ADVERSE EVENTS FOLLOWING IMMUNIZATION (AEFI) REPORTING IN A RURAL DISTRICT IN GHANA

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Abstract

Background: Even though vaccines used in routine childhood immunization programmes are safe, adverse events following immunization (AEFI) may occur. These events must be recognized for prompt and effective response. This can contribute to success of the immunization programme and sustain interest of the public in vaccination.

Methods: A descriptive cross-sectional study comprising primary and secondary data collection methods were used for the study at Jaman North District in Ghana. The secondary data was extracted from immunization reports using a Microsoft excel spread sheet. The primary data was obtained from respondents using structured interview questionnaire. Simple random sampling was used to select caregivers and health workers were purposively selected. The data was analyzed using Statistical Package for Social Sciences (SPSS) windows (version 21.0).

Results: A total of 140 mothers or caregivers and 47 health workers were studied, with mean age of 27.8 years in each group. The rates of AEFI ranged from 0.02% for pneumococcal vaccine to 0.14% for pentavalent vaccine. In all, 63.8% of the health workers could not define AEFI, and 91.5% of the health workers do not use anaphylactic pack at immunization sessions. Majority (95.7%) of the participants agreed that poor AEFIs monitoring can lead to reduction in immunization coverage. AEFI training for health workers had a strong association ($p<0.001$) on their ability to identify AEFIs. The study indicated that mothers or caregivers were knowledgeable in many of the indicators of AEFI. In all, 93.7% of mothers or caregivers indicated that attitude of health workers was very good.

Conclusion: The study revealed low (<1%) AEFI reporting rate by mothers or caregivers. Only 36.2% health workers had knowledge with respect to definition of AFEI. The study indicated that more than a third of mothers (36%) were of the view that reporting of AEFIs can lead to personal consequences. Increased national efforts at surveillance for AEFI is imperative.

Key Words: Adverse Events Reporting, Immunization, Vaccination, Rural District

Introduction

Background: The goal of immunization is to protect the individual and the public from vaccine preventable diseases. Vaccines used in national immunization programmes are extremely safe and effective but no vaccine is 100% safe and adverse events following immunization could occur. In addition to the vaccines themselves, the process of immunization is a potential source of adverse events[1]. Thus, AEFI is any untoward medical occurrence which follows immunization and does not necessarily have a causal relationship with the usage of the vaccine.

Some children experience AEFIs ranging from mild to life threatening side effects but rare illnesses. In the majority of cases, adverse events are merely coincidence, in others they are caused by the vaccine or error in the administration of vaccines or sometimes, there is no relationship at all[2]. The AEFIs can be categorized into five main types, vaccine product-related reaction, vaccine quality defect-related reaction, immunization error-related reaction, coincidental event, and immunization anxiety-related reaction[3].

Immunization safety has become important in the immunization programme since it can affect the utilization of services if not monitored and managed appropriately. Unlike drugs, the expectations from vaccinations are much higher and problems arising from vaccine or vaccinations are less acceptable to the general public. There is therefore the need to actively monitor all AEFIs and respond to them appropriately[4].

The expanded program on immunization (EPI) was introduced in Ghana in 1978 with a total of six antigens-BCG, measles, diphtheria-pertussis-tetanus (DPT) and oral polio for children under the age of one. Currently, the EPI programme in Ghana has increased the number of vaccines to a total twelve (12) which include BCG, oral polio, diphtheria-pertussis-tetanus-hepatitisB, Haemophilus influenza type B- (DPTHepBHib), measles, rubella, pneumococcal, yellow fever and rotarix for children under one year[5].

In the Jaman North District where this study was conducted, immunization is carried out routinely on

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both static and outreach points. Health workers who conduct immunization services in the district have the responsibility of identifying and reporting AEFIs to the district EPI focal person for onward submission to the region.

Methods

Study site

The study was conducted in all the six sub districts within the Jaman North District of the Brong Ahafo Region of Ghana during the period 2013-2015.

Sampling procedures

The study used a descriptive cross-sectional study involving a survey and review of secondary data. The descriptive cross-sectional was used to collect relevant information from both mothers with children under the age of one year and health workers who conduct EPI services.

