

RESEARCH PAPER



Barriers to healthcare workers reporting adverse events following immunization in Zhejiang province, China

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ABSTRACT

Objectives: A cross-sectional survey was conducted among healthcare workers (HCWs) to assess their knowledge, attitude, and reporting behavior in adverse event following immunization (AEFI) surveillance as well as to identify barriers.

Methods: A simple random sample of 170 vaccination clinics was selected and one HCW was informed to participate in this survey in each selected vaccination clinic. The survey was developed using a secure online platform and consisted of a structured online questionnaire. The distributions of the respondents' characteristics were presented. Training status, knowledge, attitude, and reporting behavior were compared between sub-groups of HCWs. Barriers and suggestions on AEFI reporting were also summarized.

Results: Of the 170 surveyed HCWs, 61.76% received the training on AEFI surveillance while 15.88% had no AEFI training at all. The higher level of knowledge and the more positive attitude and reporting behavior on AEFI surveillance were observed among HCWs with the longer working duration on AEFI surveillance, or among HCWs who received the training. The most critical barrier to reporting an AEFI was 'not being sure if the AEFI is related to the vaccine' (122, 71.76%). Other barriers were: 'I do not want to raise unnecessary public alarm about a vaccine' (105, 61.76%); 'reporting form or other method being too complicated' (65, 38.23%).

Conclusion: The study findings highlighted the need to prioritize training on AEFI surveillance for HCWs. It is recommended that the development of the targeted interventions to strengthen AEFI surveillance system be required based on the barriers found in this study.

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Introduction

Immunization is considered as one of the most economic and effective public health interventions, and prevents more than 2.5 million deaths among children in every year.¹ Immunization program depends on the foundation of a strong and efficient healthservice system that can deliver and scale-up the vaccination service. However, due to the successes of immunization, the incidence of vaccine preventable diseases (VPDs) declines significantly and public attention shifts from VPDs to the safety of vaccines and adverse events associated with vaccines.² Widespread concern about the occurrence of adverse events following immunization (AEFI) may lead to a loss of confidence in the safety of vaccines, low vaccination coverage, and even a resurgence of VPDs.^{3,4} The safety of vaccines is evaluated extensively through pre-licensure animal studies and human clinical trials, and through post-licensure surveillance.^{5,6} Safety monitoring in post-licensure surveillance has relied primarily on the passive reporting systems.

Zhejiang province is located at the east coast line of China and is one of the most populous, rapidly developing areas, with an annual birth cohort of 70 million. Zhejiang province launched the EPI since 1978 with four vaccines and it has continued to increase the number of vaccines up to 14 types of vaccines targeting 15 VPDs since 2008, providing four government-funded vaccines for all children under 7 years of

age. Over 20 million vaccination doses are administered annually. This large demand of vaccines is fulfilled by more than 50 licensed vaccine presentations, of which 80% are made domestically. As such, adequate pharmacovigilance for used vaccines is necessary and it requires a credible system to monitor adverse reactions, detect, and respond to emerging vaccine safety signals, and address concerns of the public and the social media.

China ministry of health (MOH) has established a nationwide AEFI surveillance since 2005, with the technical support of world health organization (WHO) and the experience from other countries. The national AEFI surveillance system (NAEFISS), which is a passively collected spontaneous electronic database, has been in operation since 2005.⁷ Although the reporting sensitivity has improved from 9.2/100,000 doses for the time period of 2008–2011 to 56.64/100,000 doses in 2019 in Zhejiang province,⁸ the reporting rate of AEFI detected through the passive surveillance system is likely to be lower than the true rate, due to the bias of under-reporting. A previous study indicated that the role of healthcare workers (HCWs), who interacted with persons experiencing adverse events, was indisputable in initiating the reporting and investigation process. It was also hypothesized that the under-reporting was due to the low participation of HCWs in surveillance work and the absence of a blame-free culture.⁹

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A better understanding of the determinant of the under-reporting, including the barriers to the reporting process, may be the background against which strategies to improve AEFI surveillance should be developed. As we known, no study had discussed these issues in Zhejiang province up to date. Therefore, this study aimed to evaluate the proportion of HCWs reporting AEFI and to broadly explore the reasons for under-reporting through a random sampling survey at the health facility level in Zhejiang province. Findings from this assessment provided the insight into reasons for under-reporting of AEFI and for developing the mechanisms to improve the AEFI surveillance sensitivity from the perspectives of HCWs.

