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## PSYCHOLOGICAL AND OPERATIONAL BARRIERS AFFECTING HEALTH WORKERS' FUNCTIONALITY IN AN ADVERSE EVENT FOLLOWING IMMUNIZATION (AEFI) SURVEILLANCE SYSTEM: A CROSS-SECTIONAL STUDY

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### ABSTRACT

**Background**: Adverse Events Following Immunization (AEFI) surveillance is a key mechanism for monitoring the safety of vaccines. Little is known about the barriers affecting its functionality among healthcare workers in Northern Nigeria. This study aims to identify the barriers health workers experience and provide understanding of the surveillance system.

**Methods**: A cross-sectional study was conducted among three hundred and eighty-seven (387) healthcare workers in Kano State, Nigeria. All healthcare facilities in the metropolitan zone were included. Self-administered questionnaires were used for data collection. Collected data were statistically analyzed using Stata version 15 software at a significance level of p<0.05.

**Results:** Out of the 387 respondents, 299 (77.3%) reported they had experienced an AEFI. Among those who had encountered an AEFI, over half (258, 86.3%) indicated they had reported it. The results obtained in this study showed a significant association between gender, job position, and training with reporting (p<0.05) of AEFI. Barriers to reporting AEFI were managing the patient is better than reporting (121, 40.47%), not knowing about the AEFI reporting system (115, 38.46%), guilt about having caused harm (108, 36.12%) and planned to do it later, but forgot (103, 34.45%). However, barriers that showed significant association with reporting AEFI were "those who do not think AEFI is necessary to be reported" (p=0.00), "not knowing about the AEFI reporting system" (p=0.04) and "managing the patient is better than reporting" (p=0.04).

**Conclusion:** Not knowing about the AEFI reporting system, not thinking AEFI is necessary to be reported, and managing the patient is better than reporting were the only barriers significantly associated with reporting of AEFIs. These barriers can lead to the underreporting of the adverse effects of vaccines thereby resulting in poor vaccine safety surveillance.

**Keywords:** adverse events following immunization (AEFI), health care workers (HCWS), monitoring, Nigeria, public health, routine immunization (RI), surveillance.

# INTRODUCTION

Immunization, which is one of the most affordable public health interventions,<sup>1</sup> has saved about 154 million lives (the same as 6 lives every minute per year) over the past 5 decades, of which 101 million of these are infants.<sup>2</sup> The success of an immunization program relies on the establishment of an effective and strong health service system which is able to provide and expand on immunization services.<sup>3</sup> Immunization programs in Nigeria have achieved great milestones. As a result of the successes recorded from vaccination programs, the prevalence of vaccine preventable diseases (VPDs) has grossly reduced thereby shifting public focus to vaccine safety and side effects of taking vaccines.<sup>4</sup> Vaccines are safe but may trigger side effects in some people with allergies or certain health conditions.<sup>5,6</sup> Adverse events following immunization (AEFI) has raised great concern among the populace which may result in their loss of confidence in the safety of vaccines, low vaccination coverage, and even the resurgence of

VPDs,<sup>7,8</sup> irrespective of the fact that these adverse events following immunization are an essential part of functional immunization and vaccine safety monitoring systems.<sup>9</sup>

As defined by the World Health Organization (WHO), AEFI is "any untoward medical occurrence following immunization which does not necessarily have a causal relationship to the vaccine". Vaccines are intended to protect both individuals and populations by preventing diseases; although the possibility of these vaccinations causing AEFIs always abound.<sup>10</sup> AEFI may take place immediately following vaccination or within 30 days of receiving the vaccine<sup>11</sup> and if not properly addressed could cause recipients of these vaccines or their caregivers to doubt the efficacy of the vaccine received.<sup>12</sup>

