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Research Article

Awareness of Immunisation Health Care Providers on Adverse Events Following Immunisation: A Multicentre Study

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A B S T R A C T

Introduction: Adverse events following immunisation (AEFI) are often under-reported in India due to limited awareness among immunisation health care providers negatively affecting the immunisation programme of the country. This study assesses the knowledge, attitude and reporting practices (KAP) of AEFI among immunisation healthcare providers (IHPs) of private hospitals and clinics in South India.

Methods: Using a semi-structured questionnaire, 58 IHPs were interviewed. The mean age was found to be 14.5 ± 7.2 years. Few IHPs had good knowledge (34.5%) while 91.4% had a good attitude, but it didn't influence their good reporting practices (25.9%). The overall KAP score was the highest for physicians (50%), followed by pharmacists (43.8%) and nurses (37.8%).

Results: Barriers to effective reporting were lack of knowledge about AEFI surveillance, filling an AEFI reporting form, time constraints and unfamiliarity with electronic reporting.

Conclusion: KAP of immunisation health care providers isn't satisfactory. In recent years, the rate of serious AEFIs has decreased to a greater extent. This also decreased the IHPs' awareness of AEFI reporting as they don't need to frequently report. Improving the perception of AEFI and active participation in reporting by IHPs can strengthen the nation's AEFI surveillance system.

Keywords: Awareness, Vaccine, Immunisation Healthcare Providers, Adverse Event following Immunisation, AEFI

Introduction

According to WHO/ CIOMS guidelines, "Adverse Event Following Immunisation (AEFI) refers to any unfavourable medical occurrence that occurs after immunisation that does not causally associate with vaccine use." Further, the AEFIs are classified into five categories viz. vaccine product-related reactions, vaccine quality defect-related reactions, immunisation error-related reactions, immunisation anxiety-related reactions, and coincidental events.[1] The revised PVPI guidelines (2015) classify AEFIs as common,

minor, severe, and serious AEFIs.[2,3] AEFI surveillance is also known as vaccine safety surveillance. A national AEFI surveillance system is developed and maintained by the National Regulatory Authority (NRA) and the National Immunisation Programme (NIP).[4] The AEFI surveillance system is frequently linked to an AEFI review committee as well as academic institutions and technical agencies. Pharmaceutical companies manufacturing vaccines and national control laboratories may be included in the national AEFI surveillance system in countries that manufacture their own vaccines. In 1988, India launched the Adverse Events Following Immunisation (AEFI) surveillance programme to track suspected adverse events after immunisation. The AEFI surveillance guidelines have been updated on a regular basis with the current update of 2015.[5] It is intended to identify AEFI reports and track AEFI that have a temporal response to vaccine administration.[6] The country's AEFI surveillance programme exists to provide quality immunisation services using safe vaccines while guaranteeing vaccine confidence. Being the largest consumer, manufacturer and exporter of vaccines; India is expected to have a well-developed AEFI surveillance system.

With the largest birth cohort of approximately 27 million infants in the country, the immunisation programme administers around 460 million doses annually, yet reported serious AEFIs are about 500 annually.[7,8] Although there is an increase in AEFI reporting, under-reporting still remains a limitation and the number of serious AEFIs reported is still far less than the expected numbers due to ignoring the fact that the event did not occur after immunisation (according to the definition, all events following immunisation should be reported), guilt about causing harm and being held responsible for the event, time constraints, inadequate reporting processes, and poor data management. The other factors involved are infrequent AEFI reporting and confusion about how to report an AEFI, insecurity regarding causation, (it is not possible to ascertain whether the drug caused the reaction), poor education and training of immunisation providers, and weak human resources [9] There is limited literature stating the reporting rates of AEFI, especially from India.[10,11] So, our study aims to evaluate immunisation health care providers' (IHPs) knowledge, attitude, and reporting practices regarding adverse events following immunisation (AEFI) of private hospitals and clinics in South India.

