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Prevalence and pattern of adverse events following immunization in children attending a tertiary paediatric clinic in rivers state, Nigeria

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Abstract
Background: Immunization which has been proven to be the most cost-effective intervention in promoting child health and as such one of the success stories in public health. They are safe and effective globally, but are usually not without adverse events occasionally.
Methods: A cross-sectional descriptive study was carried out over one-year, among children aged 6weeks to 18months attending the Paediatric outpatient clinic in Rivers State University Teaching Hospital (RSUTH). A sample size of 370 children who met the inclusion criteria were recruited.
Results: Of 370 mother-baby pair, 231(62.4%) mothers were aged 30-39years and attained tertiary education 250(67.6%). Most babies were aged 0-5months (58.1%) with M:F ratio of 1.06:1. Most of the mothers 158(78.6%) were told of possible Adverse events following immunization (AEFI) by the health workers prior to vaccination. AEFI was reported in 201(54.3%) children, majority were generalized reactions 170(84.6%) and none had rare adverse events. Most occurred at the 2nd immunization visit 158(78.6%), 1-11hours following vaccination (74.6%). The commonest AEFI were fever 169(84.1%) and swelling at the injection site 92(45.8%). Only 6(3.0%) mothers reported the AEFI incidence and 4(2.0%) were admitted in the hospital for fever following vaccination. No child with AEFI had their immunization schedule disrupted.
Conclusion: There was a high incidence of AEFI in children attending the Paediatric outpatient clinic, with poor level of reporting of such incidence. Education of the public about AEFI, in addition to strengthening the country's vaccination surveillance system, will improve its detection, reporting and monitoring, which are critical in managing vaccine reactions.

Keywords: Prevalence, pattern, adverse events, immunization, children, Nigeria

Introduction
Immunization is one of the success stories in public health as it has proven to be the most cost-effective intervention in the promotion of child health by the World Health Organisation (WHO) [1]. It has led to the decline in the spread of communicable diseases thereby reducing childhood morbidity and mortality [2].
Although all vaccines used for immunization programmes are safe and effective if used correctly, in practice however none is without side effects globally, thus adverse events may occur occasionally following immunizations [3]. These adverse events range from minor to severe. Suffice to note that vaccines which are manufactured and tested under strict safety guidelines are continuously monitored even after being registered and used [3].
Adverse events following immunization (AEFI) can therefore be defined as any untoward medical occurrences following immunization and which does not necessarily have a causal relationship with the usage of the vaccine [4].
Five categories of AEFI include vaccine product-related reaction caused by one or more inherent properties of the vaccine product; vaccine quality defect-related reaction caused by one or more quality defects of the vaccine product; immunization error-related reaction caused by inappropriate vaccine handling, prescribing or administration; immunization anxiety-related reaction caused by anxiety about the vaccine and coincidental event caused by factors other than the above causes [4].
According to WHO, AEFI can be serious or non-serious [5]. Serious AEFI which occur rarely, may be life threatening or warrant hospitalization and may result in death [4]. Examples of such vaccine reactions include seizures, fainting, prolonged crying, anaphylaxis, intestinal obstruction (intussusception), hyporesponsive episodes,

thrombocytopenia and Encephalitis [2, 5]. Non-serious AEFI are commoner, occur within a few hours of immunization, resolves within a short time usually 1-2 days and cause little or no damage [3, 5]. Examples of non-serious AEFI include skin reactions, localized pain, fever, vomiting, headaches and swellings. AEFI varies from place to place and time periods depending on the vaccines administered or the countries immunization programme, age of the recipient as well as the expertise of the health worker administrating the vaccine. The most common adverse effects of immunization are fever, pain, malaise, myalgia, skin redness, swelling and tenderness around the injection site [2, 3]. Ekwueme [6] in Enugu, Southeast Nigeria documented fever as the commonest adverse event accounting for 90.4% followed by pain & swelling at the injection site (27.7%) and skin rash (10.3%). Convulsion and paralysis/collapse which are serious AEFI were less common accounting for 2.7% and 0.5% respectively in the study. Similarly, Aderibigbe *et al*. [7] in Ilorin, Southwest Nigeria reported swelling at the injection site as the commonest AEFI followed by cellulitis and injection abscess accounting for 50.9%, 29.8% and 19.3% respectively. Aagaard *et al*. [8] documented that 80% of AEFI in their study were reported in children aged 0-2 years.