The Global Vaccine Action Plan for vaccine safety monitoring has set a minimum target of reporting ratio of 10 AEFIs per 100,000 surviving infants as a stand-in for an operational AEFI reporting system.<sup>13</sup> However, AEFI have been reported to be lower than the ideal rate by most low and middle-income countries (LMICs) which is below the set minimal reporting ratio.<sup>13</sup> This can be attributed to barriers affecting the effective reporting of AEFIs by healthcare workers. In a study, it was shown that healthcare workers (HCWs) had an indisputable role in initiating the reporting and investigation procedure among those experiencing AEFI.<sup>14</sup> Limited involvement of healthcare workers in surveillance work and lack of a blame-free culture has contributed to underreporting of AEFIs.<sup>13</sup> Abdu et al in their study found that major barriers to reporting AEFIs were AEFIs termed as not being serious and a lack of motivation to report these adverse events.<sup>15</sup> Although Kano State has witnessed significant advancement in vaccination programs,<sup>16</sup> the inability of the public and the medical community to properly differentiate between adverse events.<sup>17</sup> This undoubtedly has effects on the healthcare system.<sup>18</sup>

There is a paucity of data on the barriers to AEFI reporting from empirical quantitative studies that examined the knowledge, reporting practices, trends and management of AEFI in Nigeria.<sup>19-22</sup> Although the Nigerian government inaugurated AEFI National Expert Committee (NEC) in 2012 and strategies to enhance AEFI surveillance system in Nigeria have been ongoing with support from the World Health Organization,<sup>23</sup> underreporting of AEFIs is still a problem faced in Nigeria's primary healthcare system.<sup>21,22</sup> As we know, no study had discussed the psychological and operational barriers affecting health workers' functionality in an AEFI surveillance system in the northern part of Nigeria. This study aims to fill this research gap by bringing to the fore lived experiences of the healthcare workers in Kano State by identifying these barriers. This will guide national regulatory authorities (NRAs) and national expanded programs (EPIs) on what measures to put in place to enhance the effectiveness of AEFI surveillance systems and improve vaccine safety monitoring efforts.

# **METHODS**

### Study Area

This study was carried out in Kano State, Nigeria. Kano State is one of the 36 states in Nigeria, located in the northern region of the country. According to the national census done in 2006, Kano State is the most populous in Nigeria. Kano state consists of forty-four (44) Local Government Areas (LGAs) which are divided into metropolitan and non-metropolitan LGAs.

# **Study Design and Participants**

A descriptive cross-sectional study was conducted at health facilities providing routine immunization in Kano State. Only Health Care Workers (HCWs) in health facilities providing immunization in all 7 metropolitan LGAs were included in the survey. Three hundred and eighty-seven (387) participants were enrolled in the study. The exclusion criteria were HCWs who had work experience less than three consecutive months prior to the study. The inclusion criteria were all health facilities in the LGA and HCWs directly involved in routine immunization.

### **Ethical Statement**

Ethical approval with reference number SHREC/2023/3994 was obtained from the Kano State Ministry of Health Ethics Committee Board after the research protocol was reviewed.

### **Informed Consent**

Participation from healthcare professionals was entirely voluntary, informed consent was signed and responses were coded.

### **Data Collection Tools and Procedures**

Self-administered questionnaires were used for collecting data from eligible HCWs. The questionnaire consisted of a number of sections: 1) respondent characteristics 2) training and capacity building 3) general overview of AEFI, and 4) barriers towards surveillance of adverse events following immunization. The questionnaire was developed in

English language and then translated to the local Hausa language to ensure accuracy. To ensure the efficacy and feasibility of the tool, the questionnaire was pre-tested in a LGA that had similar characteristics. After pre-test the questionnaire was reviewed by experts in the field following guidance of pretest result. The participants were divided into three groups: Those who had not witnessed the event, those who had witnessed the event but did not report it and those who had witnessed the event and reported it. The period of data collection was between December 2023 and January 2024.

# Data analysis

Data were entered and analyzed by Stata version 15. All descriptive statistics, frequencies, means and standard deviations were computed as appropriate. Knowledge of reportable AEFIs was assessed using questions with a "yes" or "no" response. Chi-square test was utilized to explore the association between the dependent variable (reporting) and the independent variable (socio-demographic characteristics and training on AEFI) to identify the predictors of reporting. Respondents' barriers to reporting were assessed using 10 close-ended questions. Barriers to reporting were assessed using statements on a three-point Likert scale (Agree, Neutral, and Disagree). Positive statements were scored as: +3 (Agree); +2 (Neutral); +1 (Disagree). Negative statements were scored as: +3 (Agree); +2 (Neutral); +1 (Disagree).<sup>21</sup> A binary logistic regression was used to further investigate the relationship between barriers and reporting. A significance level of p < 0.05 was considered statistically significant.