Materials and Method

Study Design and Subject Recruitment

A cross-sectional, descriptive, prospective questionnaire-based survey was conducted among immunisation health care providers of 16 private hospitals and clinics of South India between December 2020 and May 2021. The study was approved by the Institutional Review Board of JSS College of Pharmacy, Ooty, Tamil Nadu, India (JSSCP/IRB/11/2020-21). We included immunisation health care providers, namely doctors, pharmacists, and nurses. Those who did not consent to participate in the study and who did not complete the questionnaire form were excluded. The sample size was calculated using online sample size calculator creative research system survey software. The confidence level and confidence interval were considered 95% and 12.87 respectively. The sample size, hence obtained, was 58.

Data Collection

A semi-structured questionnaire was prepared by reviewing available literature. The questionnaire was face validated and content validated by a team of 2 doctors, 2 pharmacists, and 1 nurse and was pilot tested in the local hospitals. As per the feedback obtained, some questions were modified. The reliability of the questionnaire was assessed using Cronbach's α (α = 0.81). The final questionnaire (printed and Google Forms) included 47 questions of which 5 demographics, 18 knowledge, 10 attitude, and 14 were reporting practices based questions. Most of the questions were closed-ended with yes/ no options, objective type questions, and wherever additional information was required, open-ended questions were used. Responses to attitude questions were given on a 5-point Likert scale with the following options: Strongly disagree (1 point), Disagree (2 points), Neither agree nor disagree (3 points), Agree (4 points), and Strongly agree (5 points). Each correct response received one point, while each incorrect response received zero points. Some answers were given two points based on whether or not they made an argument about the previous "yes" or "no" answer. The overall score for all respondents was calculated, and the maximum possible score was 40 points. For each participant, the total score for knowledge, attitude, and reporting practices was calculated separately. The levels of knowledge,attitude and reporting practices scores were then graded based on the following.[5]

$$\% \text{ knowledge} = \frac{\text{calculated knowledge score}}{\text{expected knowledge score}} \times 100$$

The same formula was used for attitude and practice scoring. The scores were graded as < 50% - poor, 50–70% - fair and ≥ 70% - good.

The IHPs filled the questionnaire and returned it to the investigators of the study.

Statistical Analysis

Data were coded, entered into an excel software (Microsoft Office Excel 2010) database and analysed using Statistical Package for Social Sciences, IBM® SPSS version 25 (SPSS Inc., USA). Qualitative data were expressed in terms of frequency and percentage, while quantitative data in terms of mean ± standard deviation. The Kruskal-Wallis H test was used

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to determine differences in overall KAPbetween different immunisation health care providers. A Chi-square test was done to find the association between the overall KAP of AEFIs and respondents' sociodemographic characteristics. Statistical significance was assessed at $p \leq 0.05$.

Results

Demographic Characteristics of Participants

The age distribution of the respondents showed that 32.8% (n = 19) of the immunisation health care providers (IHPs) belonged to the age groups of 21-31 and 32-42 years each. The mean age of respondents was found to be 14.5 ± 7.2 years. Male respondents were 46.5%, and female respondents were 53.4%. Regarding the profession, pharmacists were comparatively higher in number at 36.8% (n = 22) compared with other IHPs. Referring to the years of experience, 28.3% (n = 18) of the participants had 5-10 years of experience. The mean years of experience of IHPs was 14.5 ± 2.9 years. The demographic characteristics of IHPs are summarised in Table 1.

Table 1.Demographic Characteristics of Immunisation Healthcare Providers

Variables	No. of Respondents (n = 58)	Percentage of Respondents
Age (years)		
21-31	19	32.8
32-42	19	32.8
43-53	18	31.0
≥ 54	02	3.4
Gender		
Male	27	46. 5
Female	31	53.4
Profession		
Doctors	18	31.6
Nurses	18	31.6
Pharmacists	22	36.8
Experience (years)		
< 5	14	23.3
5-10	18	28.3
10-15	16	26.7
> 15	10	21.7

