

Vaccine Pharmacovigilance in India: Systematic Approaches and Lessons from Mass Immunization Programs

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Abstract- Vaccination remains a cornerstone of public health, yet monitoring vaccine safety is essential to sustain confidence and guide policy. India's large birth cohort, complex health system, and recurrent mass immunization campaigns necessitate a robust vaccine pharmacovigilance framework. This review systematically evaluates India's vaccine safety surveillance landscape, including institutional mechanisms, surveillance models, causality assessment, and operational lessons from major immunization initiatives, to propose strategic priorities for 2025–2030. Following PRISMA 2020 guidelines, literature from 2014–2025 was searched across PubMed, Scopus, and government repositories using defined keywords related to “AEFI”, “vaccine safety”, and “pharmacovigilance India”. National operational guidelines (2015, 2024), IPC/PvPI reports, and WHO/CIOMS/Brighton standards were included. Data were narratively synthesized into thematic domains. India's vaccine pharmacovigilance system has evolved through multi-institutional collaboration between MoHFW, CDSCO, IPC, and the AEFI committee network. Key advances include updated AEFI guidelines (2024), digital reporting via CoWIN, active surveillance pilots, and enhanced causality review mechanisms. Persistent challenges include underreporting, inconsistent investigation quality, limited data linkage, and uneven subnational capacity. Lessons from the polio, MR, and COVID-19 programs underscore the importance of preparedness, transparent risk communication, and integration of active surveillance.

India's vaccine safety ecosystem is transitioning from a reactive to an increasingly data-driven model. Strategic priorities include full operationalization of the 2024 AEFI guidelines, sentinel AESI networks, real-time data linkage, workforce training, and legal frameworks for data governance. Sustained investment and global collaboration will ensure timely detection of safety signals, thereby safeguarding public trust and supporting India's role as a global vaccine leader.

Keywords: Vaccine pharmacovigilance; Adverse Events Following Immunization (AEFI); India; mass immunization; causality assessment; active surveillance; PvPI; CoWIN; VigiBase

Abbreviation list

AEFI- Adverse Event Following Immunization
AESI- Adverse Event of Special Interest
ABDM- Ayushman Bharat Digital Mission
AMC- Adverse Drug Reaction Monitoring Centre
CDSCO- Central Drugs Standard Control Organization
CIOMS- Council for International Organizations of Medical Sciences
CoWIN- COVID Vaccine Intelligence Network
CEM- Cohort Event Monitoring
EMA- European Medicines Agency
GVP- Good Pharmacovigilance Practices
IPC- Indian Pharmacopoeia Commission
MAH- Marketing Authorization Holder
MoHFW- Ministry of Health and Family Welfare
PASS- Post-Authorization Safety Study
PIDM- Programme for International Drug Monitoring (WHO)
PvPI- Pharmacovigilance Programme of India
SCCS- Self-Controlled Case Series
SIA- Supplementary Immunization Activity
UIP- Universal Immunization Programme
VSD- Vaccine Safety Datalink
WHO- World Health Organization

1. INTRODUCTION

Vaccination programs are among the most successful and cost-effective public health interventions, preventing an estimated 3–5 million deaths globally each year. In India, which has one of the largest immunization programs in the world, vaccines have

played a critical role in reducing child mortality and controlling vaccine-preventable diseases. However, like all medical interventions, vaccines may be associated with adverse events following immunization (AEFI). While the vast majority of these events are minor and self-limiting such as injection site pain, transient fever, or mild allergic reactions rare but serious adverse events of special interest (AESIs) can occur. Detecting and responding to such events is vital not only for ensuring individual safety but also for maintaining public trust in immunization programs [[1], [2], [3] [4]].

Vaccine pharmacovigilance refers to the systematic monitoring of vaccine safety after a product is introduced into routine use. It encompasses a range of activities to detect, assess, understand, and prevent adverse effects or other vaccine-related issues. In the Indian context, the scale and complexity of vaccine delivery marked by a large annual birth cohort (~25 million pre-COVID), geographic and socio-economic diversity, and frequent mass immunization campaigns make pharmacovigilance both essential and uniquely challenging [[1], [5], [6]].