A multistage cluster random sampling strategy was used to select the mothers while health workers were purposively selected. The number of respondents to be included in this study was distributed proportionally according to the population of children under one year in the various sub districts. Each of the six sub districts was considered as a cluster. Simple random sampling was used to select the first cluster (sub district) based on the district's immunization itinerary. All outreach points in the various sub districts were selected using the sub district's immunization itinerary. At the outreach point, simple random sampling was used to select a total of 140 caregivers. The list of all health workers who conduct EPI services and their respective health facilities were obtained from the district EPI coordinator. At the health facilities all eligible health workers present during the study period and consented to participate were enrolled.

Data Collection procedure

Two main approaches were employed, review of secondary data and interviews with a structured questionnaire. The structured interview questionnaires were used to interview health workers and mothers or caregivers while the secondary data collection involved the review of EPI reports and AEFI case-based forms in the District. The AEFI case-based forms included types of AEFIs and the vaccines involved. Client exit interview was used to collect information from the mothers or caregivers after the immunization session using the structured interview questionnaire.

Data Analysis

Microsoft excel spread sheet was used as a data compilation sheet for the records review. Data obtained were analyzed using the Statistical Package for Social Sciences (SPSS) windows (version 21.0) by simple descriptive statistics.

Categorical variables were summarized into frequencies and proportions, continuous variables such as age was re-categorized into age groups. Frequency counts of all responses were converted to frequency tables.

Results

Socio-demographic characteristics of the study population

In Tables 1 and 2 a total of 140 mothers or caregivers and 47 health workers studied showed the mean age of health workers was 27.0 years and that of caregivers was 27.5 years. Among the health workers, 59.6% were females, while 97.9% had tertiary education. It was observed that 29.8% of health workers had worked for only one year, 89.3% were married, 63.6% had primary or basic education and 44.3% were farmers.

Table 1: Socio-demographic information of caregiver/ mothers

Variable	Total	Percentage
Age of mothers		
16-20	26	18.6
21-25	30	21.4
26-30	38	27.2
31-35	24	17.1
36-40	16	11.4
41 >	6	4.3
Total	***140***	***100***
Occupation of mothers		
Civil/public servant	4	2.9
Farmer	62	44.2
Business woman	30	21.4
Housewife	19	13.6
Artisan	20	14.3
Others(specify)	5	3.6
Total	***140***	***100***
Marital status of others		
Married	125	89.3
Divorced	8	5.8
Widowed	3	2.1
Single	1	0.7
Separated	3	2.1
Total	***140***	***100***
Educational level of mother		
No formal education	14	10.0
Primary/basic education	89	63.5
Secondary/Technical/Vocational	32	22.9
Tertiary	5	3.6
Total	***140***	***100***

Table 2: Socio-demographic information of health workers

Variable	Total	Percentage
Age		
20-24	8	17.0
25-29	21	44.7
30-34	14	29.8
35-39	4	8.5
Total	***47***	***100***
Sex		
Male	19	40.4
Female	28	59.6
Total	***47***	***100***
Education		
Tertiary	46	97.9
Secondary/Technical	1	2.1
Total	***47***	***100***
Number of years of service		
Less than a year	2	4.3
One year	14	29.8
Two years	9	19.1
Three years	8	17.0
Four years and above	14	29.8
Total	***47***	***100***

Knowledge of Health workers about AEFI reporting

It was observed that 63.8% of the health workers could not define AEFI although 89.4% have had training or sensitization on AEFI through seminars and workshops (Table 3). In addition, 46 out of the 47 health workers were of the view that immunization error-related reactions that occur during vaccine storage, preparation and administration can lead to AEFIs. Participants described AEFI as occurrence of pain, swelling and redness (28.5%) or irritability, malaise, and systemic symptoms (14.6%) amongst others. Only 57.4% of participants indicated that AEFI should be investigated and reported within 24 hours. Majority, 91.5% indicated being familiar with the AEFI form. In all, 72.3% of the participants indicated they will manage fever as an AEFI if a mother reports to them.

Practices of Health workers about AEFI reporting

Table 4 demonstrates that 93.6% of health workers do inform mothers whose children experience AEFI to report to the health facility. In addition, 66% health workers indicated an experience in detection of AEFI. More than half of health workers, (51.8%) did not use AEFI case-based form in their reporting and 55.3% did not have AEFI reference guide at their facilities.

