

# Documenting capacity and existing gaps in reporting adverse events following immunisation in Northern Ghana: a quantitative cross-sectional survey of healthcare workers

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## ABSTRACT

**Background** Immunisation remains an indispensable tool in preventing infectious diseases. A robust pharmacovigilance system assures the public of vaccine safety, particularly in countries like Ghana where there is relatively low reporting of adverse events following immunisation (AEFIs). We explored the experiences of health workers in Ghana to ascertain the existing capacity for data collection and information reporting flows for health events associated with vaccination in the country.

**Methods** We conducted a cross-sectional quantitative survey among healthcare workers (HCWs) in Ghana between December 2020 and April 2021. We documented their experiences with regard to knowledge, perceptions and practice of reporting AEFIs to the national pharmacovigilance centre (Ghana Food and Drugs Authority).

**Results** Out of 851 participants, 49.2% said their institutions had processes for AEFI reporting. Additionally, 25% of participants had encountered an AEFI within the past year. Out of this number, 55% reported the AEFI. Only 31.2% of community health nurses (vaccinators) considered AEFI reporting part of their job description. Most HCWs (59.34%) had fair to poor knowledge of AEFIs. The main factors affecting AEFI reporting were heavy workload and lack of time (54.1%) and unavailability of reporting forms (57.5%). Only 2% of participants were aware AEFIs could be reported online. Logistic regression analysis revealed female gender as a negative factor influencing AEFI reporting. Training ( $p<0.0001$ ) and profession ( $p=0.006$ ) significantly influenced knowledge level of AEFIs. Results of the multiple binary logistic regression indicate that the age and profession of HCWs are the main factors influencing knowledge of reporting AEFIs.

**Conclusion** The vaccine pharmacovigilance system in Ghana can be strengthened with targeted regular training on AEFI reporting, guidelines for reporting in all health facilities and prompt feedback from the national pharmacovigilance centre to health workers.

## WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Previous studies have focused on low reporting of adverse events following immunisation (AEFI) by vaccinators and have emphasised the fear of being accused legally and the lack of supportive supervision as reasons for low reporting of AEFIs in Ghana.

## WHAT THIS STUDY ADDS

⇒ This study sought to find out the knowledge and experiences of both prescribers and vaccinators in reporting AEFIs.  
⇒ Lack of continuous training and established guidelines for reporting at health facilities contributes to under-reporting among both vaccinators and prescribers.  
⇒ Younger health workers, women and lower-level health workers were least likely to report AEFIs.  
⇒ Poor feedback from the national pharmacovigilance centre contributed to low reporting.

## HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ The emergence of novel viral diseases of pandemic potential has led to rapid production of new vaccines and attendant vaccine hesitancy due to fears of vaccine safety.  
⇒ Improved pharmacovigilance would assure the public and help fight these diseases.  
⇒ Targeted regular training of health workers, clear guidelines on AEFI reporting in health facilities and prompt feedback to health workers would improve vaccine pharmacovigilance.

## INTRODUCTION

Immunisation is one of the most successful and cost-effective public health strategies to reduce mortality and morbidity from infectious diseases in both children and adults. It is estimated that immunisation has prevented two to three million deaths annually by 2018.<sup>1 2</sup> During the same period, it was estimated that

about 129 countries worldwide had reached at least 90% coverage of the third dose of the diphtheria and tetanus toxoids and pertussis-containing vaccine.<sup>1 2</sup> Despite this success, about 20 million children still do not receive basic vaccines and more than 1.5 million people die from vaccine-preventable diseases every year.

Continuous monitoring of immunisation activities is critical to ensuring that policies aimed at improving immunisations are guided by up-to-date data. This is because, although generally safe, vaccines can on rare occasions cause harm and illness to recipients due to their adverse effects.<sup>1 3-6</sup> Difficulty in distinguishing between adverse events caused by vaccines, natural infections and underlying causes has contributed to confusion in reporting adverse events and anxieties about vaccine safety by the public and the medical community.<sup>3</sup> Vaccine hesitancy in part due to these anxieties continues to be a major public health issue.<sup>7</sup>

Surveillance on vaccine safety is crucial to build trust and reassure the public.<sup>7</sup> Vaccine safety entails ensuring and monitoring all aspects of immunisation, including vaccine quality, adverse events, storage, handling and management of waste.<sup>8</sup> Reporting of adverse events following immunisation (AEFIs) is a key component of functional immunisation and vaccine safety monitoring systems. Postmarketing surveillance of vaccines is important because vaccines are mostly given to healthy people and in large numbers; clinical trials involve small numbers of people and do not include certain categories of people; and there is rapid development of vaccines with the emergence of infectious diseases such as COVID-19.<sup>9 10</sup>

