. Follow-up was conducted via phone calls and clinic visits to ensure comprehensive monitoring of delayed adverse reactions. Descriptive statistics were used to summarize the demographic characteristics of the study population and the incidence of AEFI.

The prevalence of different types of AEFI was calculated, and the association between demographic factors and the occurrence of AEFI was analyzed using chi-square tests. The severity and management of AEFI were also assessed, and outcomes were categorized into mild, moderate, and severe reactions based on established criteria.

The results were interpreted to identify common patterns and potential risk factors associated with AEFI in the context of the UIP. This study's findings contribute to the broader understanding of vaccine safety and help inform strategies to improve immunization practices and AEFI management in tertiary care settings in Maharashtra.

**Results**

**Table 1: Demographic Characteristics of the Study Population**

| Age Group | Gender | Number of Children (n) | Percentage (%) |
|---|---|---|---|
| 0-1 year | Male | 47 | 23.00% |
| | Female | 44 | 21.60% |
| 1-2 years | Male | 33 | 16.20% |
| | Female | 32 | 15.70% |
| 2-3 years | Male | 22 | 10.80% |
| | Female | 23 | 11.30% |
| 3-5 years | Male | 14 | 6.90% |
| | Female | 15 | 7.40% |
| **Total** | | **204** | **100%** |

Table 1 illustrates the demographic characteristics of the 204 children who participated in the study.

The data is organized by age group and gender, showing that the largest proportion of children falls within the 0-1 year age group, with 47 males (23.00%) and 44 females (21.60%). The 1-2 year age group also constitutes a significant portion, comprising 33 males (16.20%) and 32 females (15.70%). The 2-3 year age group includes 22 males (10.80%) and 23 females (11.30%), while the smallest group, the 3-5 year age group, consists

of 14 males (6.90%) and 15 females (7.40%). Overall, the table shows a slightly higher number of males compared to females, providing a comprehensive view of the age and gender distribution among the study participants. This demographic information is essential for analyzing and understanding the patterns of adverse events following immunization within the population studied.

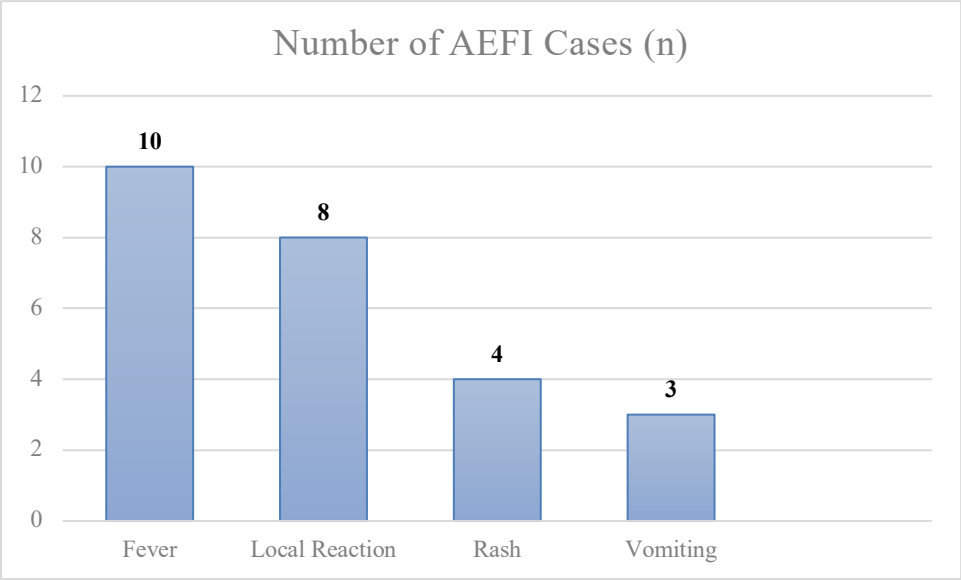


**Figure 1: Incidence of Different Types of AEFI**

The most common adverse event reported was fever, with 10 cases, indicating that it was the predominant reaction among the study population. This is followed by local reaction, which accounted for 8 cases, making it the second most frequent adverse event. Rash was observed in 4 cases, highlighting its relatively lower incidence compared to fever and local reactions. Vomiting was reported in 4 cases, showing it to be less common but still a notable reaction.

