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TREND ANALYSIS OF THE CASES OF ADVERSE EVENT FOLLOWING IMMUNIZATION (AEFI) REPORTED IN NIGERIA BETWEEN 2011 AND 2018

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ABSTRACT

Background: Assured quality vaccines and safe immunization practices are paramount to successful immunization programs. This study documented the trends of Adverse Events Following Immunization (AEFI) case reporting between 2011 and 2018 in Nigeria. **Method:** This was a descriptive retrospective secondary data analysis of the AEFI cases collected between 2011 and August 2018 through the AEFI surveillance system. The data was sourced from immunization database at National Primary Health Care Development Agency headquarters, Abuja. **Results:** In the period under review, about 20,668 AEFI cases were reported. Majority of the AEFI cases (88%) were reported during Supplementary Immunization Activities (SIAs) while the remaining AEFI cases (12%) were reported under Routine Immunization (RI) session platforms. There was no record for AEFI cases following RI from 2011 to 2016. In contrast, AEFI cases due to SIAs were recorded every year from 2011 to 2018. The highest number of AEFI cases due to SIAs was recorded in 2017 while the least was recorded in 2011. A breakdown of all the AEFI cases reported between 2011 and 2018 by the 36 states of Nigeria and the FCT showed that Kaduna, Kebbi and the FCT recorded the highest numbers of AEFI cases while Bayelsa, Kwara and Ebonyi states recorded the least. **Conclusion:** Clearly, the sensitivity of the AEFI

surveillance system in the country is quite low. However, with the renewed vigour towards improving routine immunization and AEFI surveillance, we expect improved capacity to detect, manage and report all cases of AEFI as they occur.

KEYWORDS: Adverse Event Following Immunization, Secondary data, Secondary analysis, Nigeria.

INTRODUCTION

Prevention of childhood communicable diseases through vaccination is no doubt one of the most cost effective public health intervention measures.[1] For example, over 2.5 billion children worldwide have been vaccinated against poliomyelitis, and this resulted in a 99% decline in the number of cases due to poliomyelitis.[2]

However, no vaccine is perfectly safe. Occasionally, untoward medical occurrence which follows immunization but do not necessarily have a causal relationship with the usage of the vaccine occur. These are referred to as Adverse Events Following Immunization (AEFI).[3] Adverse Events Following Immunization may be any unfavourable or unintended sign, abnormal laboratory finding, symptom or disease. An AEFI case may be classified as either serious or non-serious.[4] Serious AEFIs are those which are life-threatening, resulting in hospitalization or prolongation of hospitalization, resulting in persistent or significant disability, or where the outcome is a birth defect or death, as defined by the World Health Organization (WHO).[5,6]

The occurrence of unreported AEFI cases in most communities in Nigeria has increased concerns regarding vaccine safety.[7,8] When public confidence in vaccination is lost, herd immunity decreases because of the resultant decline in vaccination coverage, and outbreaks may occur.[9] To avoid such consequences, monitoring vaccine safety is considered to be one of the most essential public health measures that can be implemented to maintain public confidence in vaccination programs.[9]

In this light, AEFI surveillance plays a major role in detecting, notifying, investigating, reporting and responding to the community concerns while sustaining public confidence in the vaccines being administered.[10] AEFI surveillance can be active, passive or a combination of both as in many developing countries including Nigeria. Globally, a minimal reporting rate of 10 cases per 100, 000 doses administered has been set for vaccine safety

monitoring for a functional AEFI reporting system.[11,12] This, if embraced by all countries will help to strengthen AEFI reporting, just as the two core Acute Flaccid Paralysis (AFP) indicators did for AFP surveillance.[13–16] However, AEFI documentation is limited in most developing countries including Nigeria due to low case reporting rates often explained by a lack of resources. A recent analysis carried out by WHO also reported that over 36% of WHO member countries did not have a functional post-licensure safety monitoring system for vaccines.[17]

The aim of this study was therefore to document trends in the AEFI reporting in Nigeria using secondary data obtained from the National Primary Health Care Development Agency covering from 2011 to 2018. Findings from this study will be useful to National Primary Health Care Development Agency who is the sole immunization program manager in Nigeria and development partners supporting the program in re-strategizing for improved mechanisms towards AEFI case reporting.

