



ORIGINAL ARTICLE

Prevalence and Management of Perceived Adverse Events Following Immunization in Infants attending Well Baby Clinics in Benin City, Nigeria

Adam VY^{1,2}, Onowugbeda ED², Osuji OI¹, Omohwovo OD¹

¹Department of Community Health, University of Benin, Benin City, Nigeria

²Department of Community Health, University of Benin Teaching Hospital, Benin City, Nigeria

Keywords

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ABSTRACT

Background: Immunization is an important public health intervention for vaccine-preventable diseases (VPDs). However, adverse events may follow immunization of infants. This study determined the prevalence and management of Adverse Events following Immunization (AEFI) reported by caregivers of infants in Well-Baby Clinics in Benin City, Nigeria.

Methods: The study was carried out in 2015 among 400 caregivers of infants attending Well- Baby Clinics in Benin City, Nigeria. A descriptive cross-sectional study design was utilized. Respondents were selected using a systematic sampling technique. An adapted structured interviewer-administered questionnaire was used to collect data. Data analysis was done using IBM SPSS version 20.0.

Results: Less than half, 169 (42.3%) of the caregivers stated that their children had AEFI. Three-quarters 126 (74.6%) and 68 (40.2%) of the AEFI occurred following vaccination with Bacillus Calmette-Guerin and pentavalent vaccine. Fever and swelling of the injection sites occurred in 142 (84.0%) and 65 (38.5%) of the children, respectively. Almost all 167 (98.8%) of the respondents reported an AEFI. Few of those who reported an AEFI, 13 (7.8%) had their children hospitalized.

Conclusion: A significant proportion of children vaccinated experienced side effects perceived to be AEFI that presented mainly as fever and swollen injection sites which were mainly reported at the immunization clinic. Few of the reported cases of AEFI were hospitalized. Healthcare workers should continue to educate and reassure caregivers of infants of the symptoms and signs that may occur following vaccination and how they can be managed.

Correspondence to:

Dr Vincent Yakubu Adam
Department of Community Health,
School of Medicine, College of Medical Sciences,
University of Benin,
PMB 1154,
Benin City, Nigeria
Email: vincent.adam@uniben.edu
Telephone: +2348023327951

INTRODUCTION

Immunization remains one of the most important public health interventions and a

cost-effective strategy to reduce both the morbidity and mortality associated with vaccine-preventable diseases (VPDs).¹ Immunization is essential in achieving

targets 3.3 and 3.8 of the Sustainable Development Goals (SDG) which hope to end epidemics of communicable diseases and achieve universal health coverage by 2030, respectively.^{2,3} According to the International Vaccine Access Center (IVAC) projections, achieving immunization coverage of 90% in Nigeria in the next decade will increase the country's economy by \$17 billion.⁴ Despite the numerous benefits of immunization, uptake of vaccines is still very low especially in developing countries making VPDs the most common cause of childhood mortality with an estimated 2-3million deaths each year.³ Reasons for low immunization coverage have been linked to health system-related and family/caregivers factors. The health system-related factors are: lack of proper planning, issues with services delivery, decreased motivation of health workers, failure to access immunization status of children during visits to health facilities; while the family/caregivers factors include: lack of awareness, lack of time and other family issues, plus issues of mistrust and fear of adverse effects following immunization (AEFI).⁵ Although the immunization coverage in Nigeria for the last ten years has improved, it fell short of the Millennium Development Goals (MDG) 4 target of 90% by 2015.⁶ According to the Multiple Indicator Cluster Survey in 2017, full immunization coverage stood at 53 in 1000 for Nigerian children with 9% of women refusing to get their children vaccinated due to the fear of side effects.⁷

