

# Adverse Events Following Immunization (AEFI): Current Trends, Latest Autopsy Protocol, Indian Scenario, and Statistics

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# Mini Review

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# Abstract

Vaccination has been one of the most effective public health interventions in human history, saving countless lives and reducing the burden of infectious diseases. However, as with any medical intervention, vaccines can sometimes lead to adverse events following immunization (AEFI). This article explores the current trends, the latest autopsy protocols, the Indian scenario, and statistical insights into AEFI. Understanding and addressing AEFI is essential to maintain public trust in vaccination programs. Vaccine related deaths need to be investigated properly and exact cause of death can be determined with autopsy.

Keywords: Adverse Event Following Immunization; AEFI; Autopsy; Current Trends; Statistics; Indian Scenario

**Abbreviations:** AEFI: Adverse Events Following Immunization; WHO: World Health Organization; PCR: Polymerase Chain Reaction; IPC: Involvement of the Indian Pharmacopoeia Commission.

## Introduction

Vaccination programs have played a pivotal role in reducing the prevalence and impact of infectious diseases worldwide. Immunizations have saved millions of lives and are widely recognized as one of the most effective public health interventions. Nevertheless, vaccines, like any other medical treatment, can have adverse effects. These adverse events following immunization (AEFI) can vary in severity and have raised concerns among the public, healthcare professionals, and policymakers [1,2].

This article aims to shed light on AEFI by examining the current trends, the latest autopsy protocols, the Indian

scenario, and the relevant statistics. By understanding the intricacies of AEFI, we can enhance vaccine safety and maintain public trust in vaccination programs. Various vaccines are essential and adopted by National Immunization Schedule and even given free of cost in various countries. AEFI in such essential vaccines must be investigated thoroughly which can help health authority to plan accordingly for future implementation by keeping safety of citizens.

## **Current Trends in Adverse Events Following Immunization**

Adverse events following immunization are categorized into two main types: minor AEFI and serious AEFI. Minor AEFI typically involve localized reactions at the injection site, mild fever, and other self-limiting symptoms. These reactions are common and generally not cause for concern. Serious AEFI, on the other hand, are more severe and can have lasting consequences. Examples of serious AEFI include anaphylaxis,

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encephalopathy, and other rare but severe conditions [3,4].

Current trends in AEFI reveal that most adverse events are minor and transient. According to the World Health Organization (WHO), the incidence of serious AEFI is estimated to be 1-2 cases per million vaccine doses administered. This low rate underscores the overall safety of vaccines, especially when compared to the risks associated with the diseases they prevent.

Despite the rarity of serious AEFI, they are closely monitored and investigated. AEFI surveillance systems, both national and international, continually collect data and analyze trends to identify potential safety concerns. This proactive approach allows for the prompt detection and management of AEFI and the mitigation of public concerns [5].

#### Latest Autopsy Protocols for Investigating AEFI

In cases where a vaccine recipient experiences a serious AEFI and passes away, autopsies play a crucial role in determining the cause of death and investigating any potential links to vaccination. The latest autopsy protocols are designed to be comprehensive and standardized, ensuring that all relevant information is gathered and analyzed. Reconstructions of vaccine ingredients, its effect on human body at various doses and fatality need to be studied [6].

**Thorough External and Internal Examination:** Autopsies begin with a thorough external examination, including documentation of any signs of injury or allergic reactions at the injection site. The internal examination involves the assessment of vital organs, tissues, and fluids to identify any abnormalities or underlying medical conditions.

**Detailed History and Vaccine Documentation**: Autopsies also include a detailed review of the individual's medical history, including information on the administered vaccine, its lot number, and the date of vaccination.

**Histopathological Analysis:** Tissue samples are collected for histopathological analysis to determine any cellular changes or abnormalities that may have contributed to the adverse event. This analysis is instrumental in understanding the mechanisms behind AEFI.

**Toxicology Screening:** Toxicology screening is essential to rule out any poisonings or reactions to preservatives, adjuvants, or other vaccine components that could be implicated in the AEFI.

