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Vaccinovigilance (AEFI- Adverse Event Following Immunisation) in India: Current status and shortcomings

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Abstract:
With the increasing occurrence of epidemics and pandemic of communicable diseases, vaccines are becoming an effective tool and at times the only tool to curtail disease impact. India, being a major player in vaccine manufacturing, holds greater responsibility & accountability to develop better products and Vaccinovigilance to avoid untoward events & long-term implications. This review sheds light on the challenges in India about AEFI screening, reporting, association and the causality assessment of adverse events following immunisations. The concept of Vaccinovigilance in India needs modern upgradation with digitisation and inclusion of public reporting (active surveillance) to overcome the underreporting. This feedback mechanism will not only strengthen the safety profile of the vaccine to assure global validation but also augment evidence-based studies. We have also summarised in brief how Ministry of Health and Family Welfare(MoHFW) and the global regulatory bodies in collaboration, have developed the new guideline since 2020, after facing a spectrum of mild to severe adverse effects following COVID-19 vaccination. There is a need to develop awareness among healthcare provider about reporting AEFI for casualty assessment and active surveillance for a robust framework in India.

Keywords: *AEFI, Vaccinovigilance*

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I. INTRODUCTION

India, as a major vaccine manufacturer, has a greater responsibility to ensure that critical control functions (including vaccine pharmacovigilance) are implemented competently and independently. The World Health Organisation (WHO) defines an AEFI as any untoward medical occurrence that follows immunisation, which does not necessarily have a causal relationship with the use of the vaccine. The adverse event may be any unfavourable or unintended sign, abnormal laboratory finding, symptom, or disease.[1] The Government of India's AEFI Surveillance Programme is committed to early detection, management, reporting, investigation, and feedback on AEFIs to various stakeholders of the immunisation programme.[2]

TABLE NO. 1: NATIONAL VACCINOVIGILANCE BODIES OF DIFFERENT COUNTRIES:[3]

Country	Name of System	Year Started	Managing Bodies	Type of Surveillance	Reporters
United States	Vaccine Adverse Event Reporting System (VAERS)	1990	US FDA and CDC(Center for Disease Control and Prevention)	Spontaneous (Passive)	Vaccine manufacturers, health-care providers, vaccine recipients, and parents
Canada	Canadian Adverse Events Following Immunisation Surveillance System	Not specified	Public Health Agency of Canada (collaboration with federal, provincial authorities)	Both Passive and Active	Provincial/territorial health departments, health-care professionals, pharmaceutical industry
United Kingdom	Yellow Card Scheme	Not specified	Medicines and Healthcare products Regulatory Agency (MHRA)	Passive (Spontaneous)	Any individual (including health professionals and the public)
Australia	Adverse Event Following Immunisation (AEFI) Report	Not specified	Therapeutic Goods Administration (TGA)	Both Passive and Active	Healthcare providers, vaccine recipients, public
Japan	Vaccine Adverse Reactions Review Committee System	Not specified	Ministry of Health and Family Welfare, with the WHO	Passive	Healthcare professionals, marketing authorisation
European Union	EudraVigilance	2001	European Medicines Agency (EMA)	Passive	Healthcare professionals, marketing authorisation

India	Adverse Events Following Immunisation (AEFI) Survey	2005	Ministry of Health and Family Welfare, with the WHO	Passive (with some active components)	Healthcare workers, Immunisation Programme officer

The implication of immunisation against infectious diseases is continually rising worldwide.[4] This calls for the generation of reliable evidence-based data on vaccine side effects at the national level and ensuring its transparent and efficient sharing in the public domain. This is crucial for upholding a positive perception of immunisation.