Respondents' Knowledge on AEFI

All the IHPs were able to expand the abbreviation AEFI. However, only 38 (65.5%) participants were able to define AEFI correctly. However, 34.4% of participants defined it as an untoward medical occurrence that follows immunisation. Despite the fact that the majority of participants had heard of the WHO (47,81%) and PvPI (45,77.5%) classifications of AEFI, only a few correctly identified the different classes of AEFI. When asked to identify the classes of AEFI, only a few responded correctly. Around 21 (36.2%) participants correctly identified the WHO AEFI classes among the given answers, while 22 (37.9%) chose only one right answer out of two. The PvPI classification of AEFI (Common Minor, Severe, Serious) was correctly recognised by 21 (36.2%) subjects. About 31 (53.4%) participants responded that the revised AEFI guidelines by PvPI were implemented in 2015. The common causes of AEFI were known to 42 (72.4%) participants. About 37 (63.7%) respondents mentioned that while administering the intramuscular injections, the skin at the injection site should be stretched. The AEFI surveillance of India started in 1988 was mentioned correctly by 18 (31%) participants. The District Health Management Team is in charge of supervising facilities on AEFI, according to the majority of participants (49, 84.4%). Approximately 44 (75.8%) of those polled were aware that subcutaneous adrenaline administration is contraindicated during anaphylaxis. In addition, 43 (74.1%) participants correctly stated about leg elevation above the trunk and oxygen supplementation during anaphylaxis. For a descriptive question regarding the signs and symptoms of vaccine-related AEFIs, 33 (56.8%) participants rightly mentioned fever, seizure, allergic reactions, fainting, etc. as the answer. Of the given choices, severe AEFIs were identified by 35 (60.3%) participants. Alternatively, 43 (74.1) respondents identified examples of serious AEFIs. Only around half (32, 55.1%) of the participants were aware of the AEFIkit. The summary of the IHPs' knowledge of AEFI is depicted in Table 2.

Respondents' Attitude on AEFI

Majority of the participants (55, 94.8%) thought that reporting an AEFI is important, although 11 (18.9%) did not feel that reporting AEFI is their professional responsibility. About 46 (79.3%) agreed that reporting an AEFI is necessary. 51 (87.9%) believed that reporting an AEFI can reduce vaccine-preventable events. About half of the IHPs thought that reporting an AEFI is a long and hecticprocess, whereas the other half did not agree with it. Some of the IHPs (18, 31%) felt that there is a lack of proper awareness of AEFI reporting in their hospitals. Around 39 (67.2%) IHPs felt guilty about reporting an AEFI fearing the negative comments from superiors. Yet, most of the respondents (54, 93.1) were willing to attend a training on AEFI, if they were invited. Also, 53 (91.3%) responded that they would recommend their colleague to attend training on AEFI. The summary of the study participants' attitude regarding AEFI is shown in Table 3.

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Table 2.IHPs' Response on Knowledge of AEFI

Question (n = 58)	Correct Response n(%)	Incorrect Response n (%)
What does AEFI stand for?	58 (100)	0 (0)
How do you define AEFI?	38 (65.5)	20 (34.4)
Do you know about WHO classification of AEFI?	47 (81)	11 (18.9)
WHO classification of AEFI	21 (36.2) partially correct: 22(37.9)	9 (15.5)
Do you know about the PvPI classification ofAEFI?	45 (77.5)	13 (22.4)
PVPI classification of AEFI	21 (36.2)	26 (44.8)
When were the revised AEFI guidelines by PvPI implemented?	31 (53.4)	24 (41.3)
What are the causes of AEFI?	42 (72.4)	16 (27.5)
When administering the IM injection, should the skin at the injection site be stretched?	37 (63.7)	20 (34.4)
When was the AEFI surveillance started inIndia?	18 (31.0)	36 (62.0)
11.Is the District Health Management Team (DHTM) responsible for supervising facilities on AEFI?	49 (84.4)	7 (12.0)
12.Can adrenaline not be administered subcutaneously during anaphylaxis?	44 (75.8)	14 (24.1)
13.During anaphylaxis, should the patient'slegs be raised above trunk and given oxygen?	43 (74.1)	13 (22.4)
14.Can you mention the signs and symptoms of any vaccine-related AEFIs?	33 (56.8)	25 (43.1)
15.Which of the following AEFIs would beclassified as severe reaction?	35 (60.3)	22 (37.9)
16.Which of the following is/ are classified asa serious reaction?	43 (74.1)	14 (24.1)
17.Immunisation surveillance aims at earlydetection, reporting and management of AEFI?	53 (91.3)	3 (5.1)
18.Is there an AEFI kit that you are aware of?	32 (55.1)	24 (41.3)

