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Barriers to healthcare workers reporting adverse events following immunization in four regions of Ghana

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Abstract

Despite didactic training on adverse events following immunization (AEFI) in Ghana, the reporting ratio of AEFI was 1.56 per 100,000 surviving infants in 2015, below the minimum reporting ratio of 10. We aimed to estimate the proportion of health care workers (HCWs) reporting AEFI and to identify barriers to reporting.

We conducted a cross-sectional survey of HCWs in four regions in Ghana. A simple random sample of 176 health facilities was selected and up to two HCWs were randomly selected per facility. We used the Rao-Scott Chi-squared test to compare factors associated with reporting of AEFI in the last year. We used an open-ended question to identify reasons for low reporting. One supervisor from each facility, responsible for overall reporting and management of AEFI, was also interviewed.

A total of 306 HCWs from 169 facilities were interviewed. Of these, 176 (57.5%) reported they had ever encountered an AEFI. Of the 120 who had encountered an AEFI in the last year, 66 (55.0%) indicated they had reported the AEFI, and 38 (31.7%) completed a reporting form. HCWs (n = 120) reported multiple barriers to reporting of AEFI; the most common barriers were fear of

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Declaration of Competing Interest

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personal consequences (44.1%), lack of knowledge or training (25.2%), and not believing an AEFI was serious enough to report (22.2%). Discussion of AEFI during the last supervisory visit was significantly associated with reporting in the past year (OR 7.39; $p < .001$). Of 172 supervisors interviewed, 65 (37.8%) mentioned their facilties had ever encountered an AEFI; over 90% of facilities had reporting forms.

We identified low reporting of AEFI and multiple barriers to reporting among HCWs in the four selected regions of Ghana. Discussing AEFI during supervisory visits with HCWs might improve reporting. Additionally, strategies to address fear of personal consequences as a barrier to reporting of AEFI are needed.

Keywords

Adverse events following immunization; Barriers to reporting; Healthcare workers; Four regions in Ghana

1. Introduction

Immunization prevents more than 2.5 million deaths in children each year [1], and depends on a foundation of a strong health system that can deliver and scale-up vaccination services. Vaccine safety systems are a critical component of the health system, as they allow authorities to address safety concerns promptly and promote confidence in immunization, especially during the introduction of new vaccines. As more vaccines are introduced into low- and middle-income countries (LMICs)—many of which are designed exclusively for these countries—additional attention is required for vaccine safety systems to function efficiently [2,3]. In most LMICs, the reporting of adverse events following immunization (AEFI) is sub-optimal, below the minimum reporting ratio of 10 reported AEFI per 100,000 surviving infants [4]. This is a standard established by the World Health Organization (WHO) for a country with at least minimal capacity for vaccine safety monitoring. All major and minor AEFI encountered should be reported to the country surveillance system, which is used to determine the country reporting ratio. Strengthening AEFI surveillance systems supports WHO's Global Vaccine Safety Initiative (GVSI), which has recently focused on improving minimum capacity for vaccine safety in LMICs, particularly in Africa where AEFI surveillance is sub-optimal [5].

In Ghana, a national electronic data system for AEFI reporting began in 2002 following the introduction of the diphtheria-teta nus-pertussis-hepatitis B-*Haemophilus influenzae* type b (i.e., pentavalent vaccine) [6]. Monitoring of AEFI is undertaken jointly by the Food and Drug Authority (FDA) and the Expanded Programme on Immunization (EPI) with close collaboration with the African Collaborating Centre for Pharmacovigilance (ACC). In recent years, new methods for AEFI surveillance have been implemented, such as using disproportionality analysis reporting ratios to identify safety signals [7]. Didactic AEFI training courses among healthcare workers (HCWs) by the Ghana FDA and EPI program have been conducted during the last six years, especially during new vaccine introductions; however, the reporting of AEFI has remained low (reporting ratio of 1.65 per 100,000 surviving infants and only 13 AEFI reported in 2015) [8]. Given that it is especially

important to address weak AEFI systems before the introduction of a new vaccine, and Ghana is one of three countries in Africa selected by WHO to pilot test the new RTS, S malaria vaccine before universal use [9], there is a need to examine the reasons underlying the underreporting of AEFI in Ghana.