The United Kingdom's vaccine safety surveillance has its well-established Yellow Card Scheme, managed by the MHRA (Medicines and Healthcare products Regulatory Agency), allowing healthcare professionals and the public to report adverse events easily. The system benefits from a legal and regulatory framework, ensuring transparency through regular audits and public data sharing. Digital literacy[5], and user-friendly online/mobile reporting tools promote widespread participation. Additionally, the centralised NHS (National Health Service) infrastructure enables integration of electronic health records with adverse event tracking, ensuring timely and comprehensive monitoring.[6]

India faces significant challenges in effectively reporting adverse events following immunisation (AEFI). A key issue is underreporting, driven by limited awareness and training among healthcare workers and the public.[7], as well as a fear of blame[8], which discourages transparent reporting. Infrastructural limitations, particularly in rural areas, such as inadequate digital utilisation and reliance on paper-based systems, further add hurdles to real-time data collection.[2] The country's decentralised healthcare system complicates standardisation, and AEFI reporting remains unevenly implemented across public and private sectors.[9] Additionally, due to high patient loads and competing priorities, AEFI monitoring is often deprioritised in daily practice unless severe events occur.[10] While India's surveillance system under the Ministry of Health and Family Welfare (MoHFW) and Indian Pharmacopoeia Commission (IPC) is gradually improving, it still lacks the automation, scale, and integration seen in more advanced systems like those of the developing countries.

CHALLENGES IN INDIA IN THE CAUSALITY ASSESSMENT OF ADVERSE EFFECTS FOLLOWING IMMUNISATION:

India's Adverse Events Following Immunisation (AEFI) surveillance system faces multiple systemic challenges that hinder effective vaccine safety monitoring. One major issue is incomplete or poor-quality documentation in AEFI case reports, which often miss critical clinical details such as the timing of onset, pre-existing health conditions, medication history, and relevant laboratory investigations. Additionally, postmortem examinations or diagnostic confirmations are frequently omitted due to social, logistical, or religious constraints (WHO India – AEFI Surveillance Field Evaluation Report).[11] Another major concern is the delayed and infrequent reporting of adverse events, sometimes occurring weeks after the incident, thereby obstructing timely investigation, sample collection, and causality assessment. This delay undermines efforts to establish temporal associations and investigate biological plausibility (National AEFI Surveillance Guidelines, MoHFW, 2015)[2].

Furthermore, there is limited and inconsistent use of standardised causality assessment tools, such as the WHO algorithm, which is either underutilised or incorrectly applied at district and state levels. This issue is compounded by the lack of trained personnel in pharmacovigilance and epidemiology within AEFI committees (WHO AEFI Causality Assessment Manual – India version).[12] The diagnostic infrastructure also remains weak, especially in rural areas, where access to advanced laboratories or imaging is scarce, and investigations to rule out alternative causes are often non-standardised or unavailable (United Nations Children's Fund (UNICEF) India – Strengthening AEFI Systems).[12] Compounding these issues is a fragmented follow-up system and reliance on passive surveillance, with limited implementation of active surveillance or cohort event monitoring, which are largely restricted to pilot programs such as those for COVID-19 vaccines (IPC, PvPI).[9]

Additionally, fear of attribution or legal consequences deters healthcare providers from reporting suspected vaccine-related events, due to concerns about blame, public panic, or contributing to vaccine hesitancy. This often leads to underreporting or misclassification of AEFIs as outcomes of underlying illnesses (Journal of Pharmacovigilance & WHO Policy Briefs). Lastly, the high background morbidity and mortality in India, due to factors like malnutrition, chronic illnesses, and infections, make it clinically and statistically challenging to distinguish between vaccine-related events and coincidental occurrences (WHO Global Manual on AEFI Investigation and Causality Assessment).[13]

STRENGTHENING CAUSALITY ASSESSMENT OF AEFI IN INDIA: CURRENT CHALLENGES AND FUTURE DIRECTIONS

Improving the causality assessment of vaccine-related adverse effects (AEFI) in the Indian context requires multi-level reforms—spanning surveillance infrastructure, training, diagnostics, communication, and governance.