Methods

Study design and participants

An online cross-sectional survey was implemented in December, 2021 in all of 11 cities in Zhejiang province, targeting HCWs who practice in the vaccination clinics. The inclusion criterion consisted of being a physician practicing in the vaccination clinic of the community health service center, township health facility, hospital in Zhejiang province for at least one year. Other practitioners from these institutions were excluded.

Sample size

The simple random sampling method was applied in our study and the formula for the calculation of the sample size is used as follows:

$$N_{\min} = \text{deff} \times \frac{z_{(1-\alpha/2)}^2 \times p \times (1-p)}{d^2}.$$

The primary parameter was the percentage of HCWs who reported at least one AEFI in the past year. In 2020, 12,113 AEFI cases were reported and the total number of HCWs for vaccination was over 17,000 in the same period. Thus, we assumed a conservative estimate of 70% as the percentage of HCWs who reported at least one AEFI in the sample size estimation. The other parameters for the formula set are as follows: a two-tailed α error of 5% and a permissible error (d) of 0.1. To account for the expected high correlation between HCWs in the adjacent area and non-response, we assumed a design effect (deff) of 2 and inflating ratio of 5% for non-response. Finally, the sample size was 170 HCWs, randomly selecting from 170 vaccination clinics, which represented the situation in 12.73% of the vaccination clinics in Zhejiang province.

Survey tool

The survey was developed using a secure platform (Questionnaire Star) and consisted of a structured online questionnaire including 19 items. The format consisted of mainly the closed-ended questions with multiple choice answer options. The questionnaire was developed with expertise from centers for disease control and prevention (CDC) at provincial and city levels, and was pilot tested in five HCWs for appropriateness and wording before use. The questionnaire was submitted anonymously.

There were several domains addressed in the questionnaire: first, the training on the AEFI surveillance; second, the knowledge on AEFI and surveillance process; third, the attitude on AEFI surveillance; fourth, the AEFI reporting behavior of the respondent; fifth, the perceived barriers and suggestions on improving the AEFI reporting; and the characteristics of the respondent (Appendix A). Access to training was assessed through two questions. The first question was whether respondents had received any training in AEFI surveillance (including reporting and handling the common general reactions), and if so, the second question asked the channel of obtaining such training. Knowledge, attitude, and reporting behavior of AEFI surveillance were evaluated by the correct answers to five questions, three questions, and three questions, respectively.

Recruitment

A simple random sample of 170 HCWs were recruited from 170 vaccination clinics. First, we needed to select 170 vaccination clinics from the total 1335 vaccination clinics registered with the Zhejiang provincial health committee through random number table method.

One HCW presented at the time of telephone recruitment would be invited to participate in this survey in each target vaccination clinic. The participation was voluntary. If he/she refused to participate in this survey, we would try to contact the other HCWs for the recruitment until one HCW would agree to participate. If all HCWs in the target vaccination clinic refused to participate, the adjacent vaccination clinic would be selected as the alternative one till we recruit the HCW.

Before the survey, informed consent from each HCW was obtained and the personnel information would be kept confidential. After being informed about the study, the selected HCWs received an online survey link also through e-mail. Up to two reminders were sent over the next two days, followed by a final phone reminder on the third day.

Statistical analyses

Descriptive statistics were used to report the distribution of the respondents' characteristics. The access to training, knowledge, attitude, and reporting behavior on AEFI surveillance were described based on the responses to each relevant question, as well as compared between the different characteristics of HCWs (e.g., age, type of healthcare center or years of experience) through chi-square tests. Continuous variables were dichotomized at the median. Statistical significance was set at 0.05, and the analyses were not weighted. The significance level was set to 5% for all statistical tests. Analyses were conducted using SAS, version 9.3 (SAS Institute, North Carolina).