The Global Vaccine Action Plan for vaccine safety monitoring has set a target of minimal reporting ratio of 10 AEFIs per 100 000 surviving infants as a proxy measure for a functional AEFI reporting system.<sup>11</sup> In 2015, the global average ratio for AEFI reporting was 549 AEFI reports per 100 000 surviving infants. About 60% of countries in the WHO Region of the Americas reported at least 10 AEFIs per 100 000 surviving infants, followed by 55% in the European, 43% in the Eastern Mediterranean, 33% in the Western Pacific, 27% in the South-East Asian and only 21% in the African region.<sup>11</sup> 'To boost reporting of AEFIs in Africa, the WHO in conjunction with other partners is working with national pharmacovigilance authorities in Africa to enhance reporting by developing national plans, additional training and investment in vaccine pharmacovigilance. However few countries have implemented these plans'.<sup>12</sup>

Consequently, the reporting rates of AEFIs in developing countries are low, with over-reliance on routine systems which are subject to under-reporting and poor pharmacovigilance infrastructure.<sup>13</sup> Ghana is no exception to this, with the highest case detection rate of 61.45 AEFIs per 100 000 surviving infants recorded in 2018.<sup>12</sup>

As more vaccines designed exclusively for use on the continent are introduced into African countries, additional attention is required for vaccine safety systems to

function efficiently across the continent.<sup>14</sup> This requires strengthening of surveillance infrastructure in most countries in Africa. Additional efforts are required to improve the existing capacity with respect to data quality, reporting and management.<sup>11 15 16</sup>

This study sought to document the existing capacity for data collection and information reporting flows for health events associated with vaccination in Ghana. It sought to identify the gaps, potential and opportunities in the Ghanaian health system for further development of vaccinovigilance.

