Section: Community Medicine

Original Research Article

OCCURRENCE AND RESOLUTION OF ADVERSE EVENTS FOLLOWING IMMUNIZATION AMONG INFANTS: A CROSS-SECTIONAL STUDY FROM IMMUNIZATION CENTRES OF RAIPUR DISTRICT, CHHATTISGARH

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ABSTRACT

Background: Adverse Events Following Immunization (AEFI) represent a significant concern for caregivers and constitute a critical component of vaccine pharmacovigilance. Published data on the incidence, clinical pattern, and resolution of AEFI from primary healthcare settings in Central India are scarce.
Objectives: To assess the occurrence and pattern of AEFI at 24-hour, 7-day, and 28-day post-vaccination follow-up; to assess the resolution status of reported events; and to identify factors associated with AEFI occurrence among infants aged 0–12 months vaccinated at immunization centres in Raipur district, Chhattisgarh.
Materials and Methods: A prospective cross-sectional study enrolled 300 parent–infant dyads aged 0–12 months using multistage sampling from 24 immunization centres. Active follow-up was conducted at 24 hours, 7 days, and 28 days post-vaccination using a structured questionnaire. AEFI occurrence, symptom profile, onset time, duration, resolution status, and management were recorded. Chi-square tests were applied for statistical analysis.
Results: AEFI were reported in 250 of 300 infants (83.4%) at the 24-hour follow-up. Fever alone was the most common event (34.4%), followed by fever combined with injection-site reactions. Onset occurred within 3 hours of vaccination in 69.6% of cases. By the 7-day follow-up, 96.6% of early-onset AEFI had resolved; all residual events had resolved completely by 28 days. No serious AEFI or hospitalizations were recorded.
Conclusion: AEFI in Raipur district are predominantly minor, early-onset, and self-limiting, with near-complete resolution within one week. The safety profile of routine Universal Immunization Programme (UIP) vaccines is reassuring. Targeted pre-vaccination counselling is recommended for parents of younger and first-born infants.
Keywords: Adverse Events Following Immunization; AEFI occurrence; AEFI resolution; vaccine safety; cross-sectional study; Universal Immunization Programme; Chhattisgarh.

INTRODUCTION

Immunization is one of the most effective and cost-efficient public health interventions, preventing an estimated 2–3 million deaths annually from vaccine-preventable diseases.[1] India's Universal Immunization Programme (UIP) is among the largest globally, providing vaccines to approximately 26.7 million newborns and 29 million pregnant women each year.[2] Despite its proven benefits, the occurrence of Adverse Events Following

Immunization (AEFI) remains a concern for caregivers and may influence vaccine acceptance.

The World Health Organization defines an AEFI as any untoward medical occurrence following immunization that does not necessarily have a causal relationship with vaccine administration.[3] These events range from common minor reactions such as fever, pain, swelling, and redness at the injection site to rare serious events including anaphylaxis and febrile seizures.[4] Although most AEFI are mild and self-limiting, timely identification and appropriate communication are essential to maintain public confidence in immunization programmes.

India's AEFI surveillance system, guided by the Ministry of Health and Family Welfare Operational Guidelines (2024), emphasizes reporting, investigation, and causality assessment of all AEFI.[5] However, passive surveillance often underestimates the true burden because minor events remain under-reported due to normalization of expected reactions and inadequate documentation.[6] Published evidence on AEFI from Central India, particularly Raipur district of Chhattisgarh, is scarce, limiting the understanding of local occurrence and clinical patterns. The Chhattisgarh State AEFI Annual Report 2024 also indicates zero AEFI reporting from several districts despite ongoing immunization activities, suggesting possible under-reporting.[24]

Therefore, this prospective study was undertaken to assess the occurrence, clinical presentation, and resolution of AEFI among infants aged 0–12 months attending routine immunization sessions at selected healthcare facilities in Raipur district, Chhattisgarh, using active follow-up at 24 hours, 7 days, and 28 days post-vaccination.

MATERIALS AND METHODS

Study Setting and Population

A prospective cross-sectional study with active structured follow-up was conducted in Raipur district, Chhattisgarh, India. Immunization services were delivered through sub-health centres, primary health centres, community health centres, district hospitals, and a government medical college immunization clinic under the UIP. Data were collected from April to October 2025.