Results

Of the 170 HCWs contacted, all of them took the online survey yielding an overall province-wide response rate of 100%. The distribution of respondents by district is shown in [Table 1](#) along with a general survey coverage of 12.7%. Among the 170 respondents, the median age was 30.3 years and the majority were from health service center ($n = 72$, 42.4%) and

Table 1. Distribution of the respondents in the survey of AEFI surveillance in Zhejiang province.

City	Number of vaccination clinics	Number of respondents	Coverage (%)
Hangzhou	186	25	13.4
Ningbo	152	19	12.5
Wenzhou	213	27	12.7
Jiaxing	73	9	12.3
Huzhou	79	10	12.7
Shaoxing	103	13	12.6
Jinhua	127	16	12.6
Quzhou	98	12	12.2
Zhoushan	38	5	13.2
Taizhou	128	16	12.5
Lishui	138	18	13.0

township health facility (n = 70, 41.2%). Eighty-eight respondents (n = 51.8%) had worked on vaccination for 4–5 years (Table 2). Of the surveyed HCWs, 61.8% received the training on AEFI surveillance (78.1% were from workshop or special training program vs. 22.35% relied on independent reading to gain knowledge). There were 27 (n = 15.9%) respondents who had no AEFI training at all (Table 3).

The knowledge, attitude, and reporting behavior on AEFI surveillance of the respondents were presented in Table 4, by duration of being HCW for vaccination, type of healthcare center, and training status. The higher level of knowledge and the more positive attitude and reporting behavior on AEFI surveillance were observed among HCWs with the longer working duration on AEFI surveillance, or among HCWs who received the training. For example, of the 32 respondents being HCWs more than 10 years, 90.6% reported at least one AEFI in the past year and 93.7% stated they would report all AEFIs. Of the 105 respondents received training, 73.3% reported at least one AEFI in the past year and 58.1% stated they would report all AEFIs. However, the knowledge, attitude, and reporting behavior on AEFI surveillance were not significantly different among HCWs from different types of healthcare center.

Table 2. Characteristics of the respondents in the survey of AEFI surveillance in Zhejiang province.

Characteristics	Level	Number of respondents	%
Type of healthcare center	Hospital	28	16.5
	Health service center	72	42.4
	Township health facility	70	41.2
Duration of being HCWs for vaccination	1–3 years	11	6.5
	4–5 years	88	51.8
	6–10 years	39	22.9
	>10 years	32	18.8

Table 3. Access to training on AEFI surveillance for the respondents.

Access to training	n(N=170)	%
Received training	105	61.8
No training, read literatures on AEFI	38	22.4
No training	27	15.9
Types of training (n = 105)		
Medical or post-graduate training	16	15.2
Workshop or special training programme	82	78.1
Online course	7	6.7

According to respondents, the most critical barrier to reporting an AEFI was ‘not being sure if the AEFI is related to the vaccine’ (n = 122, 71.8%). Other barriers were: ‘I do not want to raise unnecessary public alarm about a vaccine’ (n = 105, 61.8%); ‘reporting form or other method being too complicated’ (n = 65, 38.2%). Among selected choices for improving AEFI reporting, many respondents selected ‘better orientation/training of health workers in AEFI surveillance’ (n = 155, 91.2%), ‘prompt feedback from health authorities on the findings of AEFI investigation’ (n = 112, 65.9%), and ‘more involvement of health workers in AEFI reporting’ (n = 89, 52.4%).

Discussion

The findings from this survey bolstered the importance of the training on AEFI surveillance. HCWs who had training had the higher level of knowledge, more positive attitude on AEFI surveillance and were more likely to detect and report AEFIs. On the contrary, poor knowledge about AEFIs would result in poor detection of such events, as several studies had amply demonstrated.^{2,10,11}