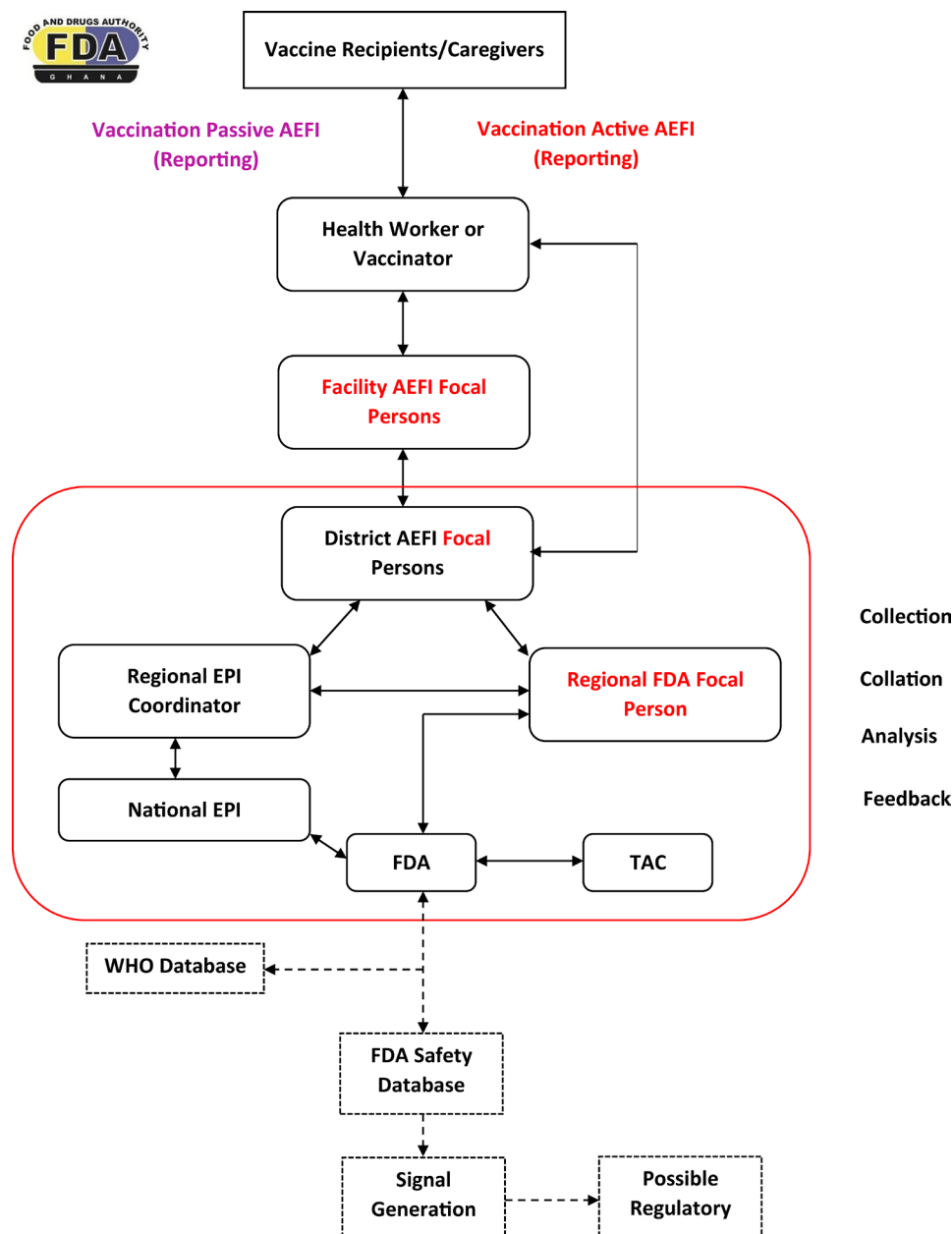
## METHODS

### Study design

This study was a cross-sectional quantitative survey that involved administering a structured questionnaire (see Post Marketing Surveillance questionnaire nurses and prescribers' version 2.0, dated 27 January 2021, in the online supplemental material) to front-line healthcare workers (HCWs) in the five regions of Northern Ghana. The study was carried out between December 2020 and April 2021. A qualitative survey involving focus group discussions and interviews of caregivers, as well as important stakeholders such as the heads of health facilities and the Ghana Food and Drugs Authority (FDA) and Expanded Program on Immunization (EPI) officers, was also conducted to identify barriers and facilitators to reporting AEFIs. The qualitative results will be published in a separate article. The study took place in 25 selected districts out of 54 in the five regions of Northern Ghana: Northern (seven districts), Northeast (three districts), Savanna (three districts), Upper West (five districts) and Upper East (seven districts).

### Healthcare system and pharmacovigilance

The healthcare system in Northern Ghana mimics the national healthcare system and comprises a teaching hospital, regional hospitals, district hospitals, health centres, maternity homes, polyclinics and community-based health planning and service (CHPS) compounds which deliver primary healthcare including immunisations. Most health facilities are owned and run by the government, with a few privately owned facilities and faith-based facilities such as Christian Health Association of Ghana (CHAG) facilities. The EPI is responsible for providing immunisations and detecting and reporting of AEFIs to the Ghana FDA. According to the Ghana FDA guidelines, the primary reporter of an AEFI could be a public health worker, vaccinator, hospital staff, volunteer, caregiver or any other person who comes across an AEFI. When HCWs receive complaints from persons who received a vaccine or from their caregivers, these HCWs complete and submit AEFI reporting forms to the focal person in charge of AEFIs in their health facility, who then reports it to the district disease control officer or to the FDA regional office. Feedback from the FDA is given to the reporter, the facility and the EPI district



**Figure 1** Flow chart of AEFI surveillance in Ghana. AEFI, adverse events following immunisation; EPI, Expanded Program on Immunization; FDA, Food and Drugs Authority; TAC, Technical Advisory Committee.

coordinator (shown in figure 1; see online supplemental material). Online reporting of AEFIs by health workers is done using an application developed by the Ghana FDA. The Med Safety App for online reporting of AEFIs and adverse drug reactions was launched by the Ghana FDA on 25 June 2019 to enable health workers and patients to directly report adverse events online to the pharmacovigilance centre.<sup>17</sup> Currently, there is no periodic monitoring of AEFI reporting by health workers and no supportive supervision programme. Furthermore, there is no reward or penalty system for reporting of AEFIs.

HCWs who worked at vaccination clinics and/or have administered vaccinations as well as prescribers took part in the survey in each region. Prescribers included anyone who prescribed treatment in their health facilities, such

as nurses, physician assistants and doctors. Participants per district included those from at least one CHPS compound, health centre and hospital as per availability of these facilities.

### Data sources and collection

A detailed and elaborate structured questionnaire was developed and administered to front-line health workers. The questionnaire was multiple choice and developed on vaccinovigilance themes, including knowledge and schedules of immunisation, vaccine safety, risks and benefits of immunisation, AEFIs, and monitoring and regulation of AEFIs, among others.

Detailed knowledge of AEFI, including its definition, was sought. Other questions were about the surveillance

system and the health system capacity to detect AEFIs, as well as the number of AEFIs seen and reported. Sociodemographic data such as age, gender, profession, rank and years of practice were also collected.

We documented participants' experiences on the ground with regard to their knowledge, perceptions and practice of reporting AEFIs to the FDA or to EPI to gain insight into why AEFIs may not be reported, as well as the challenges in the reporting process. The questionnaire was developed, pilot-tested in selected health facilities and adapted before being used in the study.

Trained field staff administered the questionnaire to the participants. Prior to administering the questionnaire, written informed consent was sought from each participant.

### Sample size and sampling of participants

Sample size was calculated based on the the percentage of HCWs who reported at least one AEFI in the past year. We assumed an estimate of 50% AEFI reporting rate among HCWs. Population proportion sample formula with 95% confidence level, 5% margin of error and 10% non-response rate was used to calculate sample size for the HCWs. A sample size of 385 was required. Adjusting for a 10% non-response rate gave a sample size of 424. We also assumed a design effect of 2 and therefore aimed for a total of 848 HCWs in the study.

