



RESEARCH ARTICLE

Knowledge, attitude, and practices regarding reporting of Adverse Events Following Immunization (AEFI) among healthcare professionals

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ARTICLE INFO ABSTRACT



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Vaccine, Adverse Event Following Immunization, Healthcare workers, Knowledge, Attitude, Practice.

Background: Vaccines enhance immunity, yet Adverse Events Following Immunization (AEFI) challenge public trust and immunization coverage by impacting safety perceptions.

Materials and Methods: In Karnataka, India, this cross-sectional study employed self-administered questionnaires at sub-centers (SC) and primary health centers (PHC). Findings were tabulated and analyzed using chi-square ($p < 0.05$).

Results: From 247 subjects, the study achieved a 95% response rate. Notably, 65% exhibited proficient AEFI knowledge, and 88% possessed a favorable attitude toward reporting practices. Age, gender, prior training, and service duration were significant factors for knowledge distinctions. Attitude variations correlated with age, AEFI knowledge, and previous training. Identified barriers impact knowledge, attitude, and reporting.

Conclusion: The majority of healthcare workers at PHC and SC had good knowledge and positive attitudes with good reporting practices of AEFI. A few factors that hinder the diagnosis and reporting must be addressed by routine in-service training. The use of e-media should be brought into practice.

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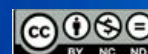
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Introduction

Pharmacovigilance Edward Jenner pioneered vaccines in 1796 for smallpox, biologically boosting immunity against infections and diseases (Pollard AJ et al., 2021). This is a perfect example of "Prevention is better than cure" Vaccines shield 75% of global children, averting 4-5 million deaths annually, according to estimates (Immunization, 2022). Vaccines, like all drugs, can lead to Adverse Events Following Immunization (AEFI), impacting safety assessment. AEFI is defined as any untoward medical occurrence followed by immunization and which does not necessarily have a causal relationship with the usage of the vaccine (Guidance on COVID-19 Vaccination at Work Places, 2022). Program errors, coincidences, reactions, or unknown causes can lead to AEFIs. They breed fear, and misinformation, and hamper vaccination efforts (Yaqub O et al., 2014). Various research papers state that mothers whose children developed AEFI are less likely to complete immunization schedules (Afolaranmi TO et al., 2020; Mishra NM et al., 2021; Datta A et al., 2017; Kumar D et al., 2010). Immunization gaps risk disease resurgence. Indian health workers, including Accredited Social Health Activists (ASHA), Anganwadi staff, primary health centers (PHC) nurses, and doctors, are vital for AEFI detection and intervention, requiring improved knowledge due to global shortcomings (Yamoah P et al., 2019; Mehmeti I et al., 2017; Mohammed LA et al., 2018; Laryea EB et al., 2022). This study evaluates AEFI reporting awareness post-routine immunization in India. Results guide administrative actions and strategy development due to limited literature.

Materials & Method

A cross-sectional study was conducted in 150 Sub Centers (SC) and Primary Health Centers (PHC) in Karnataka, India between January 2021, and January 2022. Focusing on essential health services, these centers, led by nurses, community health care workers (CHCW), and a Medical Officer, prioritize routine immunization. Ethical clearance was obtained from the institutional

ethical committee (IEC/56/2020-21 dated 27-01-2021). The study included CHCW, nurses, and doctors at these centers, excluding non-consenting and on-leave individuals.

Sample size determination

$$n = Z^2pq/d^2$$

Confidence interval at 95%. Taking a 10% non-response rate into consideration the minimum sample size was calculated to be 260.

Data collection

The data collection involved interviews using a pre-tested semi-structured standardized questionnaire with four sections: socio-demographics, AEFI knowledge, attitudes toward AEFI, and reporting practices. Experts, including co-authors and community medicine specialists, pre-tested and validated the questionnaire, resulting in simplifications for enhanced clarity and efficiency. The correct answers earned one point, and incorrect or "I don't know" responses scored zero. Correct responses were tallied and divided by the total possible correct responses, yielding a percentage. Knowledge scores exceeding 50% indicated good AEFI knowledge; lower scores indicated poor knowledge. Attitude and practice were labeled as satisfactory or unsatisfactory. Satisfactory practice earned one point, while unsatisfactory received zero. Practice was considered good if >50%, else poor. Data were tabulated and analyzed using IBM® SPSS version 20.0 (SPSS Inc, USA). Chi-square testing compared variables; significant ones underwent logistic regression to assess their relation with knowledge. A p-value <0.05 was deemed significant.

