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Barriers and strategies to improve vaccine adverse events reporting: views from health workers and managers in Northern Ghana

Nana Akosua Ansah ,[1,2] Daniel Weibel ,[2] Samuel Tamti Chatio,[1] Samuel Tomilola Oladokun,[1] Enyonam Duah,[1] Patrick Ansah,[1] Abraham Oduro,[3] Marieke Hollestelle,[2] Miriam Sturkenboom[2]

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[1]Navrongo Health Research Centre, Navrongo, Ghana
[2]UMC Utrecht, Utrecht, Utrecht, Netherlands
[3]Research and Development Division, Ghana Health Service, Accra, Ghana

Correspondence to
Dr Nana Akosua Ansah;
ansah.nanaakosua@gmail.com

ABSTRACT

Background The increasing incidence of novel vaccine-preventable diseases, such as COVID-19, has led to an increase in the development of vaccines globally. Vaccine hesitancy has risen due to fears of vaccines causing harm. African health systems have generally relied on spontaneous reporting of adverse events following immunisation (AEFIs) to monitor vaccine safety.

Objectives This study explored the views of healthcare professionals and managers regarding barriers and strategies to improve AEFI reporting in northern Ghana.

Methods This study used a qualitative research design where in-depth interviews were conducted with health professionals and managers in five administrative regions in northern Ghana between March and August 2021. The purposive sampling method was used to select districts and participants. The interviews were audio recorded, transcribed, and coded into themes using QSR NVivo V.12 software before thematic content analysis.

Results The study found that lack of feedback is the main regulatory-level factor affecting reporting adverse events. Health system-level factors, such as limited knowledge of reporting AEFIs, a lack of training, difficulties in using electronic application software to complete AEFI forms, and fear of punishment, significantly affect AEFI reporting. At the patient/community level, the main factors affecting AEFI reporting are the distance to health facilities and transportation costs. However, participants suggested continuous AEFI education, sensitisation of health workers and patients, timely feedback, and effective stakeholder collaboration among front-line health workers, health managers, and the national pharmacovigilance authority could improve AEFI reporting in Ghana.

Conclusions Reporting of AEFIs contributes to improving vaccine safety, surveillance systems and prompt case management. However, the study identified multiple key factors at the regulatory, health system, and patient levels affecting AEFI reporting. Thus, improvements in line with these suggestions, including effective stakeholder engagement, are necessary to increase AEFI reporting.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Ghana has persistently low reportage of adverse events following immunisation (AEFIs). Qualitative studies have linked this situation to the limited knowledge of front-line health workers regarding AEFIs, insufficient feedback from the national pharmacovigilance authority, and complicated reporting procedures. They have suggested supportive supervision, additional training and online reporting. Few writings discuss multidimensional strategies, including patient-level approaches, to improve the reporting of AEFIs.

WHAT THIS STUDY ADDS

⇒ This study sought to determine the barriers to vaccine-adverse reporting and suggest strategies for improvement as part of a larger study looking at the capacity and existing gaps in reporting AEFIs in a resource-constrained setting of northern Ghana. The study found that vaccine advocacy and community sensitisation improve vaccine uptake and AEFI reporting. However, barriers such as high attrition of health staff and difficulty using the online reporting form exist. There are also patient-level factors like inadequate health education plus the cost of transportation and distance, which affect patient reporting.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ A multipronged approach should be employed to improve vaccine safety. This should involve all stakeholders, including caregivers and patients. Improved patient accessibility to health facilities will have an impact on AEFI reporting. This is important in the wake of an increased threat of pandemics and epidemics from novel diseases, giving rise to many more new vaccines for adults and children. Improved vaccine safety will curb vaccine hesitancy and enhance the fight against vaccine-preventable diseases.

INTRODUCTION

Immunisation remains one of the most cost-effective means of health promotion. Vaccines have been developed for decades to reduce or

eliminate many diseases.[1] Globally, immunisation coverage increased by about 80% in children from 1974 to 2018, preventing about 2–3 million deaths annually.[1] The uptake of vaccines is increasing as most children continue to receive lifesaving vaccines with about 90% coverage of the third dose of diphtheria, tetanus and pertussis-containing vaccines in 129 countries worldwide.[1 2]