A vaccine's lifecycle in India begins with research and development, followed by clinical trials, regulatory approval by agencies such as the Central Drugs Standard Control Organization (CDSCO), and post-licensure surveillance. Once deployed under the Universal Immunization Programme (UIP) or through targeted campaigns, vaccines continue to be monitored for safety via the National AEFI Surveillance Program, coordinated by the Ministry of Health and Family Welfare (MoHFW) in collaboration with the Indian Pharmacopoeia Commission (IPC) and state-level authorities. The COVID-19 pandemic served as an inflection point accelerating digital innovations like the CoWIN platform and highlighting systemic gaps in passive and active surveillance mechanisms [[7], [8]].

This review synthesizes peer-reviewed literature, national policy documents, program evaluations, and global technical guidance to critically examine the evolution and current state of vaccine pharmacovigilance in India. Drawing on evidence from 2014 to 2025, it explores challenges, innovations, and opportunities for strengthening surveillance systems. Emphasis is placed on integrating WHO, Brighton Collaboration, and CIOMS frameworks with Indian operational

guidelines to propose actionable, context-sensitive recommendations for the future.

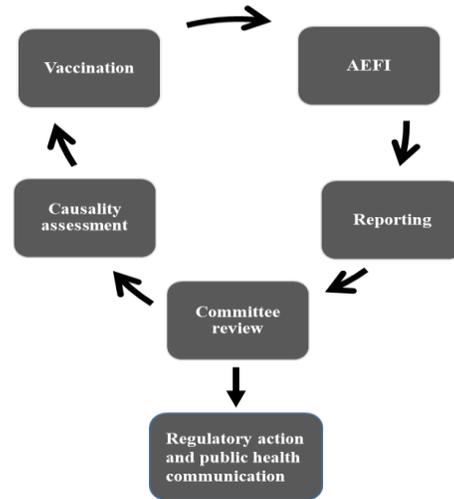


Figure 1: Lifecycle of Vaccine Pharmacovigilance in India

2. PREFERRED REPORTING ITEMS FOR SYSTEMATIC REVIEWS AND META-ANALYSES (PRISMA) APPROACH

This review adhered to the PRISMA 2020 framework to ensure systematic, transparent, and reproducible synthesis of evidence on vaccine pharmacovigilance in India.

2.1. Identification, Screening and Eligibility: A comprehensive literature search was performed across electronic databases such as PubMed, Scopus, and Google Scholar using keywords and Boolean operators: (“vaccine pharmacovigilance” OR “AEFI surveillance” OR “vaccine safety”) AND (“India” OR “immunization programme” OR “COVID-19 vaccine”). Additionally, grey literature, national policy documents, and official reports from the Ministry of Health and Family Welfare (MoHFW), Indian Pharmacopoeia Commission (IPC), Central Drugs Standard Control Organization (CDSCO), and World Health Organization (WHO) were screened. Searches included documents published between January 2014 and March 2025 to capture both pre- and post-COVID-19 developments.

Titles and abstracts were independently screened to exclude irrelevant studies (e.g., clinical trials unrelated to safety, or purely immunogenicity studies). Duplicates were removed manually. Inclusion criteria required that studies addressed post-marketing vaccine

safety, adverse events following immunization (AEFI), pharmacovigilance frameworks, or surveillance performance in India. Full-text articles, national guidelines, and program reports that included empirical data, operational analyses, or regulatory perspectives were retained. Exclusion criteria included non-English publications, editorials without data, and studies conducted outside India unless they offered global comparator frameworks (e.g., CIOMS, Brighton Collaboration, WHO-GVS Blueprint).

2.2. Inclusion and Data Synthesis: A total of 55 sources was included: 35 peer-reviewed studies, 12 WHO/CIOMS/Brighton guidance documents, and 8 national or institutional reports. Extracted data were narratively synthesized across thematic domains, institutional architecture, surveillance models, causality assessment, signal detection, and operational lessons. A qualitative thematic synthesis was undertaken to map progress, challenges, and strategic directions for vaccine safety in India. Comparative perspectives with global systems were used to contextualize the findings.