Table 3.IHPs' Response on Attitude regarding AEFI

Question (n = 58)	Correct Response n (%)	Incorrect Response n (%)
1.Do you think AEFI reporting is important?	55 (94.8)	3 (5.17)
2.Do you feel AEFI reporting is not your responsibility?	47 (81)	11 (18.9)
3.Do you think AEFI reporting will not benefit you in anyway?	38 (65.5)	20 (40)
4.Do you feel AEFI reporting is not necessary?	46 (79.3)	12 (20.6)
5.Do you think reporting an AEFI can reduce vaccinepreventable events?	51 (87.9)	7 (12.0)
6.Do you think reporting an AEFI is a long and hecticprocess?	29 (50)	29 (50)
7.Do you think there is lack of proper awareness in thehospital?	18 (31)	40 (68.9)
8.Would you feel guilty if you report an AEFI?	39 (67.2)	19 (32.7)
9.If you are invited to attend training on AEFI will you attend?	54 (93.1)	4 (6.8)
10.Will you advise your colleague to attend trainingon AEFI?	53 (91.3)	5 (8.6)

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Respondents' Reporting Practices on AEFIs

Of the 58 who responded to the questions, 49 (84.4%) followed the AEFI reporting procedure followed in their hospitals. Only 41 (70.6%) reported AEFI in their workplace. Half of the IHPs (29, 50%) responded that they report AEFI through telephone, e-mail (aefiindia@gmail.com, www.idsurv.org) and by using a reporting form. The majority of the participants (47, 81%) had never missed reporting an AEFI. Around half of the participants (32, 55.1%) did not have an AEFI reporting form in their workplace. However, 49 (84.4%) participants informed the immunised person/ caretaker regarding the possible AEFIs. Interestingly, 38 (65.5%) reported that AEFIs should be initially given to the District Immunization Officer. About 33 (56.8%) were aware that even minor AEFIs should be reported. However, only 16 (27.5%) knew how it should be reported and also that a monthly AEFI Nil report had to be submitted. Regarding the submission deadline of Preliminary Case Investigation Format (PCIF) and Final Case Investigation Format (FCIF) to be submitted to the State and National AEFI committee, the correct response (within 10 days and 70 days respectively) were mentioned by only 26 (44.8%) and 21 (36.2%) IHPs. Using a verbal autopsy form in case of unexplained deaths, inadequate information and insufficient medical records were mentioned by 34 (58.6%) participants. The summary of the study participants' reporting practices of AEFI is represented in Table 4.

Table 4.IHPs' Response on Reporting Practices of AEFI

Question (n = 58)	Correct Response n(%)	Incorrect Response n (%)
Is there an AEFI reporting procedure followed in your hospital?	49 (84.4)	9 (15.5)
Are you reporting AEFI in your workplace?	41 (70.6)	17 (29.3)
If yes, how do you report an AEFI?	29 (50)	21 (36.2)
Have you ever missed reporting an AEFI?	47 (81.0)	11 (18.9)
Do you have an AEFI reporting form in your workplace?	32 (55.1)	26 (44.8)
Do you inform the immunised person/ caretaker regarding the possible AEFI?	49 (84.4)	9 (15.5)
Whom should you report AEFI to initially?	38 (65.5)	20 (34.4)
Should a minor AEFI be reported?	33 (56.8)	25 (43.1)
If yes, how should it be reported?	16 (27.5)	42 (72.4)
When should the Preliminary Case Investigation Form be submitted to the State and National AEFI committee?	26 (44.8)	31 (53.4)
When should the Final Case Investigation Form be submitted to the State and National AEFI committee?	21 (36.2)	35 (60.3)
When should a verbal autopsy form be used?	34 (58.6)	24 (41.3)