Inclusion: Parents of infants aged 0–12 months attending immunization sessions whose children received at least one vaccine.

Exclusion: Parents declining consent or without mobile phone access.

Sample Size and Sampling

Sample size was calculated using Cochrane's single proportion formula: $n = (Z^2_{1-\alpha/2})[P(1-P)] / d^2$. Assuming an AEFI prevalence of 50% (conservative estimate), 95% confidence level (Z = 1.96), and 5% absolute precision, the minimum required sample was 267. Adding 10% for attrition, the final sample size was set at 300. Multistage sampling was employed: immunization centres were stratified by level of care and setting (urban/rural), after which 24 centres were selected proportionate to size. Infants presenting on designated study days were enrolled consecutively.

Data Collection and Outcome Definitions

A pre-designed, pre-tested semi-structured questionnaire was administered at enrolment to capture sociodemographic characteristics, immunization history, and baseline health status. Post-vaccination follow-up was conducted at three structured time points via telephonic calls at 24-hour, 7-day, and 28-day assessments. At each contact, occurrence of any adverse event, symptom type, time of onset, severity, and initial management were recorded. AEFI occurrence was defined as any parent-reported symptom arising within the follow-up window that was not present before vaccination, including fever, local injection-site reactions (redness, swelling, pain), irritability, vomiting, lethargy, or poor feeding. Resolution was defined as complete disappearance of all reported symptoms at the time of follow-up assessment.

Statistical Analysis

Data were entered into Microsoft Excel and analysed using descriptive statistics. Chi-square tests were applied to examine associations between categorical variables. A p-value of 0.05 was considered statistically significant.

RESULTS

Sociodemographic Characteristics

A total of 300 parent–infant dyads were enrolled. The majority of parents fell in the 26–30 year age group (46.3%), with a mean parental age of 28.06 ± 4.67 years. Mothers were the predominant respondents (77.3%). Joint family structures accounted for 55.7% of households. Most participants identified as Hindu (93.4%), belonged to the Other Backward Class (OBC) category (59.0%), and were classified in the upper-middle socioeconomic class (30.3%) per the Modified BG Prasad Scale 2025. Among mothers, 44.7% were graduates or above, and 92.0% were homemakers.

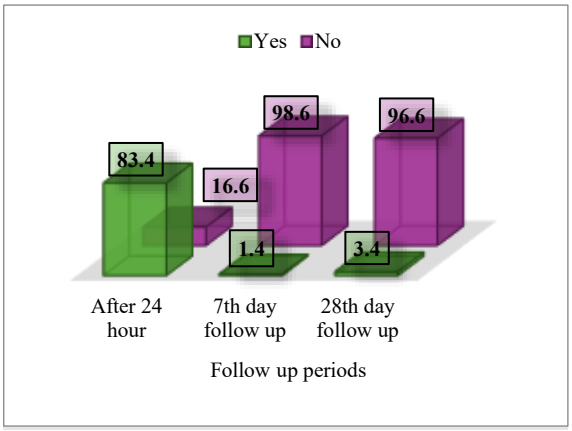

Figure 1-Occurrence of AEFI

Table 1: Sociodemographic Characteristics of Study Participants (n=300)

Variable	Category	Frequency n (%)
Age group of parents (years)	18-20	7 (2.4)
	21-25	83 (27.6)
	26-30	139 (46.3)
	31-35	58 (19.3)
	35-40	13 (4.4)
Mean age		28.06 ± 4.67 years
Respondent type	Mother	232 (77.3)
	Father	68 (22.7)
Family type	Joint	167 (55.7)
	Nuclear	133 (44.3)
Religion	Hindu	280 (93.4)
	Muslim	12 (4.0)
	Christian	8 (2.6)
Social category	Unreserved	32 (10.7)
	OBC	177 (59.0)
	SC	90 (30.0)
	ST	1 (0.3)
Socioeconomic class*	Upper (Class I)	45 (15.0)
	Upper middle (Class II)	91 (30.3)
	Middle (Class III)	80 (26.7)
	Lower middle (Class IV)	81 (27.0)
	Lower (Class V)	3 (1.0)
Maternal education	Graduate and above	134 (44.7)
	Intermediate/Diploma	50 (16.7)
	High school	74 (24.6)
	Middle/Primary/Illiterate	42 (14.0)
Maternal occupation	Homemaker	276 (92.0)
	Working	24 (8.0)