AEFI can be categorized as follows: vaccine product-related reactions due to one or more of the inherent properties of the vaccine product; vaccine quality defect-related reactions due to one or more quality defects of the vaccine product including its administration device as provided by the manufacturer. Others include immunization error-related reactions which occur when there is inappropriate vaccine handling, prescribing and administration; immunization anxiety-related reaction which arises from anxiety about the immunization; and coincidental events which are due to other factors apart from those listed above.⁸ Common AEFI include pain, swelling or redness at the site of injection, local abscess, fever, malaise and myalgia.⁹ Severe allergic reactions and encephalitis following immunization are often rare. The number of reported cases of AEFI increases during immunization campaigns. Between 2013 and the first quarter of 2018, a total of 12,637 cases of AEFI were reported with 72 classified as serious from measles, yellow fever and meningitis campaigns conducted in Nigeria. Investigation and causality assessment showed that the majority were coincidental.¹⁰ Efforts have been made to strengthen the AEFI surveillance system in Nigeria by the Federal Government through the support of the World Health Organization (WHO). For instance, the AEFI National Expert Committee was inaugurated with the responsibility of ensuring that Nigerian health workers will be able to monitor and prevent AEFI.¹⁰

A study conducted in Ilorin, Nigeria, showed that 50.9% of documented cases of AEFI reported were local swelling at the injection site, followed by cellulitis (29.8%). About half, 49.1% of the reported AEFI cases occurred after administering Diphtheria, Pertussis and Tetanus (DPT).¹¹ Another study conducted in Enugu among 331 mothers revealed that 190 (57.4%) of the respondents managed AEFI by giving paracetamol, 43 (19.5%) took their children to the hospital, while 2 (0.9%) used herbal mixtures.¹² AEFI affects immunization uptake. Hence, it is important to find out the prevailing pattern of occurrence and management of AEFI in the study locale in order to influence evidence-based policy decision-making and planning for immunization services. This study tried to determine the prevalence and management of perceived AEFI in infants attending Well-Baby Clinics in University of Benin (UNIBEN) and University of Benin Teaching Hospital (UBTH), Benin City.

METHODOLOGY

The study was carried out in two well-baby clinics: The National Programme on Immunization (NPI) Clinic, Public Health Department, UBTH and the Nutrition, Education and Rehabilitation Unit, Institute of Child Health, UNIBEN, both in Benin City, Nigeria. The NPI Clinic is located in the service area of the General Practice Clinic (GPC), UBTH. The clinic carries out children immunization every day of the week except during the weekends. Approximately 200 children are immunized daily. The

Nutrition, Education and Rehabilitation Unit of the Institute of Child Health, University of Benin Clinic is located in Oba Akenzua Building Complex in UBTH. It carries out immunizations on Mondays, Wednesdays and Fridays. About 20 children are immunized daily at the clinic. A descriptive cross-sectional study design was utilized. Caregivers who brought their infants for immunization at the Well Baby Clinics were the respondents for the study. All caregivers whose infant had received immunization at the clinics at least once were recruited. This was to ensure that the respondents' children had previously been exposed to vaccines with possible AEFI experience. The sample size was calculated using Cochran's formula for descriptive studies.¹³ A prevalence rate of 34.9% from a study conducted in Kano, Nigeria was used in calculating the minimum sample size of 349.¹⁴ However, 400 respondents were utilized for the study after adding 10% non-response rate.

The respondents were selected using systematic sampling technique. The study centres had an average daily attendance of 220 caregivers. Data collection was scheduled for 10 working days with a target of 40 respondents daily. After calculating the sampling interval of 6, simple random sampling through balloting was used to select the first sample from the sampling frame. Subsequently, every 6th client on the clinic attendance list was selected using proportional allocation of sample population for the two clinics. The tool for data collection was a pretested, structured,

interviewer-administered questionnaire. The data collected were screened for completeness and analyzed using IBM SPSS version 20.0 software. Results were presented using prose, simple frequency and cross tables. Test of association was done using Chi-square test and $p < 0.05$ was taken to be statistically significant. Ethical approval for this study was obtained from the Ethics and Research Committee in UBTH. Institutional approval was also obtained from UBTH and UNIBEN managements. In addition, verbal informed consent was also obtained from the caregivers after they were educated on the purpose, benefits and the minimal risks of the study before the questionnaire was administered.

