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Research Article

Assessment of Factors Related to Reporting AEFIs and Parameters for Vaccine Safety Surveillance Improvement: Healthcare Workers Perspective in FCT, Nigeria

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Abstract

The gross under-reporting of Adverse Event Following Immunizations (AEFIs) does not permit for appropriate planning and decision making. The objectives of this study were to evaluate health care workers' perspectives, identify barriers to reporting of AEFIs and the parameters for improvement in AEFI surveillance. A mixed method approach was employed to evaluate healthcare workers Knowledge, Attitude and Practice towards AEFI monitoring and reporting using semi-structured questionnaires. Fifteen in-depth interviews of key managers of immunization were conducted to further understand the barriers to reporting and parameters for improving AEFI reporting. Responses were audio-taped and handwritten. Data were analyzed by transcribing recorded tapes into major themes. Most of the interviewed healthcare workers had good knowledge of AEFIs with statistically significant difference in knowledge between the different qualification levels at p=0.003. Results showed various facility management of identified AEFIs without appropriate documentation which may have contributed to the gross under-reporting of AEFIs. Majority of the participants acknowledged barriers to AEFI to include poor funding and logistic support to conduct AEFI investigations and surveillance, lack of staff motivation and poor transmission of identified AEFIs to the relevant authorities for decision making. Key recommendations for improvement and sustainability of the system include training and retraining of health care workers and provision of adequate government budgetary allocations for immunization and AEFI surveillance. There is under-reporting of AEFIs across the different levels of healthcare where immunization activities take place.

Keywords: AEFI, Attitude, Health care workers, Knowledge, Practice, Quantitative, Qualitative, Safety

Introduction

Vaccines are instrumental towards curbing epidemics and eradicating infectious diseases thereby reducing morbidity and mortality [1,2]. WHO noted that with increased sound scientific researches done worldwide to improve vaccination, new vaccines and combination vaccines are added to the immunization programmes to improve protection against vaccine preventable diseases. The resultant effect is that there may be more vaccine reactions as well as more coincidental events [3].

Post marketing surveillance (PMS) of AEFI system is very critical in the life cycle of any vaccine. Due to the inherent limitations

of clinical trials during the pre-licensure phase for vaccines, ensuring a robust system for such surveillance allows you to detect, correct and prevent program errors and other coincidental events that can mar immunization [4,5]. *Cunha, et al.,* [1] in their study, agreed that successful public health immunization programs can be achieved through surveillance and assessment of AEFIs which are imperative for sustaining vaccine safety. WHO has taken steps to establish, in 1999, the Global Advisory Committee on Vaccine Safety (GACVS) that provides advice to them on all safety concerns related to use of vaccines, enabling the organization to punctually and proficiently provide feedback to identified safety issues of global importance [6-8]. The passive surveillance system is currently used in Nigeria to monitor AEFIs. This system is marked with gross under-reporting of both adverse drug reactions (ADRs) and AEFIs. Early detection and appropriate prompt response to adverse events is the overall goal of an AEFI surveillance system. This will lessen negative impact on immunization programs and improve the health of vaccinees [7]. Post-marketing surveillance of vaccines should be timely done and in collaboration with vaccine manufacturers and other relevant stakeholders to detect problems associated with the use of vaccines in real life situations.

In Nigeria, the strategic role of health care workers in monitoring and reporting of AEFIs cannot be overemphasized. The healthcare workers and patients voluntarily report issues of adverse events experienced or detected using the spontaneous reporting (passive) system. A study by *Eliseu, et al.,* [9] noted that the passive system is the easiest and cheapest monitoring system based on voluntary report of adverse events by health workers or by the patients or caregivers. Also, due to their wide population base, identification of rare events and of the safety profile of various types of vaccines in the post-licensure period is possible. *Eliseu, et al.,* [9] also, stated that the major challenge with spontaneous reporting method is its inability to provide accurate risk estimates when using a denominator such as the number of doses of vaccine distributed or administered to define the exposed population. In the light of the above, active surveillance methods should also be in use to further characterize rare adverse events picked up during passive surveillance.

Since the passive reporting system is marked with gross under-reporting of both adverse drug reactions (ADRs) and AEFIs, it is critical to understand the reason associate with this. Review of various studies on reasons for under-reporting of ADRs/AEFIs showed that poor understanding of the healthcare professionals towards the existing pharmacovigilance (PV) program is critical to under-reporting. In Malaysia, lack of awareness about the existence, function and purpose of national ADR reporting were the major reasons for under- reporting [10]. In Nigeria, the commonest factors responsible for under-reporting were lack of knowledge on the availability of reporting forms and ignorance of the reporting procedure [11]. *Bhagavathula, et al.,* [12] reported that in a systematic review and meta-analysis of studies pertaining to KAP of PV and ADR reporting by Indian health professionals between January 2011 and July 2015, 55.6% (95% CI 44.4-66.9; p<0.001) of the population studied were not aware of the existence of the Pharmacovigilance Programme in India (PvPI), and 31.9% (95% CI 16.3-47.4; p<0.001) thought that "all drugs available in the market are safe". Furthermore, 28.7% (95% CI 16.4-40.9; p<0.001) of them were not interested in reporting ADRs and 74.5%, (95% CI 67.9-81.9; p<0.001) never reported any ADR to PV centers [12]. In Nepal, the reasons for under-reporting were that the healthcare professionals had not come across an ADR (57.1%), the ADRs were common and minor (14.3%) and lack of awareness about the pharmacovigilance center in the hospital (14.3%) [13]. According to *Paralla, et al.,* [14] limited research has been conducted on healthcare professional reporting of AEFIs. This is buttressed by the gross under reporting of AEFIs witnessed in the Nigeria National Pharmacovigilance Centre Database. With health care workers being key stakeholders in monitoring and reporting of AEFIs in Nigeria, this study focused on evaluating their perspectives to determine the barriers to reporting AEFIs and parameters for improvement of the AEFI surveillance system across the three levels of healthcare facilities vis-a-vis the primary, secondary and tertiary in FCT, Nigeria.