Modified BG Prasad Scale 2025; OBC = Other Backward Class; SC = Scheduled Caste; ST = Scheduled Tribe

Infant Characteristics

Female infants constituted 52.6% of the sample. The mean infant age was 4.8 ± 3.03 months; the 3.1–6.0-month age group was the most represented (39.3%), followed by the ≤3.0 months group (35.3%). More than half (54.4%) had birth weight greater than 2.5 kg. Delivery by lower segment caesarean section (LSCS) accounted for 60.6%; 74.0% of infants were born in government facilities. First-born infants comprised 52.4% of the cohort. The majority (93.3%) were clinically healthy at the time of vaccination. The highest proportion of infants attended the 3.5-month vaccination visit (32.7%)

Table 2: Characteristics of Enrolled Infants (n=300)

Variable	Category	Frequency n (%)
Gender	Female	158 (52.6)
	Male	142 (47.4)
Age group (months)	≤3.0	106 (35.3)
	3.1–6.0	118 (39.3)
	6.1–9.0	19 (6.4)
	>9.0	57 (19.0)
	Mean age	4.8 ± 3.03 months
Birth weight	≤2.5 kg (Low birth weight)	137 (45.6)
	>2.5 kg (Normal)	163 (54.4)
Mode of delivery	LSCS	182 (60.6)
	Normal vaginal delivery	118 (39.4)
Place of delivery	Government facility	222 (74.0)
	Private facility	76 (25.4)
	Home	2 (0.6)
Birth order	First	157 (52.4)
	Second	116 (38.6)
	Third and above	27 (9.0)
Illness at vaccination	None	280 (93.3)
	Present (mild cold/cough predominant)	20 (6.7)
Vaccination schedule visit	1.5 months (6 weeks)	72 (24.0)
	2.5 months (10 weeks)	59 (19.7)
	3.5 months (14 weeks)	98 (32.7)
	9 months	71 (23.7)

LSCS = Lower Segment Caesarean Section

AEFI Occurrence and Pattern at 24-Hour Follow-up

Adverse events were reported in 250 of 300 infants (83.4%) at the 24-hour follow-up. Among these, onset occurred within 3 hours of vaccination in 69.6% of cases, between 3 and 6 hours in 19.6%, and after 6 hours in 10.8%. Of the 250 infants with AEFI, 28.4% had complete symptom resolution within 24 hours, while the remaining 71.6% (n = 179) had symptoms persisting beyond 24 hours requiring further follow-up.Fever alone was the most common adverse event (34.4%), followed by fever combined with injection-site redness or swelling (24.8%), fever with injection-site pain (15.6%), fever with other problems (14.4%), local redness or swelling with pain in the absence of fever (7.2%), other systemic symptoms such as vomiting, lethargy, or poor feeding (3.2%), and injection-site pain alone (0.4%). Only 6.4% (n = 16) of infants required medical consultation; among these, 68.75% opted for telephonic consultation and 31.25% visited a health facility in person. Among the 234 infants managed at home, 80.76% paracetamol received syrup paracetamol, 17.10% received paracetamol combined with cold compression, and 2.14% received no treatment. No infant required hospitalization.

Table 3: AEFI Occurrence, Onset Pattern, Symptom Profile, and Management at 24-Hour Follow-up (n=300)

S.No.	Variable	n	%
1	Any AEFI reported (n=300)	250	83.4
	No AEFI	50	16.6
2	Onset within 3 hours of vaccination (n=250)	174	69.6
	Onset 3–6 hours	49	19.6
	Onset after 6 hours	27	10.8
3	Resolved within 24 hours (n=250)	71	28.4
	Persisted beyond 24 hours	179	71.6
4	Fever alone (n=250)	86	34.4
	Fever + Redness/Swelling at injection site	62	24.8
	Fever + Pain at injection site	39	15.6
	Fever + Other problem	36	14.4
	Pain + Local redness/swelling (no fever)	18	7.2
	Other: vomiting, lethargy, poor feeding	8	3.2
	Pain at injection site alone	1	0.4
5	Medical consultation sought (n=250)	16	6.4
	Mode: Telephonic	11	68.75
	Mode: Facility visit	5	31.25
6	Home management – Syrup paracetamol (n=234)	189	80.76
	Paracetamol + Cold compression	40	17.10
	No treatment	5	2.14
7	Hospitalization required	0	0

