

## Original Research Article

# Factors affecting AEFI reporting among vaccine recipients in Oyo State, Nigeria

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### ABSTRACT

**Background:** Immunization has proved to be a worthy investment in reduction of morbidity and mortality related to vaccine preventable diseases. However, AEFI may deter people from assessing vaccines, leading to poor vaccine coverage and non achievement of herd immunity sufficient to break disease transmission. Despite the established vaccine safety framework, there are gaps in the reported cases of AEFI, whether by community members to health-system or HWs to the data-system.

**Methods:** This descriptive cross sectional study aimed at providing some answers to the missing aspect of AEFI reporting from the populace by conducting interview for 422 vaccine recipients from 3 randomly selected LGAs, 1 each from the 3 senatorial district in Oyo-State, Nigeria. Structured questionnaire was used in data collection and analysis was done with data subjected to descriptive (mean, range, standard deviation) and inferential (Chi-square (X<sup>2</sup>) and logistic regression) statistical analyses.

**Results:** The study demonstrated the odds of likelihood to report AEFI to be 38 times more in persons with good awareness about AEFI reporting compared to those without. Poor health workers support/reactions to previously reported AEFI cases influenced future reporting by community members negatively, resulting to lesser likelihood to report. The community member who reported that based on their experience, AEFI management cost was borne by the cases and that HWs dismiss complaints about AEFI as unnecessary report, were seen to be less likely to report AEFI.

**Conclusions:** Good awareness about the reporting system, perception about vaccine safety and satisfactory memorable experience are important at ensuring optimal AEFI reporting.

**Keywords:** AEFI reporting, Vaccine recipients, Vaccine safety

## INTRODUCTION

In order to reduce the morbidity and mortality linked to vaccine-preventable diseases (VPDs), immunization remains one of the most crucial public health measures.<sup>1</sup> To accomplish sustainable development goals (SDG) 3.3 and 3.8, which aim to stop communicable disease epidemics and achieve universal health coverage by 2030, respectively, vaccination is crucial.<sup>2</sup> According to forecasts from the International Vaccine Access Center

(IVAC), Nigeria's GDP will grow by \$17 billion over the next ten years if immunization coverage reaches 90%.<sup>3</sup> Despite the many advantages of vaccination, vaccine uptake is still very low, especially in developing nations, making vaccine-preventable diseases (VPDs) the leading cause of childhood mortality, accounting for an estimated 1-2 million deaths annually.<sup>4</sup> The health system and issues relating to families and caregivers have been implicated as causes of low immunization coverage.<sup>5</sup> While the family/caregivers factors include lack of

awareness, lack of time and other family issues, in addition, issues of mistrust and fear of adverse effects following immunization (AEFI) are also reported reasons.<sup>6</sup> Although vaccination rates have increased over the past 10 years in Nigeria, they still fell short of the MDG 4 objective of 90% by 2015.<sup>7</sup> According to the multiple indicator cluster survey in 2021, full immunization coverage stood at 36 in 100 for Nigerian children with 11% of women refusing to get their children vaccinated due to the fear of side effects, indicating that vaccination hesitancy is still a problem for public health.<sup>8,9</sup>

Therefore, it is essential to monitor vaccine safety in order to foster trust and give the public assurance that AEFIs are being watched over and precautions are being taken to limit risks. This will lessen vaccine reluctance and support immunization programs' efforts.<sup>10</sup> Currently, reporting rates of AEFIs are low, especially in developing countries.<sup>10</sup> This is because developing nations' inadequate pharmacovigilance infrastructure and over-reliance on the routine reporting system, which is susceptible to underreporting.<sup>11</sup> To address the issue of underreporting, the WHO therefore instituted the global vaccine safety initiative, which set out indicators primarily for monitoring case reporting.