RESULTS

The mean (Standard deviation) age of the caregivers was 29.1 (4.6) years. A majority of the caregivers 367 (91.8%) had at least, secondary level of education. Almost half of the children, 194 (48.5%) were less than 3 months old while 69 (17.3%) were more than 6 months old. Males made up 249 (62.3%) of the infants. Over half, 216 (54.0%) of the children were of 1st and 2nd birth order. Three-quarters, 303 (75.8%) had three or less siblings. (Table 1) In Table 2, less than half, 169 (42.3%) of caregivers stated that their children had a previous AEFI. Fever was the commonest AEFI reported by majority, 142 (84.0%) of the caregivers, followed by swelling and pain at the injection site. Majority of the respondents claimed that the AEFI occurred 24 hours or

more after the vaccine was administered 106 (62.7%) and especially after the first dose of vaccine was given 107 (63.3%). Three-quarters of the caregivers, 126 (74.6%) reported a previous AEFI episode following BCG vaccination, while 68 (40.2%), 48 (28.4%) and 40 (23.7%) stated that the AEFI occurred following pentavalent, measles and yellow fever vaccine respectively.

The occurrence of AEFI increased with the age of the infants and was experienced more by parents with not more than 4 children. Also, the occurrence of AEFI was more among infants within the 3rd and 4th birth order. The occurrence of AEFI was significantly associated with infants' age ($p < 0.001$), parent's number of children ($p = 0.018$) and child's birth order ($p < 0.001$). (Table 3) Among the 169 caregivers whose children have had AEFI, 167 (98.8%) of them had reported the occurrence. Most, 136 (81.4%) reported at the immunization clinics, mainly to the nurses 158 (94.6%). Majority of the respondents, 97 (58.1%) reported a few hours after the onset of the AEFI. The major management information given during health education session on AEFI was that the infant should be taken to the hospital. Other management options mentioned included: use of paracetamol tepid sponging. Only 13 (7.8%) of the infants reported to have had AEFI were hospitalized. Fever was the major cause of hospitalization as a result of AEFI 7 (53.8%). Other symptoms for hospitalization are skin reactions and swelling of the vaccination site. Table 4.

Table 1: Socio-demographic characteristics of the caregivers' and infants

Characteristics	Frequency (n=400)	Percent
Age of caregivers (years)		
19 – 24	33	8.2
25 – 30	267	66.8
31 – 35	78	19.5
36 – 40	16	4.0
≥ 41	6	1.5
Marital Status of caregivers		
Single	7	1.8
Married	393	98.2
Level of Education of caregivers		
No formal education	7	1.8
Primary	26	6.4
Secondary	231	57.8
Tertiary	136	34.0
Occupation of caregivers		
Unemployed	102	25.5
Skilled level I	169	42.3
Skilled level 2	67	16.8
Skilled level 3	4	1.0
Skilled level 4	58	14.7
Age of infants (months)		
< 3	194	48.5
3 – 6	137	34.3
> 6	69	17.2
Sex of infants		
Male	249	62.3
Female	151	37.7
Birth order of infants		
1 st	122	30.5
2 nd	94	23.5
3 rd	72	18.0
4 th	15	3.8
≥ 5 th	97	24.2
Number of children by parents		
≤ 4	303	75.8
> 4	97	24.2

Mean age (caregivers) = 29.1±4.6 years

Mean age (male children) = 3.8±3.0 years; Mean age (female children) = 4.4±2.0 years

DISCUSSION

The prevalence of AEFI in this study was 42.0%. This is higher than the 34.9% reported in a similar study carried out in Kano, Nigeria.¹⁴ A possible explanation for this is the difference in the educational status of caregivers observed in both studies

where 34.1% of the respondents in this study had tertiary education as against 12.4% in the Kano study. Educated mothers will likely have better understanding of possible side effects of vaccination and empowerment to access health services.