We interviewed 851 participants from 25 of 54 districts in the study area. Since the regions vary by size and the number of districts per region also varies, we applied the principle of proportionate per size such that the larger regions were well represented. The regional capital of each region was selected for the study, in addition to other districts which were randomly selected in each region. All health facilities in each selected district were listed and grouped according to their level. At least one hospital, one health centre and at least two CHPS facilities were randomly selected from each level according to availability and staffing level. A minimum of two prescribers each from the hospital, health centre and CHPS facility and a minimum of eight vaccinators were interviewed per district out of the randomly selected facilities. Per region, there were participants from at least one CHAG health facility and one private facility at any level. Within health facilities, participants were selected based on time, place availability, profession and job description (vaccinator/prescriber). A variety of staff were interviewed: doctors, physician assistants, nurses and healthcare assistants, and others such as disease control officers and pharmacists.

### Data and statistical analysis

Data were entered and coded into REDCap software. The data set was cleaned for missing values, anomalies and internal consistency of responses. Data analysis was done using Stata V.16 statistical software. Data were summarised by generating frequencies, means and SDs of all dependent and independent variables. Composite scoring was also used to assess knowledge and experience.

The capacity of health practitioners for data gathering was assessed using univariate analysis. A cross-tabulation analysis was conducted to assess the gaps, potentials and possibilities of reporting AEFIs among healthcare professionals. Composite scoring analysis was used to measure their knowledge and experience of AEFIs and these were categorised into three: poor, score below the median; fair, score is equal to the median; and good, score above the median. The questions were in the form of either a multiple-choice answer or a yes, no or not sure answer. Correct answers receive 1 point, while incorrect answers were allocated 0 points. A 'not sure' answer also receives 0 points. Further binary logistic regression analysis of factors that influence the reporting of AEFI was also done.

### Quality assurance

After training data collectors, tests for validity and reliability were carried out at the pilot stage of the investigation before the main phase of data collection. The pilot test was conducted among 85 randomly selected health workers at the War Memorial Hospital in the Kassenanankana municipal district after permission was sought from relevant authorities and participants. The validity of the questionnaire was assessed for adequacy, appropriateness, inclusiveness and relevance to the concept under study. In addition, the pilot study sought to check reliability and completeness of the questionnaire.

### Ethical considerations

Informed consent was obtained from all respondents who participated in the primary data collection. Administrative permission was obtained from the regional directors of health services of the various regions. Participants were assured of the strictest confidentiality, with no subject identifiers shown on the forms.

### Patient and public involvement

No patients were involved in this survey. A pilot study was done which involved administering the preliminary questionnaire to a few health workers. The questionnaire was then refined to ensure validity, reliability and completeness. Study findings would be disseminated to the health facilities where the survey took place, the Ghana Health Service and the Ghana FDA.

## RESULTS

### Background characteristics of HCWs

A total of 851 participants were included in the study. Majority of the 851 participants were female (440, 51.7%), with 510 participants (59.9%) between the ages of 30 and 39. Nurses constituted a substantial fraction of the participants (34.1%), with 68% of the interviewees having practised for at least 5 years. Furthermore, most of the participants (402, 47.2%) had a certificate level of education and 381 (44.8%) currently work at health centres (shown in [table 1](#)).



**Table 1** Background characteristics of healthcare workers (N=851)

Variables	Frequency	Percentage
Gender		
Male	411	48.3
Female	440	51.7
Age group		
20–29	278	32.7
30–39	510	59.9
40–49	43	5.1
50–59	9	1.1
60+	4	0.5
Missing	7	0.8
Profession		
Healthcare assistant	51	6.0
Nurse	290	34.1
Physician assistant	50	5.9
Medical doctor	14	1.7
Community health nurse	263	30.9
Midwife	126	14.8
Disease control officer	20	2.4
Other*	37	4.4
Years of practice		
0–5	583	68.8
6+	264	31.2
Missing	4	0.5
Highest level of education		
Certificate†	402	47.2
Diploma	324	38.1
Degree	113	13.3
Master's/MPhil	3	0.4
MD	5	0.6
Membership/fellowship	4	0.5
Type of facility		
CHPS compound	170	20
Health centre	381	44.8
Hospital	248	29.1
Private hospital	17	2
Others	35	4.1

\*Other includes pharmacists and disease control officers.

†Certificate programme lasts 2 years (healthcare assistants and some community health nurses), diploma lasts 3 years and degree programme lasts 4 years after high school in Ghana. CHPS, community-based health planning and service.

### Capacity for data collection (N=851)

The capacity of health practitioners for data gathering was assessed using univariate analysis. In this study, only 419 (49.2%) healthcare personnel said their institutions

had established processes (written guidelines and procedures) for recognising and reporting AEFIs. Just a little above half (57.9%) said they had the reporting form in their facility. In addition, most healthcare professionals were not aware that they could get AEFI forms from the Pharmacy Council (832, 97.8%), FDA (752, 88.4%), online (833, 97.9%), district health management team (528, 62.0%) and health facility (650, 76.4%). Additionally, 25% of those interviewed had encountered an AEFI within the past year. A little over half (55%) of health workers who encountered an AEFI within the past year reported it. The pharmacovigilance centre did not give feedback to 61.1% of those who reported AEFIs.

