Section: Community Medicine

Review Article

ADVERSE EVENT FOLLOWING IMMUNIZATION (AEFI) SURVEILLANCE: A NARRATIVE REVIEW

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ABSTRACT

Adverse Events Following Immunization (AEFI) surveillance is a critical part of vaccine safety systems, ensuring public confidence and the success of the immunization programs. This narrative review outlines the evolution, structure and operational framework of AEFI surveillance at both global and national levels (India). Globally, systems such as the Vaccine Adverse Event Reporting System (VAERS), the National Vaccine Injury Compensation Program (NVICP) and initiatives led by the World Health Organization (WHO) including the Global Advisory Committee on Vaccine Safety (GACVS) and VigiBase have strengthened vaccine safety monitoring via standardized reporting, causality assessment and international collaboration. In India, AEFI surveillance has evolved with the Universal Immunization Programme (UIP) with the establishment of the National AEFI Committee, formulation of operational guidelines and digital platforms such as SAFE-VAC and CoWIN for real-time reporting and monitoring.

AEFIs are any untoward medical occurrence following immunization and are categorized into vaccine product-related, quality defect-related, immunization error-related, anxiety-related and coincidental events. Effective management involves prompt identification, early treatment particularly for severe reactions such as anaphylaxis and systematic reporting. Strengthening surveillance is supported by quality management systems under the National Health Mission and adherence to standardized protocols. Despite significant progress, challenges such as under-reporting, data gaps and risk communication persist. Robust surveillance, timely investigation, trained personnel and responsible media engagement are essential to enhance vaccine safety. Overall, an effective AEFI surveillance system is vital for sustaining immunization coverage and public trust.

Keywords: Adverse Event Tracking, Immunization, Public Health Monitoring, Vaccine safety.

INTRODUCTION

Immunization is a cornerstone of primary health care, fundamental human right and one of the greatest achievement in global health, saving millions of lives each year by protecting against diseases. Vaccine strengthening the body's natural immune response by training it to recognize and fight off specific infections, support global health security and are essential in combating antimicrobial resistance.[1]

The UIP is one of the largest health programme in India covering 2.67 crore newborns and 2.9 crore pregnant women annually.[2]

Immunization in India is provided nationally against 9 diseases: Diphtheria, Pertussis, Tetanus, Polio, Measles, Rubella, Childhood Tuberculosis, Hepatitis B, and Meningitis & Pneumonia caused by Hemophilus Influenza type B.[2]

At the sub-national level, vaccines are administered against 3 diseases: Rotavirus diarrhea, Pneumococcal Pneumonia, and Japanese Encephalitis. The Rotavirus and Pneumococcal Conjugate vaccines are currently being expanded, while the Japanese Encephalitis vaccine is only given in endemic districts in India including Assam, Bihar, Uttar Pradesh, Odisha, Jharkhand, Chattisgarh etc.[2]

The child is vaccinated according to the timelines set under the National Immunization Schedule. (Annexure-1) which highlights the ongoing effort to protect adult and aging populations from serious diseases.

Adult vaccination has expanded considerably over time. In 1953, tetanus and diphtheria toxoids were first licensed for adult use in the U.S. Pneumococcal vaccines were introduced in the late 1970s, followed by hepatitis B in the early 1980s and hepatitis A in the mid-1990s.

The 2000s saw expansion with shingles and HPV vaccines. In 2001, the Bill & Melinda Gates Foundation helped in the development of meningococcal vaccines for Africa. By 2005, influenza and Tdap vaccines were recommended for adults and adolescents.[3]

Later, pneumococcal conjugate vaccines were added for adults ≥50 years in 2012 and expanded to ≥65 years in 2014, reflecting the growing emphasis on adult immunization. In 2016, the Advisory Committee on Immunization Practices recommended pneumococcal vaccination for adults aged 18-49 years. In 2018, the US FDA approved HPV vaccination for adults of 27-45 years, which was earlier used in younger women.[3]

In 2022, universal Hepatitis B vaccination was recommended for adults aged 19-59 years. COVID-19 vaccination began in 2020 for healthcare workers, later expanding to all adults, adolescents, children, and infants (6 months+) by 2022. In 2026, India introduced a nationwide HPV vaccination programme targeting adolescent girls aged 14–19 years.