Materials and Methods Study Design/Setting

A mixed-method approach was employed; deploying cross-sectional quantitative and qualitative methods. The study was conducted in fourteen health facilities in six Area Councils in FCT, namely: Abuja Municipal Area Council (AMAC), Abaji, Bwari, Gwagwalada, Kuje, and Kwali, dis-aggregated into primary (6), secondary (6) and tertiary (2) health facilities. The quantitative study was carried out among sixty-one healthcare workers working in the three levels of selected health facilities to understand how the knowledge, attitude and practice of health workers impact their monitoring and reporting of AEFIs. In order to better understand and answer our key research questions on the barriers to reporting of AEFIs and the parameters for system improvement, qualitative in-depth face-to-face interview was chosen to evaluate the perspectives of fifteen key managers and Disease Surveillance and Notification Officers (DSNO) across the six Area Councils.

Data collection

Knowledge, Attitude and Practice (KAP) of health care workers were evaluated using a semi-structured interviewer's questionnaire, which was converted into an electronic form (personal data file/Tablet), to evaluate their perspectives towards AEFI monitoring and reporting. The questionnaire contained four demographic information, thirteen knowledge information, four attitude questions and twelve practice questions. Also, fifteen in-depth qualitative face-to-face interviews of key managers were conducted, using the developed and validated interview topic guide to further understand the barriers and parameters for improving AEFI reporting. The topic guide contained information on the experiences of AEFI by health workers, reporting of AEFI, workplace information, AEFI surveillance system, training information and considerations for

improvement. Based on responses given by the participants, follow up questions were asked for clarity and better understanding. The interviews were audio recorded using a phone as recording device, which was later transcribed and analyzed into major themes.

Recruitment of participants

A total of sixty-one health care workers working in the fourteen selected health facilities (University Teaching Hospital, Gwagwalada, National Hospital Abuja, Asokoro General Hospital, Abaji General Hospital, Kwali General Hospital, Kubwa General Hospital, Nyanya General Hospital, Kuje General Hospital, PHC Clinic Dutse Makarantha, PHC Dabi Bako Kwali, PHC Kuje, PHC Nuku Abaji, PHC T/Maje Gwagwalada and PHC Idu) were recruited using a convenience sampling method. The health care workers were adequately briefed about the study and an informed consent was gotten before the interview was conducted. Also, a total of fifteen key managers were purposively selected for the qualitative in-depth interviews. The participants include five Disease Surveillance and Notification.

Officers (DSNOs) coded as D (D1 - D5), five Local Government Immunization Officers (LIOs) coded as l (L1

- L5), Five Health Facility Immunization Officers coded as IO (IO1 - IO5) from the six Area Councils. These participants were briefed about the study and written informed consents were received. Appropriate time and place for the interview were discussed and agreed with each participant. The interview time varied between 25 and 60 minutes.

Data analysis

Statistical Package for Social Sciences (IBM® SPSS) Version 23.was used to analyze the quantitative data. Statistical significance was assessed at P≤0.05. All categorical study variables were described using frequency and percentages, while mean and standard deviation or median and interquartile range were used to describe numerical variables. Chi-square tests were used to establish comparisons between categorical variables. Kruskal Wallis test was used to compare mean ranking of outcomes of interest between educational categories. For the qualitative analysis, recorded interviews were transcribed into the written form. The data were cleaned, and transcript structured using thematic analysis. The interview data were coded and preliminary themes that demonstrated significant information to the research questions were created. Patterns in the data signifying repetitive ideas and viewpoints that demonstrated each participants' perspectives were identified. The final analysis focused on key themes, narratives and professional histories emerging from interviews were determined. Topical saturation was achieved as related themes appeared from various participants' after initial analysis of original interviews. Quotes and expressions that clearly denote the participants' thoughts and experiences discovered during analysis are shown in the results section.

Results

(Figures 1,2) (Tables 1,2) In assessing the attitude of health workers on AEFI reporting, their willingness to report identified AEFIs was evaluated. Result shows that 95.1% of them noted that they were willing to report AEFI once they have seen it, while 4.9% noted otherwise. Further assessment to understand the reasons behind those who indicated non willingness to report identified AEFIs showed that 42.9% did not know how to report it, while 14.3% mentioned that they did not know what to report, and 14.3% said they were not interested in reporting AEFI. However, 28.6% of the respondents stated that there were no AEFI reporting forms available at the health facility to report. In further assessment of the facilities to find out information on the availability and accessibility of AEFI reporting forms and line listing forms in the health facilities, it was noted that 70.5% and 75.4% of respondents indicated the availability and accessibility of AEFI forms and line listing forms respectively. This shows that these forms are available and not being put to effective use for reporting.