Given that Africa is one of the world's poorest continents, expanding vaccination coverage might significantly reduce the illness burden and free up resources for development programs.<sup>12</sup> Therefore, it becomes crucial to strengthen African continent's pharmacovigilance infrastructure so as to enhance AEFI reporting and vaccine safety. An analysis of data from the World Health Organization (WHO) vaccine safety database, VigiBase, in June 2015 showed that Africa falls behind in the area of vaccine pharmacovigilance.<sup>13,14</sup> Less than 1% of all AEFI reports worldwide came from Africa, according to this data. The data also revealed that ten African nations e.g. Egypt, the Democratic Republic of the Congo, and Nigeria, accounted for nearly 97% of these African AEFI reports.<sup>15</sup> Ghana, according to a 2020 study, had a reporting rate of 1.56 per 100,000 surviving infants, lower than the WHO target of 10.<sup>16</sup>

According to Olsson et al, vaccine safety remains relatively sub-optimal and underfunded within most LMICs.<sup>17</sup> An example of sub-optimal safety surveillance has been reported following NVIs for vaccines against meningococcus and yellow fever vaccines in West and Sub-Saharan Africa. During vaccine introduction, AEFI underreporting and delayed transmission of AEFI reports were all observed, despite the provision of appropriate local pharmacovigilance guidance and even when reporting was performed by specifically trained health care personnel within the context of a clinical study.<sup>18,19</sup> These observations reinforced the need for improvements in AEFI reporting.

Poor reporting of AEFI cases to the health system structures may be attributed to a number of reasons. The Socio-cultural factor is one of the factors operating outside the health service delivery system but has an impact on the capacity of the health system to provide service to the population in need. For instance, poverty affects access to health services by individual or community, in turn affecting the report and management of adverse event following immunization (AEFI) cases.<sup>20</sup> In another view, having a previous medical experience, whether as a patient, caregiver or even acquaintance provides basis for improved knowledge about such medical condition and availability/accessibility to care. The same is applicable to experience with AEFI. However, incident(s) that follows or experience surrounding the occurrence of the adverse event may positively or negatively affect subsequent reporting of AEFI in future.

Studied have clearly shown AEFI to be contributory to poor immunization coverage, especially in terms of how vaccine safety is perceived. For example, some of the reasons identified to be contributing to parents forgetting to bring their children for immunizations and to immunization dropout include rumors about and fears of AEFIs.<sup>21</sup> The mis-perception about vaccine safety may be influenced by the paucity of information given and poor/ absence of channels for reporting AEFIs when they occur.<sup>22,23</sup> These could be responsible for the poor reporting with only a small number of cases of AEFIs registered and documented at the national level.<sup>24</sup> Sufficient data from AEFI reporting is required if the situation will be properly addressed. It is really unclear if the issue is with reporting from the populace itself or with the way caregivers or healthcare workers (HCWs) record AEFIs as there are insufficient data to ascertain any of these claims.

However, many of the study that have looked into potential causes of poor reporting targeted health workers and provided less information about the reasons for poor reporting from the populace. As much as the aggregated reports are from the healthcare workers and their lack of reporting will highly impact the reporting rate, it is a known fact that all reports are generated from the information reported from the populace and failure to report from this level is a major determinant of AEFI reporting rate.

This study aimed to understand factors influencing AEFI reporting among the community members in Oyo State, Nigeria.

## METHODS

This study was a descriptive cross-sectional study carried out between September 2024 and March 2025 among vaccine recipients in Oyo State who received at least a dose of vaccine in the last 10 years or the caregivers of the vaccine recipient.

A sample size of 422, drawn using Cochran's infinite population technique was adopted; Where Z is standard normal deviate set at 1.96 (i.e. 95% CI), p is the estimated proportion of an attribute that is present in the population (0.5 or 50% used as prevalence in the study population was unavailable), q is the complementary probability (1-p), and d is the margin of error set at 5% (0.05).

The respondents were selected by using multistage (3 stages) sampling procedure.

### **The first stage**

Random selection of 3 LGAs, one per senatorial district in Oyo State.

### **Second stage**

Using PPS sampling methodology, 16, 18 and 8 settlements respectively were selected in Ibadan Northwest, Iseyin and Ogo Oluwa LGAs from the 384, 439 and 204 communities/settlements on their masterlist of settlements

### **The third stage**

random selection of 10 households in each selected settlements was done, then one eligible person was randomly selected per household.

Any person who resides in the study area who has received at least a dose of vaccine in the last 10 years was eligible study participant while non residential status in the study locations excludes a person from being participant.