METHOD

Study Location

Nigeria is a country in West Africa. The country is bordered to the west by Benin republic, to the east by Chad and Cameroon and to the north by Niger. Its coasts in the south lie on the Gulf of Guinea in the Atlantic Ocean. The country is made up of 36 states (and the Federal Capital territory) and 774 Local Government Areas (LGAs) grouped into six geopolitical zones namely: south-south (SSZ), south-west (SWZ), south-east (SEZ), north-west (NWZ), north-east (NEZ) and north-central (NCZ). The current population of Nigeria is estimated at 191 million people as of 11th October 2017 based on United Nations estimates. This study consists of reports of AEFI cases from the 36 states of Nigeria, including the FCT, between 2011 and 2018.

Study Design

This was a descriptive retrospective secondary data analysis of the AEFI cases reported between 2011 and August 2018 through the AEFI surveillance system.

Study Population

All the 20,668 reported AEFI cases (both from routine immunization and supplemental immunization activities) from the National Primary Health Care Development Agency database was reviewed for this study.

AEFI surveillance in Nigeria

AEFI surveillance is a combination of active and passive AEFI surveillance systems. In passive surveillance, health workers and the general public spontaneously reports any condition they believe could be associated with vaccination. Active surveillance however, involves a systemic search of defined AEFI cases in target populations. It covers defined population and it's carried out through systemic review of hospital records for AEFI. Nigeria practices a combination of passive and active AEFI surveillance. The flow of information in the AEFI surveillance system is from the health facilities to the LGA Disease Surveillance and Notification Officers (DSNOs), to the states DSNOs and finally to the National Primary Health Care Development Agency. Feedback goes through the opposite direction. At all levels information is shared with development partners.

AEFI case reporting and documentation

All cases of AEFI must be documented in the AEFI case reporting forms and Line-list forms. If the AEFI case is classified as serious, an alert is sent to commence investigation within 24 hours by the LGA AEFI committee. All AEFI cases detected during a month are counted and entered in routine surveillance reports. If no AEFI cases are reported in a month, zero must be recorded in the AEFI surveillance forms. These forms are then submitted on monthly bases, to the LGA DNSO who shares with the state DSNO for onward transmission to the national level.

Data analysis

Relevant data was sorted and extracted from the database of the National Primary Healthcare Development Agency. Univariate and bivariate analysis was done using Microsoft excel 2016, Epi-info7, and Health-Mapper.

Ethical Consideration

Ethical approval and clearance were obtained from the National Primary Healthcare Development Agency, which is an organ of the health system under the supervision of the Federal Ministry of Health.

RESULTS

Table 1 showed the distribution of AEFI cases reported between 2011 and 2018. A total of 20,668 AEFI cases were recorded from both routine immunization sessions and Supplemental Immunization Activities (SIAs). About 88% of the AEFI cases were reported following SIAs

while the remaining 12% of AEFI cases were reported following routine immunization sessions.

AEFI cases following routine immunization were only recorded in 2017 and 2018. There was also a 2% to 60% increase in the total number of cases reported between 2017 and 2018. On the other hand, AEFI cases due to SIAs were recorded every year from 2011 to 2018. The highest number of AEFI cases due to SIAs were recorded in 2017 while the least were recorded in 2011.

Table 1: Distribution of AEFI cases reported between 2011 and 2018 in Nigeria.