The majority of respondents having been HCWs for AEFI surveillance for more than five years reflected the fact that the number of HCWs had significantly increased over the last five years. However, our results showed that almost 15% of HCWs did not receive any training on AEFI surveillance. It was in line with the previous reports from other low- or middle-income countries that showed the inadequate training in HCWs.^{11–13} We assumed that the AEFI surveillance was only a part of responsibility in the settings of healthcare center. HCWs were responsible for reporting when they were informed of AEFIs, while the AEFIs were subsequently handled by CDCs. As such, the training on routine immunization target HCWs occasionally did not included the curriculum on AEFI in some areas, where the AEFI surveillance work were not taken seriously enough. In this study, most of the respondents stated that they received the training from the workshop or special training program on AEFI rather than the medical or post-graduate training. It suggested that vaccine pharmacovigilance should be given more prominence in the routine medical education. The current reliance on infrequent AEFI training workshops as the main channel might not be an efficient use of resources. In fact, a significant training gaps had still existed since the AEFI workshop was first implemented 10 years ago. Moreover, online training already served as a platform for training and continuing medical education for HCWs in the other settings.^{14,15} Therefore, the dissemination of information on AEFI surveillance using digital and network technology was practical and should be considered as soon as possible.

In this study, we found that receiving training and longer working duration both had the positive impact on the attitude and reporting behavior on AEFI surveillance. The impact from receiving the training had been discussed earlier in the article. The mechanism of the influence from longer working duration might be due to the rich experience with the growth of working years, and similar findings were observed in the other reports.^{12,13} We recommended that bridging the gap of training for HCWs for AEFI surveillance, especially for the new

Table 4. Knowledge and attitude on AEFI surveillance for the respondents.

	Duration of being HCWs for vaccination (n,%)						Type of healthcare center (n,%)						Training (n,%)		
	1-3 years (n=11)	4-5 years (n=88)	6-10 years (n=39)	>10 years (n=32)	P		Hospital (n=28)	Health service center (n=72)	Township health facility (n=70)	Received training (n=105)	Reading literatures on AEFI (n=38)	No training (n=27)	P		
Knowledge															
Identified the correct definition of AEFI (Q4)	6(54.6)	78(88.6)	39(100.0)	32(100.0)	<0.05	66(91.7)	25(89.3)	64(91.4)	>0.05	104(99.1)	33(86.8)	18(66.7)	<0.05		
Identified all examples of AEFI correctly (Q5)	4(36.4)	75(85.2)	37(94.9)	31(96.9)	<0.05	62(86.1)	25(89.3)	60(85.7)	>0.05	105(100.0)	29(76.3)	13(48.2)	<0.05		
Identified all examples of serious AEFI correctly (Q6)	3(27.3)	69(78.4)	36(92.3)	29(90.6)	<0.05	58(80.6)	23(82.1)	56(80.0)	>0.05	104(99.1)	28(73.7)	5(18.5)	<0.05		
Identified all reportable AEFI correctly (Q7)	8(72.7)	73(83.0)	37(94.9)	32(100.0)	<0.05	64(88.9)	25(89.3)	61(87.1)	>0.05	105(100.0)	30(79.0)	15(55.6)	<0.05		
Identified the correct timeline for reporting (Q8)	4(36.4)	82(93.2)	39(100.0)	32(100.0)	<0.05	66(91.7)	26(92.9)	65(92.9)	>0.05	105(100.0)	34(89.5)	18(66.7)	<0.05		
Attitude															
Agreed a strong vaccination programme requires a strong AEFI surveillance system (Q9)	8(72.7)	82(93.2)	38(97.4)	30(93.8)	<0.05	67(93.1)	26(92.9)	65(92.9)	>0.05	104(99.1)	34(89.5)	20(74.1)	<0.05		
Agreed AEFI surveillance is needed for the full assessment of the safety of newly licensed vaccines (Q10)	5(45.5)	79(89.8)	39(100.0)	32(100.0)	<0.05	65(90.3)	26(92.9)	64(91.4)	>0.05	105(100.0)	33(86.8)	17(63.0)	<0.05		
Agreed health worker has a responsibility to report serious AEFI (Q11)	9(81.8)	86(97.7)	39(100.0)	32(100.0)	>0.05	70(97.2)	27(96.4)	69(98.6)	>0.05	105(100.0)	37(97.4)	24(89.0)	>0.05		
Reporting behavior															
Last detected an AEFI case (Q12)															
Yes, at least once in the past year	0(0.00)	53(60.2)	28(71.8)	29(90.6)	<0.05	47(65.3)	18(64.3)	45(64.3)	>0.05	79(75.2)	26(68.4)	5(18.5)	<0.05		
Yes, at least once in the last 5 years	1(9.1)	24(27.3)	9(23.1)	3(9.4)		16(22.2)	6(21.4)	15(21.4)		24(22.9)	7(18.4)	6(22.2)			
No, never	10(90.9)	11(12.5)	2(5.1)	0(0.00)		9(12.5)	4(14.3)	10(14.3)		2(1.9)	5(13.2)	16(59.3)			
Last reported an AEFI case (Q13)															
Yes, at least once in the past year	0(0.00)	50(56.8)	27(69.2)	29(90.6)	<0.05	44(61.1)	18(64.3)	44(62.9)	>0.05	77(73.3)	25(65.8)	4(14.8)	<0.05		
Yes, at least once in the last 5 years	1(9.1)	22(25.0)	7(18.0)	2(6.2)		14(19.5)	5(17.9)	13(18.6)		26(24.8)	5(13.2)	1(3.7)			
No, never	10(90.9)	16(18.2)	5(12.8)	1(3.1)		14(19.5)	5(17.9)	13(18.6)		2(1.9)	8(21.1)	22(81.45)			
Self-described reporting behavior (Q14)															
I have no time to report an AEFI	6(54.6)	15(17.1)	4(10.3)	0(0.0)	<0.05	11(15.3)	4(14.3)	10(14.3)	>0.05	8(7.6)	7(18.4)	10(37.0)	<0.05		
I would report an AEFI only if I am sure it was caused by a vaccine	1(9.1)	45(51.1)	9(23.1)	1(3.1)		24(33.3)	10(35.7)	22(31.4)		28(26.7)	18(47.4)	10(37.0)			
I would only report any serious AEFI	4(36.4)	15(17.1)	6(15.4)	1(3.1)		11(15.3)	4(14.3)	11(15.7)		8(7.6)	11(29.0)	7(25.9)			
I would report all AEFIs	0(0.00)	13(14.8)	20(51.3)	30(93.74)		26(36.1)	10(35.7)	27(38.6)		61(58.1)	2(5.3)	0(0.0)			