Table 2: Perceived AEFI experienced by respondents' children

Variable	Frequency	Percent
Child ever had AEFI (n=400)		
Yes	169	42.3
No	231	57.7
Type of AEFI experienced* (n=169)		
Fever	142	84.0
Swelling at injection site	65	38.5
Pain at injection site	62	36.7
Cough	42	24.9
Duration after vaccination for the occurrence of AEFI (n=169)		
Immediately after vaccination	1	0.6
1 – 23 hours	62	36.7
≥ 24 hours	106	62.7
Vaccine dose at which AEFI occurred (n=169)		
First	107	63.3
Second	62	36.7
Vaccine followed by AEFI* (n=169)		
Bacillus Calmette Guerin (BCG)	126	74.6
Pentavalent vaccine	68	40.2
Measles vaccine	48	28.4
Yellow fever vaccine	40	23.7
Oral polio vaccine	26	15.4

*Multiple responses

Table 3: Children's socio-demographic variables and the prevalence of AEFI

	Ever had an AEFI		Chi-square test	p-value
	Yes (n=169) Frequency (%)	No (n=231) Frequency (%)		
Age of child (months)				
< 3	45 (23.2)	149 (76.8)	62.454	< 0.001*
3 – 6	74 (54.0)	63 (46.0)		
> 6	50 (72.5)	19 (27.5)		
Sex of child				
Male	102 (41.0)	147 (59.0)	0.447	0.504
Female	67 (44.4)	84 (55.6)		
Number of children by parents				
≤ 4	138 (45.5)	165 (54.5)	5.558	0.018*
> 4	31 (32.0)	66 (68.0)		
Birth order				
1 – 2	72 (33.3)	144 (66.7)	51.533	< 0.001*
3 – 4	66 (75.9)	21 (24.1)		
≥ 5	31 (32.0)	66 (68.0)		

*Statistically significant

Table 4: AEFI reporting and management protocol among respondents

Variable	Frequency	Percent
Ever reported any AEFI (n = 169)		
Yes	167	98.8
No	2	1.2
Place of reporting (n=167)		
Immunization clinic	136	81.4
Patent Medical Store	31	18.3
Health personnel reported to (n=167)		
Doctor	9	5.4
Nurse	158	94.6
Documentation of the report (n=167)		
Yes	55	32.9
No	12	7.2
Do not know	100	59.9
Period of reporting AEFI (n=167)		
Immediately	14	8.4
When symptoms worsened	56	33.5
Few hours after onset	97	58.1
Management protocol mentioned at health education session*		
Come to the hospital	140	83.8
See your doctor	74	44.3
Give paracetamol	31	18.6
Tepid sponging	26	15.6
Do not press site	10	6.0
Cannot recall	5	3.0
*Hospitalization of respondents children because of AEFI (n=167)		
Yes	13	7.8
No	154	92.2
Cause for hospitalization (n=13)		
Fever	7	53.8
skin reactions	4	30.8
Swelling	2	15.4

*Multiple responses

^aAll the respondents also stated that their children fully recovered after treatment

The prevalence of AEFI was higher in children who were more than 6 months old. This was in contrast to findings in a study conducted in Ilorin Nigeria, where AEFI was

more in children 2-4 months old.¹¹ A possible reason for this may be because this age group has been exposed to more vaccinations, and have a higher chance of

experiencing adverse effect than children who are younger and have received fewer vaccines.