Year	Routine Immunization (%)	Supplementary Immunization Activities (%)	Total
2011	ND (0)	212 (100)	212
2012	ND (0)	146 (100)	146
2013	ND (0)	3,615 (100)	3,615
2014	ND (0)	2,244 (100)	2,244
2015	ND (0)	4,058 (100)	4,058
2016	ND (0)	1,754 (100)	1,754
2017	104 (2)	4,380 (98)	4,484
2018	2,478 (60)	1,677 (40)	4,155
Total	**2,582 (12)**	**18,092 (88)**	**20,668**

ND = No data

A breakdown of all the AEFI cases reported between 2011 and 2018 by the 36 states of Nigeria and the FCT were illustrated in table 2. Kaduna, Kebbi and the FCT recorded the highest numbers of AEFI cases while Bayelsa, Kwara and Ebonyi states recorded the least. Akwa Ibom and Rivers state were the only states with no data for AEFI between 2011 and 2018. Benue and Cross River states were the only states to record at least one case of AEFI for 5 and 6 years respectively out of the 8-year period under review in this study. Also, Bayelsa, Borno, Delta, Kwara, Ogun and Osun states only reported AEFI cases for just one year out of the 8-year study period.

Table 2: State level distribution of reported AEFI cases between 2011 and 2018 in Nigeria.

S/N	States	Number of AEFI cases reported by Year								Total
		2011	2012	2013	2014	2015	2016	2017	2018	
1	Abia	0	0	0	0	0	179	0	0	**179**
2	Adamawa	0	0	125	0	1	0	142	0	**268**
3	Akawa Ibom	ND	ND	ND	ND	ND	ND	ND	ND	**ND**
4	Anambra	0	0	0	111	0	15	0	0	**126**
5	Bauchi	151	0	0	0	364	0	464	0	**979**
6	Bayelsa	0	0	0	0	0	17	0	0	**17**
7	Benue	1	1	1	433	195	0	0	454	**1,085**
8	Borno	0	0	0	0	0	0	339	0	**339**
9	Cross river	1	1	133	370	0	119	0	0	**624**
10	Delta	0	0	0	0	0	40	0	0	**40**
11	Ebonyi	0	0	2	24	0	4	0	0	**30**
12	Edo	0	0	0	0	1	48	0	0	**49**
13	Ekiti	0	0	0	115	0	236	0	0	**351**
14	Enugu	0	0	0	222	0	47	0	0	**269**
15	FCT	0	0	54	0	0	0	85	2,890	**3,029**
16	Gombe	8	0	0	0	39	0	10	0	**57**
17	Imo	0	0	12	71	0	31	0	0	**114**
18	Jigawa	19	0	0	0	33	3	41	2	**98**
19	Kaduna	0	0	2,654	0	88	0	1,541	2	**4,285**
20	Kano	0	134	0	0	35	0	7	0	**176**
21	Katsina	31	0	0	0	88	0	146	0	**265**
22	Kebbi	0	0	506	0	2,108	0	1,051	0	**3,665**
23	Kogi	0	0	1	369	816	0	0	0	**1,186**
24	Kwara	0	0	0	103	0	0	0	0	**103**
25	Lagos	0	0	5	0	0	6	20	0	**31**
26	Nasarawa	0	0	35	0	0	0	0	431	**466**
27	Niger	0	0	2	0	0	0	0	131	**133**
28	Ogun	0	0	0	0	0	71	0	0	**71**
29	Ondo	0	0	0	94	0	96	0	0	**190**
30	Osun	0	0	0	0	0	716	0	0	**716**
31	Oyo	0	0	0	332	0	126	0	0	**458**
32	Plateau	0	0	46	0	0	0	3	244	**293**
33	Rivers	ND	ND	ND	ND	ND	ND	ND	ND	**ND**
34	Sokoto	0	10	1	0	47	0	8	0	**66**
35	Taraba	0	0	38	0	195	0	42	0	**275**
36	Yobe	0	0	0	0	0	0	579	1	**580**
37	Zamfara	1	0	0	0	48	0	6	0	**55**
Total		**212**	**146**	**3,615**	**2,244**	**4,058**	**1,754**	**4,484**	**4,155**	**20,668**

ND: No Data

DISCUSSION

Assured quality vaccines and safe immunization practices are paramount to successful immunization programs.[18] The aim of the AEFI surveillance system is therefore to ensure the detection and analysis of adverse events and the institution of appropriate measures to reduce the negative impact on the health of individuals and the immunization program. This paper documents the trends of AEFI case reporting from 2011 to 2018 in Nigeria.