A semi-structured questionnaire on ODK was used for the data collection to get information about socio-demographic characteristics, knowledge about AEFI, awareness of AEFI reporting, vaccine safety perception and previous AEFI experience among respondents. The tool was developed through extensive literature search and finalized following pretesting in similar local government areas to the study locations (10% of sample size), and deployment of Cronbach's Alpha technique for reliability test, ensuring coefficient reliability value of 0.8. In addition, content and construct validity were reviewed during the training of research assistants to ensure uniform understanding and interpretation by all research assistants that supported data collection.

The data was analyzed using IBM/Statistical Package for Social Science (SPSS) (version 24) statistical package. Cross tabulations of dependent and independent variables were done to establish associations.

The research hypotheses were tested to establish associations between the independent and dependent variables using the chi-square ( $\chi^2$ ) test at 5% probability

level for rejecting the null hypotheses. While controlling for the other independent variables, the relationship between the dependent variable and each of the independent variables were predicted using the logistic regression.

Respondents' knowledge was assessed using scale of 1 to 10, with score  $\geq 7$  termed good knowledge, 5-6 average knowledge and  $< 5$  termed poor knowledge. These same scoring were utilized for awareness about AEFI reporting.

These information from knowledge of AEFI, awareness of reporting, perception about vaccine safety and respondents' experience were cross tabulated with AEFI reporting and then logistic regression was used to further narrow down the relationship between the variables.

Ethical approval was obtained from the Oyo State Ministry of Health ethics review committee prior to the commencement of the study. Verbal informed consent was obtained from all participants and confidentiality, privacy and anonymity of information were maintained by ensuring no identifier on each respondents questionnaire.

Each respondent was interviewed in a private space and all collected data were downloaded and, kept by the investigator with no unauthorized access.

## **RESULTS**

The mean age of respondents was  $37.2 \pm 10.2$  and around 75% of total respondents are female, with similar proportion of respondents having secondary or above level of education. Greater than 80% of study participants lived within 5 km distance to the closest health facility and many of the respondents had 1 to 2 children (34.6%) or 3 to 4 children (43.8%) (Table 1).

As shown in Table 2, the age of respondents, distance from closest health facility, and number of children were statistically significantly associated with reporting of AEFI at p value of 0.035, 0.02, 0.035 respectively. However, as seen on Table 9, after adjusting for other variables, only respondent's age and number of children remained statistically significantly associated with AEFI reporting, with the result showing that the younger the respondent, the higher the odds of reporting AEFI.

Compared to respondents aged above 50 years, those aged less than 20 years were about 248 times more likely to report AEFI (OR: 248.51; 95% CI: 14.54-4248.33), those 21-35 years were about 62 times more likely to report AEFI (OR: 61.62; 95% CI: 9.24-411.02) and those aged 36 to 50 years were close to 18 times more likely to report AEFI (OR: 17.66; 95% CI: 4.07-76.72). In addition, having one to two children remain statistically significantly associated with AEFI reporting (OR: 0.08; 95% CI: 0.01-0.46).

**Table 1: Sociodemographic distribution of respondents (n=422).**

Variables	Value	Percentage
<b>Gender</b>		
Female	320	75.8
Male	80	19.0
Prefer not to answer	22	5.2
<b>Age of respondents (years)</b>		
<20	16	3.8
21-35	166	39.3
36-50	196	46.4
51-65	44	10.5
<b>Mean age (SD)</b>	37.2 ( $\pm$ 10.32)	
<b>Religion</b>		
Christianity	120	28.4
Islam	297	70.4
Traditional	5	1.2
<b>Highest level of education</b>		
Primary	101	23.9
Secondary	247	58.5
Tertiary	74	17.5
<b>Distance to closest HF</b>		
<1 km	33	7.8
2 km	203	48.1
5 km	107	25.4
>5 km	79	18.7
<b>Ethnicity</b>		
Hausa	3	7
Igbo	11	2.6
Yoruba	403	95.5
Others	5	1.2
<b>No. of children</b>		
0	51	12.1
1-2	146	34.6
3-4	185	43.8
$\geq$ 5	40	9.5

As shown in Table 3, there was no significant association between the knowledge of respondent about AEFI and the AEFI reporting. Table 4 however shows a statistically significant association between awareness of respondents about AEFI reporting and AEFI reporting at p value of 0.000, and as shown in Table 9, having average awareness about AEFI reporting remains statistically significantly associated with AEFI reporting even after adjusting for other variables (OR: 8.29; 95% CI: 2.78-24.76).