Results

Out of 260 distributed questionnaires, 247 were returned (95% response rate). Among the respondents (147 males, 100 females), the mean age was 40 ± 8 years. The majority were CHCWs (56%), followed by nurses (34%) and doctors (9%). Work experience ranged from 1 to 30 years (Mean 7.5 ± 4.8 years), detailed in Table 1.

Table 1. Socio-demographic characteristics of the respondents

Variables	N	%
Age (years)		
<20	3	(1.2)
20-29	50	(20.2)
30-39	68	(27.5)
40-49	105	(42.5)
50-59	21	(8.5)
Gender		
Male	147	(59.5)
Female	100	(40.5)
Poat of respondents		

*CHCW	139	(56.2)
Nurse	85	(34.4)
Doctor	23	(9.3)
Duration of practice		
<5years	56	(22.6)
≥5years	179	(72.4)
Not stated	12	(4.8)

*CHCW –Community Health Care Workers

The data shows the knowledge of study participants regarding definition, classification, causes, and various

features of AEFI, methods of reporting, and other aspects including treatment of AEFI have been shown in Table 2.

Table 2. Participants' knowledge of various aspects of AEFI

Variable (Knowledge category)	Correct response N (%)	Incorrect response N (%)
Definition of AEFI		
A medical incident that occurs after Immunization.	237 (95.9)	10 (4.0)
The event may not necessarily be caused by the vaccine.	213 (86.2)	34 (13.7)
It includes an unfavorable, or unintended sign, abnormal laboratory finding, symptom, or disease.	186 (75.3)	61 (24.6)
It does not occur after two weeks of vaccination.	150 (60.7)	97 (39.2)
AEFI Classification		
Vaccine reaction	226 (91.4)	21 (8.5)
Program error	240 (97.1)	07 (2.8)
Injection reaction	199 (80.5)	48 (19.4)
Coincidental reaction	185 (74.8)	62 (25.1)
Causes of AEFI may be		
Vaccine-product related	231 (93.5)	16 (6.4)
Vaccine-quality defect related	245 (99.1)	02 (0.8)
Immunization error-related	224 (90.6)	23 (9.3)
Immunization anxiety-related	240 (97.1)	07 (2.8)
AEFI features		
Fever	245 (99.1)	02 (0.8)
Mild swelling at the injection site	247 (96.9)	00 (0.0)
Redness at the injection site	240 (97.1)	07 (2.8)
Convulsions	159 (64.3)	88 (35.6)
Persistent crying	245 (99.1)	02 (0.8)
Acute flaccid paralysis	153 (61.9)	94 (38.0)
Encephalitis	86 (34.8)	161 (65.1)
Hypotonic-hyper-responsiveness Anaphylaxis	101 (40.8)	146 (59.1)
	194 (78.5)	53 (21.5)
To whom should AEFI be reported if detected? [N=247]		
Local Immunization Program Manager District Health Officer	206 (83.4)	
State immunization program managers	33 (13.3)	
	08 (3.2)	
Methods of AEFI reporting [N=247]		
Filling of AEFI form Reporting via Telephone/SMS	229 (92.7)	
Talking to colleague	10 (4.0)	
Email	06 (2.4)	
	02 (0.8)	
Can poor monitoring of AEFI cause a reduction in immunization coverage?	243 (98.3)	04 (1.6)
AEFI surveillance builds public trust in the immunization program	187 (75.7)	60 (24.2)

AEFI should be investigated in detail to determine causality	247 (100)	00 (00)
When should the AEFI investigation be commenced? [N=247]		
As soon as possible	240 (97.1)	
Within 24 hours	05 (2.0)	
After one week	02 (0.8)	
Treatment measures after immunization		
A patient should remain in the health facility and be observed for at least 15 minutes [N=247]	245 (99.1)	02 (0.8)
If fever develops, the patient should be given extra fluid to drink [N=247]	225 (91.0)	22 (8.9)
Always using paracetamol at the time of vaccination is not advisable [N=247]	241 (97.5)	06 (2.5)
In case a small, hard lump is noticed after the immunization, it should be cut immediately [N=247]	247 (100)	00 (00)

Most of the study participants (93%) had a positive attitude towards AEFI and were ready to further enhance

their perspective towards AEFI by attending seminars or workshops. Detailed analysis is shown in Table 3.