A statistically significant association was identified between the type of vaccination administered and the clinical pattern of adverse events ($p < 0.001$). Fever combined with a local reaction was most frequently observed following the 1st and 3rd pentavalent vaccine schedules, while more than 2/3rd of infants receiving the MR1/IPVb/PCVb/Vitamin A schedule remained asymptomatic. These findings are consistent with the established reactogenicity profile of pentavalent vaccines.

Table 4: Pattern of AEFI across Different Vaccination Types (n=300)

Type of Vaccination	Fever + Local Reaction n (%)	Fever Only n (%)	Local Reaction Only n (%)	Other Systemic n (%)	No Symptoms n (%)	Total n (%)	Chi-Square (χ^2)	p-value
MR1/IPVb/PCVb/Vit. A	4 (5.6)	7 (9.9)	0 (0.0)	12 (16.9)	48 (67.6)	71 (23.7)	190.592 (df = 12) **< 0.001**	
Penta1/Rota1/OPV1/IPV1/PCV1	33 (42.9)	22 (28.6)	8 (10.4)	14 (18.2)	0 (0.0)	77 (25.7)		
Penta2/Rota2/OPV2	23 (39.7)	26 (44.8)	4 (6.9)	5 (8.6)	0 (0.0)	58 (19.3)		
Penta3/PCV2/IPV2/Rota3/OPV3	41 (43.6)	31 (33.0)	7 (7.4)	13 (13.8)	2 (2.1)	94 (31.3)		
Total	**101 (33.7)**	**86 (28.7)**	**19 (6.3)**	**44 (14.7)**	**50 (16.7)**	**300 (100.0)**		

Resolution Status of AEFI

7th Day Follow-up

Of the 179 infants with symptoms persisting beyond 24 hours, 173 (96.6%) had achieved full resolution by the 7-day assessment, while 6 (3.4%) remained unresolved. Among the resolved cases, 110 (61.4%) resolved within 3–7 days and 63 (35.2%) within 1–3 days. An additional 4 infants (1.33% of the total cohort) developed new symptoms at the 7-day assessment; 75% had symptom onset within 48 hours of vaccination and 25% within 72 hours. All 4 cases resolved completely. Reported symptoms included loose stools, diarrhoea, injection-site swelling, and redness with cough (25% each).

28th Day Follow-up

All 6 infants with symptoms unresolved at the 7-day assessment had fully resolved by 28 days: 4 (66.6%) resolved within 7–15 days and 2 (33.4%) resolved after 15 days. An additional 10 infants (3.33% of the cohort) reported new symptoms at the 28-day assessment, all presenting exclusively with fever. Onset occurred within 7–10 days of vaccination in 50% and after 10 days in the remaining 50%. At the time of the 28-day assessment, 7 of these 10 (70%) had resolved and 3 (30%) had ongoing symptoms. No serious AEFI, no hospitalization, and no permanent sequelae were recorded across the entire 28-day observation period.

Table 5: Resolution Status of AEFI at 7-Day and 28-Day Follow-up

S.No.	Variable	Category	n	%
1	Status of early-onset AEFI at 7-day follow-up (n=179)	Resolved	173	96.6
		Not resolved	6	3.4
2	Duration of resolution (n=179)	1–3 days	63	35.2
		3–7 days	110	61.4
		>7 days	6	3.4
3	New symptoms at 7-day follow-up (n=300)	Yes	4	1.33
	Resolution of new 7-day symptoms (n=4)	Resolved (100%)	4	100
4	Status of residual symptoms at 28-day follow-up (n=6)	Resolved	6	100
5	Duration of residual symptoms (n=6)	7–15 days	4	66.6
		>15 days	2	33.4
6	New symptoms at 28-day follow-up (n=300)	Yes	10	3.33
	Symptom type (n=10)	Fever only (all cases)	10	100
	Resolution status (n=10)	Resolved	7	70
		Not resolved at assessment	3	30
7	Hospitalization at any follow-up	None	0	0