It is important to monitor the safety of vaccines as they are generally given to healthy individuals. Any untoward effects arising after vaccinations cause concern and contribute to public mistrust and vaccine hesitancy.[3] Postmarketing surveillance systems in Africa are still evolving.[4] There is still limited reporting of adverse drug reactions, and vaccine vigilance is a new area less developed than drug pharmacovigilance.[5] As more vaccines are designed exclusively for low-income and middle-income countries (LMICs), additional attention is required for vaccine safety systems to function efficiently across Africa.[4 6 7] This requires strengthening the surveillance infrastructure in most African countries. Thus, additional efforts are necessary to enhance the existing capacity regarding the reporting and management of adverse events.[3] Reporting adverse events following immunisations (AEFIs) is a key component of functional immunisation and vaccine safety monitoring systems. Trends in AEFI reporting ratios globally and across the six WHO regions indicated that AEFI reporting increased worldwide from 2000 to 2015 but necessitated reinforcement in most LMICs.[7 8]

In Ghana, the AEFI reporting ratio was 1.56 per 100 000 immunisations in 2015 despite the didactic training of health workers.[9] This contrasts with the Global Vaccine Action Plan for vaccine safety monitoring, establishing a minimal reporting ratio of 10 AEFI per 100,000 surviving infants as a proxy measure for a functional AEFI reporting system.[10] About one-third of Ghanaian health workers who encounter an AEFI do not complete an AEFI form, highlighting gaps in the AEFI surveillance system.[9] Although the Ghana Food and Drug Authority (FDA) has decentralised AEFI reporting within the health system, there is still under-reporting of AEFIs in the country.[11]

In Ghana, only a few qualitative studies have explored views on AEFI reporting practices over relatively small geographical areas.[11–13] With the increase in new vaccines in Ghana's Expanded Programme on Immunisation (EPI), including the malaria vaccine and adult vaccines like those against COVID-19, it is necessary to conduct more research to help inform policy on enhancing reporting of AEFIs to stem vaccine hesitancy. This study, therefore, explored stakeholders' views on the barriers affecting vaccine adverse event reporting and suggested strategies for improvement in the resource-constrained northern zone of Ghana.

METHODS

Study site

The study was conducted in five administrative regions of Northern Ghana comprising the Upper West, Upper East, Northeast, Savannah and Northern Regions, covering a total land area of 70,884 km^2. This area was chosen because it is the most resource-constrained area of Ghana. There is little data on factors affecting AEFI reporting, and little research has been conducted on AEFI reporting in this area. Demographically, the combined population of the five regions in the most recent (2021) national census was 5 825 879, representing 18.9% of the national population.[14] The healthcare system in Northern Ghana comprises one teaching hospital located in Tamale, the capital of the Northern Region, five regional hospitals and several district hospitals, as well as health centres, maternity homes, polyclinics and community-based health planning and services compounds, mandated to deliver healthcare services to people in the area. The Tamale Teaching Hospital (TTH) is a tertiary hospital and the main referral hospital in the area. Each region has a regional hospital, and every district has a district hospital. The Ghana Health Service (GHS) administers the regional and district hospitals, while TTH's governance involves the Ministry of Health and the Ministry of Education.

Study design

This study used qualitative research methods for data collection and analysis, and in-depth interviews (IDIs) were used to gather primary data. The justification for using this qualitative data collection method was that IDIs provide a depth of understanding about an issue under investigation. It allows participants to share their views and stories in their own words, offering nuanced insights into human behaviour and experiences, which presents a complete picture of a phenomenon. 27 IDIs were conducted with healthcare professionals and managers in 5 administrative regions between March and May 2021. Specifically, the study employed a narrative qualitative research technique. The qualitative research technique enables study participants to share their views and rich experiences on what they know about the issue under investigation. Therefore, this method was deemed appropriate because the study sought to investigate health professionals' perceptions about barriers to adverse event reporting and their ideas on appropriate strategies to improve adverse event reporting in Ghana.

Theoretical foundations of the study

Theories help explain human behaviours and are very important in designing and implementing research that addresses public health problems.[15] An integrative framework, the Theoretical Domains Framework (TDF), designed to facilitate behavioural change in health interventions, was adopted and used in this study. TDF was developed through a consensus process to identify factors that could influence health practitioners' behaviour. The TDF contains 14 main domains that allow assessing and explaining behavioural issues, associated barriers and improvement strategies that inform the design of appropriate interventions to address adverse event reporting, an important public health problem. The main areas include knowledge, skills, professional role and identity, beliefs about capabilities, optimism, consequences, reinforcement, intentions, goals, memory, decision processes,

environment context and resources, social influences, emotion and behavioural regulation. All these factors may influence human behaviour in health interventions to enhance outcomes, specifically reporting adverse events following vaccinations.[15]