Through the years, the US CDC has made numerous changes to the vaccination schedule that have been advised for administration in adults for different age groups with latest in 2025 for the age groups 19 years and above. **(Annexure-2)**

History:

Global

The United States Congress passed the National Childhood Vaccine Injury Act in 1986 to strengthen vaccine safety monitoring. Following this, the U.S. Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) jointly manage the Vaccine Adverse Event Reporting System (VAERS), established under the U.S. Department of Health and Human Services (HHS).

VAERS functions as a national surveillance system that collects reports of suspected adverse events after vaccination, requiring healthcare providers and vaccine manufacturers to report events specific to measles, mumps, rubella, polio, pertussis, diphtheria, tetanus, or any combination of these vaccines to HHS.[1]

The National Vaccine Injury Compensation Program (NVICP) was established in 1988 to provide financial compensation to individuals suffering injury or death due to vaccine-related adverse events. It also covers medical expenses, lost wages and attorney's fees, with a maximum $250,000 for pain and suffering along with a statutory death benefit of $250,000.

Following this, the Global Advisory Committee on Vaccine Safety (GACVS) was established in 1999 that offers independent and authoritative advice to the World Health Organization (WHO) on vaccine safety.[1]

In 2000, WHO's Expanded Programme on Immunization (EPI) made Adverse Events Following Immunization (AEFI) monitoring mandatory with new vaccine introductions in low and middle income countries. GAVI (Global Alliance for Vaccines and Immunization) aided countries in developing AEFI monitoring systems. Standardized tools, like the the Council for International Organization of Medical Sciences (CIOMS)/WHO AEFI reporting form were introduced to unify case definitions and reporting.

In 2008, WHO launched the Global Network for Post-Marketing Surveillance (PMS) of Vaccines, in collaboration with the Uppsala Monitoring Centre (UMC). Using VigiFlow software, it facilitates reporting causality assessment, and classification of AEFI cases.

In 2010, the WHO launched the Vaccine Safety Net to provide trustworthy online information about vaccine safety. The growing use of mobile applications and digital platforms have enabled both healthcare professionals and the public to contribute to AEFI reporting. There was a significant shift towards incorporating active surveillance methods such as cohort event monitoring and sentinel site surveillance along with traditional passive systems like VAERS.

By 2016, VigiBase had accumulated millions of AEFI reports. The CDC and FDA introduced VAERS 2.0 in 2017. This redesigned platform improved accessibility with a user friendly interface, improved navigation and clearer instructions. It enabled direct reporting byhealthcare providers, patients and caregivers and introduced a downloadable PDF form for offline use and later submission electronically. Additionally, it enhanced transparency by improving public access to vaccine safety data for easier analysis.

India

In 1986, India launched the AEFI surveillance program under the Universal Immunization Programme (UIP) for monitoring and safe vaccine administration for better detection, reporting and management of the adverse events. The first documented AEFI was reported in 1988 at the Indira Gandhi Medical College in Shimla, Himachal Pradesh invovling seizures and encephalopathy associated with DPT vaccine.

In 1992, this became a part of Child Survival and Safe Motherhood Programme in collaboration with UNICEF, WHO and the World Bank. In 1997, it was included in the Reproductive and Child Health (RCH) Programme emphasizing on reproductive health, safe motherhood, child health and immunization safety.

In 2005, the Ministry of Health and Family Welfare under National Rural Health Mission developed the first operational guidelines for AEFI surveillance, covering reporting system, standard operating procedures (SOP), cold chain review and training. Major milestones of UIP include polio elimination in 2014 and maternal and neonatal tetanus elimination in 2015.

In 2008, National AEFI committee was established in Lady Hardinge Medical College (LHMC), Delhi for causality assessment and guideline formulation, involving experts and representatives from the Integrated Disease Surveillance Programme (IDSP), the Drug Control Department, the Indian Medical Association (IMA) and the Indian Academy of Paediatrics (IAP). AEFI guidelines were revised in 2010. In 2013, the National AEFI Secretariat and Technical Collaborating Centre were established.

eVIn was launched in October, 2015 which tracked vaccine cold chain integrity and batch traceability. Rotavirus and PCV vaccines were introduced for the diseases which are major contributors to deaths in the under-5 age group in India.

In January 2021, India launched the CoWIN platform for COVID-19 vaccination enabling real-time reporting of AEFIs, rapid investigation and enhanced traceability of vaccine batches and manufacturers. It aligned with global surveillance systems, enabling the WHO during the global roll-out of COVID-19 vaccines. It also provided digital vaccination certificates.