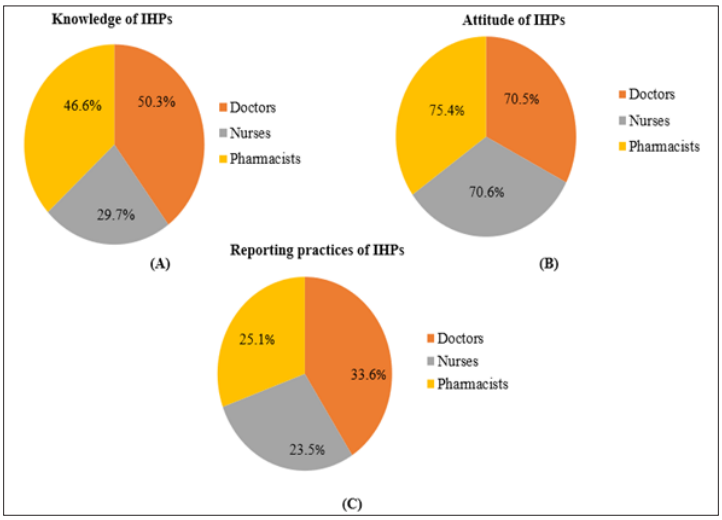

Figure 1.KAP of Immunization Health Care Providers on AEFI

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Table 5.Comparison of Knowledge, Attitude and Reporting Practices between Different IHPs

Variable	H statistic	P value
Knowledge of IHPs	6.59806	*0.03692
Attitude of IHPs	7.06903	*0.02917
Reporting practices	4.80258	*0.09060

*p value < 0.05 is considered statistically significant.

The knowledge, attitude and reporting practices (KAP) scores of the IHPs were calculated and are portrayed in Figure 1.

Analysis of the data in MS Excel showed a skewed distribution. Hence non-parametric tests were used to analyse thesignificance of the results. The Kruskal-Wallis H test was used to determine differences in overall KAP between different immunisation healthcare providers. The results obtained are as follows (Table 5).

Table 6.Association between Demographics and Overall KAP of Immunisation Healthcare Providers

Classification	Variables	Overall KAP of AEFI			df	X^2	P value
		Poor n (%)	Fair n (%)	Good n (%)			
Age (years)	21-31	11 (57.8)	4 (21)	4 (21)	9	16.017	*< 0.0001
	32-42	10 (52.6)	7 (36.8)	2 (10.5)			
	43-53	12 (66.6)	4 (22.2)	2 (11)			
	≥ 54	2 (100)	-	-			
Gender	Male	12 (44.4)	10 (37)	5 (18.5)	12	14.982	0.242
	Female	23 (74)	4 (12.9)	4 (12.9)			
Profession	Doctors	5 (27.7)	6 (33.3)	7 (38.8)	9	20.645	*0.006
	Nurses	12 (66.6)	2 (11.1)	4 (22.2)			
	Pharmacists	14 (63.6)	8 (36.6)	-			
Years of experience	< 5	8 (57.1)	2 (14.2)	4 (28.5)	9	11.329	*0.002
	5-10	10 (55.5)	5 (27.7)	3 (16.6)			
	10-15	9 (56.2)	5 (31.2)	2 (12.5)			
	> 15	8 (80)	2 (20)	-			

*p value < 0.05 is considered statistically significant.

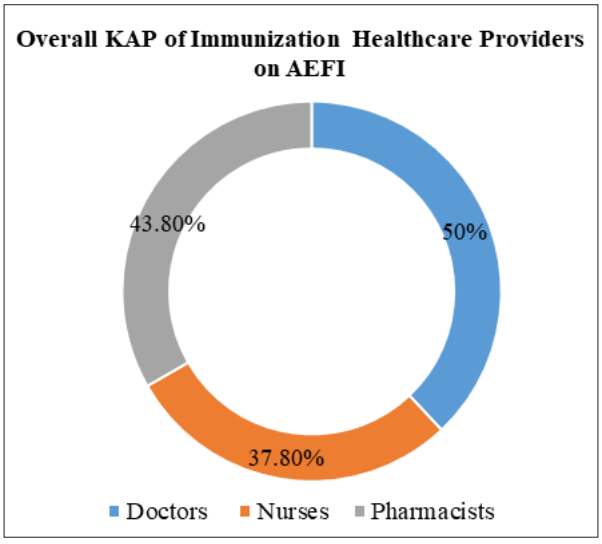

Figure 2.Overall KAP of Immunisation Healthcare Providers on AEFI

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There is a statistically significant difference in the knowledge and attitude of doctors, nurses, and pharmacists. The association between the overall KAP of AEFIs and respondents' demographic characteristics was found statistically significant for age, profession and years of experience. The results of the chi-square tests of the association are summarised in Table 6.