The commonest AEFI reported was fever, followed by pain and swelling at the site of administration of the vaccines. Similar findings were documented in other studies done in Nigeria.^{15,16} BCG and Pentavalent vaccines were the most commonly reported causes of AEFI. This corresponds to the findings in a record based descriptive study done in Brazil which reported that BCG vaccine was responsible for 41.3% of all cases of cold subcutaneous abscess, lymphadenitis and ulcers bigger than 1cm.¹⁷ The findings also tallied with results from a study done in Ilorin, Nigeria where DPT was the most commonly reported cause of AEFI.¹¹ This might, however, be due to difference in timing of administration of the vaccines as caregivers tend to remember events that are closer to the birth of the child. Majority of the AEFI occurred more than 24 hours after vaccination, a finding similar to what was observed in a study conducted in China.¹⁸ This may support evidence that the adverse events were due to vaccination and not coincidental. The majority of the respondents showed that the AEFI occurred after the first dose of the vaccines. A similar finding was reported in a study done in Iran which revealed that most AEFI were more frequently observed after the first dose than the second dose of vaccination with the pentavalent vaccine.¹⁹ This may be because the immune system is already sensitized after the first dose leading to better tolerance upon administration of

the second dose. There was no obvious difference in the prevalence of AEFI with respect to the sex of the children. This is different from the results obtained from studies conducted in Ilorin, Nigeria¹¹ and Oman²⁰ where male children experienced AEFI more than their female counterparts. This may be a chance occurrence since the study population of males was more than that of females in the studies.

All the caregivers who had reported AEFI also stated that they received health educations on AEFI and its management from health workers in the clinic. This is commendable and indicates that health workers are familiar with AEFI identification and management. A study done in Alimosho, Lagos State, Nigeria revealed a similar finding.²¹ This would reinforce the knowledge of the caregivers about AEFI and allay possible fears that might occur as a result of side effects resulting from vaccination of children. Thus leading to improvement in routine immunization uptake. The major management measures mentioned at the immunization clinics during health education included: follow-up visits with the child to the hospital or see their doctor/nurses in cases of AEFI and use of simple interventions to reduce fever and pain from the AEFI. This implies that the content of health education is good and effective.

Almost all the caregivers who had children with AEFI reported the occurrence at the immunization clinic and to a doctor or a nurse. A study done in the Netherlands

reported similar results.²² About a third of these caregivers were sure of the documentation of the reported AEFI. Documentation of AEFIs should be encouraged and sustained. Health workers should be trained and retrained on the importance of documenting AEFI since this will enhance surveillance in case of an outbreak. The supposed low documentation of AEFI reported by caregivers might be because health workers are aware that not all side effects reported from vaccination are AEFI that should be notified. Health education of mothers on possible side effects of vaccination should be done routinely.

More than half of the caregivers reported adverse effects few hours after vaccination. This further emphasizes the good health-seeking behaviour of the respondents. This will enable early detection and management of any life-threatening conditions associated with immunization. Only a small proportion of respondents' children were hospitalized for signs of AEFI such as fever, skin reactions including swellings of vaccination sites and they fully recovered from the condition. This was similar to findings in a study conducted in Cotonou, Benin Republic.²³ Hospitalization and mortality from reported AEFI are rare. This may be because majority of the AEFI observed were minor and not life threatening. This explains why several literatures are of the view that the benefits of immunizing a child far outweighs the risk and the chances of dying from vaccine-preventable diseases (VPDs) is higher than dying from the AEFI.^{4,24,25} The

limitation of study included possible recall bias and self-reporting by the respondents which could not be verified by the researchers because of the study design utilized for the study.

Conclusion: The prevalence of perceived AEFI was 42.3%. The AEFI occurred mainly after BCG and pentavalent vaccines administration. Almost all cases of perceived AEFI were reported promptly at the health facility. The caregivers exhibited good health-seeking behaviour with respect to the perceived AEFI occurrence which could be linked to valuable health education sessions attended in the health facilities. Documentation of reported AEFI should be improved on at the health facilities in order to detect surges of AEFI and ensure early diagnosis and prompt management of AEFI.

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Authors' Contribution:

VYA - Conception, design, manuscript drafting and revision for intellectual content, including final approval of the manuscript.

EDO - Data collection, statistical analysis and manuscript drafting

IOO - Data collection and literature review

ODO - Data collection and literature review

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