Nigeria had no data for AEFI activities following RI sessions between 2011 and 2016 against the recommended WHO case detection rate of 10 serious cases per 100,000 surviving infants for a sensitive AEFI surveillance system. Records of AEFI cases reported following RI only started to surface in 2017 and 2018. This result disagrees with a study carried out in Guruve district, Zimbabwe where no case of AEFI was recorded between 2017 and 2018.[3]

Clearly, the AEFI surveillance system in the country lacks sensitivity and is therefore unable to monitor changes in the number of cases reported over time. This lack of sensitivity was also observed in another study carried out in Kwekwe district Zimbabwe even though their reason for poor sensitivity was solely attributed to a lack of Knowledge.[19] In Nigeria, numerous reasons have been given to explain the poor sensitivity of AEFI surveillance, which could make the system to perform sub-optimally. Such reasons include lack of awareness, knowledge and reporting practices of healthcare workers, behaviour of consumers and manufacturers of vaccines, fear of indictment on the part of the health worker, lack of motivation, etc.[7, 20, 21]

While all these reasons are plausible, we believe that the lack of sensitivity in the AEFI surveillance system especially following RI sessions could mainly be attributed to insufficient funding or a complete lack of resources/funding. This was inferred because our results indicated a steady rise in the number of AEFI cases reported between 2011 and 2018 during SIAs, which might be as a result of the donor support usually given to sensitize clinicians prior to every campaign. This in turn translates into a more structured system where clinicians and health workers are constantly on the lookout for signs and symptoms that constitute a case of AEFI for prompt action. Therefore, we recommend that resources be made available to enable the health facilities conduct constant refresher trainings for their health workers on AEFI, put in place structures that would enable the health workers carry

out routine outreach sessions with the mothers in the community, sensitizing them on AEFI and dispelling any rumours concerning vaccine safety that they may have.

From our results, it was also obvious that the AEFI reports sent to the NPHCDA were those that followed from SIAs at the state level. Even though AEFI cases were constantly reported by majority of the states, the figures recorded were far less than expected.[11] This is based on the fact that the country conducts various preventive and reactive campaign vaccinations that involve the vaccination of millions of children. Over the years, the states have exhibited different level of reporting AEFI cases; Bayelsa state for example, had the lowest number of cases reported[17] while Kaduna State had the highest reporting rate with 4,285 cases. Kaduna state is one state that has always been commended for their strong AEFI case-reporting attitude as evidenced in several studies while poor reporting or a complete lack of data (Akwa Ibom and Rivers states) continues to plague other states in the country.[22,23] To overcome the issue of poor reporting and documentation, provision of Internet access to ease electronic reporting system of AEFI surveillance as well as the continuous creation of awareness on AEFI is recommended.[24]

However, there was a noticeable increase in the number of AEFI reported between 2017 and 2018 following both RI and SIA campaigns compared to previous years. This may not be unconnected to the efforts made by constituted Surveillance Working Group (SWG) towards ensuring that AEFI cases were reported from all the states. In fact, the country's National Expert Committee, Immunization managers, pharmacovigilance staff and partner agencies were trained on AEFI case detection, investigation and casualty assessment with the support of WHO AFRO support team in June 2019 all in a bid to strengthen the AEFI surveillance system in the country. This training has since been cascaded to the various states and health facilities for implementation.

CONCLUSION

Poor documentation, poor case reporting and a lack of funding have greatly affected the AEFI surveillance system in the country. However, with the renewed vigour towards improving routine immunization and AEFI surveillance, we expect improved capacity to detect, manage and report all cases of AEFI as they occur.

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