Adverse Event Following Immunization (AEFI)

Adverse Event Following Immunization (AEFI) is any untoward medical occurrence that follows immunization but does not necessarily have a causal relationship with the administration of vaccine. The event may be any unfavourable or unintended sign, abnormal laboratory finding, symptom or disease. The event maybe truly associated with the vaccine i.e. due to one or more inherent properties of the vaccine product, defective vaccine including manufacturer defect, inappropriate vaccine handling. prescribing or improper administration, immunization anxiety-related reaction; formerly "injection reaction" or any coincidental event.[3]

In 2012, CIOMS/WHO had further divided this into vaccine product-related reaction and vaccine quality-defect related reactions.[5]

1. Vaccine product-related reactions: These reactions may be caused due to one or more inherent properties of vaccine which can be allergic or anaphylaxis reactions and vaccine quality defect-related reaction which These are generally classified as minor, severe, or serious. These are common and can be seen in about 10% of vaccine recipients, though rates may be higher with certain vaccines like DPT or tetanus boosters (20-40%).
2. Vaccine quality-defect related reactions: These are precipitated due to one or more quality defects of the vaccine including its administration device as provided by the manufacturer or its constituents that maybe adjuvant, antibiotics, preservatives or stabilizers.
3. Immunization error-related reactions (programme error): Errors related to vaccine handling, prescribing, and administration can compromise safety and effectiveness. Improper handling like exposure to extreme temperatures or use of expired vaccines reduces potency or cause adverse reactions. Prescribing errors, including incorrect dosage, timing or failure to consider contraindications, can lead to serious outcomes. Similarly, administration mistakes like use of wrong diluent, poor technique or administering the wrong vaccine may result in infections, injury or ineffective immunization.
4. Immunization anxiety-related reactions (injection reaction): These are commonly seen in children over 5 years of age as a result of fear or painful injection rather than the properties of the vaccine itself.
5. Coincidental event: These include the events that have occurred after vaccination but is not caused due to vaccine or during the process of vaccination.

As vaccines are usually given during infancy, a time when congenital conditions or neurological disorders often begin to show; this timing coincides with the vaccination schedule. Additionally, infancy is a period when various illnesses and infections are commonly observed which may cause wrongful diagnosis of an AEFI if not assessed carefully.

AEFIs can also be classified according to frequency and severity as very common, common, uncommon, rare and very rare. Categorization of frequency distribution is given in Table-I.

Table 1: Categorization of Frequency Rates of AEFI.4

S. No.	Category	Frequency Rate
1.	Very Common	≥1/10
2.	Common	≥1/100 and <1/10
3.	Uncommon	≥1/1000 and <1/100
4.	Rare	≥1/10,000 and <1/1000
5.	Very Rare	<1/10,000

AEFIs can be classified into three categories for reporting:

1) Minor AEFIs: Common and mild reactions (e.g., low-grade fever, pain at injection site) that appear within few hours after vaccination and resolve on their own without health risks.
2) Severe AEFIs: Such as neurological complications or severe allergic responses that

can cause disability but are rarely life-threatening.

3) Serious AEFIs: Rare but critical events (e.g., anaphylaxis, encephalitis) that are life-threatening and may lead to hospitalization, long-term disability or death.

Table-II describes the minor, serious/severe vaccine reactions due to different vaccines.

Table 2: Minor, Serious/Severe AEFIs by different Vaccines under National Immunization Schedule (NIS).[2]

Vaccine	Minor	Serious/Severe
BCG	Local abscess, Keloid, Cutaneous Skin Lesions, Lymphadenitis, Suppuration, Local reactions- Pain, Redness, Swelling	Osteitis, Suppurative lymphadenitis, Fatal dissemination of BCG infection
OPV	-	Vaccine associated Paralytic Poliomyelitis (VAPP)
DTaP	Local reactions- Pain, Redness, Swelling	Prolonged crying (>1hr), Hypotonic Hyporesponsive episodes (HHE), Seizures, Anaphylaxis
Measles/MR	Local reactions- Pain, Redness, Swelling	Thrombocytopenia, Anaphylaxis, Febrile Seizures
Rotavirus	-	Intussusception
Japanese Encephalitis	Myalgia, Low Grade Fever	Encephalitis/ Encephalopathy, Peripheral Neuropathy, Myelitis, Aseptic Meningitis
Tetanus	Local reactions- Pain, Redness, Swelling	Brachial Neutiris, Anaphylaxis

Management of AEFI

1. At the Site of Immunization

The vaccinator/ANM is supposed to carry an Anaphylaxis Kit to every immunization session for proper and immediate management of a suspected case of anaphylaxis. The kit includes adrenaline (1:1000) ampoule with an age-wise dose chart, syringes, swabs, and updated contact details of the DIO, MO, PHC/CHC, nearest referral centers and ambulance services. It should be stored in an airtight container away from light to avoid damage. Administration of 1mL adrenaline plays a critical role in saving life. All suspected or confirmed cases must be clearly documented on the immunization card. Any future vaccinations should only be administered in a hospital setting where adrenaline and other resuscitation equipment are readily available.