In this study, we aimed to estimate the proportion of HCWs reporting AEFI and to broadly examine reasons for underreporting using a systematic method at the health facility level in four regions in Ghana. Findings from this assessment provide insight into reasons for underreporting of AEFI and inform targeted interventions.

2. Methods

2.1. Study setting

Ghana is a tropical coastal country located in West Africa, bordered by Togo, Burkina Faso, and Cote d'Ivoire. It has a population of about 27 million with a birth cohort of roughly 900,000 [10]. Health services, including immunization, are packaged and delivered in communities by clinics, health centers, and tertiary hospitals. Public facilities provide approximately 60% of the country's health service delivery [11]. Community-based health planning services (CHPS) are the lowest healthcare unit that provides immunizations. Health facility in-charges (referred to as ''in-charges'' throughout the manuscript) are persons who have supervisory responsibility for the day-to-day operation of the healthcare facilities in Ghana. The incharges are responsible for the overall management of any AEFI that occur and support the investigation if serious, followed by reporting to the next level and providing feedback to HCWs at the facility. The HCW is the frontline worker providing immunization and responsible for case management and filling out the AEFI form. Although verbal reporting of AEFI can also occur to in-charges, HCWs should fill out a reporting form for all AEFI.

2.2. Study design and participants

We conducted two cross-sectional surveys in December 2017, targeting HCWs and in-charges of healthcare facilities in four of the ten regions in Ghana. The study regions were selected purposively and included the Northern Region, Volta Region, Greater Accra Region, and Upper East Region. Three of the regions (Northern, Volta, and Greater Accra) were chosen due to an ongoing Centers for Disease Control and Prevention (CDC) second year of life project in those regions [12]. We included one additional region, Upper East, to complement WHO's efforts for monitoring the safety of the RTS,S malaria vaccine, as Upper East is one of the regions where sites were selected for the RTS,S pilot. We also conducted interviews with key informants at the district, regional, and national level during the assessment; the qualitative results will be published in a separate article.

A simple random sample of 176 health facilities was selected from a line-listing of 943 public health facilities registered with the Ghana Health Service in the four regions. Up to two HCWs were randomly selected at each selected facility from among those that were present and eligible at the time of the visit, for a total sample size of 352. HCWs were eligible for inclusion if they administered immunizations and had been working in the EPI

for at least one year. In-charges of all health facilities were selected for a separate interview and were interviewed even if HCWs were not available. Interviewers obtained informed consent from each HCW and incharge, who were informed that their information would be kept confidential. Participation was voluntary, and verbal informed consent in English was obtained from those who agreed to participate.

3. Sample size considerations

The sample size was calculated based on the primary outcome of the percentage of HCWs who reported at least one AEFI in the past year. There was no data on the primary outcome, and thus we assumed a conservative estimate of 50% AEFI reporting among HCWs. A sample size of 167 was required for estimating p = 50% with ± 7.5% precision (Wilson method). Inflating for 5% nonresponse gave an adjusted n = 176. To account for the expected high correlation between HCWs in the same facility, we assumed a design effect of two. With two HCWs selected per health facility, we aimed for a total of 176 healthcare facilities and 352 HCWs in this study.

3.1. Data collection

The data collection tools were developed with expertise from CDC, ACC and Navrongo Health Research Centre (NHRC) and were pilot tested for appropriateness and wording before use. The HCW questionnaire captured self-reported data on the primary outcome of AEFI reporting and potential factors and barriers, based on a list as identified previously from the literature [13,14] and by expert review; background demographic and educational information from the respondent was also collected. To identify reasons or barriers to underreporting, we asked an open-ended question “What would be the main reason that a HCW would not report an AEFI?”, supplemented by additional probing qustions. The in-charge questionnaire collected information including form availability, if the facility had ever encountered an AEFI, and facility training history. At each selected health facility, up to two HCWs were randomly selected for an interview-administered survey, and the in-charge at each facility was selected to be interviewed. Reporting form availability for AEFI was verified by data collectors. Data were collected on paper forms, stored securely, and entered into KoBo Toolbox [15].