The overall knowledge, attitude and reporting practices (KAP) of immunisation health care providers are depicted in Figure 2.

Discussion

Detection and reporting of AEFIs are essential, especially in the current COVID pandemic situation. However, in hospitals and clinics in private settings, it's being ignored due to unawareness and fear of reporting. This will affect public confidence in vaccination and reduce immunisation coverage.[12,13] In our study, a significant difference was noticed in the knowledge, attitude, and reporting practices of the three groups of IHPs. Also, there was an association between age, profession, and years of experience of IHPs with their overall KAP. We observed that the overall KAP score was the highest for physicians, followed by pharmacists, and nurses. Despite being the frontline warriors in immunisation, nurses' KAP wasn't at par with the expectations, especially in private clinics.[14] The authors also observed that even though a good number of IHPs demonstrated a positive attitude towards reporting AEFI, they didn't have adequate knowledge and skills to practice effective AEFI reporting. [15]The reasons quoted were AEFI occurs infrequently, AEFI is not recognised/ if recognised, it's not reported due to inexperience with the reporting process.[16]

In our study, we found out that there is infrequent AEFI reporting by immunisation health care providers, which is similar to the results obtained in a study conducted by Parella A et al.[11] We observed, in our study, that few of the respondents had good knowledge levels (34%) and almost half the proportion had poor knowledge levels (51.8%). A study by Mehmeti I et al. also delivered similar results, where very few respondents had good knowledge scores (2%) but the poor knowledge level proportion (86.3%) was higher and the study also stated that there was a statistically significant difference in total scoring points between categories of health professionals as determined by one-way ANOVA (F (4,97) = 7,565, p 0.0001) similar to our study.[5,17,18] Another study conducted by Masika CW et al. stated that the reporting practice level towards AEFI surveillance increased with years of experience (x^2 31.47; $p < 0.0001$), but our findings have shown that those with less years of experience have better KAP (x^2 11.329; $p = 0.002$).[9] In a study conducted by Mohammed LA et al., there was a statistically significant association of KAP with age ($p = 0.009$), work experience ($p = 0.001$) and previous training ($p = 0.001$), while gender had no association with knowledge.[25] Similar results were obtained in our study i.e., overall KAP had an association with age ($p = 0.0001$), profession ($p = 0.006$) and years of experience ($p = 0.002$), but no association with gender ($p = 0.242$). There were different barriers to reporting AEFI among IHPs that we came across in our study. Some of the barriers were lack of knowledge about AEFI surveillance system and practices, lack of training related to immunisation or AEFI, lack of knowledge regarding filling an AEFI reporting form, lack of time and unfamiliarity with electronic or internet-based system of reporting. In order to overcome these barriers, appropriate recommendations must be followed. Doctors should be educated about the AEFI surveillance system and they should encourage the nurses, pharmacists and other healthcare providers to actively participate in the documentation.[19,20] There is a need to develop training programmes and educate the immunisation providers regarding the reporting form. Doctors, nurses, pharmacists and other healthcare professionals should be provided with information regarding how to use the electronic-based system of reporting and it should be ensured that they find time to fill these forms.[21-24]

Strengths and Limitations of the Study

This study is the first of its kind to be conducted in south India on KAP of AEFI among immunisation health care providers. While conducting the interviews of IHPs, many of them expressed interest in knowing more about AEFI reporting from the interviewer. Though we were able to assess theKAP of IHPs, our study was limited by low sample size, inability to reach out to IHPs in all states of South India due to the COVID-19 pandemic (busy schedules of IHPs), low willingness to participate in the study fearing a negative impact on reputation and poor reliability of data obtained through electronic means of communication.

Conclusion

Even though the IHPs responded to some extent in our study, it was insufficient to support an effective AEFI surveillance. Doctors had a better KAP in general, yet nurses, who are the frontline IHPs involved in vaccination, are not very aware of AEFI reporting. In recent years, the rate of serious AEFIs has decreased to a greater extent. This also decreases the awareness of IHPs towards AEFI reporting as they do not need to frequently report. Routine in-service training can improve the perception regarding AEFI and active participation in reporting, thereby strengthening the AEFI surveillance system in the country.

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Conflict of Interest: None

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