### Gaps and potential and opportunity (N=851)

A cross-tabulation analysis was conducted to assess the gaps, potentials and possibilities of healthcare professionals in detecting and reporting AEFIs, described in table 2. According to the data, close to half of physician assistants had received AEFI training, while nurses received the least (31.0%). HCWs who worked for at least 6 years received more AEFI training (56.4%) than those who worked for 5 years or less (29.8%). In addition, HCWs with a membership or fellowship level of education had a higher proportion of AEFI training (50.0%) compared with others. The CHPS compounds had the highest percentage of AEFI training (42.9%) at the health facility level compared with the private facilities (17.6%).

Majority of the different HCWs did not consider reporting AEFIs as part of their job description. Only 31.2% of community health nurses (CHNs) (vaccinators) considered AEFI reporting as part of their job description.

### Knowledge and experiences of health workers

Composite scoring analysis was used to measure overall knowledge on AEFI and this was categorised into three: poor, score below the median; fair, score is equal to the median; and good, score above the median. The questions were in the form of either a multiple-choice answer or a yes, no or not sure answer. Correct answers receive 1 point, while incorrect answers were allocated 0 point. A 'not sure' answer also receives 0 points. Most HCWs (59.34%) had fair to poor knowledge of AEFIs, while 40.66% had good knowledge.

### Factors affecting AEFI reporting

Table 3 summarises the results of the univariate analysis of the factors influencing AEFI reporting. The main factors affecting AEFI reporting among HCWs were found to be heavy workload and lack of time (54.1%), as well as unavailability of reporting forms (57.5%). Furthermore, nearly three-quarters of healthcare professionals (75.3%) thought that healthcare personnel should be rewarded for reporting AEFIs, with extra points on the performance appraisal form (33.1%) being the most popular option.

**Table 2** Gaps, potential and opportunity

Variables	Have you had training in AEFI since you started working?		
	Yes		Total
	Frequency	Percentage	responses (n)
Profession (N=851)			
Healthcare assistant	17	33.3	51
Nurse	90	31	290
Physician assistant	24	48	50
Medical doctor	4	28.6	14
Community health nurse	114	43.3	263
Midwife	48	38.1	126
Disease control officer	15	75	20
Other	12	32.4	37
Years of practice			
0–5	174	29.8	583
6+	149	56.4	264
Highest level of education			
Certificate	140	34.8	402
Diploma	135	41.7	324
Degree	45	39.8	113
Master's/MPhil	0	0	3
MD	2	40	5
Membership/fellowship	2	50	4
Type of facility			
CHPS compound	73	42.9	170
Health centre	153	40.2	381
Hospital	82	33.1	248
Private hospital	3	17.6	17
Others	13	37.1	35
Is 'reporting AEFIs' part of your job description?			
Yes			
	Frequency	Percentage	Total
Profession			
Healthcare assistant	9	17.6	51
Nurse	29	10	290
Physician assistant	7	14	50
Medical doctor	2	14.3	14
Community health nurse	82	31.2	263
Midwife	12	9.5	126
Disease control officer	13	65.0	20
Other	5	13.51	57

AEFIs, adverse events following immunisation; CHPS, community-based health planning and service.

### Relation between training and knowledge level

Compared with individuals who were not trained (19.4%), trained healthcare personnel were more knowledgeable (33.7%) about AEFI reporting. Non-trained healthcare professionals, on the other hand, had a higher rate of poor knowledge concerning AEFI reporting (80.6%)

**Table 3** Factors affecting AEFI reporting

Variables	Percentage
Heavy workload and lack of time.	54.10
Unavailability of reporting forms.	57.50
Ignorance of reporting procedure and how forms can be obtained.	31.50
Ignorance of the need to report AEFIs.	25.60
All AEFIs are well documented before the award of marketing authorisation for medications.	11.40
Inability to recognise AEFIs.	23.40
Fear of being legally accused of administering the wrong medication.	22.90
Lack of confidence in the reporting system.	28.30
Fear of the negative impact on the vaccine manufacturer.	8.10
Fear of negative publicity for my facility.	19.20
Consumers who suffer an AEFI should be responsible for reporting it.	7.30
Lack of reward or incentive package for personnel who report it.	17.20
It is not part of my professional responsibility to report AEFIs.	7.50
The AEFI focal person is the only one mandated to report AEFIs in my facility.	7.50
Difficulty identifying an AEFI.	12.60
Other.	14.30
Do you think health workers should be rewarded for reporting AEFIs?	75.30
AEFIs, adverse events following immunisation.	

than trained healthcare professionals (66.3%). Also, training ( $p<0.0001$ ) and profession ( $p=0.006$ ) significantly influenced knowledge level of AEFI (table 4).