3.2. Data analysis

We summarized the respondent demographics and background information. Results included the proportion of HCWs ever encountering an AEFI while working in the Ghana EPI, experiencing an AEFI in the past year, reporting the AEFI experienced in the past year and filling out a reporting form. We focused on reporting in the last year to reduce recall bias and elucidate current barriers to reporting. We explored associations between background characteristics and AEFI reporting using Rao-Scott Chi-squared test. Continuous variables were dichotomized at the median. Statistical significance was set at 0.05, and the analyses were not weighted. The HCW analysis accounted for clustering at the health facility level using Taylor-series methods. To identify reasons for or barriers to underreporting, we coded the responses to the open-ended question on reasons for low reporting into themes informed by expert knowledge and the literature. To determine knowledge of AEFI, we asked HCWs

to define an AEFI, and responses were recoded into knowledge levels by a vaccine safety expert at CDC. The qualitative data on in-charges were coded and categorized into themes descriptively. All data analyses were performed using SAS version 9.4 [16].

3.3. Ethical Approval

This study was reviewed by the CDC's Human Subject's Office and the Ghana Health Service's Ethical Review Committee and was considered an assessment of a public health program.

4. Results

4.1. HCW survey

Of the 176 healthcare facilities randomly selected (Fig. 1), HCWs were identified for participation in 169 (96%) facilities across all four regions. Twenty-two (13.0%) of these facilities were located in Greater Accra Region, 54 facilities (32.0%) in Volta Region, 56 facilities (33.1%) in Northern Region and 37 facilities (21.9%) in Upper East.

Overall, 306 HCWs in 169 facilities were interviewed across the four regions; in 32 selected facilities only one HCW was available and eligible to be interviewed. Of the 306 HCWs, the majority were Community Health Nurses (71.6%). The median number of years of experience was five years, while the median number of years working at the health facility was two years. The median age among HCWs was 29 years (Table 1, Fig. 2).

When asked to state the definition of an AEFI, 271 (88.6%) HCWs provided a satisfactory or accurate definition. However, when asked if they knew how an AEFI should be reported, 199 (65.0%) HCWs stated they knew how to report an AEFI. All 306 HCWs indicated that they believe reporting AEFIs is important. A total of 176 (57.5%) HCWs reported they had ever encountered an AEFI and 120 (39.2%) indicated they had encountered one within the past year (Fig. 2).

The most common barriers to AEFI reporting mentioned by HCWs included fear of personal consequences (44.1%), such as losing one's job or being punished, lack of knowledge/ training (25.2%), and not believing an AEFI was serious enough to report (22.2%). Other barriers mentioned included work pressure, lack of parental awareness to report, reporting form availability, logistical issues, and late or no feedback from supervisors (Fig. 3).

4.2. Bivariate results for HCWs reporting an AEFI in the last year

We conducted a sub-analysis among those who had encountered an AEFI in the past year (N = 120). Among those who had encountered an AEFI in the past year, 66 (55.0%) HCWs reported the last AEFI they encountered, either verbally or through a written report (Fig. 2). Among those who had filled out a reporting form, 30 (78.9%) reported that it was easy to do.

Discussing AEFI at the last supervisory monitoring visit was the only factor identified that was significantly associated with AEFI reporting in the past year (OR 7.39; $p < .001$) (Table 2). No significant associations were found between AEFI reporting and the participant's age, region of residence, years of experience since qualification level, and training, although

a higher percentage (80%) of HCWs in Greater Accra reported AEFI in the last year compared to the other regions.

4.3. In-charge survey

A total of 172 in-charges participated in the survey, and of these, 65 (37.8%) mentioned that their facilities had ever encountered an AEFI. Furthermore, 145 (84.3%) in-charges reported they had a focal person for AEFI reporting at their healthcare facilities, and 157 (91.3%) stated they had copies of reporting forms available on the day of the interview (this was subsequently verified by the study team). When asked about feedback received on AEFI reports, 81 (47.1%) in-charges indicated they received feedback from staff at higher levels in the system on the quality of reports in their health facility. Eighteen (10.5%) in-charges reported that they had training planned for HCWs on AEFI for the upcoming year (Table 3).