Reactions caused by vaccines usually are observed within a day or two following immunizations, it may however be much longer up to 6-12 days as seen after measles immunization [4].

It is worthy of note that detecting, reporting and monitoring these adverse events following immunization is critical in managing vaccine reactions. Caregivers are therefore encouraged to report cases of AEFI as soon as detected in order to commence treatment early. AEFI has also been observed as an important cause of vaccine hesitancy as observed in Nigeria where findings of the 2016 National Immunization Coverage Survey revealed that 9% of caregivers did not vaccinate their children because of the fear of side effects [9]. It is pertinent to note that there are now measures to strengthen AEFI surveillance systems in Nigeria with the support of WHO [9].

Considering the dwindling immunization coverage in developing countries like Nigeria at present, vaccine preventable diseases remain one of the commonest causes of childhood morbidity and mortality [10]. This low coverage has been attributed to health system-related and family/caregivers-related factors [2]. One of the family/caregivers related factors have been identified to be issues of mistrust and fear of adverse effects following immunization thus the present study was carried out to identify the prevalence, pattern and mother's response to AEFI in the paediatric outpatient clinic of the Rivers State University Teaching Hospital. Findings of this study would be useful in educating the public on AEFI, increase sensitization on the benefits of immunization thereby boosting the public confidence in vaccines, improve their understanding on the safety of these vaccines which will on the long run improve immunization coverage.

Materials and methods

Study design

This was a cross sectional descriptive study carried out in the out-patient clinic of the Rivers State University Teaching Hospital, Port Harcourt over a one-year period from July 2020 to June 2021.

Study site

The Rivers State University Teaching Hospital (RSUTH) is a tertiary health care facility, located in one of the states in the south-south region of Nigeria. It is a 375 bedded health care facility that offers services to the inhabitants of Port Harcourt metropolis and also serves as a referral centre to the secondary and primary health care facilities in the State. The Paediatric out-patient clinic operates 5 days in a week and is manned by Registrars, Senior Registrars and House Officers in addition to other complimentary staff of nurses, clerks and cleaners. Daily activities in the clinic are supervised by a consultant Paediatrician. The clinic attends to about 800 patients monthly.

Study population

The study population is made up of all children aged 6 weeks to 18 months attending the Paediatric out- patient clinic in the hospital. Babies who had received vaccination at least once, attended clinic with their mothers who gave informed consent to participate in the study were included in the study. To avoid recall bias as much as possible, babies older than 18 months were excluded. Also excluded were babies who had never been vaccinated or those whose mothers declined to participate in the study.

Sample size and method

The sample size was calculated using the formula for single proportion $n = z^2(pq)/e,^2$ where n = minimal sample size, z = 95% confidence interval set at (1.96), p = prevalence of AEFI in Kano, Nigeria which was 34.9% [11] q = 100 – p and e = sampling error 5%. The minimum sampling size calculated was 349. A total of 370 babies were recruited to participate in the study. A convenient sampling method was used to select eligible participants for the study until the sample size was completed.

Ethical consideration

Ethical clearance was obtained from the Rivers State University Teaching Hospital Ethics Committee and written informed consent obtained from the mothers of the participants.

Study procedure

The investigators trained a research assistant to collect data for the study using a pre tested research proforma. The research assistant and investigators conducted the interview on the mothers of the babies during clinic hours. Information included in the proforma included demographic information from the mothers and babies, vaccination history, types, time and duration of AEFI experienced after immunisation and also on what was done for the child following the AEFI.

Data analysis

Data analysis was done with Statistical Package for Social Sciences (SPSS) version 23.0 software, using descriptive statistics. The chi square test was used to test for association between sub groups. A probability value of less than 0.05 was considered statistically significant at 95% confidence interval.