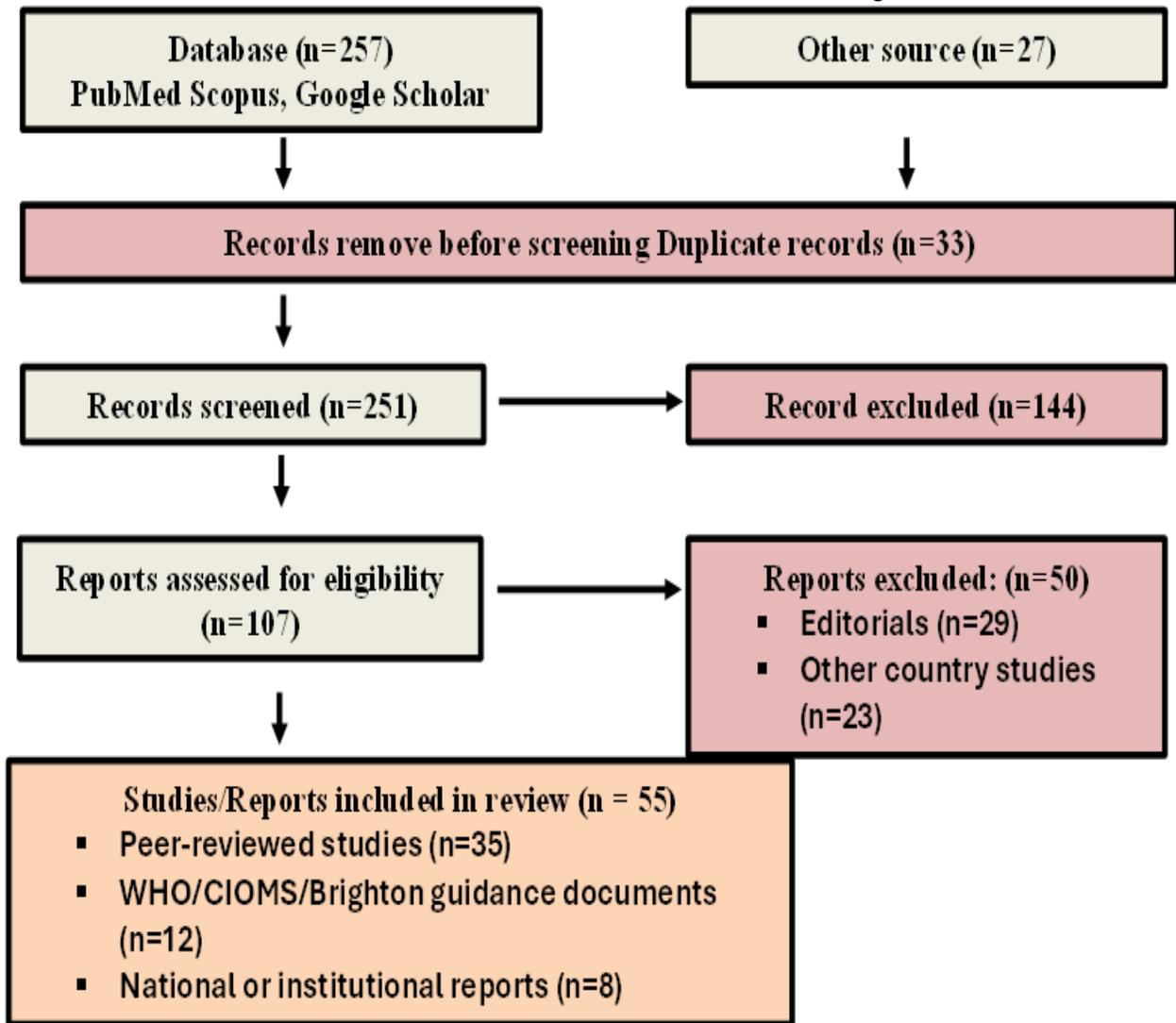


Figure 2: PRISMA Methodology

3. HISTORICAL EVOLUTION AND POLICY CONTEXT IN INDIA

3.1 Early systems and the Universal Immunization Programme

India's Universal Immunization Programme (UIP), launched in 1985 (as the Expanded Programme on Immunization in the 1970s evolved into UIP), progressively expanded the portfolio of vaccines and strengthened delivery systems. Adverse event reporting formally became part of immunization safety monitoring as UIP matured and new vaccines were introduced. Early passive AEFI systems were paper-based, limited by underreporting and delays, but provided a framework for decentralized investigation and review [[1], [9], [10]].