5. Discussion

The results from the present study indicate low reporting of AEFI among HCWs in the four selected regions in Ghana. While many HCWs (>80%) correctly defined an AEFI, we found that only a third of those who encountered an AEFI in the previous year filled out a reporting form for the most recent AEFI. This indicates gaps in the AEFI surveillance system, and also implies that the system would benefit from additional strengthening. Moreover, approximately half of HCWs reported that they had ever encountered an AEFI in their entire career. An even smaller percentage of healthcare facility in-charges reported that their facilities had encountered an AEFI which may indicate a discrepancy in reporting between frontline staff and in-charges who should be receiving all reports of AEFI at the facility.

Our findings differ from other studies on AEFI reporting in the African region, as over half of HCWs in the present study stated they had ever encountered an AEFI, compared to only a third of HCWs from a recent study in Nigeria [14]. Furthermore, unlike previous studies, no significant relationship between years of experience and AEFI reporting practices was found in our study [17]. This might be reated to the younger age of nurses in this study compared to HCWs in earlier studies (HCWs in Ghana were 9-11 years younger than HCWs in Kenya and Nigeria) [14,17].

We identified multiple barriers that might contribute to low reporting of AEFI among HCWs involved in immunization in the four regions of Ghana. The most frequently mentioned barriers to reporting AEFI were fear of personal consequences and lack of knowledge and training. However, lack of AEFI knowledge might not sufficiently explain underreporting in Ghana, as most HCWs were able to correctly define an AEFI. Indeed, our results showed that HCWs had less knowledge about the reporting system in genereal (e.g., almost a quarter of HCWs did not know that all AEFI need to be reported).

Fear of personal consequences was the most pervasive barrier across all four study regions in Ghana and was mentioned by almost half of the HCWs surveyed. Given that fewer in-charges reported that their healthcare facilities had ever experienced an AEFI compared to

HCWs encountering an AEFI, this may indicate that HCWs may not be alerting in-charges to AEFI because of fear of consequences after reporting AEFI.

The barriers we identified in this study mirror barrriers identified in prior studies in Kenya, Zimbabwe and Nigeria, which found that HCWs lacked training on AEFI and that fear of personal consequences after reporting AEFI may prevent reporting [14,17,18]. This finding is further complicated by the fact that many AEFI in LMICs result from administration errors by the immunizing HCWs, [19] who would thus implicate themselves by reporting. While fear of personal consequences after reporting AEFI could be discussed during in-service training, it will need to be ameliorated through encouragement from supervisors, providing supportive supervision to address fear on an ongoing basis, implementing a supportive policy to protect HCWs who report, and changing organizational norms surrounding the importance of reporting without punishment. Additionally, unlike previous studies, reporting forms were readily available at the time of the interview in most facilities, indicating that form availability was not an explaination for underreporting [20]. Strategies at the individual and organizational level that have been successful at rewarding the reporting of AEFI, include encouraging open communication to facilitate reporting [21]. Safety monitoring is a quality assurance mechanism of immunization programs that should be valued by managers and decision makers rather that being a source of fear for HCWs.

Finally, few HCW respondents indicated they received a supervisory visit where AEFI were discussed, which is problematic as receiving an AEFI monitoring visit was the only factor that was found to be significantly associated with AEFI reporting in the previous year. This is also a critical finding given that district supervisory visits occur quarterly in Ghana, providing a useful platform to address barriers to reporting. Discussing AEFI with HCWs during supervisory visits should promote reporting and serves as an opportunity to train on AEFI in a work environment. Less than half of in-charges stated that they receive feedback on AEFI reports, also indicating a need for more supportive supervision at the district level (or higher levels). Lack of feedback as a barrier to reporting has been corroborated in other studies [18].