AEFI reporting structure in Ghana

Surveillance of AEFIs in Ghana is a collaborative effort involving the EPI, the FDA, the WHO and UNICEF. Other stakeholders include vaccine recipients, parents and caregivers, community members, civil society and private health providers. The objective of the surveillance is to promptly detect and manage AEFIs, whether real or perceived. According to the FDA guidelines, suspicion alone is sufficient grounds for reporting.[12 16]

Routine vaccinations adhere to the GHS structure. However, the reporting flow varies depending on whether the AEFI emanated from a routine vaccination or mass immunisation activities. Generally, four levels of reporting are used during mass immunisation campaigns. First, vaccine recipients or caregivers report all AEFIs to their healthcare providers, who represent the lowest administrative level in the AEFI surveillance system. The health providers communicate possible adverse events and how to manage mild and common reactions to vaccines before vaccination. They also detect, manage and report AEFIs according to the guidelines. The AEFI focal person at the health facility is a trained health worker based in a clinic or hospital who raises awareness among health workers to detect, manage and report AEFIs, conduct clinical investigations and compile weekly AEFI reports for submission to the district AEFI focal person. The district AEFI focal person is a surveillance officer or health worker designated by the district health authorities as a focal person for AEFIs and has received training from the FDA and the EPI. The district AEFI focal person, among other responsibilities, validates AEFI reports, maintains an AEFI database at the district level, performs analysis on AEFI data to determine distribution and patterns of occurrence, compiles the reports and submits them to the Regional EPI Coordinator and/or the FDA regional focal person. Among other responsibilities, the FDA regional focal person collects, validates and ensures the completion of reports from reference hospitals, gathers and qualifies reports from the district focal person, and reports to the National EPI coordinator and finally to the FDA for possible regulatory action.[12 16]

Study population and justification

The study population comprised health professionals and managers, such as district directors, EEPI Nurses, Disease Control Officers, Food and Drugs Authority officers and Pharmacists.

Health professionals and managers

The study justified including these categories of health workers because they are involved in vaccination activities, play active roles in planning and implementing vaccinations, and report AEFIs in their respective regions, districts and health facilities. Therefore, they were included to share their experiences and views on adverse event reporting.

Pharmacists

Pharmacists oversee AEFI reporting in hospitals as AEFI focal persons, help with the quality and quantity of vaccination services and increase community awareness, participation and education. They are usually the AEFI focal persons in hospitals. Pharmacists are important in providing patient information and informed choices regarding immunisation and benefit–risk comparisons. Pharmacists know and can identify patients with target groups for certain vaccinations. They can also ease patients' fears by providing information and facts about the risks of not being immunised, thus reducing hesitancy about vaccination.

Food and Drug Authority

Ghana's FDA has been mandated to provide a legal basis for preventing, promoting, safeguarding, maintaining and protecting human health and allied matters in Ghana. The core function of the Ghana FDA is to ensure the quality, safety and efficacy of medicines, vaccines, blood and blood products, medical devices, household chemical substances and clinical trials, including steps to address AEFIs resulting from immunisations. They were included in the study because of their crucial role in regulating immunisation activities and reporting adverse events in the country.

Sampling procedures

Purposive sampling is a traditional sampling method in qualitative research designs. In this method, the researcher selects study participants with certain experiences and knowledge to provide appropriate information to address the research questions and objectives.[17] Consequently, a purposive sampling method was employed to choose the study districts and participants. Five districts, one from each region, were selected for the interviews.

Before launching data collection, official letters were written to the regional directors of health services in the five regions to inform them about the study and solicit their support to conduct the interviews in their respective regions. Afterwards, a list of districts in the study regions was obtained, and one district in each region was selected for the interviews. Subsequently, the study team, led by the lead author, visited the selected districts to explain the purpose of the study to the district directors and to request their permission and support for conducting the study. The study team then identified participants for the interviews based on the categories outlined above based on their availability, after which written informed consent was obtained. The interviews with the Food and Drugs Authority (FDA) officers and pharmacists were conducted at the regional level. In contrast, the interviews

with health workers and managers were conducted at the district level.

Recruitment of research assistants and training

The study recruited 10 experienced graduate-level research assistants (RAs), 2 from each region, and trained them for data collection. The RAs received training on the purpose of the study, data collection tools, consent procedures, and qualitative interviewing techniques. During training, mock interviews were conducted to evaluate data collectors' performance and ability to ask questions appropriately during data collection. The RAs conducted a pretest after training, aiding the study team in finalising the interview guides before data collection. The pretest data were not included in the study.