Result

A total of 370 mothers with their babies participated in this study. Majority of the mothers 231 (62.4%) were aged 30-

39 years, attained tertiary education 250 (67.6%), and married 362 (97.8%), Table 1.

Table 1: Demographic characteristics of mothers and children in the study population

Demographic parameters	Frequency	Percentage
Age of mothers		
20-29	116	31.4
30-39	231	62.4
40-49	21	5.7
>49	2	0.5
Educational level of mothers		
Primary	1	0.3
Secondary	119	32.3
Tertiary	250	67.6
Occupation of mothers		
Civil servants	15	4.0
Professionals	68	18.4
Skilled Workers	42	11.4
Businesswomen	126	34.0
Traders	45	12.2
Unemployed/housewives	74	20.0
Marital status of mothers		
Married	362	97.8
Single	8	2.2

The babies were mostly aged 0-5 months (58.1%). The mean age of the babies was 5.15 $\pm$ 3.33 years. There was a slight male preponderance with a male to female ratio of 1.06:1. Most of them were appropriately vaccinated for their age, Table 2. Of the 370 babies, 112 (30.3%) were vaccinated in our hospital, while 258 (69.7%) were vaccinated in other immunization clinics in Port Harcourt metropolis.

Table 2: Demographic characteristics of the babies in the study population

Demographic parameters	Frequency	Percent
Age group of children		
0-5	215	58.1
6-11	146	39.5
$\geq$ 12	9	2.4
Gender of babies		
Female	180	48.6
Male	191	51.4
Age appropriateness of vaccination status		
Up to date	354	95.7
Not up to date	16	4.3

Prevalence and pattern of AEFI in the study population

Of the 370 mothers who participated in the study, 295 (79.7%) said the health care workers told them of possible AEFI before their children were vaccinated. Two hundred and one (54.3%) babies had AEFI. These AEFI were mostly systemic or generalized reactions 170 (84.6%). No baby developed rare adverse events following immunization. Fever 169 (84.1%) was the commonest AEFI reported followed by swelling of injection site 92 (45.8%). Most AEFI occurred at the 2nd immunization visit 158 (78.6%) and between 1-11 hours following vaccination 150 (74.6%), Table 3. The response of mothers to the development of AEFI in their babies was to give paracetamol (87.5%), Figure 1.

Table 3: Prevalence and pattern of adverse events following immunization in the study population

Parameters	Frequency	Percent
Did HCW inform mother of possible AEFI before vaccinating the child? (N=370)		
Yes	295	79.7
No	75	20.3
Did child have any AEFI after vaccination? (N=370)		
Yes	201	54.3
No	169	45.7
Type of AEFI reported among the babies*		
Local reaction	125	62.2
Systemic/generalized reactions	170	84.6
Rare reactions	0	0
Symptoms of AEFI reported among children*		
Fever	169	84.1
Swelling of injection	92	45.8
Pain at injection site	76	37.8
Inconsolable cry	31	15.4
Refusal to suck	9	4.5
Abscess	9	4.5
Redness at injection site	8	4.0
Malaise	3	1.5
Immunization visits in which AEFI occurred*		
1st visit	30	14.9
2nd visit	158	78.6
3rd visit	93	46.3
4th visit	72	35.8
5th visit	5	2.5
6th visit	2	1.0
Time interval for onset of AEFI following vaccination (hour)		
< 1	6	3.0
1-11	150	74.6
12-23	30	14.9
23-72	11	5.5
> 72	4	2.0