3.2 Institutional architecture: MoHFW, PvPI, CDSCO and AEFI Committees

The modern pharmacovigilance architecture involves several institutions with complementary roles: the Ministry of Health and Family Welfare (MoHFW) provides policy leadership for UIP and the AEFI framework; the Indian Pharmacopoeia Commission (IPC) hosts the Pharmacovigilance Programme of India (PvPI) which aggregates adverse event reports from Adverse Drug Reaction Monitoring Centers (AMCs) and AEFI reporting sources; the Central Drugs Standard Control Organization (CDSCO) governs regulatory safety actions for vaccine products; and state/district AEFI committees conduct immediate investigations and causality review per the national operational guidelines [[3], [11], [12]]. The National AEFI Secretariat coordinates cross-cutting activities, capacity building, and national causality review processes. The organizational model reflects a split between programme (immunization delivery and AEFI investigation) and regulation (product safety and licensure), requiring strong collaboration for timely policy decisions [[3], [11]].

3.3 Recent policy updates and the post-COVID era

The COVID-19 vaccination campaign catalyzed rapid evolution in reporting platforms, digital registries

(notably CoWIN), and active surveillance efforts. Recognizing these changes, MoHFW released an updated National AEFI Surveillance and Response Operational Guidelines (2024) to align investigation processes, reporting timelines, and roles/responsibilities across levels of the health system [[9]]. The IPC's PvPI also published performance reports (2023–24) documenting expanded reporting network and training activities. These documents reflect increasing institutional attention to vaccine safety and provide a platform for modernization [[13], [14]].

4. THE CONCEPTUAL AND REGULATORY FRAMEWORK OF VACCINE PHARMACOVIGILANCE

4.1 Key concepts and terminologies

- **AEFI (Adverse Event Following Immunization):** Any untoward medical occurrence temporally associated with immunization, not necessarily causally related to vaccine administration. WHO standardizes definitions and classification to improve comparability across settings [[15]].
- **AESI (Adverse Events of Special Interest):** Pre-specified conditions (e.g., myocarditis, Guillain–Barre syndrome) prioritized for closer monitoring due to biological plausibility or previous associations with vaccines [[6], [16]].
- **Causality assessment:** Systematic process to determine the likelihood that a vaccine caused an adverse event; WHO and CIOMS frameworks provide operational algorithms [[15]].
- **Signal detection:** Identification of a new or unexpected association between a vaccine and an event based on aggregate data and statistical methods (e.g., disproportionality) and clinical review [[6], [17]].

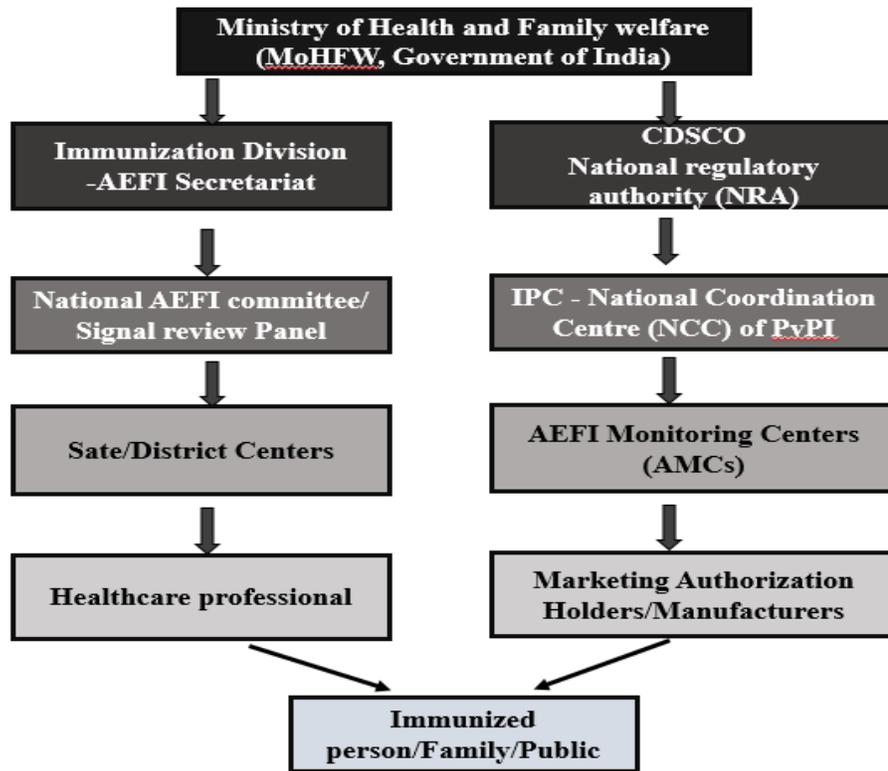


Figure 3: Administrative Hierarchy Flowchart: Vaccine Pharmacovigilance Stakeholders in India