The public is involved in this research's dissemination plans.

Data collection procedures and tools

Data were collected between March and August 2021 after ethics approval was obtained. Before data collection, appointments were scheduled with study participants on suitable dates and times before face-to-face interviews were conducted. All interviews were conducted in English and lasted for about 1 hour. All participants who were contacted agreed to participate in the study. The interviews were audio recorded with the consent of participants; no written notes were taken. The interviews lasted 45 min and were conducted with participants in their respective offices. A total of 27 interviews were conducted after data saturation was reached.

An interview guide was used to conduct the IDIs (see online supplemental material for the Stakeholders Questionnaire, FDA, DDHS, Pharmacist). The guide was developed based on the research objectives and questions. Participants shared their views on pharmacovigilance activities, procedures and capacity to report adverse events, factors affecting adverse event reporting and strategies to improve adverse event reporting within the health system. Transcripts were not returned to participants for comment.

Data management and analysis

All the recorded interviews were transcribed verbatim after repeatedly listening to the recordings. The lead author edited the transcripts without changing the original meaning of participant statements. The transcripts were edited merely to correct grammatical mistakes, to make them readable, and to ensure high-quality information before data coding and analysis. Each transcript was given a unique identifier based on the interview type and the participant category. Guided by the study's objectives and the themes in the interview guide, we developed a codebook using established categories based on the original research questions. Examples of broad themes included the 'perception of pharmacovigilance activities, procedures and capacity to report adverse events, factors affecting adverse event reporting and strategies to improve adverse events reporting' along with the subthemes that emerged from the data such as 'lack of feedback, inadequate staff, distance and transportation.'

The third and fifth authors coded the data using QSR NVivo V.12, validated by the first, fourth and last authors. The coding process involved critically reviewing each transcript and coding the data into themes. Regular discussions occurred among the coders to agree on the coding pattern. Data analysis was carried out using a framework thematic content analysis approach,[18] which involved familiarisation of data and themes that emerged from the data as well as their interpretation. The results were subsequently presented as a narrative, accompanied by quotes from the data.

Table 1 Background characteristics of participants

Characteristics	Levels	Frequency (N=27)	Per cent (%)
Age in years			
	29–39	10	37.04
	40–50	9	33.33
	51–59	8	29.63
Sex			
	Female	5	18.52
	Male	22	81.48
Level of education			
	Advanced diploma	2	7.40
	Certificate	2	7.41
	Masters	23	85.19
Years of practice			
	Mean (SD)	12.30±7.67	
	1–10	12	44.45
	11–20	11	40.74
	21–30	4	14.82
	26–30	2	7.41

RESULTS

Background information of participants

A total of 27 interviews were conducted. Most participants (37.40%) were between 29 and 39 years old, and about 82% were male. Most participants (44.45%) had between 1 and 10 years of practice, while only 7.41% had 21–30 years of work experience (table 1).

Themes

The themes that emerged from the study are summarised in table 2 and discussed in the results.

Perceptions of pharmacovigilance activities

Most participants shared positive experiences regarding the pharmacovigilance system in Ghana. However, they

Table 2 Main and subthemes on barriers and strategies to improve adverse event reporting

Main theme	Subtheme
Perceptions on pharmacovigilance activities	
Procedures and capacity to report adverse events	
Factors affecting adverse events reporting	**Regulatory level factors**
	Lack of feedback
	Health facility-level factors
	Lack of capacity building
	Inadequate staff
	Community/patient-level factors Non-availability of community surveillance workers
	Distance and issue of transportation
	Inadequate information
Strategies to improve adverse event reporting	Health education to create awareness
	Effective collaboration

indicated that even though there were risks associated with vaccines, it was very important and beneficial for vaccines to be administered to people. They reported that certain diseases, such as measles and polio, had been reduced or eliminated through vaccines.

> Since we involved the entire nation in Measles and Supplementary Immunization activities (SIA) in 2002 and 2003, we have not recorded any measles deaths in Ghana. A comparison of the years when people were dying from these diseases to now indicates that the vaccines have worked. (IDI-Disease Control Officer-02)

A good number of participants believed that advocacy and community sensitisation had helped improve the patronage of vaccine interventions and facilitated the reporting of adverse events by recipients of these vaccines, thereby helping to reduce complications.