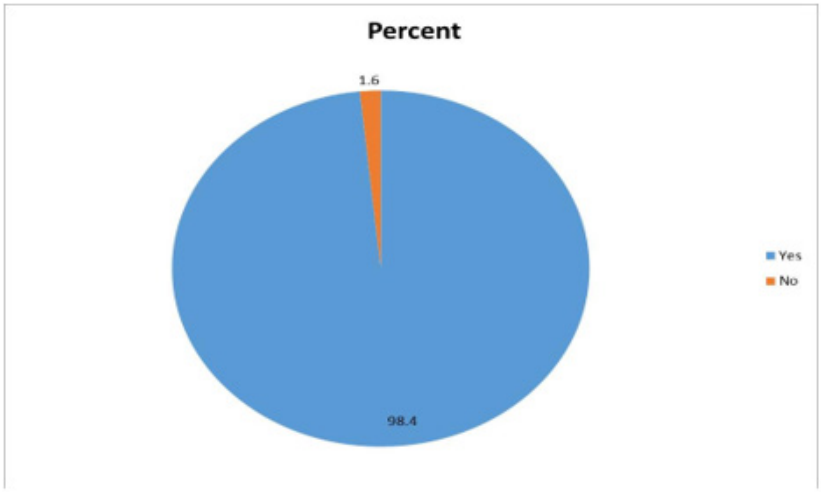

Figure 1: Health Care worker's Knowledge of AEFIs.

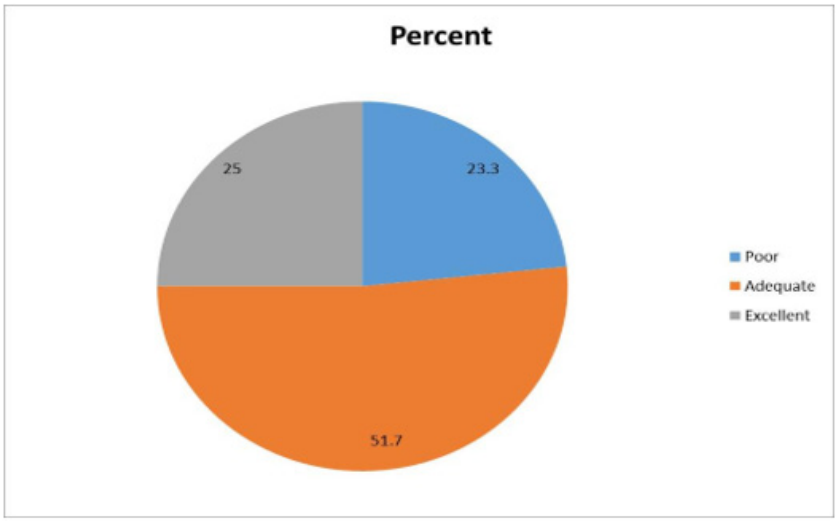

Figure 2: Healthcare worker's Knowledge Rating on AEFI.

Table 1: Demographic Information of Interviewed Health Workers for the Quantitative Assessment.

	N = 61	
	n	%
Sex		
Male	12	19.7
Female	49	80.3
Age Distribution (Years)		
20 -29	5	8.2
30 - 39	19	31.1
40 - 49	32	52.5
50 - 59	5	8.2
Qualification		
Certificate	7	11.5
Diploma	32	52.5
Higher Diploma	14	23
Degree	8	13.1
Distribution of Years of Experience of Health Care Workers		
0 - 3	4	6.6
>3 - 6	2	3.3
> 6 - 9	11	18
>10	44	72.1

Table 2: Assessment of Healthcare Worker's Knowledge Ratings on AEFI Information Compared with Qualification.

	Poor		Adequate		Excellent		Mean Ranking	P Value
	n	%	n	%	n	%		
Qualification								
Certificate (N = 7)	2	28.57	5	71.42	0	0	23.57	0.003
Diploma (N = 32)	11	34.37	15	46.87	5	15.62	25.73	
Higher Diploma (N = 14)	1	7.14	9	64.28	4	28.57	34.96	
Degree (N = 8)	0	0	2	25	6	75	47.25	

Results of analysis also revealed that 98.4% of the health workers accepted the AEFI monitoring, investigation and reporting as their professional responsibility with only 1.6% not agreeing to it. This shows a positive attitude but needs concerted effort by all healthcare workers to ensure they are put into effective use.

All the healthcare workers interviewed noted that that have witnessed at least one type of AEFI or the other during the course of their practice but they were mostly non-serious AEFIs as shown in Figure 4. Evaluating different actions taken by healthcare workers once an AEFI is identified has revealed a lot of facility management of the case as shown in Figure 5 with only 13.0% noting that they will fill the AEFI after administering treatment. This has revealed poor documentation is contributory as anything not documented is done (Figures 3-5) (Table 3).

Table 3: Demographic Information of Interviewed Health Workers for the Qualitative Assessment.