4.2 Regulatory responsibilities and post-marketing obligations

Vaccines in India are regulated by CDSO under the Drugs and Cosmetics Act, with manufacturers required to submit post-marketing safety data for regulatory review. For new vaccines and emergency authorizations, regulatory authorities often impose specific post-authorization safety study (PASS) commitments. The programmatic arm, MoHFW/UIP retains responsibility for programmatic risk management, communication, and implementation of AEFI investigation SOPs. Harmonizing expectations between regulatory and programmatic stakeholders for data sharing, timelines, and analytic standards is essential but challenging in practice [[3], [11]].

4.3 International standards and global linkages

India participates in global pharmacovigilance through the WHO Programme for International Drug Monitoring (WHO-PIDM) and shares reports with Vigibase; Indian data contribute to global signal detection and benefit-risk assessments. International standards, Brighton Collaboration case definitions,

CIOMS guidance on active surveillance, and WHO vaccine safety manuals inform national tools and case definitions, enabling cross-national comparability and joint investigation of rare events [[18], [19], [20]].

5. SURVEILLANCE APPROACHES: DESIGN, IMPLEMENTATION AND METRICS

Vaccine safety surveillance comprises complementary methods. Each approach carries trade-offs between sensitivity, specificity, resource needs, and timeliness. A mixed surveillance strategy that leverages passive reporting for broad coverage and active surveillance for accurate incidence estimation is optimal for large, diverse countries like India.

5.1 Passive surveillance: AEFI spontaneous reporting

Passive spontaneous reporting remains the foundational surveillance mechanism due to its wide coverage and low incremental cost. In India, reports originate from immunization session staff, peripheral health workers, hospitals, and increasingly from digital reporting portals and helplines. The PvPI/IPC

aggregates spontaneous reports from AMCs and AEFI reports from immunization programs [[13]].

Strengths: broad population coverage, ability to detect rare and unexpected events; low cost per event. Limitations: underreporting (especially for non-serious events), reporting bias (publicity triggers spikes), variable completeness of reports (missing clinical details, timelines), and inability to easily calculate incidence rates without robust denominators [[8], [21], [22]]

Key program metrics for passive systems include number of reports per 100,000 doses, proportion of serious reports, timeliness of reporting, completeness score (proportion of core variables captured), and proportion of reports investigated within defined timelines.

5.2 Active surveillance models

Active surveillance intentionally seeks out adverse events through planned follow-up, sentinel hospital surveillance, cohort event monitoring, and record linkage studies. These designs provide accurate incidence measures and can test signals detected in passive systems.

Sentinel surveillance: Selected hospitals (e.g., tertiary care centers) report predefined AESI and provide clinical details validated against Brighton criteria. Sentinel networks are particularly useful for AESI with clear clinical phenotypes (e.g., myocarditis with raised troponin and ECG changes) [[16], [19], [23] [24]].

Cohort event monitoring (CEM): Enrolls defined cohorts receiving a vaccine (e.g., health workers, [21]adolescents in school-based campaigns) and follows them prospectively for adverse events using active contact or electronic follow-up. CEM was piloted during COVID-19 in India and yielded robust short-term safety estimates for Covishield and Covaxin in multiple settings [[7], [14], [24], [25]].

Record linkage / vaccine safety datalink (VSD) style studies: Linking vaccination registries (e.g., CoWIN) with hospital discharge datasets and mortality registries enables near-real time rate calculations and self-controlled designs (SCCS) that control for time-invariant confounding [[25], [26], [27]]. Implementing linkage requires unique identifiers, data sharing agreements, and privacy safeguards [[3], [28], [29]].