## RESULTS

The questionnaire was administered to a total of 387 respondents. All respondents were health workers across the three levels of health facilities in Kano State, Northern Nigeria with mean age of  $37.5 \pm 8.74$  years. Some of the respondents (40.1%) fell in the age category of 30-39 years and were predominantly females (76.5%). Almost half of the study population (46.5%) were Community Health Extension Workers (CHEW) and the mean and standard deviation of years of job experience was  $12.1 \pm 7.9$  years. About three-fifths of the respondents (60.7%) were vaccinators and (89.9%) had obtained a tertiary education. Furthermore, most (92.5%) of the health workers had undergone training on AEFI. Over half of the respondents (77.3%) had encountered AEFI. Out of those that encountered AEFI, majority (86.3%) acknowledged they reported, however only a minimal proportion (8.9%) actually adhered to the World Health Organization (WHO) standard of reporting within 24 hours (Table 1).

Variables	-	Frequency	Percentage (%)
Age	<20	2	0.5
	20-29	72	18.6
	30-39	155	40.1
	40-49	114	29.5
	50-59	44	11.4
Gender	Female	296	76.5
	Male	91	23.5
Job Position	CHEW	180	46.5
	СНО	25	6.4
	Nurse	13	3.3
	Doctor	33	8.5
	Others	136	35.1
Years of Experience	0-9	183	47.3
	10-19	148	38.2
	20-29	43	11.1
	30-40	13	3.4
Role in Immunization	Vaccinator	235	60.7
	Recorder	28	7.2
	Health educator	12	3.1

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Table 1: Socio-demog	raphics charac	cteristics of 1	respondents	(n=387)

	OIC	91	23.5	
	Others	21	5.4	
Level of Education	Primary	16	4.1	
	Secondary	5	1.3	
	Tertiary	348	89.9	
	No formal education	1	0.3	
	Others	17	4.4	
Capacity Building	Yes	358	92.5	
	No	29	7.5	
Have you encountered AEFI	Yes	299	77.3	
	No	88	22.7	
	Yes	258	86.3	
Reported the AEFI (n=299)	No	41	13.7	

CHEW: Community health extension worker

CHO: Community health officer

OIC: Officer in charge

Table 2 shows the knowledge of reportable AEFIs among health care workers. Majority of the respondents indicated that they did not know that immunization related hospitalizations (71.3%), Bacille-Calmette Guerin lymphadenitis (95.6%), immunization related deaths (55.0%) and fever >36°c (71.8%) were reportable AEFIs. **Table 2: Knowledge of reportable AEFIs among health care workers (n=387)** 

Tuble 2. Knowledge of reportable fills is among neural care workers (n=507)					
Variables		Frequency	Percentage (%)		
Immunization related hospitalizations	Yes	111	28.7		
	No	276	71.3		
Bacille-Calmette Guerin lymphadenitis	Yes	17	4.4		
	No	370	95.6		
Immunization related deaths	Yes	174	45.0		
	No	213	55.0		
Fever > 36°	Yes	109	28.2		
	No	278	71.8		

Table 3 shows the factors associated with reporting AEFI among health care workers. Chi-square analysis was only conducted on the latter two groups (those who had witnessed the events but did not report it and those who had witnessed the event and reported it). A sub-analysis was conducted among those who had encountered the AEFI (n=299) across the two groups. There was no significant association or relationship between age, years of experience, role in immunization, level of education and reporting of AEFI (p>0.05). However, gender ( $\chi^2$ =8.212, p=0.004), job position ( $\chi^2$ =10.127, p=0.038) and training ( $\chi^2$ =6.009, 0.014) were significantly associated with reporting.