	N = 15	
	n	%
Sex		
Male	11	73.3
Female	4	26.7
Age Distribution (Years)		
30 - 39	7	46.6
40 - 49	4	26.7
50 - 59	4	26.7
Qualification		
Certificate	1	6.7
Diploma	1	6.7
Higher Diploma	7	46.6
Degree	6	40
Distribution of Years of Experience of Health Care Workers		
3 ->6	1	6.7
9-Jun	3	20
>10	11	73.3
Designation		
Registered Nurse	1	6.7
Community Health Officer	4	26.7
Community Health Extension	4	26.7
Worker		
Public Health Officer	5	33.2
Health Education	1	6.7

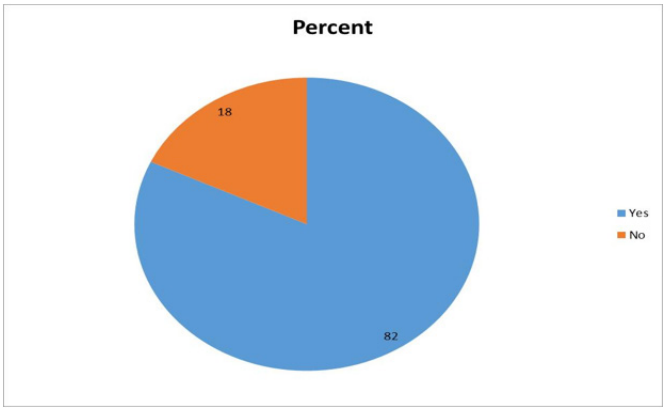

Figure 3: Healthcare workers who have witnessed AEFIs in Practice.

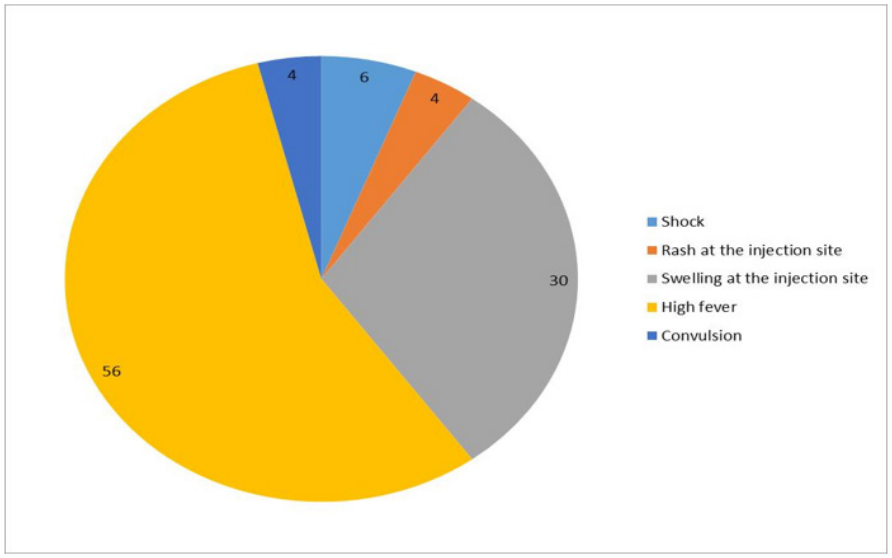

Figure 4: Patterns of AEFIs witnessed by Healthcare workers in Practice.

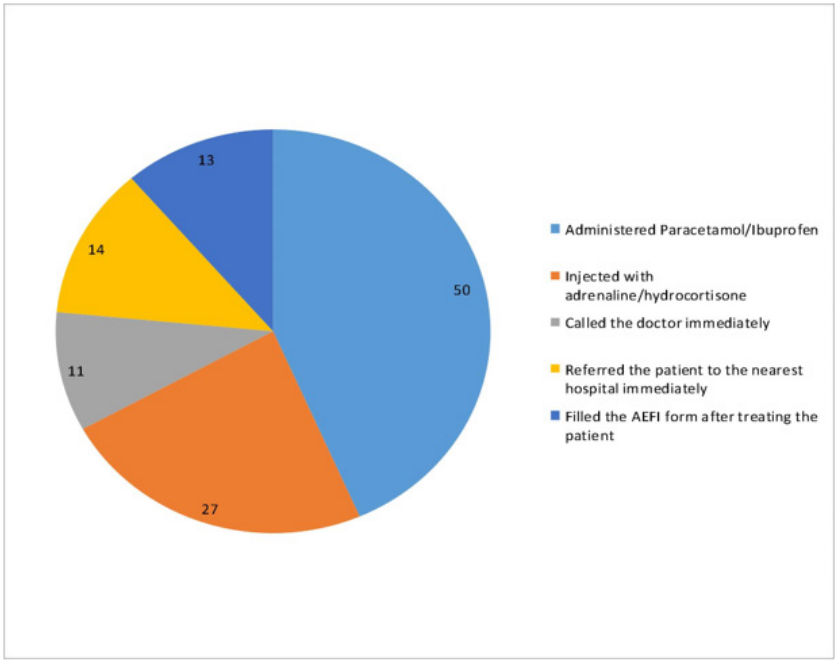

Figure 5: Actions taken by Health Workers to Manage Identified AEFIs.

Theme 1: Past Experiences of Health Workers in relation to AEFI and Reporting

While assessing the past experiences of participants in relation to monitoring and reporting AEFI, it was noted that all the interviewed participants have had one experience or the other with AEFIs. 66.7% of the participants noted that most of the AEFIs they have seen in their different settings were mostly minor ranging from fever, excessive crying, swelling and pain at the immunization site. Only 33.3% noted that they had witnessed serious AEFIs presenting as shock, convulsion, swollen eyes, rashes all over the body and abscess. Shown below are excerpts from the study participants.