In case of a local reaction, cold cloth is placed at the injection site and syrup paracetamol is given according to the dosage chart [Annexure-3]. In case of fever of > 38.5°C (101.3F), or if the patient is irritable or has malaise or any systemic symptoms like muscle pain, headache or loss of appetite, extra fluids are given with tepid sponging along with syrup paracetamol.

2. At Health Facility

All health facilities with an appointed MO, in both public and private sector, should be designated as AEFI management centers. PHC, CHC and district hospital must create a geographically distributed list of these centers to ensure prompt referral and care during AEF. The Routine Immunization (RI) microplan should include the contact details of the nearest AEFI management center. All designated MOs should be trained in standard AEFI management and reporting. These centers should be equipped with AEFI treatment kits and reporting forms.

The AEFI treatment kit should be equipped with key emergency medical supplies, including three ampoules of adrenaline injection (1:1000 solution) and three vials of hydrocortisone injection (100 mg). It must also contain three tuberculin or insulin syringes (1 mL or 40 units, without fixed needle), one 5 mL disposable syringe, and three sets of 24/25G IM needles. In addition, two scalp vein sets or IV cannula sets, ten paracetamol tablets (500 mg), two bottles each of IV fluids (Ringer lactate or normal saline and 5% dextrose), and two IV drip sets should be included. Essential supporting items like a vial cutter, cotton wool, and adhesive tape (one of each) must be available. The kit should also include an AEFI Case Reporting Form (CRF), a label noting the date of inspection, the expiry date of the adrenaline injection and the earliest expiry date among all items in the kit. Dosage charts for adrenaline and hydrocortisone injections should be provided for reference in the kit. Furthermore, in hospital settings, oxygen supply and airway intubation equipment must be available and accessible to ensure readiness for managing severe reactions.[5]

Reporting of an AEFI

An AEFI may be suspected by the patient, a family member or the vaccination service provider. Any healthcare provider, public or private, who encounters an AEFI should be familiar with recognizing it.

All AEFIs, regardless of their level of severity, must be reported. They can be reported anytime irrespective of time duration between the introduction of vaccine and the occurrence of the adverse event. They can be reported even when the vaccine is given under the UIP schedule or not; if it is given by government or private institution; or to a child or an adult.

In India, the AEFI is to be reported on SAFE-VAC portal. The portal records all the minor, severe or serious AEFIs. The reports are to be entered by the district or state by DIO or SEPIOs (State Expanded Programme on Immunization officer) respectively and these cases that have been entered can be visualized and monitored at state and national levels.[6] The reporting of an AEFI is done immediately in AEFI register, full cases are to be updated weekly on the SAFE-VAC and number of AEFIs are uploaded at a monthly basis on Health Management Information System (HMIS) portal.

a) Reporting of Minor AEFI

Reporting of minor AEFIs are done in AEFI registers at facility/block level. The aggregate number of cases are later entered in the HMIS Portal on a monthly basis to monitor the monthly progress report of the PHCs. The CRF for minor AEFIs need not be filled.

b) Reporting of Serious/Severe AEFI

Serious/severe AEFI needs immediate reporting to the MO or the DIO as soon as possible as these have a negative impact on the health program. The MO completes the CRF within 24 hours of notification after thorough investigation, collecting essential information including details about the reporter, patient information, data regarding the vaccine and any diluent, specifics of the adverse event and information related to decision-making. The CRF is then sent to the DIO who enters it in the SAFE-VAC to generate a case ID which is used for any future investigation and follow-up.

The Case Investigation Form (CIF) is then filled by the DIO or the District AEFI Surveillance Committee within 21 days of notification to ensure proper assessment of an AEFI. It collects comprehensive information including patient details, medical and socio-demographic details, clinical findings, treatment provided and vaccination details. The form also reviews immunization practices, cold chain management, transport facilities, community investigation findings and other significant observations are also included. Specimens are collected only if recommended by the district AEFI committee. The CIF includes the committees' review and investigation report, supported by inputs from front-line health workers, to help determine the cause of the event.[6]

The timeline for reporting of an AEFI is given in Figure-1.