DISCUSSION

This prospective cross-sectional study from Raipur district provides the 24-hour follow-up showed an AEFI occurrence of 83.4%, with events mostly minor, early-onset, and resolving within one week, comparable to the 80.2% 24-hour prevalence reported by Santos et al. in Brazil.[10] Similarly, Ogundele et al. in Nigeria found that 63.8% of adverse events occurred within 6 hours of vaccination.[17] The emergence of new AEFI cases at the 7-day (1.33%) and 28-day (3.33%) follow-ups demonstrates that while the overwhelming majority of post-vaccination reactions manifest within the first 24 hours, a small but clinically relevant proportion presents later. This finding underscores the value of multi-point active follow-up and is consistent with the structured surveillance framework advocated by the WHO Global Manual on AEFI Surveillance.[3]

Fever alone (34.4%) was the predominant AEFI in the present study, consistent with findings reported by Joshi et al. (34.59%),[11] and Gupta et al,[19] The combined presentation of fever with injection-site reactions (redness, swelling, or pain) accounted for an additional 54.8% of cases, reflecting the anticipated inflammatory and systemic response to whole-cell pertussis-containing vaccines such as pentavalent DTwP-HBV-Hib.[23] Systemic non-febrile events including vomiting, lethargy, and poor feeding were reported in only 3.2% of infants, which is consistent with the low rate of such reactions described in the Indian AEFI literature.[6,11] Notably, no anaphylaxis, severe and serious AEFI was recorded, confirming the favourable safety profile of UIP vaccines.[6]

The 96.6% resolution rate of early-onset AEFI by the 7-day follow-up—with 61.4% resolving within 3–7 days and 35.2% within 1–3 days—confirms the self-limiting nature of post-vaccination reactions. Santos et al. similarly reported that 95.8% of non-severe reactions resolved without complications.[11] Complete resolution (100%) of all residual symptoms by 28 days is particularly reassuring from a programme communication perspective. The 30% non-resolution at the 28-day assessment among the 10 infants with late-onset fever likely reflects intercurrent febrile illnesses during the post-vaccination period rather than true late vaccine reactions, given that all cases presented with fever as the sole symptom without associated danger signs.

A statistically significant association was observed between the type of vaccination administered and the clinical pattern of AEFI ($p<0.001$). Fever with local reaction was most common following the first and third pentavalent vaccine schedules, whereas more than two-thirds of infants receiving the MR1/IPVb/PCVb/Vitamin A schedule remained asymptomatic. These findings are consistent with previous studies demonstrating the higher reactogenicity of pentavalent-containing vaccines. Izadi et al. reported fever as the most frequent AEFI

after pentavalent vaccination, with local reactions also commonly observed.[25]

The absence of hospitalization across the entire 28-day observation period, despite an 83.4% AEFI prevalence, unequivocally demonstrates that the adverse events encountered were mild and manageable at home or with primary-level consultation.[19] The strengths of this study include its prospective design, multi-point active follow-up, However, formal WHO/MoHFW causality assessment was not performed for individual AEFI.

CONCLUSION

This prospective cross-sectional study with active follow-up demonstrates that AEFI among infants receiving routine UIP vaccines in Raipur district, Chhattisgarh, are predominantly minor, early-onset, and self-limiting. The 83.4% AEFI occurrence at 24-hour active follow-up reflects the expected reactogenicity of the primary immunization schedule. Near-complete resolution (96.6%) within one week, complete resolution of all residual events by 28 days, and zero hospitalizations across the study confirm the safety of routine childhood immunization in this setting. Multi-point follow-up at 24 hours, 7 days, and 28 days provides a comprehensive picture of the AEFI trajectory and resolution cascade that cannot be captured by single-point assessment. The mostly mild and self-limiting nature of AEFI should be communicated to sustain vaccine confidence. Brief pre-vaccination counselling on common AEFI, expected duration, and home care, supported by simple leaflets or digital messages, is recommended.

Declarations

Ethics Approval: The study was approved by the Institutional Ethics Committee

Conflict of Interest: The authors declare no conflict of interest.