To strengthen India's AEFI (Adverse Events Following Immunisation) surveillance system, several strategic measures are recommended across key operational areas. First, documentation and case investigation should be improved by using standardised reporting formats with checklists and mandatory fields, ensuring the collection of comprehensive clinical history, vaccination details, comorbidities, and follow-up status, as emphasised in the MoHFW AEFI Operational Guidelines and WHO AEFI Manual.[2] Second, capacity for timely and accurate reporting must be built by training frontline health workers and medical officers in AEFI identification and reporting, and by deploying mobile-based digital apps to reduce delays—a need highlighted in UNICEF India's vaccine safety initiatives and WHO India field assessments.[14] Third, diagnostic and laboratory access should be enhanced by designating regional diagnostic hubs equipped with imaging and lab facilities, and offering free diagnostic packages for serious AEFIs, as recommended in the WHO Global Vaccine Safety Blueprint and WHO–India Joint Review Mission.[15] Fourth, active surveillance and sentinel site development are essential; establishing hospital networks and conducting cohort event monitoring for high-risk vaccines can strengthen real-time safety monitoring, supported by IPC and WHO's global strategies.[9,11] Fifth, causality assessment processes should be standardised through regular training on WHO algorithms and the use of digital decision-support tools, to avoid misclassification, as indicated by IPC training modules.[9] Sixth, promoting a blame-free reporting culture is vital to encourage honest reporting; this can be achieved by removing punitive consequences and issuing protective circulars, aligning with WHO policy briefs and the India Vaccine Confidence Initiative.[16][17] Lastly, public and professional awareness needs to be improved by running educational campaigns for healthcare providers and the general public, and by integrating AEFI training into medical and nursing curricula, following guidance from the National Health Mission and WHO eLearning modules.[18] Collectively, these interventions can significantly enhance vaccine safety surveillance and public confidence in immunisation programs.

NATIONAL FRAMEWORK FOR ADVERSE EVENTS POST-IMMUNISATION[2]

The government's Universal Immunisation Programme (UIP) is the main service provider for childhood immunisation in India. Immunisation sessions are conducted in government-managed centres in primary, secondary and tertiary care institutions on fixed days (which vary in individual states) at least once a week. In India, most of the routine immunisation services are provided through outreach sessions within the public health sector. The private sector also contributes to routine childhood immunisation and offers non-UIP vaccines in addition to routine immunisation services.[2]

Based on the cause, vaccine reactions or AEFIs may be broadly grouped as Vaccine product-related reactions, Vaccine Quality Defect Related Reactions, & Immunisation Error–Related Reactions**:**[19]

TABLE NO. 2: DEFINITIONS OF REACTIONS AND EVENTS

Cause-specific AEFI	**Definition**
Vaccine product-related reaction	An event that is caused or precipitated by a vaccine due to one or more of the inherent properties of the vaccine product.
Vaccine quality defect-related reaction	An event that is caused or precipitated by a vaccine that is due to one or more quality defects of the vaccine product, including its administration device as provided by the manufacturer.
Immunisation error related Reaction (formerly "programme error")	An event that is caused by inappropriate vaccine handling, prescribing or administration and thus by its nature is preventable.
Immunisation triggered stress response (earlier Immunisation anxiety-related reaction)	An event arising from anxiety about the immunisation.
Coincidental event	An event that is caused by something other than the vaccine product, immunisation error or immunisation anxiety.
"Immunisation" as used in these definitions means the usage of a vaccine for immunizing individuals. "Usage" includes all processes that occur after a vaccine product has left the manufacturing/ packaging site, i.e. handling, prescribing and administration of the vaccine. Reference: AEFI Adverse Event Following Immunisation Surveillance and Response 2024 Operational Guidelines, MoHFW, CIOMS/WHO 2018	

WHO CAN INFORM ABOUT AN AEFI CASE?[2]

The following healthcare providers may be the first ones to be informed of an adverse event following immunisation (AEFI) or who may suspect/identify an AEFI:

1. Frontline workers such as Accredited Social Health Activists (ASHA) and Anganwadi workers (AWW)
2. Vaccinators such as Auxiliary Nurse Midwife (ANM), male multipurpose health workers and their supervisory staff (Lady Health Visitor (LHV), Health Supervisors), etc.
3. Medical Officers (MOs) and other paramedical staff of Health and Wellness Centres (HWCs), Primary Health Centres (PHCs) and Community Health Centres (CHCs).
4. Doctors and staff nurses working in private clinics, dispensaries, nursing homes and hospitals.
5. Media, lay public and community mobilizers can also report AEFIs.