Figure 1: Reporting of an AEFI

Quality Management System (QMS) for AEFI Surveillance

Under the National Health Mission, a Quality Assurance Programme has been implemented to improve service quality in public health facilities. The National Quality Assurance Standards (NQAS) establishes quality teams at various levels to regularly assess facilities against defined standards. Facilities that meet these standards receive NQAS certification. Oversight is provided by State and District Quality Assurance Committees (SQAC and DQAC), supported by trained quality professionals across India.

Quality standards are applicable at all levels starting from the session site up to national level. It includes orientation meetings of state and district quality assurance managers and immunization managers for QMS in AEFI Surveillance, development of SOPs and budget for the implementation. Implementing the QMS at the state, district, PHC and session-site levels involves staff training, developing quality policies, conducting internal and external assessments and completing the certification process.

Each state implements NQAS for AEFI Surveillance with support from the AEFI Secretariat, National Health Systems Resource Centre (NHSRC) and state quality assurance committee. All districts are directed to initiate its implementation following the set protocol.

Media and Public Health

Public health often gets limited media coverage but adverse events attract significant coverage in print and social media for generating community awareness which can help raise community awareness and encourage quick responses from the health authorities. However, balanced and responsible media coverage is important to ensure the public stays informed about health risks and ongoing public health initiatives.

Communication for routine immunization follow an annual plan with an approved budget. It also helps in preparation of crisis situations. Both state and district must plan and prepare for potential crisis scenarios following any major AEFI. Effective crisis management requires not only timely decisions but also a clear understanding of ground realities and strong, accurate communication with the media to prevent panic. Trained spokespersons are assigned to address media queries, ensuring that responses are evidence-based and supported by data and reports. Continuous follow-up and transparent communication help reassure the public and build trust in future public health interventions.

In a session setting, the health workers must inform the beneficiaries and the caregivers about the possible minor or serious/severe post-vaccination reactions and their management. They should also address and clear any other misconceptions, myths or rumors associated with vaccination.

Annexure 1: National Immunization Schedule as per National Health Mission, Ministry of Health and Family Welfare.

Vaccine	When to Give	Dose	Route	Site
For Pregnant Women				
Td-1	As early as possible	0.5 ml	Intramuscular	Upper Arm
Td-2	4 weeks after Td-1	0.5 ml	Intramuscular	Upper Arm

Td Booster	If received 2 doses within last 3 years	0.5 ml	Intramuscular	Upper Arm
For Infants				
BCG	At birth or as early as possible till 1 year of age	0.1 ml (0.05 ml if <1 month)	Intra-dermal	Left Upper Arm
Hepatitis B Birth Dose	At birth or as early as possible within 24 hours	0.5 ml	Intramuscular	Anterolateral side of mid-thigh- Left
OPV Birth Dose	At birth or as early as possible within 15 days	2 drops	Oral	Oral
OPV 1, 2, 3	At 6, 10, 14 weeks	2 drops	Oral	Oral
IPV	At 6 & 14 weeks and 9 month	0.1 ml	Intra-dermal	Right Upper Arm
Pentavalent 1, 2, 3	At 6, 10, 14 weeks	0.5 ml	Intramuscular	Anterolateral side of mid-thigh- Left
Rota Virus Vaccine	At 6, 10, 14 weeks	5 drops	Oral	Oral
PCV	At 6 weeks, 14 weeks & 9 months (booster)	0.5 ml	Intramuscular	Anterolateral side of mid-thigh- Right
MR 1st dose	At 9 completed months–12 months	0.5 ml	Subcutaneous	Right Upper Arm
Vitamin A 1st Dose	At 9 months with MR	1 ml (1 lakh IU)	Oral	Oral
For Children				
DPT 1st Booster	16-24 months	0.5 ml	Intramuscular	Anterolateral side of mid-thigh- Left
OPV Booster	16-24 months	2 drops	Oral	Oral
MR 2nd Dose	16-24 months	0.5 ml	Subcutaneous	Right Upper Arm
Vitamin A 2nd–9th Dose	16 months with DPT/OPV booster, then every 6 months up to 5 years	2 ml (2 lakh IU)	Oral	Oral
DPT 2nd Booster	5-6 years	0.5 ml	Intramuscular	Left Upper Arm
Td	10 years & 16 years	0.5 ml	Intramuscular	Upper Arm
Td- Tetanus Diphtheria vaccine, OPV- Oral Polio Vaccine, BCG- Bacille Calmette-Guérin Vaccine, IPV- Fractional Inactivated Polio Vaccine, PCV- Pneumococcal Conjugate Vaccine, MR- Measles Rubella, DPT- Diphtheria Pertussis Tetanus Vaccine				

Annexure 2: Adult Immunization Schedule (19 years and above), as recommended by U.S. Center for Disease Control and Prevention, 2025.