> We have done a lot of community sensitization, and a lot of planning was done with other stakeholders, including community chiefs. So, because of this, the chiefs played a major role in convincing their subjects to be aware of the COVID-19 disease and practice the prescribed protocol, including patronage of vaccines when they are introduced. (IDI-District Director-01)

> Education is crucial; if you don't know something, you are naïve and won't do it right. If you raise awareness among healthcare providers and within the community, they will be vigilant regarding adverse events after receiving any vaccine. Other caregivers who did not receive the vaccine will also notice and encourage them to report. (IDI-District Director-05)

However, some participants expressed dissatisfaction with attitudes towards pharmacovigilance activities and vaccinations in the study area. These individuals complained about the negative attitude of some people who did not see the need to take their children for vaccination exercises because they believed that they were very healthy.

> Complacency has set in, and because of that, people do not patronize vaccine exercises in recent times in our communities. People do not see what they used to see, like measles, and some say that the children are healthy, so why should I worry myself? (IDI-Disease Control Officer-02)

Procedures and capacity to report adverse events

The study explored stakeholders' views on the procedures and capacity to report adverse events within the health system. Views expressed by participants suggested that there existed a hierarchy within the Ghana Health system for reporting adverse events. Participants explained that persons who received a vaccine and experienced any side effects had to report to the nearest health facility, where a form was filled and submitted to the facility focal person. They added that the focal person was then supposed to submit the form to the district level to be forwarded to the regional level and then to the national level for action to be taken.

> This is how it has been: caregivers or people who experience side effects must report at the health facility, and then a form is filled out and submitted to the district; the officer in charge at the district must work on the form and submit the form to the regional level and finally to National level. The data is synchronized nationally, and unique IDs are assigned to each case. (IDI-Disease Control Officer-03)

> Pharmacovigilance is part of drug and therapeutic activities in our health facilities. Therefore, the forms are distributed to the wards and consulting rooms so all prescribers can use them to report adverse events. (IDI-Regional Pharmacist-02)

Once more, participants indicated that a communication strategy was in place at all health facilities to address issues related to adverse events. They reported that information about adverse events would usually come from the national to the regional and district levels and then to the communities.

> We assess communication from the district, and if we have any feedback, we get it from the FDA to the national, to the region to the district, and then to us. (IDI-EPI-02)

Few participants also held that capacity-building strategies for health staff, such as appropriate training regarding procedures for reporting adverse events within the healthcare system and at the health facility level, were implemented.

> We have educated the staff on the importance of reporting adverse reactions. Therefore, we train them and provide forms to report these adverse events at various health facilities. We are collaborating with the FDA, and any person who experiences adverse reactions will have to first report. Then, a form will be filled out and forwarded to the Food and Drugs Authority at the national level. (IDI-District Director-02)

Community members and patients were also educated on adverse events and the need to report them, as demonstrated in the quotes below:

> Also, at the pharmacy, we educate our clients; we tell them that if they experience any reaction, they should come and inform us, and then we will fill out the adverse events form. (IDI-Regional Pharmacist-02)

> We have our community radio, where we broadcast much information to the public. Additionally, we have community volunteers who act as our mouthpieces, sending information about vaccines and the importance of reporting any adverse events that may occur due to vaccination vaccines to the communities. (IDI-Disease Control Officer-03)

Factors affecting adverse events reporting

Factors affecting adverse event reporting were grouped into three broad themes: regulatory level, health facility level, and community/patient-level factors, and are discussed below.

Regulatory-level factors

Lack of feedback

Participants reported that one key factor affecting adverse event reporting was the regulator's lack of feedback on submitted adverse event forms. According to some participants, the lack of feedback had affected their morale and zeal to complete these forms. They added that it was difficult to know whether the forms were correctly filled out without feedback.

> One major gap is the lack of feedback. We do not get feedback when we forward or submit completed forms to the national level, which affects the capturing of adverse events at the health facilities. We spend time filling in the forms and submit to the authorities, but you don't get feedback, and I think that does not encourage capturing these events if you ask me. (IDI-District Director-01)

Another significant factor that influenced adverse event reporting was the challenge of using the MED safety application created by the FDA to record adverse events at the facility level. For instance, the complexity and process involved in downloading the app before using it to collect information were described as cumbersome. According to views expressed by participants, the App was designed to simplify the collection of information on adverse events; most officers were not using it due to challenges associated with its usage. Additionally, the system failed to identify some of the AEFIs, resulting in some not being reported.