Table 5 shows the association between variables for respondents' perception about vaccine safety and AEFI reporting. There were statistically significant association between perceiving that many health workers administer vaccines in a harmful manner (p value =0.033), getting worried about vaccine safety when self or ward/family member is going for vaccination (p value =0.046), agreeing that follow-up counselling about AEFI is usually

conducted by health workers after vaccination (p value =0.034), agreeing that health workers provide counselling about AEFI management (p value =0.03) as well as perceiving that vaccine do more harm than good (p value =0.003) and AEFI reporting. The logistics regression as shown on Table 6 further elicits the relationships. Respondents who perceived that many health workers administer vaccines in harmful manner were about 2 times less likely to report AEFI compared to those who do not share that perception (OR: 0.52; 95% CI: 0.32-0.86). The odds of reporting AEFI was lower in respondents that perceived that vaccine do more harm than good compared to others (OR: 0.44; 95% CI: 0.26-0.74). Those that perceived that vaccines do more harm than good were above 2 times less likely to report AEFI compared to those who perceived otherwise. Results shown on Table 9 however show that after adjusting for other variables, none of these associations remain statistically significant.

**Table 2: Crosstab of respondents' sociodemographic characteristics and AEFI reported (n=268).**

Variables	AEFI reporting		Total (%)	$\chi^2$	P value
	No (%)	Yes (%)			
<b>Gender</b>					
Female	112 (56.3)	87 (43.7)	199 (100.0)	0.117	0.943
Male	30 (58.8)	21 (41.2)	51 (100.0)		
Prefer not to mention	10 (55.6)	8 (44.4)	18 (100.0)		
<b>Age of respondents (years)</b>					
<20	7 (53.9)	6 (46.2)	13 (100.0)	8.637	0.035*
21-35	65 (62.5)	39 (37.5)	104 (100.0)		
36-50	58 (47.9)	63 (52.1)	121 (100.0)		
51-65	22 (73.3)	8 (26.7)	30 (100.0)		
<b>Religion</b>					
Christianity	50 (63.3)	29 (36.7)	79 (100.0)	1.985	0.371
Islam	101 (54.0)	86 (46.0)	187 (100.0)		
Traditional	1 (50.0)	1 (50.0)	2 (100.0)		
<b>Respondents highest level of education</b>					
Primary	34 (69.4)	15 (30.6)	49 (100.0)	3.942	0.139
Secondary	89 (53.6)	77 (46.4)	166 (100.0)		
tertiary	29 (54.7)	24 (45.3)	53 (100.0)		
<b>Distance to closest HF</b>					
<1 km	10 (32.3)	21 (67.7)	31 (100.0)	9.657	0.02*
1-2 km	77 (61.1)	49 (38.9)	126 (100.0)		
2-5 km	32 (54.2)	27 (45.8)	59 (100.0)		
>5 km	33 (63.5)	19 (36.5)	52 (100.0)		
<b>No. of children</b>					
0	26 (76.5)	8 (23.5)	34 (100.0)	8.618	0.035*
1 to 2	54 (60.0)	36 (40.0)	90 (100.0)		
3 to 4	58 (50.9)	56 (49.1)	114 (100.0)		
>5	14 (46.7)	16 (53.3)	30 (100.0)		

\*Significant at p<0.05.

**Table 3: Crosstab of respondents' knowledge about AEFI and AEFI reported (n=268).**

Variables	AEFI reporting		Total (%)	$\chi^2$	P value
	No (%)	Yes (%)			
<b>Knowledge about AEFI</b>					
Good	84 (53.5)	73 (46.5)	157 (100.0)	4.825	0.09
Average	48 (67.6)	23 (32.4)	71 (100.0)		
Poor	20 (50.0)	20 (50.0)	40 (100.0)		

\*Significant at p<0.05.

**Table 4: Association between respondents' awareness about reporting AEFI and AEFI reported (n=268).**

Variables	AEFI Reporting		Total (%)	$\chi^2$	P value
	No (%)	Yes (%)			
<b>Awareness about AEFI reporting</b>					
Good	1 (10.0)	9 (90.0)	10 (100.0)	37.951	0.0001*
Average	78 (46.4)	90 (53.6)	168 (100.0)		
Poor	73 (81.1)	17 (18.9)	90 (100.0)		

\*Significant at p<0.05.