Almost all (91.8%) the health workers did not use anaphylactic pack and adrenaline at immunization sessions. In addition, less than two-thirds (61.7%) of them educate mothers and caregivers about AEFIs on routine basis. However, 83.0% of the participants did feel reluctant to report AEFI for fear of being blamed.

Perception of health workers about AEFI reporting

Table 5 indicates that 44.7% of the mothers and caregivers acknowledged that they will feel guilty to report injection abscess as an AEFI and 34.0% were of the view that reporting of AEFIs could lead to personal consequences. Overall, 95.7% believed that poor AEFI monitoring can lead to reduction in immunization coverage and that AEFIs can also be investigated and reported by the EPI service provider and not only the medical doctor (80.9%). Close to half (48.9%) of the participants indicated that investigating AEFI is time consuming and yet all the respondents expressed readiness to learn more about AEFI reporting and investigation.

Knowledge of mothers on AEFI and the Attitude of health workers toward mothers who report AEFI

Tables 6 and 7 show that 98.6% of the respondents have heard about AEFI and 96.4% were aware that AEFI should be reported to the health worker. Also, 96.4% were aware that treatment of AEFIs is free of charge and that 92.1% have had counselling or education about AEFI. It was observed that reporting AEFI can help improve immunization services in close to half of participants (46.4%). The most common condition that respondents will report as AEFIs after vaccination were fever, pain and swelling at site of injection.

Rate of AEFI reporting

Table 8 shows AEFIs recorded in the district were mainly associated with pneumococcal and Pentavalent vaccines for the period under review. The most common event reported in all the years was pain, swelling and redness and was mainly associated with the Pentavalent. In addition, from district records, no AEFI was recorded for BCG, Measles/Rubella, Tetanus Diphtheria, Rotarix and OPV.

Table 3: Knowledge of Health workers about AEFI

Variable	Total	Percentage
Training/Sensitization on AEFI		
Yes	42	89.4
No	5	10.6
Total	***47***	***100***
Definition of AEFI		
Any ontoward medical occurrence which follows immunization and does not have any causal relationship with the usage of the vaccine	17	36.2
Any medical event which occurs as a result of only the vaccine	11	23.4
Any issue which arises from vaccination either social or medical	8	17.0
Vaccination which leads to side effects which cannot be managed by mother	11	23.4
Total	***47***	***100***
Description of AEFIs		
Pain, swelling, and redness at site of injection	43	28.5
Refusing to breastfeed or eat	20	13.2
Irritability, malaise, and systemic symptoms	22	14.6
Diarrhoea	11	7.3
Anaphylaxis/shock	20	13.2
Type of training		
Onsite training on the job	5	10.6
Orientation through workshop and seminars	42	89.4
Total	***47***	***100***
Immunization error leading to AEFI		
Yes	46	97.9
No	1	2.1
Total	***47***	***100***
Have seen AEFI reporting form before		
Yes	43	91.5
No	4	8.5
Total	***47***	***100***
Hours within which AEFIs should be investigated		
Within 24 hours	27	57.4
Within three days	17	36.4
Within three to five days	3	6.4
Total	***47***	***100***
Management of fever as an AEFI after vaccination		
Yes	34	72.3
No	13	27.7
Total	***47***	***100***

Table 4: Practices of Health workers about AEFIs

Variable	Total	Percentage
Information health workers give to mothers when their children experience AEFIs		
Manage it in the home	3	6.4
Report to health worker or health facility	44	93.6
Total	***47***	***100***
Form used by respondents in reporting AEFIs		
AEFI case-based form	23	48.2
Referred the patient without filling form	9	18.5
EPI reporting form	15	33.3
Total	***47***	***100***
Use of anaphylactic pack and adrenaline at immunization sessions		
Yes	4	8.5
No	43	91.5
Total	***47***	***100***
Detection of AEFI by health workers		
Yes	31	66.0
No	16	34.0
Total	***47***	***100***
Reluctant to reporting AEFI for fear of blame		
Yes	8	17.0
No	39	83.0
Total	***47***	***100***
Frequency at which health workers educate mothers about AEFIs		
Routinely	29	61.7
Monthly	18	38.3
Total	***47***	***100***