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REFERENCES

1. Centers for Disease Control and Prevention. Ten great public health achievements – United States, 1900–1999. MMWR Morb Mortal Wkly Rep. 1999;48(12):241–3.
2. National Health Portal of India. Universal Immunisation Programme [Internet]. New Delhi: Ministry of Health and Family Welfare, Government of India; 2023 [cited 2025 Jan]. Available from: https://www.nhp.gov.in
3. World Health Organization. Global manual on surveillance of adverse events following immunization. Geneva: WHO Press; 2014.
4. Stratton K, Ford A, Rusch E, Clayton EW, editors. Adverse effects of vaccines: evidence and causality. Washington DC: National Academies Press; 2012.
5. Ministry of Health and Family Welfare, Government of India. AEFI: adverse event following immunization – surveillance and response: operational guidelines 2024. New Delhi: MoHFW; 2024.
6. Joshi J, Das MK, Polpakara D, Aneja S, Agarwal M, Arora NK. Vaccine safety and surveillance for adverse events following immunization (AEFI) in India. Indian J Pediatr. 2018;85(2):139–48.
7. Santos AM, Guerra-Junior AA, Coelho GL. Adverse events associated with DPT and DT childhood immunizations: a cross-sectional study. J Pediatr (Rio J). 2002;78(3):173–80.
8. Joshi AV, Dandge P, Maniar J, Shah R, Desai HG. Adverse vaccine events following immunization in a pediatric population: a prospective observational study. Int J Contemp Pediatr. 2019;6(4):1714–9.
9. Mittal S, Singh P, Bhagat A, Kumar A. Adverse events following immunization (AEFI) in children: a community-based observational study in Uttarakhand, India. J Evid Based Med Healthc. 2021;8(14):866–71.
10. Sebastian T, Bhatt GC, Bhat NK, et al. AEFI surveillance findings from a tertiary referral centre in North India. Indian J Pediatr. 2012;79(1):95–9.
11. Pagar VS, Raut AV, Maliye CH, Gupta SS, Mehendale AM. Epidemiological study of adverse events following immunization at a tertiary care hospital. Int J Community Med Public Health. 2019;6(11):4748–54.
12. Paramkusham S, Pillai L, Murthy K, Sarangi SK. Adverse events following immunization in the pediatric age group. J Family Med Prim Care. 2017;6(3):604–9.
13. Arora NK, Das MK, Poluru R, et al. A prospective cohort study on the safety of infant pentavalent and oral polio vaccines in two South Indian districts. Pediatr Infect Dis J. 2020;39(5):389–96.
14. Ogundele OA, Ogundele T, Olabisi O. Adverse events following childhood immunization among children 0–24 months in Nigeria. Niger J Paediatr. 2016;43(3):181–6.
15. Adam VY, Onowugbeda ED, Osuji OI, Omohwovo OD. Prevalence and management of perceived adverse events following immunization in infants in Benin City, Nigeria. J Community Med Prim Health Care. 2020;32(2):57–67.
16. Gupta A, Maheshwari P, Rao YK. A prospective study to assess the adverse events following immunization in paediatric population. Int J Basic Clin Pharmacol. 2017;6(6):1407–13.
17. Lawan UM, Iliyasu Z, Abubakar IS. Prevalence and management of adverse events following childhood immunization in Kano, northern Nigeria. Ther Clin Risk Manag. 2012;8:467–74.
18. Datta A, Baidya S, Das S, Mog C, Datta S. Assessment of mother's knowledge and practices regarding adverse events following immunization in Tripura. Natl J Community Med. 2017;8(4):159–63.
19. Shamshad Ahmad, Singh A, Kapoor A. Pattern of adverse events following routine immunization in infants at a tertiary care centre. J Clin Diagn Res. 2018;12(7):SC01–04.
20. 23. Directorate of Health Services, Government of Chhattisgarh. Annual AEFI surveillance report, Chhattisgarh – 2024. Raipur: State Immunization Office; 2024.
21. 24. Bordo P, Wirsing von Koenig CH, Gilsdorf A, Bechini A, Bonanni P. Surveillance for adverse events following immunization in infants: a six-month prospective study. Vaccine. 2021;39(28):3748–56.
22. Izadi S, Mohammadi M, Sartipi M, Karami M, Karimi H. Acute adverse events following immunization with DTP-HB-Hib pentavalent vaccine in the first year of life. East Mediterr Health J. 2023;29(1):6–14.