6. Limitations

There were several limitations of our study. First, the study was conducted in only four regions of Ghana using an unweighted analysis, and thus the results of the study cannot be considered generalizable beyond the four regions. Furthermore, because we chose to focus only on HCWs who encountered an AEFI in the last year, reporting levels may be inflated. Finally, self-reported information from HCWs on AEFI may be skewed towards compliance with country-specific reporting guidelines, especially given that fear was the primary barrier to reporting identified in the current study. Additionally, in-charges may not have been able to accurately represent the experience of the whole facility.

7. Conclusion

We identified low reporting of AEFI among HCWs in four regions of Ghana. Multiple barriers might contribute to low reporting, which should inform targeted interventions. Fear

of personal consequences after reporting AEFI is a difficult barrier to address and requires multiple interventions such as clear policy protecting HCWs, supportive supervision, feedback on reports, and adequate training. Addressing the barriers to AEFI reporting that were identified in this study will strengthen the Ghana EPI.

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Disclaimer

The findings and conclusions in this report are those of the author(s) and do not necessarily represent the official position of the Centers for Disease Control and Prevention/the Agency for Toxic Substances and Disease Registry.

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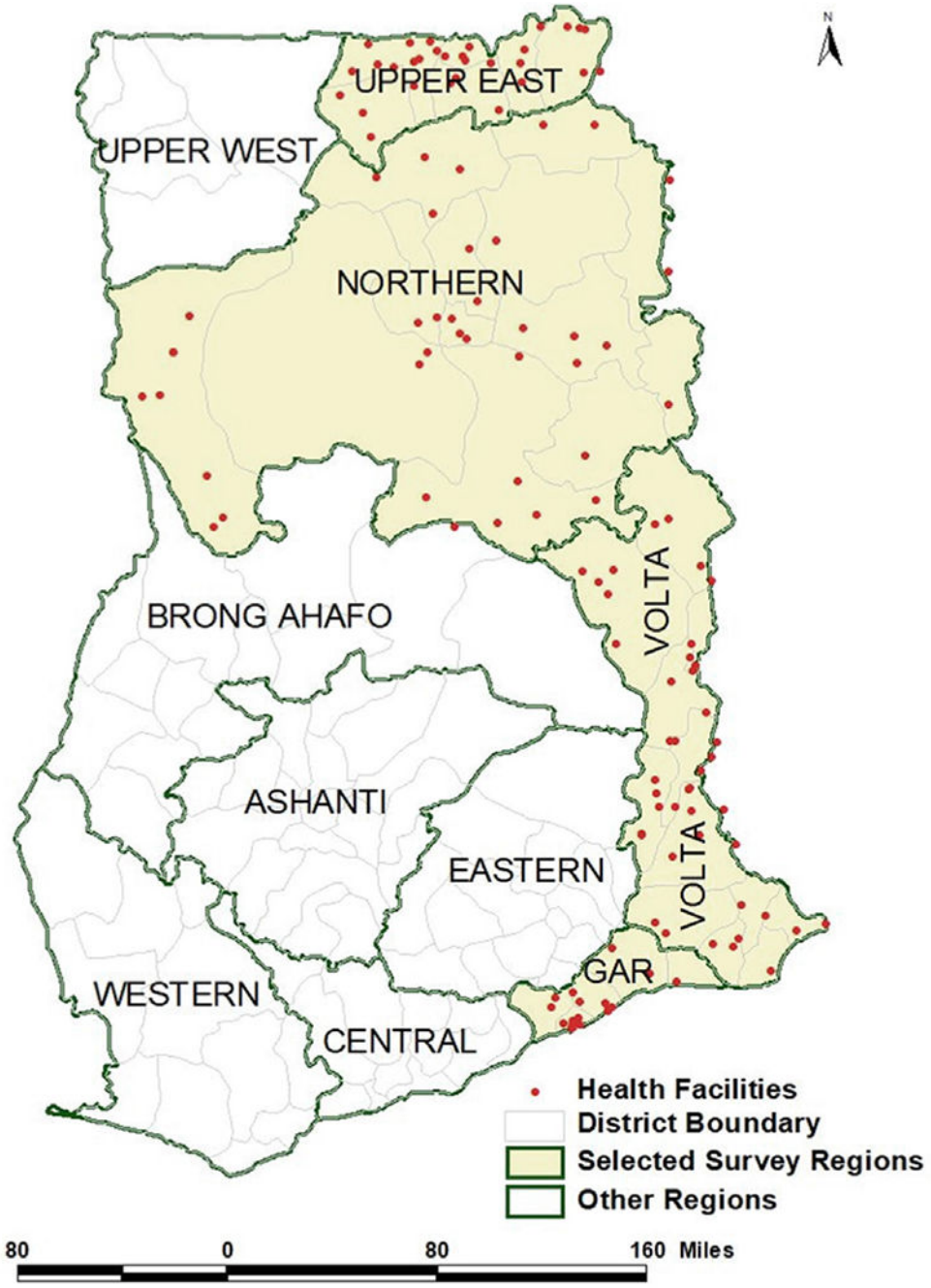