> Up to now, the app designed for us to use is not user-friendly to people. Health workers still have challenges using it. I would say that reporting has been a challenge with regard to the network, and so many people do not report. (IDI-EPI Officer-03)

Health facility-level factors

Lack of capacity building

This study also reported that various health facility-level factors affect adverse event reporting. Lack of capacity building and training for health staff involved in immunisation activities seriously affected AEFI reporting. According to opinions expressed by participants, the cadre that would typically be selected for training was not involved in providing immunisation services, which made it impossible for them to educate patients on the need to report adverse events after receiving these vaccinations.

> We have not built the capacity of health staff directly involved in immunisation activities. Therefore, awareness has not been created for vaccinated people who experienced side effects to report. (IDI- Disease control officer-01)

Inadequate staff

Another key factor identified as negatively affecting adverse event reporting was inadequate staff, which resulted in a high staff attrition rate at the health facility level. Most health workers who had served for several years could depart for further studies, which affected the staffing situation at some health facilities and made it difficult to get them to fill out adverse event forms.

> I would say we have a very high staff attrition rate because some of them leave for school after serving for some years. The transfer and the other ways that you may lose staff also count, and the new ones that come will need frequent reminders in terms of orientation and retraining, which makes it difficult. (IDI-District Director-05)

In a related development, inadequate knowledge on what to report also affected adverse events reporting at the health facility level, according to participants. In addition, the fear of being punished for reporting and some health workers not seeing the need to report these adverse events were not encouraged to report them.

> The challenge is serious underreporting; the only reports I have or usually get are reports on programs being run. Routine pharmacovigilance reporting is minimal, and it doesn't even go on at all. (IDI-Regional Pharmacist-01)

> People (referring to health staff) think they will be blamed and criticized for reporting adverse events, so they don't report them. Others also think it is not serious and do not see the need to report. (IDI -Facility Head-0)

Non-availability of community surveillance workers

Participants also reported community-level factors contributing to low reporting of adverse events in the study area. For instance, the lack of community surveillance workers posed a challenge in getting adverse event cases compared with previous years.

> When community-based surveillance workers were available, they were our interface. We trained them, and the community knows them, so if there is anything they communicate to us, and if there is a problem, they call and tell us, and we go and assess the situation. It is no longer like that, and that is contributing to the underreporting of adverse events. (IDI-District Director-02)

Distance and issue of transportation

Another challenge participants reported was the distance from some communities to the health facility. If a participant takes a vaccine and an adverse event occurs, it's difficult for the person to report back to the facility due to the distance and lack of transportation.

> The issue relates to the distant communities, as I personally believe that is where we fail to receive the cases. For here, when you come on Wednesday for a jab and realize that the next day there is swelling, you come, but what about those places where the distance is too far? They are not able to come back and report to us if they take these injections and experience side effects because of a lack of transportation. (IDI-District Director-03)

Inadequate information

Participants noted that health workers' failure to educate individuals about the importance of reporting to healthcare facilities after receiving vaccinations and experiencing adverse reactions significantly impacted adverse event reporting.

> The fact is that they are informed before the immunization that this is likely to happen, but what we don't add is if it happens, where to go, and that has been the problem. (IDI-Disease Control Officer-02)

> If the patient is aware that these are some of the adverse events I can experience when I take this vaccine, and I must go back and report at the health facility, it will help the patient report. However, if we do not give prior education to these patients, they will not be aware, and they will be silent even if it is affecting them. (IDI-District Director-02)

Strategies to improve adverse events reporting

Despite various factors affecting adverse event reporting in the study area, participants made several recommendations to improve adverse event reporting in Ghana.

Health education to create awareness

Most participants believed that intensive education to create awareness of the need for people to report adverse events could help improve the reporting of such events within the health system.

> Sensitisation: if the client knows that if they take any vaccine and feel otherwise, they should report it, it will help improve the reporting of adverse events. Sensitizing the public and caregivers on their need to report these side effects will help us to get there. (IDI-District Director-01)

Some participants also believed adequate training for health staff, especially those overseeing immunisation activities, could improve adverse event reporting in Ghana.

> Keep training the health workers and create awareness among health care providers and the general populace. Awareness should encompass not only reporting but also what defines an AEFI. I also think that the existing structures for reporting should be well-resourced as there will be challenges in reaching out to people. You will need fuel or something to connect with people experiencing these things, along with some motivation for healthcare workers, since it adds extra work. (IDI-District Director-05)

Most participants surmised that active patient reporting will enhance the reporting of adverse events.