Table 3. Attitude of study participants for reporting AEFI

Variable	Yes/Correct response N (%)	No/Incorrect response N (%)
If you were invited to attend training on AEFI, would you attend?	230 (93.1)	17 (6.8)
Would you advise your worker colleague to attend training on AEFI if he/she was invited?	230 (93.1)	17 (6.8)
Why would you not attend training on AEFI if invited? [N=17]		
I feel it is not necessary	5 (29.4)	
AEFI management is not my responsibility	4 (23.5)	
I think it is a difficult topic for me	4 (23.5)	
I do not think it will benefit me	4 (23.5)	
Is it necessary to report an AEFI?	35 (95.1)	12 (4.8)
Why is it not necessary to report an AEFI? [N=12]		
Time-consuming	5 (41.6)	
May cause unnecessary fear/alarm	3 (25.0)	
I may be blamed by my supervisors	2 (16.6)	
Nothing can be done even if I report it	2 (16.6)	
Would you advise your co-worker to report a case of AEFI?	235 (95.1)	12 (4.8)

Regarding reporting practices, 73% reported encountering AEFI at least once, while a quarter cited

reasons for non-reporting. Another aspect of reporting practices is shown in Table 4.

Table 4. Reporting practices of study participants

Variable	Yes/Correct response N (%)	No/Incorrect response N (%)
Have you ever received any training on adverse events following immunization (AEFI)?	230 (93.1)	17 (6.8)

If you had received training on AEFI, what type of training was it? [N=230]		
On-the-job training Seminar/Workshop	179 (77.8)	
Class lecture	37 (16.0)	
	14 (6.08)	
Have you encountered an AEFI in your practice? [N=247]	231 (93.5)	16 (6.4)
Do you routinely report an AEFI you encountered? [N=247]	183 (74.0)	64 (25.9)
Why don't you report AEFI routinely? [N=64]		
I am too busy and have no time	18 (28.1)	
The reporting form was not available	16 (25.0)	
I am afraid that I will be blamed	15 (23.4)	
Reason not stated	12 (18.7)	
I feel it is not related to immunization	03 (4.6)	
If you do report AEFI routinely, when did you report the AEFI you observed? [N=183]		
Immediately	157 (85.7)	
Within 24 hours	17 (9.2)	
After 24 hours	09 (4.9)	
What method did you use to report the observed AEFI? [N=183]		
Filling AEFI form	147 (80.3)	
Via telephone/SMS	34 (23.1)	
Via e-mail	02 (1.0)	
Have you ever seen an AEFI reporting and investigation form	232 (93.9)	15 (6.0)
Do you have AEFI reference guidelines materials at your workstation?	227 (91.9)	20 (8.0)
Do you routinely recommend the use of Paracetamol to prevent post-immunization fever?	173 (70.0)	74 (29.9)
Do you routinely counsel parents on AEFI when immunizing their children?	203 (82.1)	44 (17.8)

In determining proficient knowledge about AEFI, factors including previous training, duration of service, age, and gender exhibited significance (p-value < 0.05) (table 5). For attitudes, gender, cadre, and duration had no

significant impact, while AEFI knowledge and prior training were highly significant (p-value < 0.00001), (table 5).

Table 5. Factors affecting AEFI knowledge and attitude of immunization providers

Variable (Factors affecting knowledge)	Poor Knowledge	Good knowledge	Test statistics/ p-value
Previous training experience			
Yes	77	153	X ² = 4.45, p = 0.034
No	10	07	
Duration of service			
<5years	36	20	X ² = 21.01, p = <0.00001
≥5years	54	125	
Age group (years)			