Vaccine	**19–26 Years**	**27–49 Years**	**50–64 Years**	**65+ Years**
COVID-19	Aged 64 and younger: At least 1 dose	Aged 64 and younger: At least 1 dose	Aged 64 and younger: At least 1 dose	65+: At least 2 doses
Influenza/Flu	Every Year	Every Year	Every Year	Every Year
RSV	If pregnant during RSV season	If pregnant during RSV season	If aged 50 through 74 years	If aged 75 years or older
Tdap/Td	Tdap every pregnancy. Td/Tdap every 10 years for all adults	Tdap every pregnancy. Td/Tdap every 10 years for all adults	Td/Tdap every 10 years for all adults	Td/Tdap every 10 years for all adults
MMR	If aged 68 years or younger	If aged 68 years or younger		
Chickenpox	If U.S. born and aged 45 years or younger	If U.S. born and aged ≤45 years		
Shingles	Not routinely recommended	Not routinely recommended	Recommended for age group	Recommended for age group
HPV	Recommended for age group	Aged 27–45 years		
Pneumococcal	Recommended for age group	Recommended for age group	Recommended for age group	Recommended for age group
Hepatitis A	Recommended for age group	Recommended for age group	Recommended for age group	Recommended for age group
Hepatitis B	Through 59 years	Through 59 years	Through 59 years	
Meningococcal	Recommended for age group	Recommended for age group	Recommended for age group	Recommended for age group
Hib	Recommended for age group	Recommended for age group	Recommended for age group	Recommended for age group
Mpox	Recommended for age group	Recommended for age group	Recommended for age group	Recommended for age group
RSV- Tdap/Td- Tetanus Diphtheria Pertussis/Tetanus Diphtheria Vaccine, MMR- Measles Mumps Rubella Vaccine, HPV- Human Papilloma Virus Vaccine, Hib- Human Influenza B Vaccine, Mpox- Monkeypox Vaccine				

Annexure 3: Dose of Paracetamol (post vaccination)

Age wise dose of Paracetamol syrup (125 mg/5 ml) in infants (Recommended dose of Paracetamol: 10-15 mg/kg body weight)	
Age Group	**Dose (mL)**
6 week- 6 month	2.5
6-24 months	5
2-4 years	7.5
4-6 years	10

Paracetamol is not recommended in children weighing <2 kg. Maximum four doses in 24 hours with a gap of at least four hours between two doses.

CONCLUSION

In conclusion, an effective AEFI surveillance system is necessary for ensuring vaccine safety, maintaining public trust and ensuring the success of immunization programme. Strengthening of the reporting system, timely and systematic investigations and collaboration among stakeholders are key to improved vaccine safety and sustaining confidence in immunization efforts. Such integrated efforts are necessary for resilient health systems and the continued success of public health interventions.

REFERENCES

1. VAERS- Vaccine Adverse Effect Reporting System. About Us. [Internet]. Available from: https://vaers.hhs.gov/about.html
2. Ministry of Health & Family Welfare. National Health Mission. Immunization. [Internet]. Available from: https://nhm.gov.in/index1.php?lang=1&level=2&sublinkid=824&lid=220.
3. Immunize.org. Vaccine history timeline. [Internet]. 2025. Available from: https://www.immunize.org/vaccines/vaccine-timeline.
4. World Health Organization. Global Advisory Committee on Vaccine Safety, 6–7 December 2017. Weekly Epidemiological Record, 93 (3), 17 - 30. Available at: https://iris.who.int/bitstream/handle/10665/259875/WER9303-17-30.pdf?sequence=1.
5. Ministry of Health and Family Welfare, Government of India. National AEFI Surveillance and Response-Operational Guideline. 2024.
6. Ministry of Health and Family Welfare, Government of India. Routine Immunization Manual for Medical Officers. 2nd Edition. 2024.