> Reporting will be enhanced if patients are actively reporting AEFI to the next step; let's say you take a vaccine; there should be a facility where the person can go and report, not necessarily where the person took the vaccination. So, if clients are educated on what to do, they will even be reporting more than the healthcare workers. (IDI-EPI Officer-03)

Concerning improvements to adverse event reporting within the healthcare system, a District Director of Health Services shared the following when asked for his views on the issue:

> We need to get focal persons who can coordinate this for us. In every facility, we need a designated person responsible for pharmacovigilance so that whenever side effects are reported, they will be the first point of contact. This will be very helpful. (IDI-District Director-02)

Effective collaboration

Some participants suggested a strong collaboration between regulatory authorities and health facilities. They explained that getting feedback from regulatory authorities on reported adverse events could encourage health workers to document these events regularly, thereby improving pharmacovigilance activities and reporting adverse events.

> I think there should be strong collaboration between facilities and FDA. Also, feedback should be provided on time; even when we go to meetings, the same issue with feedback keeps coming up. So, if they (referring to the FDA) have a good system for feedback, that will help greatly. (IDI-EPI Officer-03)

Other participants suggested revising the MED Safety app to make it easier for health workers to use and capture information on adverse events at the health facility level. As one participant put it:

> The reporting has been a challenge because of the app and issues regarding the network. So, they should simplify the app and reduce the information on the form to make it easier to use. (IDI-EPI Officer-03)

DISCUSSION

This study explored the views of health workers and managers about barriers to adverse event reporting and their ideas to improve AEFI reporting in the study area. Barriers to vaccine adverse reporting still exist at all levels despite measures put in place at the community, health facility and regulatory levels to enhance reporting. Regulatory-level barriers include a lack of feedback to reporters and a complex electronic app. Health facility barriers include insufficient training, high staff attrition and fear of being blamed for causing the AEFI. Caregivers are hindered from reporting due to inadequate education and the distance and cost of transportation to health facilities. Participants suggested that a multipronged approach, including community education, training of health workers and feedback from the Ghana FDA, will improve AEFI reporting.

Participants asserted that the introduction of vaccines has significantly contributed to eradicating certain diseases, such as measles and polio, although low vaccine uptake among some parents persists. They attributed this low uptake to misinformation about vaccines. Prior research indicates that trust in immunisation programmes significantly influences vaccine uptake.[3 19 20] As shown in this study, this issue of trust arises from misinformation and complacency among some mothers regarding immunisations.

According to respondents, lack of feedback was the main factor affecting AEFI reporting at the regulatory level. The absence of feedback on AEFI reports discourages HCWs from reporting AEFIs. Previous studies support this assertion. Lack of feedback prevents health workers from appreciating vaccine-associated risks and how to handle them.[12 21 22]

Respondents said the electronic reporting app is challenging and has not helped improve reporting. This explains the finding in the quantitative arm of this study, which showed that less than 2% of HCWs had used the electronic app[23]. However, a survey conducted by Seaneke *et al* suggested most participants thought the app was easy to use even though less than a third had used it to report AEFIs.[24] This suggests more training is needed for the app to be useful, as reported in an earlier study.[25]

At the health system level, our findings suggest that front-line health workers have limited knowledge of reporting AEFIs due to a lack of training on AEFI reporting guidelines, particularly for health workers involved in immunisation activities. It is suggested that many front-line health workers are not familiar with the AEFI reporting procedures, what to report, who to report to and how to report. This is mainly because those in supervisory roles, such as health facility in-charges, usually attend the training programmes on immunisations and AEFI reporting instead of the health workers involved in immunisation activities.[9]

The study also identified difficulty in using electronic application software to capture AEFI, which affected their reporting. The difficulty in using electronic apps to capture AEFI could be because of a lack of training to build the capacity of health workers who are supposed to use the app to report AEFI. Reporting requirements of AEFI by national FDAs can be complex and cumbersome. Under-reporting is common if processes are unclear, making it challenging to use reporting tools, in this case, the AEFI electronic app. It is demonstrated that knowledge gaps and limited ICT skills resulting from inadequate training affected using electronic applications to report AEFI.[4] As pointed out by the TDF used in this study, knowledge and skills are very important factors that can affect the successful implementation of health intervention programmes, in this case, the use of electronic applications to report AEFI.[15]

Additionally, participants cited health workers' fear of blame or punishment as a significant factor influencing AEFI reporting. Participants did not explain the reasons for this fear. However, it is possible that a lack of training on appropriately reporting AEFI, along with the fear of making mistakes and the potential effect on performance appraisals for such individuals, could explain why health workers do not complete AEFI forms, as demonstrated earlier in both current literature and the theoretical framework used in the design of this study.[12 15] Closely related to this, there is a high rate of health worker attrition in the study area, where health workers leave for the southern part of the country with the belief that conditions of service, including educational facilities, are much better compared with the northern part of the country, where this study was conducted.[26 27] This high attrition rate necessitates constant training or orientation of new employees on AEFI reporting.[26] Factors such as excessive workload and lack of staff motivation have been noted in the current literature to negatively impact adverse event reporting.[28] Moreover, attitudinal issues related to poor supervision have been indicated to affect AEFI reporting[4]; however, the current study did not identify negative health worker behaviour and inadequate supervision as factors influencing adverse event reporting.