5.3 Enhanced surveillance during supplementary immunization activities (SIAs)

Mass campaigns demand rapid surge capacity. Best practice elements include pre-campaign training on AEFI recognition and reporting, deployment of rapid response teams for on-site investigation, dedicated helplines, micro-plans with AEFI focal points, and temporary sentinel sites to monitor severe or clustered events. The polio and measles-rubella SIAs demonstrated that preparedness and rapid investigation decrease time to causality classification and help manage community concerns [[2], [30], [31], [32]].

5.4 Metrics for active surveillance and integration with passive reporting

Key metrics for active surveillance include incidence rates per 100,000 doses (with confidence intervals), attributable risk estimates, risk ratios comparing vaccinated vs background rates, sensitivity and positive predictive value of sentinel surveillance, and time-to-signal detection. Integration with passive data is essential, active systems can validate passive signals and provide denominator-based rates that support risk communication and regulatory decisions [[18], [27], [33], [34]].

6. CAUSALITY ASSESSMENT, CASE INVESTIGATION AND CLASSIFICATION

Causality assessment is a structured process that determines the likelihood of a causal association between a vaccine and an adverse event. In India, investigations follow WHO guidelines and the national operational SOPs, progressing from district-level fact-finding to state and national causality committees for complex or serious events [[10], [15], [35]].

6.1 Investigation steps and required documentation

- a. Immediate clinical care and stabilization: Prioritize patient care and document clinical course.
- b. Timely notification and triage: Serious AEFIs must be reported immediately to district/state AEFI committees per timelines specified in operational guidelines.
- c. On-site investigation: Field teams collect detailed vaccine history (product, batch, and injection technique), medical history, comorbidities,

concomitant medications, timeline of symptom onset, and laboratory/imaging data.

- d. Data abstraction and standardization: Use Brighton Collaboration case definitions to standardize phenotype classification where applicable.
- e. Causality algorithm application: Employ WHO/CIOMS causality categories (consistent, probable, possible, unlikely, coincidental, and unclassifiable) and document rationale.
- f. Synthesis and communication: National committee reviews aggregated evidence and recommends programmatic/regulatory actions and risk communication messages [[15], [35], [36]].

6.2 Common pitfalls and solutions

- Incomplete investigations: Ensure rapid deployment of trained district investigators and standardized checklists.
- Lack of baseline incidence data: Establish sentinel networks to estimate background rates for AESI, stratified by age, sex and geography.
- Inter-committee variability: Standardize training and periodic calibration exercises for causality committees, including mock case reviews and use of standard tools [[4], [8], [37], [38]].

6.3 Case examples and classification trends

Multiple programmatic reviews and published analyses from India show that a substantial fraction of serious AEFIs are classified as coincidental or due to underlying disease especially when events occur in young infants with pre-existing conditions reinforcing the importance of high-quality investigations and transparent communication to distinguish causation from coincidence [[4], [39], [40]].

7. SIGNAL DETECTION, EPIDEMIOLOGIC STUDIES, AND DATA ANALYTICS

Signal detection is the process of identifying potential new safety concerns that warrant further investigation. Methodological rigor and triangulation across multiple data sources are key.

7.1 Disproportionality analysis and spontaneous report databases

Disproportionality techniques (e.g., reporting odds ratio, proportional reporting ratio) applied to

spontaneous reporting databases (PvPI data and VigiBase) can flag vaccine–event combinations that occur more frequently than expected. Such signals are hypothesis-generating and require clinical review and epidemiologic testing [[27], [41], [42]]. Limitations include reporter biases, variable report quality, and inability to compute incidence without denominators.

7.2 Epidemiologic designs for signal evaluation

- Case–control studies: Useful when events are rare and cases can be ascertained reliably; matching controls reduces confounding.
- Self-controlled case series (SCCS): Compares incidence of events in risk windows post-vaccination with other time periods within the same individuals; controls for fixed confounders and is efficient for events with abrupt onset. SCCS has been used extensively for COVID-19 vaccine AESI evaluation globally [[26], [28]].
- Retrospective cohort and propensity score approaches: When linked vaccination and outcome data exist, these designs estimate risk ratios and absolute risks while adjusting for measured confounders.

7.3 Data linkage, privacy and practical considerations

Implementing VSD-style linked analyses hinges on unique identifiers or robust probabilistic linkage methods. India’s digital health initiatives (Ayushman Bharat, electronic health records pilots) and CoWIN offer infrastructure to link vaccination records with hospitalizations and mortality datasets. Data sharing agreements, privacy safeguards, and technical capacity are prerequisites [[3], [43]].