Fig. 1.
Map of Ghana showing sampled facilities, AEFI reporting survey, Ghana, December 2017.

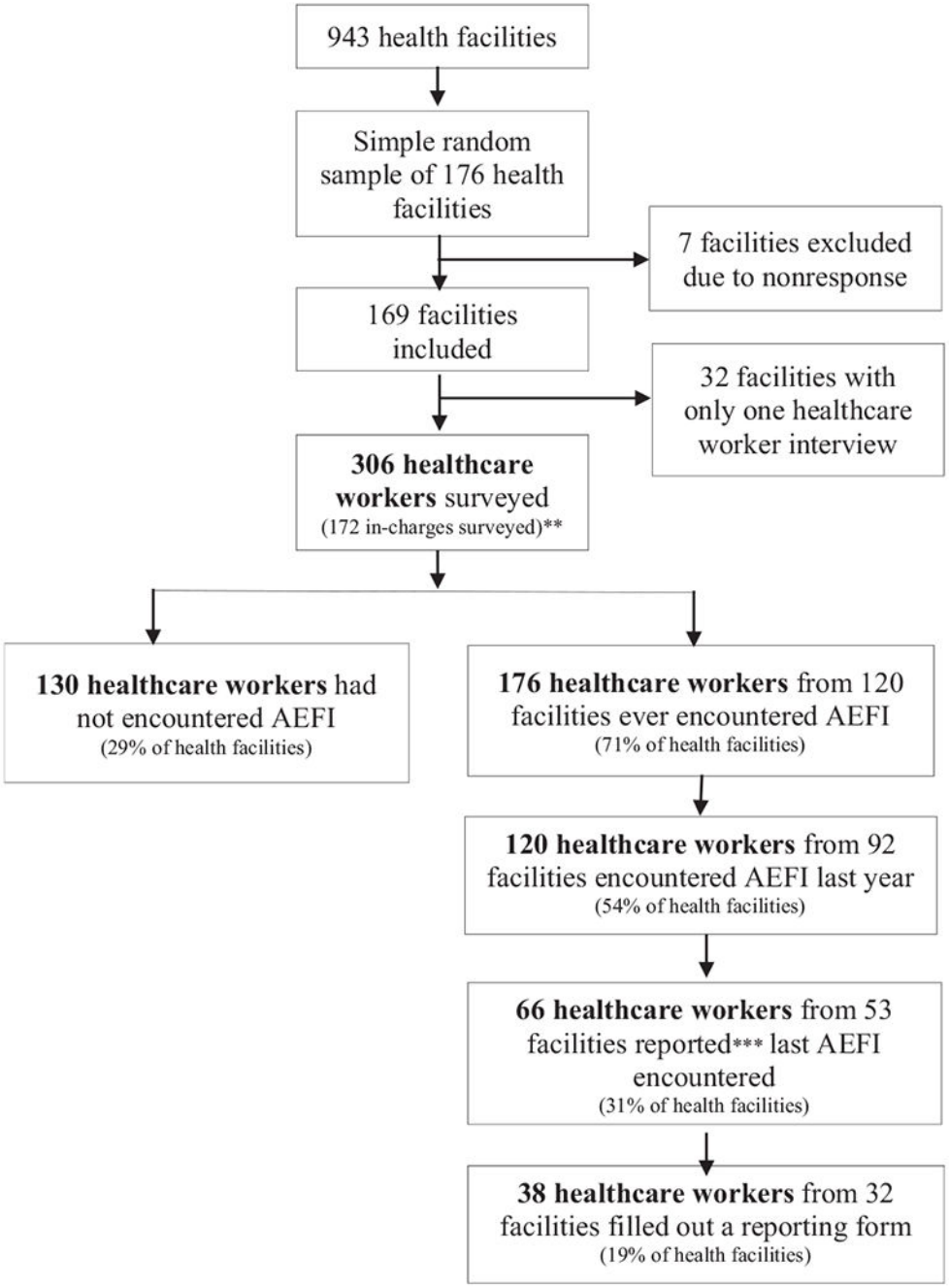

Fig. 2.

Flow Diagram of AEFI Encounters and Reporting Among Sampled health care workers (N = 306), AEFI reporting survey, Ghana, December 2017 AEFI: adverse events following immunization. *In some facilities, in-charges were interviewed even if frontline immunization providers were absent.**AEFI were reported either verbally or through written report.