According to participants, the main patient-level factors affecting AEFI reporting are lack of information, distance to health facilities and transportation issues. We found a key factor contributing to the low reporting of AEFIs is a lack of patient knowledge regarding the necessity and appropriate channels for reporting vaccine adverse events. This may stem from health workers failing to deliver essential health education to caregivers. Previous studies by Omoleke *et al* and Laryea *et al* also indicated

that inadequate health education led to low reporting of AEFIs by caregivers.[4 11] Furthermore, caregivers were discouraged from reporting AEFIs due to the distance to health facilities and transportation costs. This suggests that the expenses involved and the time necessary to travel to the health facility made it unduly challenging to report AEFIs. The study area is one of the poorest regions in Ghana, with many families facing low socioeconomic status. Consequently, individuals may hesitate to visit the health facility to report AEFIs because they do not view it as significant enough to warrant the associated costs. This mirrors other studies that found that factors such as socioeconomic status, poverty, geographical barriers and insufficient community engagement by health workers considerably impact AEFI reporting by patients.[4 11]

Participants recommended several strategies to improve AEFI reporting in Ghana. Adequate community engagement and sensitisation will improve patients' knowledge about AEFIs and enhance reporting. Timely feedback from the FDA and discussing AEFIs with health workers during supervisory visits could facilitate reporting and serve as an opportunity to train on AEFI reporting in the working environment.[9] Healthcare workers newly posted to facilities should be trained on AEFI reporting, as suggested by previous studies.[4 11] The electronic app should be streamlined, and training should be provided to assist health workers in completing AEFI forms. These strategies may enhance AEFI reporting by fostering effective collaboration among stakeholders. Stakeholders include the Ghana FDA, health managers and front-line health workers directly involved in immunisation activities.

Limitations

The study has the following limitations. The choice of qualitative approach and purposive sampling methods limit the generalisability of the findings because the views expressed by participants are their personal views and may not necessarily represent the views of the larger population. Additionally, data collected by many RAs may have distorted the presentation of the questions to the participants. Nonetheless, this was minimised because the data collectors were graduate-level RAs with experience in qualitative research, and they received standard training that included role plays and pretests of the study guides.

CONCLUSION

Reporting AEFIs enhances vaccine safety, strengthens surveillance systems and may facilitate prompt case management. This study identified several key factors (ie, regulatory, health system and patient levels) that significantly affected adverse event reporting in the study area. These factors include lack of feedback, difficulty using electronic application software to complete AEFI forms, limited knowledge of reporting AEFIs due to lack of training, distance to health facilities and transportation costs.

Timely feedback from the Ghana FDA and training for health workers could enhance the reporting of vaccine adverse events. Furthermore, the electronic app should be simplified, and training should be offered to enable health workers to complete AEFI forms. This strategy could improve vaccine adverse event reporting by fostering effective stakeholder collaboration between the FDA, health managers and front-line health workers, especially those involved in immunisation activities. In addition, adequate community engagement and sensitisation to improve patients' knowledge about adverse events resulting from receiving vaccines and the need to report them is highly recommended to enhance AEFI reporting at the patient level.

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Patient consent for publication Not applicable.

Ethics approval The study protocol was reviewed and approved by the Navrongo Health Research Centre Institutional Review Board (Approval ID: NHRCIRB400) in 2021 before the commencement of the study. Written informed consent was obtained from all participants before the interviews. The study's rationale, objectives and participants' responsibilities were adequately explained to them by data collectors before their participation. In addition, participants' rights were observed, and they were informed that they could discontinue the interview at any time without consequences. To enhance the confidentiality of participants' information, codes were assigned to them and used in the transcripts and data analyses.

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ORCID iDs

Nana Akosua Ansah http://orcid.org/0009-0001-0536-6349

Daniel Weibel http://orcid.org/0000-0003-1685-1478

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