7.4 Analytical capacity and automation

Real-time dashboards, automated signal detection algorithms and machine learning tools can augment human review. However, algorithmic signals require clinical interpretation and must be transparent; overreliance on invalidated machine outputs risks false alarms. Building national analytic capacity (biostatisticians and pharmaco-epidemiologists) is essential for sustainable signal evaluation [[26], [27], [28]].

8. OPERATIONAL LESSONS FROM MASS IMMUNIZATION PROGRAMS

India's experience with polio eradication, measles-rubella campaigns and the COVID-19 vaccine roll-out provides a rich set of operational lessons for vaccine pharmacovigilance.

8.1 Polio eradication: micro-planning and rapid response

Polio SIAs demonstrated meticulous micro-planning, local stakeholder engagement, and surge capacity for surveillance and rapid response. The surveillance networks (acute flaccid paralysis and environmental surveillance) created managerial and logistical assets that supported AEFI surveillance in later campaigns. Polio's legacy emphasizes the value of community-level engagement and decentralized accountability for prompt reporting and investigation [[2], [29], [31]].

8.2 Intensified Mission Indradhanush (IMI) and MR SIAs: targeted strategies and safety preparedness

IMI and MR SIAs targeted underserved populations (zero-dose children) and underlined the need to pair intensified delivery with AEFI preparedness: pre-campaign training on AEFI identification, strengthening cold chain and immunization error prevention, and proactive communication plans to preempt hesitancy arising from adverse events or rumors [[5], [29]].

8.3 COVID-19 vaccination: scale, speed, and digital transformation

The COVID-19 vaccination campaign beginning January 2021 was unprecedented in scale and speed. Innovations included CoWIN for digital registration, appointment scheduling, and certificate issuance; electronic AEFI reporting portals; large-scale cohort monitoring of healthcare workers and special populations; and collaborations with academic centers for active safety studies. These advances improved timeliness of reporting and created opportunities for dose-linked safety analyses, but also revealed gaps: underreporting from private facilities, variable investigation quality, and the need to integrate multiple data sources for denominator calculations [[13], [25], [44], [45], [46]].

8.4 Crisis communication and trust building

During COVID-19, rapid transparent communication of safety findings (including context about background rates and rarity of serious AESI) was crucial to maintain vaccine confidence. Instances of miscommunication or delayed updates amplified vaccine hesitancy, illustrating that technical analysis alone is insufficient risk communication must be pre-planned, proactive, and tailored to local contexts [[19], [47], [48], [49]].

9. KEY CHALLENGES IN OPERATIONAL, ETHICAL AND EQUITY CONSIDERATIONS

9.1 Underreporting and data completeness

Underreporting remains a major limitation, particularly for events occurring outside formal healthcare settings or in marginalized populations. Improving frontline awareness, simplified reporting pathways (mobile apps, toll-free numbers), and active follow-up for high-risk groups can improve completeness [[14] [35], [50], [51] [52]].

9.2 Denominator data, Workforce capacity and training

Absence of accurate dose administration denominators (by age, sex, geography) impairs rate calculations and meaningful international comparisons. Strengthening electronic immunization registries and systematic reporting from private sector providers is essential for representative surveillance [[8], [13], [44]]. Investigating serious AEFIs requires clinical, epidemiologic and forensic expertise. Subnational variability in committee capacity leads to inconsistent classification and delays. Investment in continuous training, tele-mentoring, and standardized investigation toolkits can reduce variability [[13], [14], [53], [54]].

9.3 Privacy, data governance and legal frameworks

Linking vaccination registries to health outcomes raises privacy concerns. Clear legal frameworks, data minimization principles, and secure technical platforms are required to enable linkage studies while protecting individual privacy [[3], [55]].

9.4 Equity and access: ensuring safety monitoring reaches marginalized groups

Surveillance systems must be designed to capture events among marginalized, remote and underserved

populations. Translation of reporting materials into vernacular languages, mobile reporting units, and community health worker engagement are necessary to prevent surveillance blind spots [[29]].