Table 5: Perception of Health workers about AEFIs reporting

Variable	Total	Percentage
AEFI reporting leading to personal consequences		
Yes	16	34.0
No	31	66.0
Total	***47***	***100***
Poor AEFI monitoring leading to low immunization coverage		
Yes	45	95.7
No	2	4.3
Total	***47***	***100***
Processes involve in AEFI reporting		
Too long and time consuming	15	31.9
Not time consuming	24	51.1
Very easy	8	17.0
Total	***47***	***100***
Feeling guilty to report injection abscess for causing harm to child		
Yes	21	44.7
No	26	55.3
Total	***47***	***100***
Should AEFI investigation be conducted only by the medical doctor		
Yes	9	19.1
No	38	80.9
Total	***47***	***100***
Interest to learn more about AEFI reporting		
Yes	47	100.0
Total	***47***	***100***

Table 6: Knowledge and Reporting on AEFI in Caregivers

Variable	Total	Percentage
Ever Heard about AEFI		
Yes	138	98.6
No	2	1.4
Total	***140***	***100***
Awareness about free treatment of AEFIs		
Yes	135	96.4
No	5	3.6
Total	***140***	***100***
Importance of AEFI reporting		
To improve vaccine quality	13	9.3
Improve upon EPI services	67	47.9
Just for record keeping	2	1.4
Help manage the AEFI	55	39.3
Others(specify)	3	2.1
Total	***140***	***100***
Reasons for not reporting AEFIs		
Too busy	3	6.1
Long distance to facility	4	8.2
I don't think it is necessary	5	10.2
Condition not serious	10	20.4
Was asked to manage it the home with paracetamol syrup	27	55.1
Total	***49***	***100***
Reporting of AEFI to health workers		
Yes	135	96.4
No	5	3.6
Total	***140***	***100***

Table 7: Frequency and Attitude on AEFI among care givers

Ever had counseling/education about AEFI		
Yes	129	92.1
No	11	7.9
Total	***140***	***100***
Number of times child has been vaccinated		
Once	12	8.6
Twice	11	7.9
Three times	29	20.7
More than three times	88	62.8
Total	***140***	***100***
Child ever had AEFI		
Yes	113	80.7
No	27	19.3
Total	***140***	***100***

Table 8: Number of AEFI reported in the district 2013 – 2015

Reported Event	Pentavalent			Pneumococcal		
	2013	2014	2015	2013	2014	2015
Fever	1	0	0	0	0	0
Pain, swelling and redness	11	2	1	0	0	2
Irritability, malaise and systemic symptoms	0	0	0	0	0	0
Total Reported	***12***	***2***	***1***	***0***	***0***	***2***

Discussion

Socio-demographic characteristics of the study population

A total of 140 mothers/caregivers and 47 health workers were studied. Association between level of education of health workers and ability to identify AEFI was not significant(p=0.159). The study did not demonstrate any significant association (p=0.282) between the level of education of mothers and reporting of AEFI to health workers. In addition, there was no significant association (p=0.194) between occupation of mothers and AEFI reporting majority of whom were farmers.

Knowledge, practices and perception of health workers about AEFI

The study revealed that respondents were knowledgeable in some of the indicators while some shortfalls in knowledge were identified. Majority of the respondents have had training or sensitization about AEFIs through workshops and seminars. This is in contrast with a study conducted in Zimbabwe which indicated that only 6% of health workers have had training on AEFI[9]. One observation was that AEFI training for health workers has a strong association (p=0.001) on their ability to identify AEFI. It was evident that health workers who have had previous training on AEFI are more likely to identify AEFI; hence the need to build the capacity of health workers who provide EPI services on AEFI. Few respondents were able to provide the correct definition of AEFI which is similar to a study in Zimbabwe [6].

Majority of the participants were knowledgeable about AEFIs associated with vaccine storage, preparation and administration. This is in contrast with a study in Kenya in 2014 which found a small proportion of the respondents had knowledge on the causes of AEFI[8]. Respondents' knowledge about conditions that should be reported as AEFIs was not encouraging since all the responses were far below 50%. It was observed that most respondents will not recognize systemic symptoms such as refusal to breastfeed or eat, irritability, malaise, diarrhoea, anaphylaxis or shock as AEFI after vaccination. In contrast, a study in 2013 in Zimbabwe showed that anaphylaxis, febrile convulsions, limb swelling, high fevers and skin rashes were the conditions recognised by participants as indicative of AEFIs[11].