**Immunohistochemistry and Special Stains:** These techniques are employed to detect specific markers or pathogens that may be linked to the AEFI.

**Molecular Testing:** Molecular techniques, such as PCR (polymerase chain reaction), may be used to identify genetic predispositions or the presence of infectious agents.

**Expert Review:** Autopsy findings are reviewed by a panel of experts, including pathologists, immunologists, and vaccinologists, to assess the potential role of the vaccine in the adverse event. It is necessary to practice evidence based Forensic Medicine in such cases [7].

#### **Indian Scenario and AEFI**

India, with its vast population, has one of the world's largest immunization programs. The country has made significant strides in improving vaccine coverage and reducing vaccine-preventable diseases. However, the sheer scale of the program also means that India faces unique challenges in monitoring and addressing AEFI.

**National AEFI Surveillance:** India has a robust national AEFI surveillance system in place. It relies on healthcare professionals and the public to report adverse events following immunization, ensuring that even rare events are captured. This system allows for prompt investigation and response.

**Involvement of the Indian Pharmacopoeia Commission (IPC):** The IPC plays a vital role in the Indian scenario by standardizing and monitoring the quality of vaccines and other biological products. This helps ensure that vaccines meet safety and efficacy standards.

**Rapid Response Teams:** India has established rapid response teams to investigate AEFI in a timely manner. These teams consist of experts who assess and manage adverse events, provide medical care, and communicate with the public.

**Vaccine Safety Communication:** Effective communication about vaccine safety is critical in the Indian context. Misinformation and vaccine hesitancy can be addressed through accurate and transparent information dissemination. It is essential to preserve documents related to vaccines with proper confidentiality to overcome medical negligence and future litigations [8-11].

#### Statistics and Analysis of AEFI in India

In India, as in other countries, AEFI statistics are closely monitored and analyzed to enhance vaccine safety. The following key statistics and insights shed light on the Indian scenario:

**AEFI Incidence:** The incidence of AEFI in India remains relatively low, with the majority of cases being minor and self-limiting. Serious AEFI is rare, occurring in approximately 1-2 cases per million doses administered, in line with global figures.

**Types of AEFI:** Common types of AEFI in India include localized reactions, mild fever, and occasional allergic reactions. Severe AEFI, such as anaphylaxis, are exceedingly

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rare but are systematically investigated and managed.

**Gender and Age Patterns:** AEFI patterns in India often show no significant gender or age-related differences. However, infants and young children, who receive several vaccines in the early years of life, may experience more AEFI events, largely due to the sheer number of vaccinations administered.

**Vaccine-Specific AEFI:** Some vaccines may be associated with specific AEFI. These associations are thoroughly investigated, and corrective measures, such as changes in vaccine administration protocols, may be implemented.

**Impact on Immunization Programs:** While AEFI can raise concerns, it is essential to emphasize that the benefits of vaccination far outweigh the risks. Vaccines continue to be a cornerstone of public health efforts in India, preventing countless cases of infectious diseases and reducing mortality. Humanitarian approach, proper funding to reach every citizen, use of artificial intelligence like drone delivery of vaccines in remote area, updated autopsy protocol and facilities, etc. are notable steps in Indian set up [12-17].

### Conclusion

Adverse events following immunization are an inherent aspect of vaccination programs, albeit a rare one. Current trends, latest autopsy protocols, the Indian scenario, and statistical insights collectively contribute to our understanding of AEFI and help maintain public trust in vaccination. Verbal autopsy through asking questions to the next of kin also plays a vital role in AEFI related deaths. Proper investigation of AEFI is required to avoid misconceptions among general population. Healthcare workers, media, Health authority, etc. should spread awareness among public in sensitive cases [18,19].

Vaccines have had an enormous impact on global public health, saving lives and reducing the burden of infectious diseases. Continual efforts to monitor, investigate, and mitigate AEFI are essential to ensure vaccine safety and efficacy. By adhering to standardized autopsy protocols and fostering transparency and trust, we can sustain the successes achieved through immunization and continue to protect communities from vaccine-preventable diseases. Various guidelines given by WHO should be follow to deal with AEFI.

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