### How to improve AEFI reporting among health workers

Continuous professional education and training on pharmacovigilance could improve AEFI reporting according to most healthcare assistants (82.4%), nurses (70.0%), physician assistants (90.0%), medical doctors (92.9%), community health workers (74.9%) and midwives (77.8%). The incorporation of pharmacovigilance and AEFI reporting into the training curriculum was another strategy to improve AEFI reporting according to the healthcare professionals (healthcare assistants: 66.7%; nurses: 60.3%; physician assistants: 68.0%). Most physician assistants (60.0%) and medical doctors (64.3%) cited the national pharmacovigilance centre's creation of awareness to improve AEFI reporting. Furthermore, except for medical doctors (57.1%), other health professionals indicated that making AEFI reporting mandatory would not enhance AEFI reporting (table 5).

### Binary logistic regression analysis of factors that influence reporting of AEFI

The factors that influence AEFI reporting among healthcare providers were investigated using binary logistic

**Table 4** Relation between training and knowledge level

	Knowledge level				
Variable	Poor knowledge	Fair knowledge	Good knowledge	Total	X <sup>2</sup> (p value)
Training					
No training	425 (80.6)	44 (8.4)	58 (11.0)	527 (100.00)	22.88 (0.000)
Training	215 (66.36)	54 (16.7)	55 (17.0)	324 (100.00)	
Total	640 (75.2)	98 (11.5)	113 (13.3)	851 (100.00)	
Profession					
Healthcare assistant	39 (76.5)	7 (13.7)	5 (9.8)	51 (100)	30.98 (0.006)
Nurse	223 (76.9)	33 (11.4)	34 (11.7)	290 (100)	
Physician assistant	25 (50.0)	13 (26.0)	12 (24.0)	50 (100)	
Medical doctor	8 (57.1)	1 (7.1)	5 (35.7)	14 (100)	
Community health nurse	202 (76.8)	25 (9.5)	36 (13.7)	263 (100)	
Midwife	97 (77.0)	16 (12.7)	13 (10.3)	126 (100)	
Disease control officer	16 (80.0)	0 (0.0)	4 (20.0)	20 (100)	
Other	30 (81.1)	3 (8.1)	4 (10.8)	37 (100)	

regression analysis. Gender was discovered to be a negative factor that influences AEFI reporting. Age and profession were reported to be positive factors that influence AEFI reporting. When compared with their male counterparts, female healthcare professionals were 58% less likely to report AEFI and the difference was statistically significant (OR=0.42, 95% CI 0.28 to 0.64,  $p<0.0001$ ). Also, participants within the 40–49 age bracket had higher likelihood of reporting AEFI compared with those in the 20–29 years age group (OR=3.98, 95% CI 1.93 to 8.21,  $p<0.0001$ ). In addition, medical doctors were six times more likely to report AEFI compared with other health professions (OR=4.582, 95% CI 1.02 to 20.69  $p=0.048$ ) (table 5).

#### Binary logistic regression data on factors that influence knowledge of reporting AEFI

Results of the multiple binary logistic regression indicate that the age and profession of HCWs are the main factors influencing the knowledge of reporting AEFI. Increased odds of having good knowledge on the reporting of AEFI were observed among HCWs aged 30–39 (adjusted OR (aOR)=2.95), 40–49 (aOR=5.65) and 50–59 (aOR=6.36) and this was statistically significant. It was also noted that physician assistants, CHNs and disease control officers were more likely to have good knowledge of the reporting of AEFI compared with healthcare assistants and the difference was statistically significant (aOR=3.06, 95% CI 1.27 to 7.40,  $p=0.013$ ; aOR=2.99, 95% CI 1.57 to 5.63,  $p=0.001$ ; and aOR=5.06, 95% CI 1.53 to 16.72,  $p=0.008$ , respectively) (table 5).

## DISCUSSION

We found that there remains a great need to improve the capacity of health workers to recognise, gather and report AEFIs to reduce under-reporting. There is also

inadequate knowledge of data collection tools, including online reporting of AEFIs, which contributes to under-reporting.

In a large representative sample of health workers working at all levels of the healthcare system in Ghana, using structured questionnaire to gather data, only about 25% had identified at least one AEFI, of whom 55% had reported to the Ghana FDA/EPI. Additionally, only 57.9% were aware of the existence of reporting forms in their health facilities.

The lack of clear guidelines in health facilities further compounds under-reporting, with only less than half of those interviewed saying their institutions had established processes for recognising and reporting AEFIs. This contrasts a study carried out in one district in the national capital which indicated there were guidelines for reporting AEFIs and reporting forms at all levels.<sup>12 18 19</sup> A similar study in the USA showed that of 40% of health workers who identified an AEFI, only 18% reported these AEFIs and this was attributed to a lack of knowledge of the reporting system.<sup>20</sup> In India, a study to measure sensitivity of the reporting system among paediatricians showed that there were no problems with guidelines or access to reporting forms; however, the forms were not considered user-friendly.<sup>21</sup>

There is a need to provide clearly laid out processes and guidelines at every health facility and to periodically train all staff on these processes and guidelines. There is currently no periodic monitoring of AEFI reporting or review of AEFI reports by supportive supervision.