Yes, in the over 15-16 years that I have been in service, I have not experienced any serious type of AEFI. But, with mild AEFI, I think they are uncountable, especially the routine vaccine we do every day that is the pentavalent vaccine that leads to rise in temperature of the child and make the child uncomfortable. It is a concern to the parents and they report back to us. They report restlessness, rashes, vomiting and swelling at the site of injection. L3

Well, the kind of AEFIs I have seen before are local reactions at the site of the injection or excessive crying of the child for more than 3 hours or fever after receiving the immunization. D3

Yes, in 1998 or 1999 when I was in Kubwa, one of my colleagues experienced it. You know by then we were giving DPT, when we gave the child DPT, so after 30 minutes or an hour later, the child started having convulsion. That was then and thank God we were in the hospital. So, the child was rushed- to emergency. That was the serious one I have ever seen. And since then I have not come across any to be sincere. IO2

The one I have seen is rashes in the body and swelling at the site of injection. Even shock I have seen it and anaphylactic shock I have seen it was when we were doing MenAfriVac meningitis immunization, that was when I saw the shock and since I was part of the team with the team of doctors we were able to manage the situation. L5

Theme 2: Awareness of AEFI Reporting System

All participants interviewed noted that they were conversant with the reporting system as they enumerated the use of line listing forms provided to them in booklet form to record the minor AEFIs. They also explained that there is an AEFI reporting and investigation forms provided for use for serious AEFIs. They further explained the reporting processes in their workplaces, noting that the immunization clinic staff compile these reports in the line listing form and submit to the Local Immunization Officer at the Area Council at the end of every month for onward submission to the State. Few excerpts include:

Yes, usually it is the same procedure, they call us we now line list their names and we also do the same thing, we forward to the state as usual so I don't think the system will change because the system is okay L2

We have a form we document all the information. The form is called the line listing form where we write the name of the child, the address, the time the immunization was administered, the time the mother notice the changes, and the time she comes to lay the complain to you and the type of vaccine you are relating the reaction to. L3

No, we report them that is why I told you that we have a line listing form. We report all those AEFI on line listing form because they are minor cases to God be the Glory, we have not had a case that we have to use adrenaline or cortisone. IO3

Well, by and large is to call the officers in charge that is if I am not at the level of investigating, the LIO is there, the DSNO is there, the WHO, the disease surveillance officers will be called upon, but first it starts with the focal person at the ward level, the LIO, DSNO at the LGA level, then the State DSNO, the state epidemiologist like that we have the hierarchy in reporting immediately those cases are investigated depending on the severity but there are mild ones that we document and we don't need to report those ones but the ones that are severe that needed intervention are to be reported. D2

Theme 3: Factors that Facilitate the Reporting of AEFIs

In order to understand participants' attitude towards reporting AEFIs, we evaluated why they would want to report AEFI once they identify it during their practice. Several reasons proffered revealed that the health workers understood the importance of reporting AEFIs. Such reasons included the need to save the life of the child by understanding the cause of the AEFI and identifying corrective measures so that immunization is not marred. Few key responses are as stated below:

One of the reasons why I am reporting is to know what is the cause of the reaction because sometimes the cause can be from the health workers or it can be from the manufacturer because, let's give an example, if you are using the diluent of measles to dilute another vaccine it can be a cause of reaction or from the manufacturer you are buying from so reporting can give you a chance to verify or to know what is the cause or why is the problem coming. D4

Okay when the case becomes so serious we have to report to them because if it involves death the parents may take it as if it is because of the vaccine that was administered and that may affect other immunization, so we report it for immediate intervention so that other people will not run away from immunization activities. D5

Yes, because it helps in research, so when we have such report or important reporting pattern based on what is happening, a study will be made and see what is causing that so we can take another dimension to succeed in what we want to do. IO2

From my own perspective it is my duty to report and document, and the reporting is taken for planning to enable them see what can be done to bring improvement to the vaccine. It is important so that it can be investigated so as to know whether it is really related to what we are giving. D2

Theme 4: Barriers to Reporting of AEFIs

Due to the low reporting of AEFIs, the study tried to identify possible barriers to AEFI reporting. Reasons noted from the interview varied from poor attitude and relationship of health workers with clients; inadequate human resources at the immunization clinics leading to increased pressure of work; poor logistic support to conduct AEFI investigations and surveillance; fear of punitive measures when they report AEFIs; poor feedback on reported AEFIs; inadequate Government Budgetary allocation for immunization activities leading to high dependence on Partners supported funds; poor transmission of reported AEFIs to the appropriate authority; and lack of staff motivation to conduct AEFI surveillance. Excerpts from the interview are represented below:

As I said, it depends on your relationship with your clients because if you do not have good relationship with your clients, your clients will not be able to come back to you and tell you what their experiences are. If you don't have that care or that passion you may not be able to keep a cordial relationship with them. IO2

Immunization is not funded by government. What am trying to say is that when you look at it, it is only partners that assist routine immunization currently; it is only when the partners come in that we get funding. When they are not in there is no support from government, the local government is not really supporting the immunization program. There is no logistic support for AEFI monitoring, outreach services, supervision and regular meetings we conduct. So, you can see if all these things are to be put in place there will be improvement for Nigeria health systems and it will really help in AEFI monitoring and reporting. L1

It may be due to the pressure of work. A lot of documentations have to be done at the end of the day, you have to count the vaccines used and compare with what is remaining. Also, you need to do vaccine accountability; we account to different supervisors coming to our clinic so the pressure of work can be a barrier. IO5