As shown in Table 7, there was statistically significant association between claiming from experience that referrals were made when required during the

management of AEFI and AEFI reporting (p value =0.0001). There was also statistically significant association between knowing from experience that

expenses of AEFI management were borne by self/family and AEFI reporting (p value =0.0001). Relationship between the claim that health workers dismiss complaints about AEFI as unnecessary and reporting AEFI was also

statistically significant at p value of 0.0001. Similarly, feeling encouraged, based on experience, to report or to guide others to report AEFI case(s) was statistically associated with AEFI reporting (p value =0.0001).

**Table 5: Association between vaccine safety perception and AEFI reporting among respondents (n=268).**

Variables	AEFI Reporting		Total (%)	$\chi^2$	P value
	No (%)	Yes (%)			
<b>Vaccines safe &amp; effective against VPDs</b>					
Agree	147 (57.2)	110 (42.8)	257 (100.0)	0.704	0.703
Don't Know	3 (50.0)	3 (50.0)	6 (100.0)		
Disagree	2 (40.0)	3 (60.0)	5 (100.0)		
<b>Many HWs administer vaccines in harmful manner</b>					
Agree	73 (49.7)	74 (50.3)	147 (100.0)	6.840	0.033*
Don't Know	30(68.2)	14 (31.8%)	44 (100.0)		
Disagree	49 (63.6)	28 (36.4)	77 (100.0)		
<b>Vaccines not necessary unless sick</b>					
Agree	63 (51.2)	60 (48.8)	123 (100.0)	2.883	0.237
Don't Know	16 (64.0)	9 (36.0)	25 (100.0)		
Disagree	73 (60.8)	47 (39.2)	120 (100.0)		
<b>AEFI commonly developed</b>					
Agree	106 (53.8)	91 (46.2)	197 (100.0)	2.688	0.261
Don't Know	20 (62.5)	12 (37.5)	32 (100.0)		
Disagree	26 (66.7)	13 (33.3)	39 (100.0)		
<b>I get worried about vaccine safety when my family/ I am going to receive vaccine</b>					
Agree	98 (56.6)	75 (43.3)	173 (100.0)	6.176	0.046*
Don't Know	6 (31.6)	13 (68.4)	19 (100.0)		
Disagree	48 (63.2)	28 (36.8)	76 (100.0)		
<b>Pre-counselling about AEFI done by HWs before vaccination</b>					
Agree	116 (56.6)	89 (43.4)	205 (100.0)	0.900	0.638
Don't Know	19 (63.3)	11 (36.7)	30 (100.0)		
Disagree	17 (51.5)	16 (48.5)	33 (100.0)		
<b>Follow-up counselling about AEFI done by HWs after vaccination</b>					
Agree	100 (53.8)	86 (46.2)	186 (100.0)	6.744	0.034*
Don't Know	15 (48.4)	16 (51.6)	31(100.0)		
Disagree	37 (72.5)	14 (27.5)	51(100.0)		
<b>HWs provide counselling about AEFI management</b>					
Agree	111 (54.7)	92 (45.3)	203 (100.0)	6.984	0.030*
Don't Know	10 (43.5)	13 (56.5)	23 (100.0)		
Disagree	31 (73.8)	11 (26.2)	42 (100.0)		
<b>Satisfy with AEFI counselling HWs provide</b>					
Agree	106 (54.6)	88 (45.4)	194 (100.0)	4.320	0.115
Don't Know	12 (48.0)	13 (52.0)	25 (100.0)		
Disagree	34 (69.4)	15 (30.6)	49 (100.0)		
<b>Safety precautions on AEFI observed at immunization posts</b>					
Agree	103 (53.6)	89 (46.4)	192 (100.0)	3.341	0.188
Don't Know	34 (68.0)	16 (32.0)	50 (100.0)		
Disagree	15 (57.7)	11 (42.3)	26 (100.0)		
<b>Vaccines do more harm than good</b>					
Agree	36 (42.9)	48 (57.1)	84 (100.0)	11.939	0.003*
Don't Know	13 (81.3)	3 (18.8)	16 (100.0)		
Disagree	103 (61.3)	65 (38.7)	168 (100.0)		

\*Significant at p<0.05.