staff, should be prioritized. However, we did not observe the discrepancy in knowledge, attitude, and behavior in AEFI surveillance between different types of healthcare center. This result indicated that the critical determinants of AEFI surveillance did not differ significantly among different types of healthcare facilities.

A fine distinction between respondents' self-described reporting behavior and actual reporting behavior was observed. Most of the respondents whose duration of being HCWs for a short time knew the definition of AEFI well but they could not identify AEFI or serious AEFI when we gave some specific examples. Another gap was the lack of deep understanding of the purpose and method of AEFI surveillance among HCWs without training or with a short working duration of vaccination. These HCWs had the misconception that only serious AEFI or AEFI caused by vaccines should be reported. These findings could be interpreted in several ways. One interpretation would be that the high level for self-described reporting behavior pointed to a sense of obligation among respondents, but they might not actually meet this high standard in the actual work settings.^{16,17} Second, we assumed that not all the staff in vaccination clinic participated in the AEFI surveillance and they might have theoretical knowledge but little practical experience. Another explanation was that the respondents had a low index of suspicion for AEFIs and did not really expect to see AEFI in their practice, for the reasons like 'AEFI is rare event' or 'only serious AEFI case is referred to vaccine'.¹⁷⁻²⁰ According to our findings, we recommended that the training program should be designed to adapt the actual surveillance needs. Specifically, the purpose and importance of AEFI surveillance after the vaccine license should be clarified in the training course. Besides, we suggested that the AEFI training should cover all HCWs in vaccination clinic and the AEFI reporting or surveillance should be the responsibility of all HCWs in their practice.