Yes, there is logistic issue and I think that is the major barrier. What I mean is that the supervisors that are to monitor this AEFI issue do not have transportation and sometimes, even if they have to release the transportation, it usually come in at late hour. If you have a session like tomorrow, you need the transportation to have been released earlier for adequate planning. Also, distance is a barrier, it is difficult to get there on time. Time factor could also be another barrier. So, logistics and commitment are also part of it because if you are not committed, even if you are given the support, you may divert the fund and not carry out the work. IO4

Even those that report, there is no feedback, so how would you know that something is being done with such report. Are they just collecting the report for reporting sake? Do you understand, but if there is feedback from those collecting the report, you will know that oh! Something is going on. There are people that are responsible for this thing knowing that you are their down line and you need to report to them because they cannot be everywhere that is the truth but if you are reporting and there is no feedback, you will not know if your report is being used or not. IO2

They assume that when they report AEFI they will be penalized or sanctioned thinking that maybe they are the cause of such AEFI but with the orientation we are now giving our health workers they are now reporting it. We use to tell them that reporting AEFI is not fault finding just that we want to know how people are reacting to the vaccine that we are administering so that action could be taken. L4

Yes, let me say ignorance is number one, the person giving the injection, if he is not aware of what an AEFI is, he will not report it. D3

Lack of man power, lack of motivation to encourage the health workers these two are very key, then training of the health workers. Sometimes, you also know that those living in the city are different from those in the rural area. Rural areas are hard to reach with less manpower. In the town, you see they often tend to have more staff but in the rural area, you have one or two and you see the number of clients that visit our clinics in the rural areas. IO2

There is problem of poor transmission of reported AEFIs from those that collected the data from the health facilities. If we report and they don't submit to the appropriate authority, they will not know that we are reporting. Supposing you are not here, you will not know that I am reporting AEFI on monthly basis but it is not getting to you over there. I believe it is not only me because there are others that are reporting too but it is not getting to the right channel maybe. So those that are collecting the data may not be submitting it. IO2

Theme 5: Receipt of Feedback on Submitted AEFIs from Higher Authorities

Poor feedback mechanism from National to States and to health facilities on reported AEFIs was clearly noted as a major barrier to reporting. Key managers noted that if they received adequate feedback on reported AEFIs, they will be able to understand if they are due to the vaccines, immunization error related or other causes. This will help them identify corrective measures in order to improve immunization integrity. Few excerpts from the interview are stated below:

We do not usually receive prompt feedback from the States on submitted AEFI reports. Any further information on submitted AEFI report is only obtained during monthly review meetings. Whenever we submit AEFI even if they cannot follow up, they should at least be able to trace through the LGA, that will encourage us that truly they are acting on the report we are giving them, but anytime we submit such report unless we come for monthly review meetings before we hear anything about it because at least any report you submit you are expected to get feedback for you to be able to improve more. IO4

As we are reporting our monthly summary, we send it to the LIO who sends it to the state and then we identify the AEFI cases that we experience during the period and then we send it to them but we do not know what they do with it. They do not give us any feedback from the State on AEFI reports we submitted.IO2

Theme 6: Workplace Information Sharing on AEFI

The workplace information sharing on AEFI was evaluated to determine if there is freedom of discussions and peer reviews on issues bothering on AEFIs monitoring and reporting. The results showed that the healthcare workers were aware of the existing guidelines for monitoring and reporting AEFIs in the workplace and AEFIs reporting form part of their monthly meeting accountability framework. Few excerps from interview are:

Yes, we do. We discuss it freely for example like this workshop we are having now, we discuss it, even during our monthly RI meetings, and we discuss AEFI with the health workers and we also advise them not to be holding AEFI cases, that they should be reporting it. L4

Yes, every day before we start the immunization session we sit down and discuss. During health talk also we tell mothers about AEFIs. IO1

Theme 7: Preferred Reporting Format

In order to identify whether there is need for a change or improvement in the current reporting format, the health care workers were asked of their preferred reporting format. It was noted that most of them still preferred the already existing paper format of using the line listing form for non-serious AEFIs and AEFI reporting and investigation forms for serious AEFIs. They identified gaps in availability of the forms as at when needed and the poor transmission of filled AEFI and investigation forms to the national office for causality assessment of reported serious AEFIs is huge. Key reported findings include:

I think that is what we are already doing every month we give paper report. So I think the current format is okay if there is any case, the DNSO must know, the LIO must know, the HOD must also know and then they take it up from there.IO3

Yes, the current format like the line listing form is very okay. We write the child name, the address, the phone number of the parent, the type of vaccine taken by the child, the code and the line of management.IO1

The format we are using now I think I am okay with that because when you see a case is for you to make a call and fill the form. I don't think I have any other idea of better formats and if it is a serious one we already have a contact we can take the patients to so I don't think there is any other. D4

I think that is what we are already doing every month we give report. So I think the current format is okay if there is any case, the DNSO must know, the LIO must know, the HOD must also know and then they take it up from there. IO3

Yes, there is a designed form already on ground that will be required to fill in the name of the child, in fact, all the information required from the child will be there and then the type of AEFI that you see from the child you must have to fill it. Then you keep a copy for you own record purpose then forward the other copy to the higher level that is to the LIO as I told you, then the LIO will now submit to the state then the state will submit it to national. L4

Theme 8: Health Care Worker Trainings and Ideal Way to Improve Training

All the interviewed participants noted that they have attended one training or the other during their practice. Few reports are shown below.