**Table 6: Logistic regression of respondents' vaccine safety perception and AEFI reporting (n=268).**

Variables	Crude odds ratio	95% CI	P value
<b>Many HWs administer vaccines in harmful manner</b>			
Agree	0.52	0.32-0.86	0.011*
Disagree/ don't know	-		
<b>I get worried about vaccine safety when my family/ I am going to receive vaccine</b>			
Agree	0.99	0.60-1.64	0.975
Disagree/ don't know	-		
<b>Follow-up counselling about AEFI done by HWs after vaccination</b>			
Agree	0.67	0.39-1.14	0.143
Disagree/ don't know	-		
<b>HWs provide counselling about AEFI management</b>			
Agree	0.71	0.40-1.26	0.235
Disagree/ don't know	-		
<b>Vaccines do more harm than good</b>			
Agree	0.44	0.26-0.74	0.002*
Disagree/ don't know	-		

\*Significant at p<0.05

**Table 7: Association between previous AEFI experience of respondents and AEFI reporting (n=268).**

Variables	AEFI reporting		Total (%)	$\chi^2$	P value
	No (%)	Yes (%)			
<b>Reported cases of AEFI are given proper attention</b>					
Yes	21 (51.2)	20 (48.8)	41 (100.0)	0.596	0.440
No/ Don't Know	131 (54.7)	96 (45.3)	227 (100.0)		
<b>Referrals are made during AEFI management when required</b>					
Yes	39 (38.6)	62 (61.4)	101 (100.0)	21.637	0.0001*
No/ Don't Know	113 (50.8)	54 (49.2)	167 (100.0)		
<b>Expenses of AEFI management borne by case/ family</b>					
Yes	70 (44.6)	87 (55.4)	157 (100.0)	22.721	0.0001*
No/ Don't Know	82 (73.9)	29 (26.1)	111 (100.0)		
<b>HWs dismisses complaints about AEFI as unnecessary report</b>					
Yes	42 (26.9)	114 (73.1)	156 (100.0)	139.973	0.0001*
No/ Don't Know	110 (98.2)	2 (1.8)	112 (100.0)		
<b>I feel encouraged to report/ guide other to report</b>					
Yes	87 (89.7)	10 (10.3)	97 (100.0)	67.333	0.0001*
No/ Don't Know	65 (38.0)	106 (62.0)	171 (100.0)		
<b>AEFI should be left unreported until helpless based on my experience</b>					
Yes	34 (56.7)	26 (43.3)	60 (100.0)	0.000	0.993
No/ Don't Know	118 (56.4)	90 (43.6)	208 (100.0)		

\*Significant at p<0.05.

Table 8 depicted that the respondents who based on experience reported that referrals were made when required when about 3 times less likely to report AEFI compared to others (OR: 0.30; 95% CI: 0.18-0.50). The odds of reporting AEFI decreases with knowing from experience that cost managing AEFI is borne by self/ family (OR: 0.29; 95% CI: 0.17-0.48). Those with this claim are 3.5 times less likely to report AEFI. Similarly, the odds of reporting AEFI greatly decreases with knowing from experience that health workers dismiss

complaint about AEFI as unnecessary report, those who claim to know from experience that health workers dismiss complaint about AEFI as unnecessary report were about 100 times less likely to report (OR: 0.01; 95% CI: 0.02-0.03) compared to respondents who do not. Respondents that based on their AEFI experience, felt encouraged to report/ guide others to report were about 14 times more likely to report AEFI compared to those that did not have favorable experience that encouraged them to report/guide other to report (OR: 14.19; 95% CI: 6.88-29.25).

**Table 8: Logistic regression of selected variables and AEFI reporting among respondents (N=268).**

Variables	Crude odds ratio	95% CI	P value
<b>Referrals are made during AEFI management when required</b>			
Yes	0.301	0.18-0.503	0.0001*
No/ don't know			
<b>Expenses of AEFI management borne by case/ family</b>			
Yes	0.285	0.17-0.48	0.0001*
No/ don't know			
<b>Based on experience, HWs dismisses complaints about AEFI as unnecessary report</b>			
Yes	0.007	0.02-0.03	0.0001*
No/ don't know			
<b>Based on experience, I feel encouraged to report/ guide other to report</b>			
Yes	14.19	6.88-29.25	0.0001*
No/ don't know			