RECORDING AND REPORTING AEFIs [2]

1. Dispensaries, urban health centres and maternal and child health centres under urban local bodies (municipalities and corporations).
2. Government sub-divisional, divisional and district hospitals.
3. Government and private medical colleges (including staff of the Adverse Drug Reaction Monitoring Centres under the Pharmacovigilance Programme of India).
4. Health care facilities run by the central government or public sector organisations such as the CGHS(Central Government Health Scheme), Railways, Defence, Employees' State Insurance (ESI) Corporation, airport authorities (vaccination for international travel), other industry and autonomous bodies.
5. Private healthcare providers – practitioners, paediatricians, obstetricians-gynaecologists, physicians, neonatologists, and other clinicians/specialists in secondary and tertiary care hospitals.

WHO SHOULD BE INFORMED/NOTIFIED ABOUT AN AEFI CASE?[2]

The detailed framework for reporting to the authorities at multiple levels is as mentioned in the diagram:

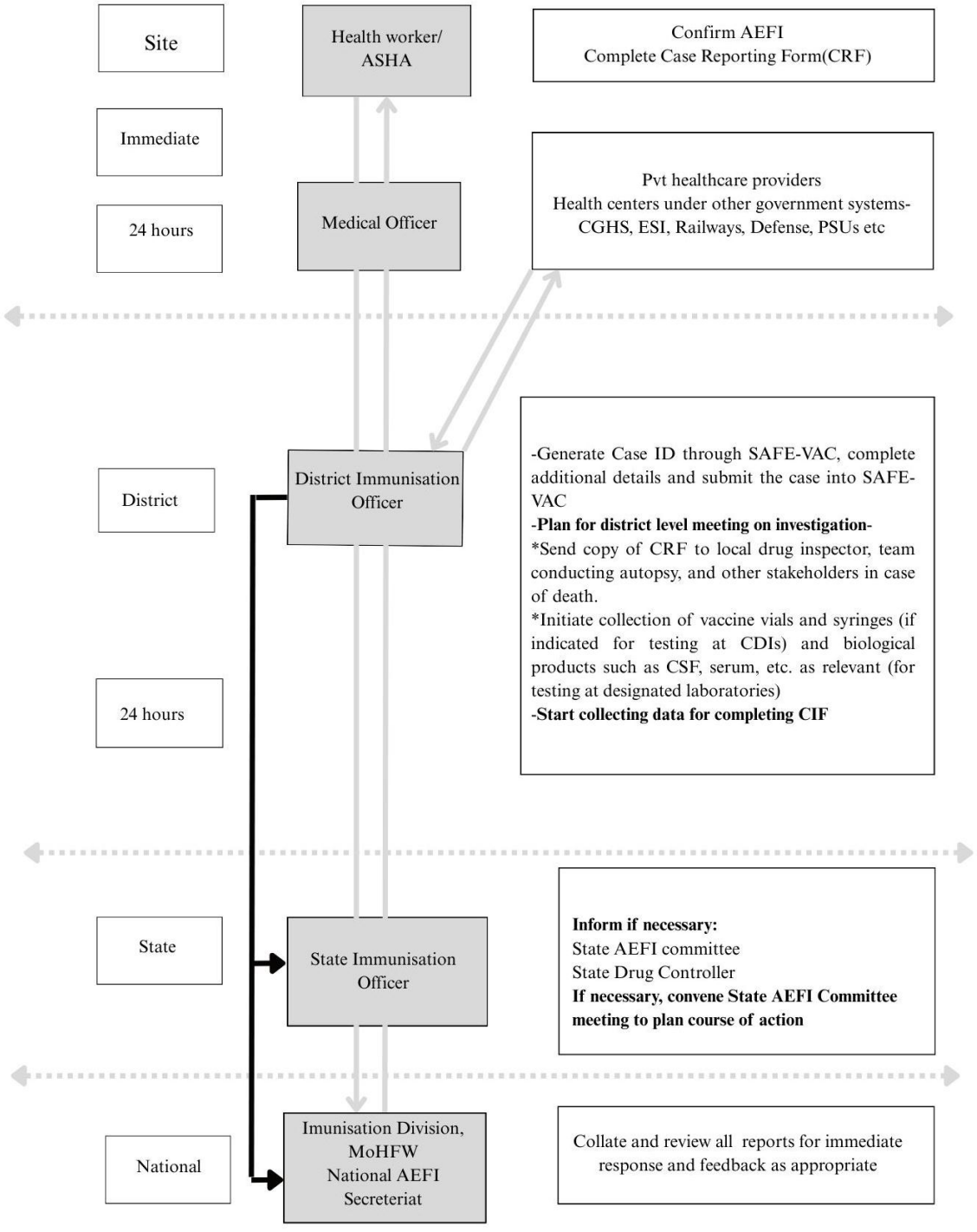

FIG. 1: FRAMEWORK FOR REPORTING TO THE AUTHORITIES.