<20	02	01	X2 = 9.63, p = 0.0470	
20-29	18	32		
30-39	28	40		
40-49	45	60		
50-59	02	19		
Gender				
Male	32	115	X2 = 27.24, p = <0.00001	
Female	54	46		
Variable (Factors affecting attitude)	Appropriate (%)	N Inappropriate (%)	N Test statistics/ p-value	
Age group (in years)				
<20	01	02	X2 = 9.65, p = 0.0467	
20-29	43	07		
30-39	60	08		
40-49	93	12		
50-59	20	01		
Gender				
Male	130	17	X2 = 0.114, p = 0.734	
Female	87	13		
Cadre of staff				
CHCW	121	18	X2 = 0.352, p = 0.838	
Nurses	75	10		
Doctors	21	02		
Knowledge on AEFI				
Poor knowledge	67	27	X2 = 39.08, p = <0.00001	
Good knowledge	150	03		
Previous training on AEFI				
Yes	216	14	X2 = 114.96, p = <0.00001	
No	01	16		
Duration of practice				
<5years	49	07	X2 = 5.448, p = 0.0656	
≥5years	160	19		
Not stated	08	04		

Discussion

AEFI sensitivity fuels public fear, eroding immunization trust and coverage, and impacting public health profoundly (Yaqub O et al., 2014). In our study most participants (56%) were grassroots-level CHCWs, aiding accurate insights and generalizable outcomes to larger populations. Research work with a similar approach and findings were seen in the study by Yamoah et al where nurses made up 67.8% of the total respondents (Yamoah P et al., 2019). In our study, it was found that 161 respondents i.e., 65% (115 male and 46 female) had good knowledge about AEFI which was kindred to the study done in 2016 by Ogunyemi et al and Sani et al in 2019 (Ogunyemi RA et al., 2016; Sani UM et al., 2019). Age, experience and prior AEFI training enhance knowledge. On-field exposure improves understanding; healthcare workers interacting with more patients observe and learn from AEFI. A study done recently by Suresh et al showed similar results where age and years of experience differences were statistically significant among the two

groups (Suresh A et al., 2022). Gender impacted AEFI knowledge in our study, unlike Suresh et al. Unequal male and female distribution in our study possibly caused biased outcomes; Suresh et al. had nearly equal distribution. Even in a study done by Mohammed LA, the biased result (like ours) can be explained by the unequal gender distribution among the subjects (Mohammed LA et al., 2018). Our study revealed that 217 subjects (88%), including 130 males and 87 females, possessed a suitable AEFI reporting attitude. Participant age, AEFI knowledge, and prior training significantly influenced attitude, corroborating Masika et al findings (Suresh A et al., 2022). Of the 12% with a negative reporting attitude, reasons included unavailable AEFI forms, busy schedules, lack of causation knowledge, time constraints, and indifference. Muchekeza et al and Lafond et al found similar barriers (Muchekeza M et al., 2014; Lafond K et al., 2014). A way to rectify some of the problems was suggested by Kimpton et al who suggested that the use of electronic reporting increased the compliance of

healthcare workers for reporting AEFIs (Lafond K et al., 2014). Web-based programs should be promoted, and their utilization as smartphone apps could streamline reporting for healthcare workers. A unique hindrance identified was fear of superiors or blame, echoed by Zvanaka et al (Zvanaka S et al., 2017). Comprehensive analysis reveals that well-trained healthcare workers possess strong AEFI knowledge, fostering positive attitudes in identification and reporting. Seminars, workshops, and electronic media aid knowledge enhancement, improving reporting practices in the smartphone era.

Conclusion

The study concludes that most healthcare workers in Primary Health Centers (PHC) and Sub-Centers (SC) possess good knowledge, positive attitudes, and commendable reporting practices concerning Adverse Events Following Immunization (AEFI). However, a few obstacles to diagnosis and reporting must be addressed. Improved vaccine chain management has reduced AEFI occurrences, leaving newcomers ill-equipped to handle and report such cases. To remedy this, regular in-service seminars, workshops, and symposia should be conducted for healthcare staff. The study reveals that poor AEFI reporting is linked to insufficient knowledge. It emphasizes barriers to adopting a positive attitude and effective reporting, endangering the national AEFI surveillance system. The underutilization of electronic media hampers AEFI surveillance and its potential for improvement. This research contributes by highlighting the pivotal role of knowledge in AEFI reporting and the significance of electronic media in overcoming surveillance challenges.

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Conflicts of interest

There are no conflicts of interest.

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