\*Significant at p<0.05

**Table 9: Independent predictors of AEFI reporting among respondents (n=268).**

Variables	Adjusted Odds Ratio	95% CI	P value
<b>Age of the respondents</b>			
<20	248.51	14.54-4248.33	0.001*
21-35	61.62	9.24-411.02	0.001*
36-50	17.66	4.07-76.72	0.001*
51-65			
<b>No. of children</b>			
0	3.76	0.723-19.49	0.115
1 to 2	0.08	0.01-0.46	0.004*
3 to 4	0.71	0.20-2.46	0.584
>5			
<b>Awareness about AEFI reporting</b>			
Good	8.45	0.64-111.17	0.104
Average	8.29	2.78-24.76	0.001*
Poor			
<b>Many HWs administer vaccines in harmful manner</b>			
Agree	0.63	0.24-1.67	0.359
Disagree			
<b>Vaccines do more harm than good</b>			
Agree	0.24	0.07-2.04	0.770
Disagree/ don't know			
<b>Referrals are made during AEFI management when required</b>			
Yes	0.21	0.08-0.57	0.002*
No/ don't know			
<b>Expenses of AEFI management borne by case/ family</b>			
Yes	0.28	0.10-0.73	0.010*
No/ don't know			
<b>HWs dismisses complaints about AEFI as unnecessary report</b>			
Yes	0.002	0.000-0.019	0.001*
No			
<b>I feel encouraged to report/ guide other to report</b>			
Yes	0.70	0.10-4.92	0.720
No			

\*Significant at p<0.05

After adjusting for other variables, all these association remain statistically significant except feeling encourage to report or guide others to report as shown in Table 9.

## DISCUSSION

The study showed that age of respondents, distance of respondent's residence from closest health facility and number of respondent's children as the socio-demographic characteristics that have statistically significant relationship with AEFI reporting. However, following adjustment with other variables that have statistically significant association with AEFI reporting, only the association between age and number of children with AEFI reporting remain statistically significant among the socio-demographic characteristics considered in this study. For the age, those aged less or equal to 20 years were most likely to report AEFI cases, followed by those aged 21 to 35 years and then those 36 to 50 years compared to those aged 51 to 65 years. This implies that the younger the person, the more likely he/she is likely to report an AEFI when it occurs. This finding can be due to the fact that many young adults/teen parents have no previous experience of AEFI (that they can remember-might have AEFI as kids), often struggle with social network as found in a study by De Jonge, thus deal with their pregnancies/birth alone, and may see the AEFI situation/ symptom as strange and see the health workers/health facilities as the point of call for assistance.<sup>25</sup> However, the older ones may become tougher through series of experience, ranging from knowing basic management of non-serious AEFIs to experiencing bad attitude from health workers in previous instances that deter them from reporting subsequent cases as they become older. On the other hand, having one or two children stand out to be statistically significant in relation to reporting AEFI. Those with one or two children were about 13 times less likely to report an AEFI compared to those with more than 5 children. Many people with 1 to 2 children, especially if young and with new family, tend to be guided by family support (old folks) in this part of the world and this may be responsible for the finding because these people result to home remedies as prescribed by the older family member and tradition instead of reporting back to the health facilities unlike the more autonomous persons with greater than 5 children.

This is in tandem with results from a systematic review and meta-analysis study by Balgovind and Mohammadnezhad, which indicated that being young mothers and number of children in the family play key role in immunization decisions.<sup>6</sup> However, the result from this study contrasts with result from a study conducted in Ghana which reported 65% reduction in odds of health seeking behavior of caregiver with forth born or higher birth order children.<sup>26</sup> The later however focuses on general health seeking behavior and not only immunization and AEFI reporting as is the focus in this study.

The community members knowledge about AEFI in this study does not show statistical association with AEFI reporting, though respondents with average knowledge reported more AEFI cases. This finding implies that though providing knowledge about AEFI to community members is a great effort at improving AEFI reporting, it is not enough to really bring about the required improvement, unless other considerations are well targeted.