Yes, there is one that UNICEF gave us on vaccine handling and in most cases, they organize training on vaccine at the state level. And sometimes it is the CCO that are called upon for training because they handle the vaccine more and the cold-chain officer. Yes, we are always trained and we also do refreshers training always too. L5

The training…. Like that of last year that just passed that was during November and December, we had a training of all the vaccines even the one that we have and the ones they are yet to bring like Rota virus. We are yet to handle it but the training has been going on. There is no any vaccine that comes that the training will not begin just like when we were changing from DPT to Pentavalent vaccine, we had training. So most of the time, we have training and also most of the time in the year they call us for training to assess us whether we are doing well. The WHO, the state and the LGA come for supervision on how we handle vaccines and to make sure that the training we received we are making use of them. IO2

Well, the ideal way in my own thinking is to train the health workers for certain number of times and make sure the training is participatory. Like I say the training should be hands-on, you do small training and do more of practical. L5

To train all health workers, I know it will not be easy, but you can train them in batches since we have our nominal role, we can gather them per LGA and give them quarterly training or yearly. IO1

Theme 9: Recommendations for Improving AEFI Reporting

In order to improve AEFI reporting in Nigeria, continuous training and re-training of health care workers is key. Continuous assessment and evaluation of impact of training of health workers in their day to day work is also imperative. Motivation of health care workers who have performed excellently in their work can stimulate positive competition thereby improving reporting. There is the need for appropriate government budgetary allocation for the immunization programme and logistics for AEFI surveillance. Result also showed that making provision for free treatment of AEFI cases can stimulate reporting. Extracts from results are shown below.

Yes, if you see another person that is given incentive for doing what is good, maybe others will try and emulate that person and incentive could be in many ways. It could be monetary, it could be award, and it could be certificate. It could just be anything just to acknowledge the person's good work. Like me I just do my work because of the passion I have for children. You see they call me mama yara. So you cannot change people the way they are everybody with his own motive. IO3

Well number 1, the health workers need to know what an AEFI is and they need to know what they should do if they see it and then if there is a way that fund can be released to them just like they have made some of this priority disease they pay like guinea worm anybody that sees guinea worm you will be give an amount of money so if you can empower the health workers and release fund to them it will help in the reporting of AEFI. D3

First of all, I will ensure that I provide logistics support to my subordinates, and also I will look for a way of committing them that the right things are done at the right time. And if they go out to a place for supervision, they should ensure they come up with evidence by snapping pictures of the place. They need to motivate them because motivation plays a key role in the life of health workers by supporting them with logistics and encouraging them to bring back evidence that they have visited the places. You don't expect them to use their salaries to work. IO4

Training and also with this AEFI let them provide first aids so that if the mothers know that when they report, they will give them something to give to their children they will be reporting. The mothers don't report because they know that when they report they don't know have money to buy cards and the drugs that will be prescribed to them they may not have money to buy the drugs, because like this measles campaign, we were given AEFI Kit, we were given paracetamol, adrenaline with syringe you know people will be aware that if they report AEFI something can be done and something will be given to me. Treatment should be made free for those who experience AEFI after receiving immunization. By this, mothers will be encouraged to report. NIO2

Discussion

The passive surveillance system currently used in Nigeria for AEFI surveillance is inundated with gross under-reporting of AEFIs as witnessed by the number of AEFI reports in the NPC database [15]. In order to understand the reasons for under-reporting of AEFIs in Nigeria, the strategic role of healthcare workers in AEFI monitoring and reporting cannot be overemphasized. The knowledge, attitude and practice of healthcare providers working in immunization clinics were studied for better understanding of the reasons for under-reporting of AEFIs in Nigeria. Result of the quantitative assessment revealed that healthcare workers had very good knowledge of what constitutes an AEFI, the causes of AEFIs and the content of an AEFI kit which is used to manage serious AEFIs at the primary health facilities before the patient is referred to the secondary health facility for adequate management. This could be explained by the routine trainings that they have undergone during their practice and these results are in concordant with the result of the study by *Ogunyemi, et al.,* [16], which showed that health workers had good knowledge of what constitutes an AEFI16. Although, most of the reports made by the health care workers showed mostly non-serious AEFIs, it may be deduced that lack of knowledge in identifying symptoms that constitute serious AEFIs may be the reason for their under-reporting. Also, serious AEFIs can be under-reported or missed out completely due to their low frequency of occurrence. For subject having a serious AEFI that need medical attention, it is critical that careful medical evaluation is carried out to confirm the diagnosis, causally assess the probability that vaccine caused the AEFI and assess the safety of future immunizations [17].