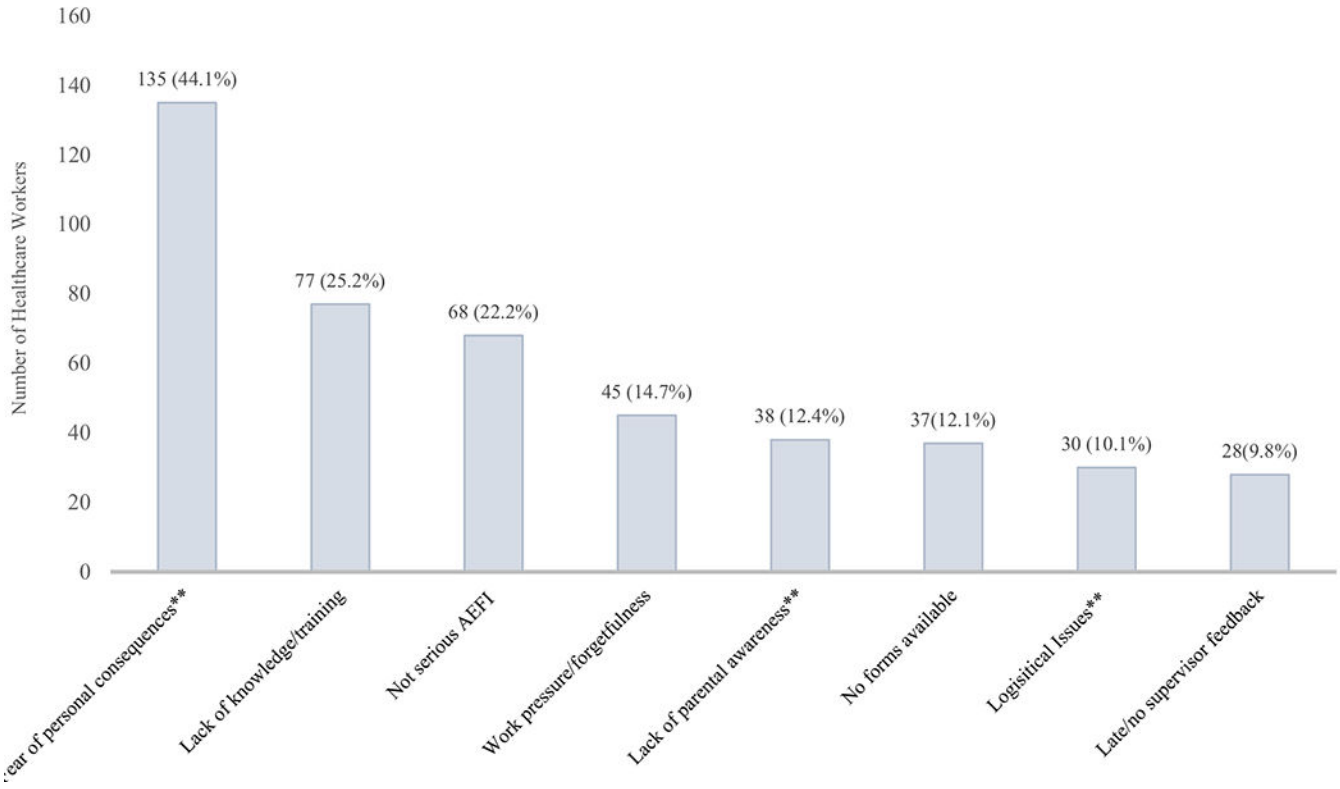

Fig. 3.

Identified barriers to reporting among 306* health care workers, AEFI reporting survey, Ghana, December 2017 *Counts exceed 306, as healthcare workers could provide more than one response. AEFI are adverse events following immunization. ** Fear of personal consequences included responses such as “Fear of being accused of incompetence,” “fear of being punished or sacked,” “they may say he or she does not give the injection well”; Lack of parental awareness/reporting included responses such as “Caregivers do not report,” “ Mothers are unaware of reporting back,” “At time we don’t receive any complaints from caregivers”; Logistical issues included responses such as “Road network/distance,” “Cost involved in checking the cases,” “Transportation,” “When facilities are far and when there is no network to call”.

Table 1

Characteristics of 306 health care workers, AEFI reporting survey, Ghana, December 2017.

	Frequency	%
Region		
Greater Accra	42	13.7
Volta	95	31.0
Northern	96	31.4
Upper East	73	23.9
Position		
Community Health Nurse	219	71.6
Enrolled Nurse/Public Health Nurse	39	12.7
Midwife	15	4.9
Disease Control Officer	10	3.3
Other	23	7.5
	Median	**Interquartile Range**
Age	29.0	27.0, 32.0
Years of experience (since qualification exam)	5.0	4.0, 7.0
Years worked at facility	2.0	1.0, 3.0

*AEFI are adverse events following immunization.

Table 2

Factors associated with AEFI reporting among 120 health care workers who encountered an AEFI within the previous year, AEFI reporting survey, Ghana, December 2017.