Awareness level about AEFI reporting was statistically significantly associated with AEFI reporting, even after adjusting for age, number of children, and some vaccine safety perception and experience variables that were statistically significantly associated with AEFI reporting in the logistic regression. Average awareness about AEFI reporting resulted in greater than 8 times likelihood of reporting AEFI. This finding indicates that when more community members know about reporting AEFI in terms of why, where, when and to whom to report AEFI cases, there will be improvement in the pharmacovigilance. The result from this study is in contrast with findings from a 2014 study conducted in Australia which reported no association between the awareness of surveillance system and reporting of AEFI.<sup>27</sup> The later study was however among Australians with a completely different demography compared to the study area in this study.

The perception of community members about vaccine safety was explored using various information that may inform what community members think about vaccine safety. Perceiving that many health workers administer vaccines in a harmful manner resulted in about 2 times less likelihood of reporting AEFI from this study, though the association becomes insignificant after adjusting for other variables such as age, number of children and some other vaccine safety perception and experience variables. The same finding was applicable to perceiving that vaccine do more harm than good with those with such perception just more than 2 times less likely to report AEFI compared to those that perceived otherwise. The finding from the logistic regression may be as result of clients already losing faith about any good coming from the health worker, who are already being perceived as providing the good intervention in a manner that may be harmful, therefore seeking help from such individual may also be perceived as a futile effort.

Getting worried about vaccine safety when going for vaccination, believing that follow-up counselling by HWs about AEFI and counselling about AEFI management are done well also showed significant association with the AEFI reporting. Respondents who agreed to getting worried about vaccine safety when they or their family member was to go for vaccination were more likely to report AEFI. This association is similar to findings from a study by Parella et al which indicates that those who perceived that a serious reaction would occur following the immunization were more likely to report AEFI.<sup>27</sup> In addition, from this study, those who believed that HWs

provide follow-up counselling and those who believed HWs provide counselling about AEFI management were more likely to report AEFI. However, these associations become insignificant when subjected to logistic regression. Though the unique effect of these variables were not observed in this study, the importance of providing counselling to allay the fear of the clients cannot be over-emphasized. Adubi et al in their study observed that providing counselling can result into higher number of observed AEFI cases being reported.<sup>23</sup>

As humans, our previous experience could have a serious impact in the way we act or respond to situations. In this study, we try to explore how previous AEFI experience of respondents affect their manner of reporting AEFI cases. Respondents who claimed to know from experience that referrals were made during AEFI management when required, those that claimed to know from experience that expenses of AEFI management were borne by the case or his/her family members and those who also claimed to know from experience that many health workers dismiss complaints about AEFI as unnecessary report were less likely to report AEFI when it occurs. These associations remain statistically significant even after adjusting for other variables such as age, no of children and some other vaccine safety perception variables. These finding corroborates the results from a systematic review conducted in 2017 that identified prior negative reporting experience as some of the main barriers to patient reporting of adverse drug reactions.<sup>28</sup> The finding is not surprising as it is normal for any human to see reporting as unnecessary after experiencing lack of desired attention during previous report(s). In addition, the fear of referral may also be linked to fear of increased out of pocket expenditure that may likely occur in management of the case in higher healthcare facility.

Behavioral/attitudinal reaction to reported cases of AEFI should be included in the AEFI training package to prevent dissuading people from reporting AEFI cases. Health workers should be guided to treat all cases of AEFI with due regards irrespective of being non serious or serious cases.

Study limitations were: there was limited literature about AEFI reporting from the populace, thus limiting the comparison that was possible in discussing the results/findings from this study. Causal relationship cannot be established with this study because of the cross-sectional study design which cannot determine temporal sequence of the identified factors and the AEFI reporting.

## CONCLUSION

In conclusion, this study has demonstrated that knowledge alone is not enough to improve AEFI reporting, rather good awareness about the reporting system, perception about vaccine safety and satisfactory memorable experience are very important to ensure that majority of AEFI cases that occur get reported.

All these can only be achieved by improving on the guidance that is being provided to the health workers who are closest to the people that receives vaccines and is expected to be the first recipient of news of AEFIs when they occur, as well as professionally crafted mass awareness messages about vaccine safety and AEFI reporting targeted at improving community members' perception about vaccine safety.

There is need to have more research studies on AEFI targeting community people as the cases to be reported actually comes from these population. Intervention studies with follow up by future research can also help in assessment of the reporting patterns to better understand magnitude of effect on AEFI reporting from the community if there is improvement on awareness about reporting as well as improving peoples' experience when cases are reported.

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