Efforts to strengthen AEFI surveillance system should consider the perspectives of HCWs on the barriers to reporting AEFI in their respective settings. Similar to the studies conducted in other settings,^{2,20,21} the most important barrier identified by respondents in our investigation was relate to the training deficiencies. The supervisory visit where AEFI were discussed, provided a useful platform to address barriers to reporting. Discussing AEFI with HCWs during the supervisory visits should promote reporting and serve as an opportunity to training on AEFI in the work environment. Furthermore, HCWs from other settings had stated that they needed more supportive supervisions at the district level or the higher levels.^{22,23}

The second barrier to reporting AEFI was relate to the fear of personal consequences, which was consistent with the finding from the previous reports.^{11,12,24} The fear of raising public alarm, which in turn could result in vaccine refusal, had been shown to deter HCWs from making AEFI reports in the other settings.^{11,12} Our finding highlighted the importance of a blame free culture in strengthening the AEFI surveillance system. This barrier could be ameliorated through encouragement from supervisors, providing supportive supervision to address fear on the negative consequences, implementing a supportive policy to protect HCWs, and changing organizational policy

surrounding the importance of reporting without any punishment. Besides, strategies at the individual or organizational level that had been successful at rewarding the AEFI reporting should be considered, including the encouragement of the open communication to facilitate reporting. AEFI surveillance was a quality assurance of the immunization program and it should be valued by the policy-makers rather a source of fear for HCWs.²⁴⁻²⁶

The user-friendliness of AEFI reporting method was the third barrier to reporting. The reporting process differed widely between countries. The proportions of HCW's dissatisfaction with the reporting process varied widely, from 0.6% in Canada to 60% in Ghana.^{10,24,27-29} A very detailed AEFI reporting form, which was designed to fulfill the requirement for proper documentation to support the subsequent investigation, was currently applied. The time required for form filling could deter HCWs to finish the other routine work. A re-thinking of reporting process and the simplification of this process was thus essential. Most of the minor AEFIs should not require lengthy paper trail for causality assessment. Only the serious, rare or unexpected AEFI, such as anaphylaxis, needed the clinician's assessment of causality. Simpler AEFI reporting formats used in other settings might be adapted to our setting.

Prompt feedback from health authorities on the findings of AEFI investigation could provide the evidence of improvement or gap in the application of AEFI surveillance, and coached the HCWs by modeling the positive behavior. Such feedback might include the assessments of data quality, data from other facilities, reports of actions taken at local and higher levels, interpersonal communication skills in surveillance. Lack of feedback as a barrier to AEFI reporting had been corroborated in other study.^{2,28} Our finding indicated the need for prompt feedback on AEFI investigation could be considered as a mechanism for strengthening AEFI surveillance and a better public messaging on the vaccine safety.

There were several limitations of this study. First, the study was conducted in 12% of the vaccination clinics using an unweighted analysis and thus the generalizable value would be insufficient. Second, self-reported information from HCWs on AEFI may be skewed toward compliance with AEFI surveillance guidelines or socially desirable responses. Third, participation bias might be existed. Although the vaccination clinics were selected randomly, the participation of HCWs was voluntary. It might reasonably be assumed that the HCWs who agreed to take the survey had generally more favorable attitude and better understanding of AEFI surveillance than those who declined to participate. Yet, important gaps were identified even if such participation bias were present.

Conclusions

The study findings highlighted the need to prioritize training on AEFI surveillance for HCWs. HCWs who had training had the higher level of knowledge, more positive attitude on AEFI surveillance and were more likely to detect and report AEFIs. The current knowledge, attitude, and reporting behavior were found to be sub-optimal which was due to inadequate training,

fear of personal consequences after reporting, complexity of the reporting process, which were required the development of the targeted interventions to strengthen AEFI surveillance system.

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Author contributions

Conceptualization, Y.H. and H.K. L.; methodology, H.L. and X.J. P.; formal analysis, X.J. P.; investigation, Y.W.; writing-original draft preparation, Y.H. All authors have read and agreed to the published version of the manuscript.

Disclosure statement

No potential conflicts of interest were disclosed.

Ethics approval and consent to participate

The study was approved by the Institutional Ethics Committees of Zhejiang provincial center for disease control and prevention (TR-008). A written informed consent was obtained prior to proceeding to the survey. No personal identifier was collected.

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Informed consent statement

A written informed consent was obtained prior to proceeding to the survey. No personal identifier was collected.

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