Approach	Strengths	Limitations	Recommended use cases
Passive AEFI reporting (PvPI/UIP)	Broad coverage; low incremental cost	Underreporting; limited denominators; reporting bias	Routine monitoring; initial signal generation; public reporting
Sentinel hospital surveillance	Validated case ascertainment; clinical detail	Resource intensive; limited geographic representativeness	AESI monitoring (myocarditis, GBS, anaphylaxis)
Cohort event monitoring (CEM)	Precise short-term risk estimates; prospective follow-up	Needs cohort enrolment and follow-up systems	New vaccine introductions; special populations (pregnant women)
Record linkage (VSD style)	Denominator-based rates; robust epidemiologic designs (SCCS)	Requires unique IDs, EHRs, data sharing	Evaluation of signals requiring incidence rates; comparative safety studies
Disproportionality in spontaneous databases	Rapid, low-cost signal detection	Confounded by reporting practices; hypothesis generating only	Generate hypotheses for epidemiologic testing

Table 1. Vaccine Surveillance approaches: strengths, limitations and recommended use cases

10. STRATEGIC PRIORITIES AND A ROADMAP FOR STRENGTHENING VACCINE SAFETY IN INDIA (2025–2030)

Building on recent progress, we propose a pragmatic roadmap with short-, medium- and long-term actions.

10.1 Short term (0–12 months)

- Operationalize the 2024 national AEFI guidelines across all states, including standardized investigation checklists and reporting timelines.
- Scale up training: national cascade training for district investigators and AEFI committees using standardized modules and periodic competency assessments.
- Enhance digital reporting: ensure CoWIN and AEFI portals exchange information (dose-linked reports) and simplify reporting from private sector facilities.
- Transparent dashboards: publish anonymized weekly/monthly safety summaries for public and professional stakeholders to build trust.

10.2 Medium term (13 years)

- Establish a national sentinel AESI network: select hospitals across regions to provide validated case

ascertainment and background incidence estimates for priority AESI.

- Implement cohort event monitoring for new vaccine introductions to quantify short-term risk profiles.
- Pilot data linkage projects in selected states combining CoWIN, hospital discharge datasets, and mortality records, using privacy-preserving probabilistic linkage.
- Create a national pharmaco-epidemiology unit (or strengthen existing units) to conduct SCCS and comparative studies and to support national causality committees.

10.3 Long term (3–5+ years)

- Integrated vaccine safety ecosystem: full linkage between immunization registries, electronic health records, laboratory networks, and mortality registries enabling near-real time cohort analyses and automated alerts.
- Sustained investment in workforce and infrastructure: fellowship programs in pharmaco-epidemiology, expanded IPC/PvPI network, and regional centers of excellence.

- International collaboration: strengthen contributions to VigiBase, participate in multi-country collaborative studies for AESI evaluation, and adopt global standards proactively for novel platforms.

10.4 Cross-cutting priorities

- Risk communication by design: build communication plans into vaccine introduction/pre-campaign planning, emphasizing plain-language summaries, FAQs, and community engagement.
- Equity lens: monitor surveillance performance across socioeconomic strata and use targeted strategies to address gaps.
- Governance and legal enablers: update data sharing policies to facilitate research while protecting privacy, and align regulatory expectations for post-marketing studies.

11. CONCLUSION AND FUTURE PERSPECTIVE

India's vaccine pharmacovigilance system has matured substantially, particularly since the COVID-19 pandemic, which catalyzed digital transformation and multi-institutional collaboration. The integration of CoWIN, strengthened PvPI reporting, and enhanced AEFI investigation protocols demonstrate a commitment to transparency and responsiveness. Yet, underreporting, fragmented data streams, and insufficient analytical capacity continue to constrain rapid signal detection and evidence-based policymaking.

Future efforts must focus on three strategic priorities: (1) Integration and digitization, linking immunization, hospitalization, and mortality databases to enable near-real-time signal evaluation; (2) Analytical and human resource capacity, developing regional centers of excellence in pharmaco-epidemiology and strengthening state AEFI committees through continuous training; and (3) Risk communication and community engagement ensuring timely, transparent updates to sustain vaccine confidence.

By 2030, India should aim to build an interoperable, learning vaccine safety ecosystem aligned with global best practices. International collaboration with WHO, CIOMS, and regulatory counterparts can accelerate harmonization of causality assessment, AESI monitoring, and data governance frameworks. This

proactive and technology-enabled approach will not only reinforce public trust but also strengthen India's position as a model for vaccine pharmacovigilance in low- and middle-income settings.

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