	n (%) of total	Reported AEFI* n (%)	χ^{2}**	OR	p-value
Age					
Under median age (29 years)	67 (55.8)	36 (53.7)	0.10	0.89	0.7573
Over median age	53 (44.2)	30 (56.6)			
Region					
Greater Accra	15 (12.5)	12 (80.0)	4.2	–	0.2353
Northern	48 (40.0)	27 (56.3)			
Upper East	30 (25.0)	15 (50.0)			
Volta	27 (22.5)	12 (44.4)			
Experience level***					
Low (<2 years)	52 (43.3)	30 (57.7)	0.26	0.82	0.6130
High (≥2 years)	68 (55.7)	36 (52.9)			
Trained on AEFI					
Yes	48 (40.0)	29 (60.4)	0.82	1.44	0.3628
No	72 (60.0)	37 (51.4)			
Discussed AEFI during last supervisory visit					
Yes	23 (19.2)	20 (87.0)	13.1	7.39	0.0003^
No	97 (80.8)	46 (47.4)			

AEFI: adverse events following immunization.

*Reporting encompasses verbal or written reports.

**Rao-Scott Chi-Square Test.

***Number of years working in the Ghana immunization program.

^Significant finding.

Table 3

Recording and reporting practices of 172 in-charge supervisors, AEFI reporting survey, Ghana, December 2017.

	Frequency	%
Has your health facility ever encountered an AEFI?		
Yes	65	37.8
Do you have a focal person for AEFI reporting at your healthcare facility?		
Yes	145	84.3
Do you have copies of AEFI reporting forms?*		
Yes	157	91.3
Do you get any feedback about the quality of your AEFI reports from higher levels?		
Yes	81	47.1
Do you have any planned training for HCWs on AEFI this year?		
Yes	18	10.5

AEFI: adverse events following immunization.

* Form availability was verified by data collectors.