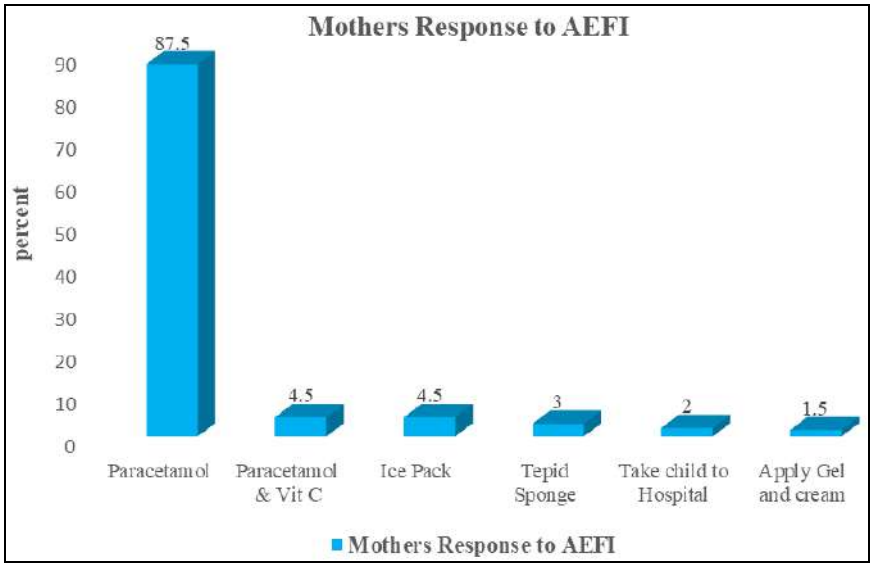

Fig 1: Mothers Response to AEFI

In all, only 6 (3.0%) mothers whose children had AEFI went back to the clinic to report the incidence. Four (2.0%) children with AEFI were admitted in the hospital for high grade fever. Of the 202 mothers whose babies had AEFI, 163 (81.1%) said the health care worker specifically told them of the symptoms their children had and 160 (79.6%) of them claimed that they were told of what to do if such symptoms occurred after the vaccination. No child with AEFI had their immunization schedule disrupted because of the AEFI. Although 45 (22.4%) of the mothers were bothered about the AEFI their babies had, most prevalent being the excessive crying of the babies 13 (28.9%), Table 4, but these concerns they said would not stop them from immunizing another child. All the mothers who participated in the study said they were willing to encourage other mothers to bring their children for vaccination.

Table 4: Concerns expressed by mothers whose babies had AEFI

Mother's concerns	Frequency	Percent
Excessive crying of baby	13	28.9
High grade fever	10	22.2
Baby restless and uncomfortable	6	13.3
Swelling of the limb will affect ability to walk	6	13.3
Present AEFI causing other complications	3	6.7
Inexperience of first-time mothers	3	6.7
Others	4	8.9

Discussion

Majority of the mothers in our study were less than 40 years. This is similar to the mothers recruited in the study by Afolaranmi *et al.* in Jos and in Benin City [2, 12]. Most of the mothers had at least secondary level of education. Although most of them were either business women, skilled workers or professionals, a significant proportion (20%) were unemployed/housewives. Almost all the children in our study (95.7%) had their vaccine status up to date. This finding is much higher than that reported in a study by Adedokun *et al*, [13] which reported that over 76.3% of children from the 37 states in Nigeria were not fully immunized. The study noted that children born to young mothers (83%), illiterate mothers (94%), mothers from poor households (94.6%) and those who had difficulty accessing health care facilities (71.8%) were reported to have incomplete immunization. This difference may be due to the fact that our study subjects were older mothers with higher educational and socio-economic status, thus were more likely to understand the importance of completing a child's vaccination. Also, our study centre was located in an urban area.

The prevalence of AEFI in our study was 54.3%. This finding is higher than that reported in Jos, [12] Kano [11] and Poland [14] but lower than that reported in Enugu [6]. The differences observed in prevalence rate could be attributed to the fact that these studies were conducted in different locations, in some instances, countries (the Poland study) and therefore likely had different levels of health care service provision. Besides, the study subjects in the Kano [11] study were different, as it compared AEFI in both nourished and malnourished children.

Our study reported fever as the most common AEFI, followed by swelling at the injection site. This is similar to the findings of several studies done in Nigeria [6, 11, 12] and other parts of Africa [15, 16].