Table 3: Factors associated with reporting AEFI among health care workers (n=387)						
Variables		Reported	Not reported	Chi-square	P-value	
		n (%)	n (%)	$(\chi^2)$		
Age	<20	0 (0)	0 (0)	0.107	0.99	
	20-29	42 (85.7)	7 (14.3)			
	30-39	103 (85.8)	17 (14.2)			
	40-49	82 (87.2)	12 (12.8)			_

		50.50	21 (96 1)	5 (12 0)		
Conton		50-59 Example	31 (80.1)	5 (13.9) 28 (17.0)	9 010	0.00*
Gender		Female	185 (83.0)	38 (17.0)	8.212	0.00*
		Male	73 (96.1)	3 (4.0)		
Job Position		CHEW	118 (84.3)	22 (15.3)	10.127	0.03*
		СНО	19 (95.0)	1 (5.0)		
		Nurse	8 (66.7)	4 (33.3)		
		Doctor	28 (100)	0 (0)		
		Others	85 (85.9)	14 (14.1)		
Years	of	0-9	112 (84.9)	20 (15.2)	1.846	0.60
Experience		10-19	105 (86.8)	16 (13.2)		
		20-29	31 (86.1)	5 (13.9)		
		30-40	10 (100)	0 (0)		
Role	in	Vaccinator	147 (86.0)	24 (14.0)	2.445	0.69
Immunization		Recorder	17 (89.5)	2 (10.5)		
		Health educator	6 (75.0)	2(25.0)		
		OIC	70 (85.4)	12(14.6)		
		Other	18 (94.7)	1(5.3)		
Level	of	Primary	12 (100)	0 (0)	3.035	0.55
Education		Secondary	3 (75.0)	1(25.0)		
		Tertiary	230 (85.5)	39(14.5)		
		No formal education	1 (100)	0 (0)		
		Others	12 (92.3)	1 (7.7)		
Capacity		Yes	249 (87.4)	36 (12.6)	6.009	0.01*
Building		No	9 (64.3)	5 (35.7)		

CHEW: Community health extension worker

CHO: Community health officer

OIC: Officer in charge

This study further revealed the various barriers encountered by health workers that restricted them from reporting incidents (Fig. 1). Various sub-themes related to two themes were identified. The two themes are; i) psychological barriers and ii) operational barriers. Among the operational barriers, the commonly reported barriers were "managing the patient was more preferable than reporting" (40.5%), "not knowing about the AEFI reporting system" (38.5%), with over one third of health workers acknowledging other barriers which includes; "that they planned to do it later but forgot" (34.5%), "client confidentiality issues" (33.8%) and "time constraint" (33.1%). For psychological barriers, specifically, over one-third of the health workers surveyed indicated that they do have "guilt about causing harm" (36.1%) and "fear that report would lead to personal repercussions" (33.1%). One-fourth (n=74) of the respondents mentioned that they "do not think it is necessary for AEFI to be reported", 28.4% of the respondents indicated that "no one uses the information" and 27.4% indicated "lack of interest in reporting". **Figure 1: Barriers to AEFI reporting among health workers** 



Binary logistic regression was done on the barriers to HCWs reporting. There were significant differences between groups that responded "not knowing about the AEFI reporting system" (p=0.04, OR:0.54, CI: 0.30-0.98), "I do not think AEFI is necessary to be reported" (p=0.00, OR:6.88, CI: 2.18-21.7) and "managing the patient is better than reporting" (p=0.04, OR:0.57, CI: 0.33-0.97). The result of the bivariate analysis of predictors to reporting and binary logistic analysis of the barriers across the two groups are summarized in table 3 and 4.