(Reference: AEFI Adverse Event Following Immunisation Surveillance and Response 2024 Operational Guidelines)

SURVEILLANCE AND ACTION FOR EVENTS FOLLOWING VACCINATION (SAFE-VAC)

In a move to digitise the AEFI surveillance processes, MoHFW conceptualised the development of a web-based application named Surveillance and Action for Events Following Vaccination (SAFE-VAC). This can be accessed at https://safevac.mohfw.gov.in

Currently, data regarding AEFIs can be entered into SAFE-VAC by the DIOs(District Immunisation Officer), SEPIOs and national level. They can monitor the progress by analysing the data and taking appropriate corrective measures.

The adverse events known to be associated with Vaccines under UIP mentioned in AEFI guidelines on the MoHFW website(e.g BCG: Local abscess, Keloid, Cutaneous skin lesions, Lymphadenitis, Suppuration. Systemic: Osteitis, Osteomyelitis, Disseminated BCG disease, Immune Reconstitution Syndrome (HIV patients). But the real-time data reporting and measures to rectify it show disconnect.

SUMMARY

- Any health care provider (public or private), ICDS(Integrated Child Development Services) worker, ASHA, community lay person can notify AEFIs to the medical officer of the PHC or the district health authority/immunisation officer by the quickest means of communication, e.g. telephone, WhatsApp, Email, SMS, messenger, etc.
- All AEFIs following the use of any licensed vaccines (UIP and non-UIP) given in both the government and private sectors in India should be reported through the AEFI surveillance system.
- Minor, serious and severe AEFIs should be recorded in AEFI registers and their numbers reported in HMIS(Health Management Information System)
- The process of notification to the medical officer or the DIO begins when an AEFI case is reported to any frontline worker or health staff, or doctor (in private or public sector).
- The Case Reporting Form (CRF) captures basic minimal information pertaining to the patient, event, vaccine, diluent and reporter.
- CRF is filled by the MO(Medical officer) in charge and sent to DIO within 24 hrs after notification. DIO has another 24 hours to verify the case and submit the CRF into SAFE-VAC. The case ID will be generated by SAFE-VAC.
- The DIO will plan and lead the investigation of an AEFI case with the support of members of the District AEFI Committee. DIO must submit the Case Investigation Form (CIF) within 21 days of notification.
- A private practitioner or health care facility, or ADR Monitoring centres can inform/notify an AEFI case to concerned government MO / DIO. Thereafter, the case should be investigated by the district health authorities.
- Separate CRFs and CIFs need to be filled out for each case of a cluster. A summary of the investigations and a single-line list with details of each case of the cluster should also be prepared for a better understanding of the cause of the events.
- Minor AEFIs are currently reported through AEFI registers and monthly progress reports. The data should be analysed periodically for inference and necessary action.
- It is proposed to enable routine immunisation software management systems to form electronic reporting of minor AEFIs (in addition to serious and severe AEFIs)
- The major limitation of the AEFI programs is a lack of objective assessment for causality.
- With the digital boom in India, public data collection needs an hour to develop an active surveillance arm
- There should random sampling survey for the vaccination drive independent state and national level authorities to avoid underreporting by health care providers.

II. CONCLUSION:

This review overviews the current framework of AEFI surveillance and the need to develop the active surveillance arm to avoid bias and overcome the under-reporting at various levels. With growing digitisation and increasing awareness, a robust system can become a reality in India.

CONFLICTS OF INTEREST

None

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REFERENCES:

[1]. WHO. Global Manual on Surveillance of Adverse Events Following Immunisation. World Heal Organ 2016;1–124.
[2]. Event A. AEFI ADVERSE EVENT FOLLOWING IMMUNISATION Surveillance and Response 2024 OPERATIONAL GUIDELINES.
[3]. Meher B. Vaccine pharmacovigilance in India: Current context and future perspective. Indian J Pharmacol 2019;51:243–7.
[4]. Scholtz M, Duclos P. Special Theme ± Immunisation Safety Editorial Immunisation safety: a global priority. 2000;78(0479):2–3.