The Med Safety App for online reporting of AEFIs and adverse drug reactions was launched by the Ghana FDA on 25 June 2019 with the aim of enhancing pharmacovigilance reporting.<sup>17</sup> However, only 2.1% of health workers interviewed were aware they could report AEFIs online, an indication that they were not making use of multiple

**Table 5** Binary logistic regression analysis of factors that influence the reporting of AEFI

Variables	Univariate model			Multivariable model		
	OR	P value	95% CI	aOR	P value	95% CI
Factors that influence the reporting of AEFI by health workers						
Gender						
Male	1.00					
Female	0.42	<0.0001	0.28 to 0.64			
Age group						
20–29	1.00					
30–39	1.05	0.843	0.67 to 1.64			
40–49	3.98	<0.0001	1.93 to 8.21			
50–59	1.00	–	–			
60+	2.48	0.438	0.25 to 24.49			
Profession						
Healthcare assistant	0.90	0.878	0.22 to 3.60			
Nurse	1.10	0.870	0.37 to 3.28			
Physician assistant	2.61	0.125	0.77 to 8.86			
Medical doctor	4.58	0.048	1.02 to 20.69			
Community health nurse	1.31	0.631	0.44 to 3.91			
Midwife	0.95	0.931	0.29 to 3.11			
Disease control officer	2.06	0.347	0.46 to 9.33			
Other	1.00					
Years of practice						
<1	1.00					
1	1.01	0.983	0.51 to 2.00			
2	0.49	0.190	0.16 to 1.43			
3 and above	0.97	0.959	0.32 to 2.97			
Factors that influence the reporting of AEFI based on knowledge						
Gender						
Male	1.00			1.00		
Female	0.74	0.028	0.56 to 0.97	0.82	0.230	0.59 to 1.14
Age in years						
20–29	1.00			1.00		
30–39	2.63	<0.0001	1.94 to 3.55	2.95	<0.0001	2.13 to 4.07
40–49	4.67	<0.0001	2.30 to 9.50	5.65	<0.0001	2.66 to 12.04
50–59	6.33	0.023	1.29 to 31.05	6.36	0.030	1.20 to 33.72
60+	1.81	0.557	0.25 to 13.03	2.96	0.305	0.37 to 23.51
Profession						
Healthcare assistant	1.00			1.00		
Nurse	1.06	0.858	0.58 to 1.93	1.21	0.554	0.65 to 2.25
Physician assistant	4.17	0.001	1.78 to 9.80	3.06	0.013	1.27 to 7.40
Medical doctor	1.32	0.648	0.40 to 4.31	1.05	0.938	0.31 to 3.57
Community health nurse	2.26	0.009	1.23 to 4.14	2.99	0.001	1.57 to 5.63
Midwife	0.87	0.672	0.45 to 1.68	0.87	0.710	0.43 to 1.78
Disease control officer	3.95	0.020	1.25 to 12.54	5.06	0.008	1.53 to 16.72
Other	1.57	0.244	0.73 to 3.36	0.98	0.956	0.76 to 3.67
Years of practice						
<1	1.00					
1	1.83	0.039	1.03 to 3.26			
2	2.10	0.071	0.94 to 4.69			
3 and above	2.12	0.145	0.77 to 5.80			
AEFIs, adverse events following immunisation; aOR, adjusted OR.						



options for data collection. A study in the USA found that in 2005 only 6% of HCWs reported AEFIs electronically; however, CDC unpublished data showed the proportion of internet based VAERS reports had increased to 30.5% in 2011.<sup>20</sup> Efforts must be made to increase knowledge and use of online reporting systems to enhance electronic AEFI data collection in countries like Ghana. Internet-based reporting is convenient and enhances the timeliness of AEFI reporting.<sup>20</sup>

With the introduction of electronic medical records, there is increased use of internet in health facilities, and internet-based AEFI reporting can enhance reporting as seen in the USA.<sup>20</sup> In India, when asked about their preferences for reporting formats, most respondents selected an online format, while a smaller proportion of paediatricians preferred a shorter, simpler form or a system of reporting by phone. This could also be explored in countries like Ghana.<sup>21</sup>

Per the workflow for reporting of AEFIs, the Ghana FDA has to give feedback on the reports received. Respondents cited the lack of feedback by the Ghana FDA and EPI programmes as a major disincentive and barrier to reporting AEFIs. Provision of adequate feedback to health workers who submit AEFI reports is likely to increase AEFI reporting. To improve reporting, a study in India<sup>20</sup> also recommends prompt feedback on the AEFI cases reported.