-	-					
Table	4: Logistic	regression of barriers,	compared be	etween the Non-Rep	porting and Re	porting Groups

Variables	OR	Lower CI	Upper CI	p-value
Not knowing about the AEFI reporting system	0.54	0.30	0.98	0.04**
Fear that report will lead to personal repercussion	0.88	0.48	1.60	0.67
Planned to do it later but forgot	0.67	0.36	1.25	0.21
Time constraint	0.92	0.52	1.65	0.78
Guilt about having caused harm	0.68	0.36	1.29	0.24
Lack of interest in reporting	1.15	0.63	2.10	0.65
Client confidentiality issues	1.03	0.52	2.02	0.94
No one uses the information	1.19	0.64	2.23	0.59
I do not think AEFI is necessary to be reported	6.88	2.18	21.72	0.00***
Managing the patient is better than reporting	0.57	0.33	0.97	0.04**

\*\*\* *p*<.01, \*\* *p*<.05, \* *p*<.1

OR: Odd Ratio, CI: Confidence Interval

### DISCUSSION

Reporting is crucial to surveillance as it could, through aggregation and analysis of data, result in reduction of medical and health care error, influence the success of vaccination programs and identify issues affecting patient safety. Consequently, it is recorded that being at the front-line, the health worker is more privy to information that the organization might not know.<sup>24</sup> Reporting gives ample opportunity to bring the organization to awareness.

The results from this study showed that majority of the respondents had encountered AEFI (299, 77.3%) and more than half (258, 86.3%) were acquainted with the reporting structure, however adherence to WHO guidelines for reporting was markedly inadequate. This indicates gaps in the AEFI surveillance and highlights the need for targeted compliance to international standards in AEFI surveillance. Our findings is similar to that in Ghana where over half of the HCWs had encountered AEFI.<sup>3</sup> Consequently, unlike a review that was conducted in China within a period of 2010-2019 and identified lack of reporting tools among health facilities,<sup>25</sup> this study found that majority of all facilities had almost all data tools. This cannot be explanatory to the cause of underreporting.

A noteworthy finding in our study is that even though over half of the respondents (258, 86.3%) indicated that they were familiar with AEFI reporting, only one-third (109, 28.2%) of the respondents knew reportable AEFIs. Reportable AEFIs such as immunization related death, immunization related hospitalization and fever were known by one-third of the respondents, Bacilli-Calmette lymphadenitis was rarely known this could be related to its uncommon occurrence. The findings in this study are not dissimilar to a study in the United States where most respondents did not know reportable AEFIs.<sup>29</sup> Implications of this are that it would result to underreporting, it reflects the limited understanding of health workers towards reporting, and consequently inhibiting timely response to vaccine safety concerns.

This study presented an association between several factors. Gender, job position and training were significantly associated with reporting of AEFI (p<0.05). Although unlike previous studies, age and years of experience was not significantly associated with reporting in our study.<sup>22</sup> Reporting was more associated with females; being a female increases the risk of reporting. This is consistent with a cross-sectional study conducted in Korea where reporting was associated with being female.<sup>26</sup> This could be attributable to the possibility that the female counterpart due to their innate behavior perceive disease more seriously resulting in higher reporting rate. Additionally, training was significantly associated with increased reporting which is consistent with other studies.<sup>27</sup> Consistent with our results, previous studies have shown that nurses were more familiar with reporting than doctors, and reporting was significantly associated with nurses.<sup>27,28</sup> They were more involved in AEFI reporting and this could be related to the fact that their type and procedure of work are different from the doctors. This underscores the need to strengthen the behaviour of the doctors on reporting to foster an inter-disciplinary collaborative approach to surveillance.

Findings from this study identified multiple barriers that could negatively influence reporting of AEFI among HCWs involved in immunization. Not knowing about the AEFI reporting system was the most pervasive barrier. This is also in line with a study in Brazil and Indonesia that deficient knowledge was a barrier to incident reporting.<sup>3,30,31</sup> This implies that not knowing where to report is a pivotal stage in the 3 essential stages outlined by Rashed and Hamdan,<sup>32</sup> with regards to the success of a surveillance system. The lack of not knowing the AEFI reporting system could be attributable to the cumbersome documentation process or availability of multiple reporting system. However, this can be ameliorated through training and education of HCWs to enhance their knowledge on reporting systems and it significance. It is interesting to note that this study found training to be predictor to reporting.