When the level of qualifications of health care providers were assessed with respect to their knowledge of immunization and what constitutes an AEFI, it was noted that qualification was significantly associated with knowledge. This is also in agreement with the result of study conducted by *Calistus, et al.,* [18], which showed that increased education had positive impact on knowledge of AEFI surveillance [18]. Although, a greater percentage of the healthcare workers indicated willingness to report identified AEFIs, there is still gross under-reporting. Key reasons documented in the study for not willing to report AEFIs include not knowing what to report and how to report. These findings are in agreement with the study by *Irsida, et al.,* [19], which revealed that barriers to reporting included lack of interest, unclear definition of AEFI and lack of awareness of what to report. Continuous training and re-training of healthcare workers are critical to ensure that they are updated with current information on immunization resulting from new vaccines or new vaccines combinations that may be added to the routine immunization schedules including educating them on current and updated AEFIs reporting tools. It has been noted from this study and other studies that non-serious AEFIs are the most commonly reported AEFIs. Healthcare workers engage greatly in facility management of these non-serious AEFIs without appropriately documenting them. This can be explained by their poor attitude of thinking that only serious AEFIs should be reported. This may have contributed to the gross under-reporting of AEFIs noted in our system. It is important to note that all AEFIs whether serious or non-serious should be documented appropriately and transmitted to the regulatory authority where informed decisions about the safety of the vaccines can be made. This underscores the importance of continuous training and retraining of health workers about the AEFI surveillance system in the country and the importance of reporting all identified AEFIs.

A further in-depth assessment to determine key barriers to AEFI reporting and parameters for improvement of the AEFI surveillance system was conducted. Although health care workers understand that it is part of their professional responsibility to monitor and report AEFIs, key factor that facilitate reporting is to ensure that mothers/caregivers do not lose confidence in the overall immunization activities thereby resulting in outbreaks of preventable diseases.

Major reasons for under-reporting of AEFIs by health care workers as revealed from the study showed that poor attitude of healthcare workers leading to poor relationship with clients is critical. When health care workers are not cordial with their clients it becomes difficult for them to come back to report any negative events experienced. Also, fear of being punished or stigmatized as inefficient in executing their duties was identified as a barrier to reporting. It is important for health care workers to know that reporting identified AEFIs does not translate to punishment but rather to improve safety use of those vaccines within our own population. This should be brought out as a key message in the training modules on AEFI surveillance in Nigeria.

Another key barrier identified in this study was the poor funding of immunization activities by the government. It was noted that immunization is largely partner driven and that AEFI surveillance at the states and local government areas are not well funded. This creates a huge gap when AEFI reports are notified from remote villages where it becomes impossible for investigation to be conducted and documented appropriately.

Feedback from the interview results showed that fewer health care workers are posted to immunization clinics in the rural health facilities as compared to the urban facilities. With the population that visits the rural facilities and the over-whelming work schedule, this may contribute to the gross under-reporting of AEFIs.

Although results revealed that paper reporting of AEFIs is preferred by health care workers, but the identified gaps in availability of the forms as at when needed and the poor transmission of filled AEFI and investigation forms to the national office for causality assessment of reported serious AEFIs is huge. This, therefore, underscores the need to create an appropriate electronic platform that will ensure real time reporting of AEFIs to enable prompt regulatory decisions and actions on the identified AEFIs.

In order to improve AEFI reporting in Nigeria, it was noted that the need for training and re-training of health care workers cannot be overemphasized as they need to be continuously reminded of what an AEFI is and what to do in presence of an AEFI. Continuous assessment and evaluation of impacts of training in their day to day work is imperative as it was clear from the results that the reasons proffered by some health workers for not willing to report is lack of knowledge on how and what to report. Increasing supervisory visits to immunization clinics and assessment of their record keeping and documentation can actually correct the gaps in AEFI reporting. Healthcare workers identified as doing well in their job schedules can be given incentives for excellent work done. This could serve as good motivation among their peers and could stimulate positive competition. Strong recommendation for treatment to be made free for those who experience AEFI after receiving immunization was noted from this study. This could encourage mothers whose babies experience AEFIs to come and report since they know their babies would receive free treatment. The Government of Nigeria should therefore begin to look at modalities to implement this as this could improve monitoring and reporting of AEFIs.

Providing adequate logistics support for AEFI surveillance has been elaborated as one of the ways to improve monitoring and reporting. The funding of the immunization clinics and support for AEFI surveillance has been grossly inadequate. The routine immunization programme and the vaccine campaigns are majorly donor and partner supported. This puts the sustainability of the immunization programme in Nigeria questionable. The need for appropriate government budgetary allocation for the immunization programme and logistics for AEFI surveillance is critical towards improving monitoring and reporting of AEFIs in Nigeria.

Conclusion

This study has shown that there is gross under-reporting of AEFIs across all levels of health care. Although, healthcare workers are knowledgeable on components of immunization, AEFI monitoring and reporting, with high willingness to report but the large-scale facility management of these identified AEFIs without appropriate documentation may have contributed to the gross under-reporting prevalent in the healthcare system. The need for training and retraining of healthcare workers cannot be overemphasized but it is critical to standardize and harmonize the content of information that healthcare workers receive and also provide to mothers during the early morning talks before routine immunization. This study also revealed that poor funding for AEFI surveillance and investigation of serious AEFIs from Government of Nigeria has contributed to under-reporting as most of the activities are donor funded and does not create room for sustainability. There is great need for a concerted effort by government at all levels of operation and care to work closely and provide adequate budgetary allocation for AEFI surveillance as this will help curb this menace of under-reporting and provide evidence-based information for decision making to ensure safety use of vaccines in country.

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Author Contributions

EUG, EE and ECO developed concept and design of the study, UGE collected the data, analyzed data and drafted the article. The three authors interpreted the data, reviewed article content and approved final version.

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Declarations

ETHICS Approval and Consent to Participate

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All participants of the study were orally informed about the objectives and anonymity of the study and informed consent were sought from participants before commencement of Interview. All data collected were kept confidential.

Consent for Publication

Not applicable.

Competing Interests

The authors declare that they have no competing interests.

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