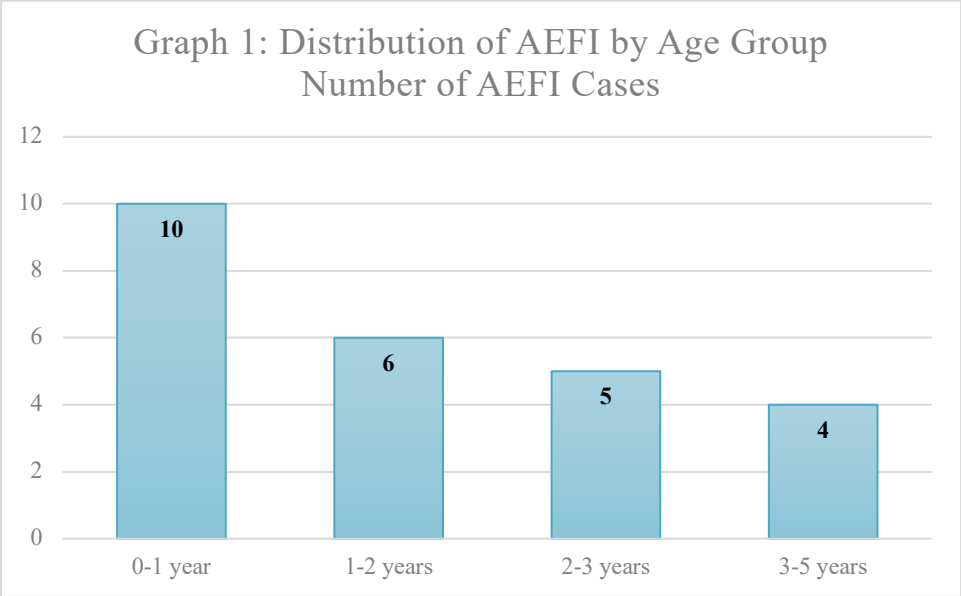


**Figure 2: Distribution of AEFI by Age Group**

The highest number of AEFI cases occurred in the 0-1 year age group, with 10 cases. This indicates that infants in this age group experienced the most adverse events following immunization. The 1-2 years age group had 6 AEFI cases, making it the second highest in terms of AEFI incidence. The 2-3 years age group recorded 5 cases, while the 3-5 years age group had the lowest number of AEFI cases, with 4 reported incidents.

**Table 2: Incidence and Types of Adverse Events Following Immunization (AEFI)**

| Type of Vaccine Administered | Total Number of Doses Administered | Number of AEFI Cases | Incidence Rate (%) | Common AEFI Observed |
|---|---|---|---|---|
| Pentavalent | 102 | 5 | 4.90% | Fever, Local Reaction, Vomiting |
| BCG | 49 | 5 | 10.20% | Fever, Local Reaction, Abscess |
| MR | 58 | 3 | 5.20% | Rash, Fever |
| Rotavirus | 81 | 2 | 2.50% | Diarrhea, Vomiting |
| IPV/OPV | 119 | 4 | 3.40% | Fever, Local Reaction, Vomiting |
| PCV | 101 | 6 | 5.90% | Fever, Local Reaction, Irritability |
| **Total** | **410** | **25** | **6.10%** | |

Table 2 presents the incidence and types of adverse events following immunization (AEFI) for various vaccines administered in the study. A total of 410 doses of different vaccines were administered, resulting in 25 AEFI cases, which gives an overall incidence rate of 6.10%. For the Pentavalent vaccine, out of 102 doses administered, there were 5 AEFI cases, resulting in an incidence rate of 4.90%.

The common adverse events observed for this vaccine included fever, local reaction, and vomiting. The BCG vaccine had 49 doses administered with 5 cases of AEFI, leading to a higher incidence rate of 10.20%, with fever, local reaction, and abscess being the common reactions. The MR vaccine had 58 doses administered and 3 AEFI cases, yielding an incidence rate of 5.20%, with rash and fever as the most common adverse events. For the Rotavirus vaccine, out of 81 doses, there were 2 cases of AEFI, resulting in an incidence rate of 2.50%, and the commonly observed adverse events were diarrhea and vomiting. The IPV/OPV vaccine had 119 doses administered with 4 AEFI cases, resulting in an incidence rate of 3.40%, with fever, local reaction, and vomiting being the common adverse events.