This similarity may be due to the fact that African countries have similar vaccination schedule with similar antigens administered to children of similar ages, thus, their antigenic response may be similar. In contrast the study done in Poland [14]. Reported redness, pain and swelling as being more common than fever. This difference may be due to the fact that the Poland study involved a larger sample size (1239 subjects) and children born in a different country receiving vaccination with a different immunization schedule. Our study reported no case of rare or severe AEFI. Similarly, the study by Lawan [11] reported no case of severe AEFI while the study by Ekwueme [6] reported collapse and

paralysis in only 0.5% of cases. Other AEFI reported by our study included inconsolable cry, abscess and malaise which is similar to that reported by several other studies [6, 11-15]. Other AEFI reported in other studies include diarrhoea, vomiting, ocular disorders, convulsions, collapse, paralysis, urticarial rashes, ulceration and even death [6, 12, 14, 15-17].

Our study showed most AEFI occurred with the 2nd immunization visit and within the first 11-hour post-vaccination. This is similar to the findings of Lawan [11] and Ekwueme [6] which reported most AEFI occurred within the first 3 visits and within the first 24 hrs post- vaccination.

Our study showed more AEFI associated with 2nd immunization visit, when Pentavalent vaccine (which include diphtheria, pertussis, tetanus, hepatitis B and HIB vaccine) is given. This is similar to the findings of Ekwueme [6] which reported diphtheria, pertussis, tetanus (DPT) vaccine as the most commonly associated vaccine with AEFI. This in contrast to the study done in Zimbabwe, [16] which reported more fever with measles, followed by local swelling with pentavalent vaccines [16].

Over 80% of mothers whose babies had AEFI in this study, gave paracetamol in response to the incidence. This is similar to that reported by other studies [6, 11-15]. Other agents used by the mothers include ice packs, tepid sponging, and topical application of gel/creams. However, Ekwueme [6] reported that 0.9% of mothers took their affected babies to native doctors and applied herbal concoctions. This same study also reported as high as 21.1% of the mothers whose babies had AEFI had their immunization stopped/ discontinued. This is in contrast to our study as no child's immunization schedule was disrupted. The higher proportion of mothers (67.7%) with tertiary level of education as opposed to Ekwueme's study (40.3%) could have been responsible for this difference. Besides, Ekwueme's study was carried out much earlier when vaccine acceptability was a challenge, and parents used every excuse they could find to stop or not vaccinate their children [9].

Although most of the mothers (79.9%) said the health workers informed them about the possibility of AEFI before their babies were vaccinated, only 3% of them reported the incidence of AEFI when it occurred. This could possibly be because they were not specifically informed about the importance of reporting every incidence of AEFI. A study done in Zimbabwe [16] assessing trends of AEFI reporting showed an annual overall low reporting rate of 0.58 per 100,000 vaccine doses [16]. Several strategies can be employed to strengthen the AEFI surveillance system including improving health care worker awareness of vaccine safety reporting and providing appropriate and timely feedback to reporters of AEFI. [16] Providing fully functional, identifiable AEFI reporting sites, the linkage of AEFI data with immunization registers and the use of National vaccine safety experts may enhance patient follow-up [9, 12, 16].

Our study showed majority of the mothers, though bothered about the AEFI their babies had, did not let it disrupt the child's immunization schedule. This may be due to the fact that most of the mothers in our study had at least secondary level of education and thus likely understood the importance of full/complete vaccination of their children. Also, our hospital though serving as a referral centre for several health care facilities, is located in Port Harcourt city, an urban environment.

The role of the use of public health campaigns to properly educate mothers/caregivers, Health Care Workers, and the general public about AEFI, the importance of reporting and what to do if it occurs cannot be over-emphasized. Establishment and strengthening of vaccination surveillance system at all levels of health care with simplified reporting channels is essential [9, 12, 16]. Incorporating health education on AEFI into immunization routines, antenatal health talks and other appropriate information techniques will greatly improve mother/caregivers response to AEFI when it occurs [12, 16].

Conclusion

This study showed a fairly high incidence of AEFI in children attending the paediatric outpatient clinic in RSUTH. It also showed a high level of appropriate action taken in response to the AEFI despite a poor level of reporting of the incidence. The role of health education on AEFI and the establishment of vaccination surveillance systems in the improvement of mother or care-givers response to AEFI cannot be over-emphasized.

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