Majority of the participants were familiar with the AEFI reporting form and agreed with findings from a study in 2013 in the United States[14] which showed weak association (p=0.241) between years of service of health workers and having seen an AEFI reporting form before. Close to half of the participants did not know that AEFIs should be investigated and reported within 24 hours after detection. This demonstrated limited knowledge on the timing and reporting of AEFIs per recommendations by the WHO. It was also observed that all participants knew the importance of AEFI reporting and that reporting are to improve immunization services, record keeping and the target group involved. This study found that most caregiver were of the view that AEFIs should be investigated and reported by both the EPI service provider and a medical doctor and not only the medical doctor. This was in contradistinction to a study in Brazil in 2010, which revealed that nurses working in primary health care units showed little interest in AEFI surveillance because of its complexity[12].

Majority of the health workers do tell mothers/caregivers whose children experience AEFIs to report to the health facility for management. Most of the respondents have ever detected and reported an AEFI before to the next level, even though most did not use AEFI case-based form for reporting. This finding disagreed with that of a study in Kenya and Zimbabwe which indicated most health workers had never diagnosed a patient with an AEFI[6,8].

Interestingly, majority of the caregivers were willing to report AEFIs, unlike the observation from a 2013 study in Uganda where health workers were usually reluctant to report AEFIs due to the possible negative repercussions and fear of being blamed[10]. Moreover, some studies in United States and Nigeria showed significant proportion of respondents felt reluctant to report AEFIs because it could lead to personal consequences, and punitive actions[11,13]. Gender disparities in willingness to report AEFI was observed in this study. Female health workers were more likely to report AEFIs compare to male health workers (p=0.029).

Another undesirable observation was that, most facilities did not have AEFI reference guide and that almost all health workers did not use anaphylactic pack of adrenaline and hydrocortisone for emergencies during immunization services. This was mainly because the medications were not available.

Knowledge of mothers or caregivers about AEFI

Many of the mothers/caregivers knew about AEFIs indicators, this was, however, unrelated to their educational level (p=0.945). Majority of caregivers have reported AEFI before and were aware that treatment for

AEFIs is free of charge. Most have had counselling and education on AEFIs in contrast to a study in Zimbabwe where only 43.5% of caregivers had received education on AEFI[6]. Caregivers in this study were able to identify what will constitute an AEFI, compared to Mukkur et al., 2013 in Nigeria where a significant percentage of the mothers could not mention any of the adverse events that may follow immunization[15].

Rate of AEFI reporting

Generally, AEFIs were reported for only Pentavalent and Pneumococcal vaccines for the period 2013 to 2015. The low rate of AEFI reporting could likely be that most of the health workers did not know the definition of AEFI. This is supported by evidence from Zimbabwe that health workers did not know the definition of AEFIs[6]. Most of the AEFIs recorded were associated with pentavalent, unlike studies in Colombia and United States where the rates of AEFIs reported were associated with other vaccines as well[14]. The AEFIs reported in this current study were pain, swelling and redness compared to another Ghanaian study a decade ago (2007) which had fever, common cold, cough, vomiting, and diarrhoea as the commonest reported events[7].

Limitations

Caregivers who have been through all the scheduled immunization would be more likely to experience and AEFI. The current study had some caregivers who had only accessed only some of the vaccines for their children may not be likely to have had an AEFI experience.

Conclusion

The study revealed that, the rates of AEFI reported in the district from the year 2013 to 2015 for all the various antigens were below the WHO recommendations. There were gaps in knowledge of health workers with respect to the definition of AEFI, duration of AEFI investigation, and conditions that should be reported as AEFIs. In addition, health workers did not use anaphylactic pack at immunization sessions regularly as recommended. It is, however, important to observe that most caregiver believed poor AEFIs monitoring can lead to reduction in immunization coverage. The general challenges with immunization surveillance deserve unreserved attention to sustain interest in EPI services.

Abbreviations

Adverse events following immunization (AEFI), Bacille Calmette-Guerin (BCG), Diphtheria-pertussis-tetanus(DPT), Diphtheria-pertussis-tetanus-hepatitis B, Haemophilus influenza type B (DPTHepBHib), Oral polio vaccine(OPV), Statistical package for social sciences(SPSS),

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