In addition to the barriers, HCWs indicated that no one uses information. Using information provided by the HCWs via reporting serves as a feedback mechanism. The lack of feedback can alter the effectiveness of a given system. Consistent with our findings, other studies corroborated that lack of feedback was a barrier to reporting and this can affect the motivation of HCWs negatively as they might not engage fully with the system as they may feel their effort is not appreciated or impactful.<sup>33</sup> It is very important that supervisory visits are conducted and HCWs are made to know that the information is used and any feedback as regards inaccuracies or inconsistencies should be passed across to them. This may suggest the need for a two-way reporting system such that after reporting, AEFIs are investigated and feedback channeled back to reporting facilities.

Fear that report will lead to personal repercussions was reported by HCWs. This is similar to findings by other studies.<sup>22,33</sup> This barrier has been so consistent across varying studies in Africa. To address this challenge, we suggest that HCWs should be constantly reassured during supportive supervisory visit that such practice is very crucial to AEFI surveillance. Secondly, the nature of the disciplinary action that triggers fear should be identified and addressed as some HCWs may fear losing their job and so would prefer not to be engaged in any activity that would point to a hole in their job. Thirdly, training and education is very important in re-orienting the HCWs on the inclusiveness of reporting in surveillance.

It was highly reported that managing the patient is better than reporting. This is a major issue and more studies should be done to investigate why HCWs would prefer managing to reporting. It could be due to overwhelming workload, seeing the event as mild or taking the next step of action which is provision of care since no one uses the information (a previous barrier initially highlighted). Most HCWs believed that AEFI was not necessary to be reported and this is in tandem with another study.<sup>25</sup> This attitudinal barrier is needed to be addressed because if health workers do not see the necessity to report, the motivation to participate actively in the reporting process is undermined. There is a need to foster a will among health care providers to see value in reporting and be more motivated and consistent in practicing reporting.

"Not knowing about the AEFI reporting system", "I do not think AEFI is necessary to be reported" and "managing the patient is better than reporting" were the barriers found to be significantly associated with reporting. This might explain the complexity of the workload and unimportance of reporting perceived by the HCWs. HCWs should be made to know the effect of reporting on decision-making and sub-optimal reporting would proliferate wrong judgment or incomplete policy. Additionally, the government should prioritize AEFI surveillance as a core component of routine immunization activities. This is very pivotal if the government mandates such practices because this would improve reporting.

This study is not without limitations. Firstly, the participants are prone to have recall bias on differentiating the type of training they have undergone, if it was AEFI specific or tailored towards AEFI. Secondly, our study was quantitative. A qualitative study would have assisted immensely in providing a deeper and more comprehensive understanding to the complexity of human behaviours, emotions and feelings. In this study we propose the following framework this would help further understanding into the factors that may influence a strong surveillance system for AEFI.

# CONCLUSION

This study identified that HCWs faced significant challenges to implementing a strong surveillance system for AEFI. Most of the HCWs had encountered AEFI in their practice but reporting was suboptimal. 'Not knowing about the AEFI surveillance system', 'I do not think AEFI is necessary to be reported' and 'managing the patient is better than reporting' were barriers that were observed to be significant with reporting AEFI. These barriers can lead to the underreporting of the adverse effects of vaccines thereby resulting in paucity of data on vaccine safety. This finding informs the need for policymakers and health authorities to urgently train health workers on AEFI surveillance systems to curb the challenge of being unable to effectively monitor and address vaccine-related risks consequently influencing reporting positively.

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### **AUTHOR'S CONTRIBUTION**

Faith Oluwatosin Sangodele developed the concept of the paper, did the data analysis and contributed to the development of the manuscript. Grace Charles Ishatah was involved in the development of the manuscript. Luke Oche Peter and Don Eliseo Lucero-Prisno III reviewed and edited the manuscript.

## DISCLOSURE STATEMENT

No conflict of interest.

# ETHICAL APPROVAL

Ethical approval with reference number SHREC/2023/3994 was obtained from the Kano State Ministry of Health Ethics Committee Board after the research protocol was reviewed.

### INFORMED CONSENT STATEMENT

Participation from healthcare professionals was entirely voluntary, informed consent was signed and responses were coded.

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