[5]. OECD. 2023 OECD Digital Government Index: Results and key findings. OECD Public Gov Policy Pap 2024;44.
[6]. About the Yellow Card scheme. https://yellowcard.mhra.gov.uk/about-yellow-card
[7]. Biplab Lenin PR. Navigating Adverse Drug Reactions: Extent of Pharmacovigilance in India. https://corporate.cyrilamarchandblogs.com/2025/02/navigating-adverse-drug-reactions-extent-of-pharmacovigilance-in-india/
[8]. Muthukumaran T, Sam Johnson J. PHARMACOVIGILANCE SYSTEM IN INDIA IN COMPARISON WITH USA, EUROPEAN UNION AND FEW ASIAN COUNTRIES T. Int J Pharm Sci Res 2021;12(6):3051–7.
[9]. Indian Pharmacopoeia Commission. https://ipc.gov.in/
[10]. Immunisation and Child Health. https://www.unicef.org/india/what-we-do/immunization
[11]. Global manual on surveillance of adverse events following immunisation. https://www.who.int/publications/i/item/9789241507769
[12]. Causality assessment of an adverse event following immunisation (AEFI): user manual for the revised WHO classification, 2nd ed., 2019 update. https://www.who.int/publications/i/item/9789241516990
[13]. Guidance and information. https://www.who.int/teams/regulation-prequalification/regulation-and-safety/pharmacovigilance/guidance
[14]. UNICEF. Effective Supportive Supervision in Immunisation Health Systems Strengthening Case Study Madhya Pradesh , India April 2020. 2020;(April).
[15]. Global vaccine safety blueprint 2.0 (GVSB2.0) 2021-2023. https://www.who.int/publications/i/item/9789240036963
[16]. Statement of the WHO Global Advisory Committee on Vaccine Safety (GACVS) on the safety of the mpox vaccines for use in high-risk groups. https://www.who.int/news/item/04-10-2024-statement-gacvs-safety-mpox-vaccines-for-use-in-high-risk-groups
[17]. WHO. Global Patient Safety Action Plan 2021-2030 Third-Draft. World Health Organ 2021;
[18]. Omoleke SA, de Kiev LC. An evaluation of the surveillance system for monitoring and reporting adverse events following immunisation in Kebbi State, Northern Nigeria: a mixed-method approach. BMC Public Health 2024;24(1).
[19]. Vaccine Safety • COUNCIL FOR INTERNATIONAL ORGANISATIONS OF MEDICAL SCIENCES. https://cioms.ch/working_groups/cioms-working-group-on-vaccine-safety/

ABBREVIATIONS:

ASHA - Accredited Social Health Activists
AEFI- Adverse Event Following Immunisation
AWW - Anganwadi workers
ANM - Auxiliary Nurse Midwife
CIF -Case Investigation Form
CRF - Case Reporting Form
CDC- Center for Disease Control and Prevention
CGHS- Central Government Health Scheme
CIF- Case Investigation Form
CIOMS- Council for International Organizations of Medical Sciences
CHC - Community Health Centres
CRF- Case Reporting Form
DIO- District Immunisation Officer
ESI -Employees' State Insurance
EMA - European Medicines Agency
HWC- Health and Wellness
ICDS- Integrated Child Development Services
IPC -Indian Pharmacopoeia Commission
LHV -Lady Health Visitor
MO-Medical Officer
MHRA -Medicines and Healthcare products Regulatory Agency
MoHFW-Ministry of Health and Family Welfare
NHS- National Health Service
PHC-Primary Health Centres
PSU- Public Sector Undertaking
SEPIO- State Immunization Officer / State Expanded Programme on Immunization Officer
SAFE-VAC- Surveillance And Action For Events Following Vaccination
TGA -Therapeutic Goods Administration
UNICEF- United Nations Children's Fund
UIP- Universal Immunisation Programme
US FDA- United States- Food and Drug Administration
VAERS -Vaccine Adverse Event Reporting System
WHO-World Health Organisation