### Gaps, potential and opportunity

There are gaps in training of health workers, especially in the lower cadre, both in schools and on the job. Younger health workers (20–29 years) were less likely to report AEFIs compared with older ones (40–49 years). Additionally, privately owned facilities were largely left out of refresher trainings on AEFIs even though they provide a wide range of services, including vaccination and inpatient care.

We found that the most accessible health facilities, health centres and CHPS compounds are manned by nurses and nurse assistants who are not well trained on AEFI recognition and reporting. They did not consider AEFI reporting as part of their job description. There is a potential to improve reporting especially of serious AEFIs if knowledge is increased through training. We found that training significantly influenced knowledge of AEFIs, which in turn increased the level of reporting. This is shown by an increased level of reporting of AEFIs by doctors, who were six times more likely to report AEFIs than healthcare assistants.

Furthermore, most health workers interviewed thought that there is a potential for continuous professional education and training on pharmacovigilance for all levels of HCWs to improve reporting of AEFIs. Training as a tool to improve reporting of AEFIs is also recommended by similar studies.<sup>12 22</sup> The WHO, in a bid to strengthen vaccine pharmacovigilance in Africa, is focusing on creating a network of trainers who can cascade training activities down to the lowest levels.<sup>13</sup>

Another suggestion to improve AEFI reporting is making it part of annual performance appraisals of health workers. This will increase the level of importance attached to it and increase reporting. Currently, there is no programme that provides incentives to encourage AEFI reporting or penalties for not reporting. Considering that the majority of the health workers are government employees, all incentives considered were non-monetary.

We found that, contrary to previous studies, fear of victimisation following reporting of AEFIs was not a major disincentive.<sup>23</sup> The most important barriers were lack of reporting forms, heavy workload, and ignorance of the reporting procedure and the need to report. This suggests active steps have been taken to address fear of victimisation, and offers hope that once other barriers are tackled the reporting would increase.

### Limitations

There were several limitations to our study. This study was conducted in the northern part of Ghana, which is generally more resource-constrained than the southern part. The paucity of high-level health workers such as doctors and pharmacists in the resource-constrained north of Ghana resulted in comparatively few of them taking part in the survey. The results may therefore not accurately reflect what occurs in better endowed regions south of the country which are better equipped with higher-level healthcare professionals.

We purposively selected 25 out of 54 districts in Northern Ghana due to time constraints and cost. Some of the districts did not have the health facilities required and therefore were not selected. This introduced a small chance that their responses might have been different. There were many more healthcare centres and CHPS compounds, resulting in most participants being interviewed from these locations. Some districts did not have district hospitals.

Our study is also limited by potential response bias, as is present in any survey. Responses may be skewed towards complying with Ghana-specific guidelines since the survey involved self-reporting. However, the survey was private and confidential with no identifiers used to ensure these.

Both quantitative and qualitative studies were carried out within the same period addressing the same question. This paper looks only at the quantitative aspect, while the qualitative aspect will be addressed in another paper.

The strengths of our survey included the standardised survey method, the number of participants interviewed from all types of health facilities and the independence of the survey.

### CONCLUSIONS AND RECOMMENDATIONS

Even though strides have been made in improving AEFI reporting in Ghana, there are still significant gaps that need to be addressed. There is great opportunity and

potential to strengthen the pharmacovigilance system especially as Ghana and the world grapple with vaccine hesitancy in the face of emerging viral infectious diseases of epidemic and pandemic potential, such as Ebola, COVID-19, Lassa fever and mpox. Clear guidelines on AEFI reporting need to be developed and made into posters and displayed visibly in consulting rooms, outpatient departments, vaccination clinics, pharmacies and wards of all health facilities, including private ones. Reporting forms should be made readily available to all health workers. There should be no ambiguity about who must report AEFIs and where the forms can be obtained. We also suggest that the Ghana Health Service and Ghana FDA enter into an agreement with the telcos in the country to make online reporting of AEFIs free. This would enhance online reporting and thus increase AEFI reporting.

Training of all health workers on identifying and reporting AEFIs should be an annual routine, and emphasis should be placed on the dangers of vaccine hesitancy and how building and maintaining a robust pharmacovigilance system will help address this. Trainings should be practical and followed by supportive supervision and monitoring. Vaccine pharmacovigilance should be factored into all trainings held on new emerging infectious diseases so that every opportunity is seized to improve it and to reassure the public and even health workers of the safety of rapidly developed vaccines. The Ghana FDA needs to improve on giving prompt feedback to individuals and facilities on the AEFIs reported. Time-lines should be set and adhered to. This would encourage more health workers to report AEFIs. The communication system must also be strengthened. The quest to find effective treatment and vaccines for surge in viral infectious diseases that have epidemic and pandemic potential will be in vain if these vaccines are not used due to vaccine hesitancy. The most important reasons for vaccine hesitancy are concerns about vaccine safety and effectiveness and these can be adequately addressed with an effective and robust vaccine pharmacovigilance system.

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