The PCV vaccine had 101 doses administered with 6 cases of AEFI, corresponding to an incidence rate of 5.90%, and the common adverse events included fever, local reaction, and irritability. This table highlights the variation in incidence rates of AEFI among different vaccines and provides insights into the most common types of adverse reactions observed for each vaccine, which is crucial for understanding the safety profile of these vaccines within the study population.

**Table 3: Severity and Management of Adverse Events Following Immunization**

| Type of AEFI | Severity | Number of Cases (n) | Percentage (%) | Management Provided | Outcome |
|---|---|---|---|---|---|
| Fever | Mild | 9 | 36.00% | Home Care | Recovered |
| Local Reaction | Mild | 7 | 28.00% | Home Care | Recovered |
| Rash | Moderate | 4 | 16.00% | Medical Intervention | Recovered |
| Vomiting | Moderate | 3 | 12.00% | Medical Intervention | Recovered |
| Abscess | Moderate | 2 | 8.00% | Medical Intervention | Recovered |
| **Total** | | **25** | **100%** | | |

Table 3 provides an overview of the severity and management of adverse events following immunization (AEFI) observed in the study. The table categorizes the types of AEFI, their severity, the number of cases, their percentage, the management provided, and the outcomes. The most common AEFI observed was fever, with 9 cases (36.00%) classified as mild. All cases of fever were managed with home care, and all patients recovered. Local reactions were the second most common AEFI, with 7 cases (28.00%), also classified as mild. These were similarly managed with home care, and all patients recovered. Rash was observed in 4 cases (16.00%), classified as moderate. These cases required medical intervention, and all patients recovered. Vomiting occurred in 3 cases (12.00%), also classified as moderate, necessitating medical intervention, with all patients recovering. Abscess was the least common AEFI, with 2 cases (8.00%), classified as moderate. These cases also required medical intervention, and all patients recovered.

## Discussion

The findings of this study provide valuable insights into the incidence and management of adverse events following immunization (AEFI) in a tertiary care hospital setting in Maharashtra. The overall incidence rate of AEFI was found to be 6.10%, with variations observed among different vaccines and age groups. This incidence is consistent with other studies conducted in similar settings, where the reported incidence rates of AEFI vary widely but generally remain within a comparable range. [5,6]

The highest incidence rate was observed with the BCG vaccine (10.20%), followed by the PCV vaccine (5.90%), and the MR vaccine (5.20%). These findings align with previous research indicating that live vaccines, such as BCG, tend to

have higher rates of local and systemic reactions. The high incidence rate for the BCG vaccine can be attributed to the nature of the vaccine and the common occurrence of local reactions such as abscess formation, which was also observed in this study.

Age-wise distribution of AEFI revealed that the 0-1 year age group experienced the highest number of adverse events, accounting for 10 cases. This trend is consistent with other studies that highlight infants as being more susceptible to AEFI due to their developing immune systems and the higher number of vaccines administered at this age. The findings emphasize the need for vigilant monitoring and robust AEFI surveillance in this age group to promptly identify and manage any adverse reactions. [5,7,8]

The severity of AEFI in this study was predominantly mild, with fever and local reactions being the most common types of adverse events, observed in 36.00% and 28.00% of cases, respectively. This is in line with global data where mild reactions such as fever and local site reactions are the most frequently reported AEFI. The management of mild cases with home care and the recovery of all patients underline the effectiveness of current AEFI management protocols. Moderate AEFI, including rash, vomiting, and abscess, accounted for a smaller proportion of cases (16.00%, 12.00%, and 8.00% respectively) and required medical intervention. These moderate reactions, though less frequent, necessitate medical attention to prevent complications and ensure patient safety. The successful recovery of all patients in this study reflects the efficiency of the healthcare system in managing moderate to severe AEFI.

This study highlights the importance of continuous AEFI surveillance to maintain and enhance vaccine safety. The data supports the need for targeted education and training for healthcare providers to manage AEFI effectively, particularly in high-risk groups such as infants. Furthermore, the findings can inform policy decisions and improvements in immunization practices to minimize the incidence of AEFI and bolster public confidence in vaccination programs.

## Conclusion

In conclusion, while the incidence of AEFI observed in this study is within expected ranges, the higher rates in certain vaccines and age groups underscore the necessity for ongoing monitoring and improvement in immunization practices. Future studies with larger sample sizes and in diverse settings are recommended to further elucidate the patterns and determinants of AEFI.

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