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Pattern and treatment of adverse event following immunization (AEFI) in infants attending well-baby clinics in secondary health facilities in Benin City, Nigeria

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Abstract

Background: Despite its numerous benefits, the fear of adverse event following immunization (AEFI) may affect vaccination uptake. This study determined the pattern and treatment of AEFI in infants attending well-baby clinics in secondary health facilities in Benin City.
Methods: This descriptive cross-sectional study was carried out among 404 caregivers of infants that attended immunization clinics in two public secondary health facilities in Benin City, Nigeria. Systematic sampling technique was used in selecting the respondents. Data was collected using an adapted structured, interviewer-administered questionnaire.
Results: A total of 404 respondents participated in the study. Almost a third of the caregivers, 128 (31.8%) mentioned faulty method of vaccine administration, while 91 (22.6%) of them reported non-viable vaccines as causes of AEFI. BCG, OPV and pentavalent vaccines were responsible for most of the AEFI observed. Only 37 (9.2%) of the caregivers had ever reported an AEFI. Pain at the injection site 10 (27.0%), boils 10 (27.0%), and fever 9 (24.3%) were the common AEFI reported at the health facilities by the caregivers. Drugs 58 (77.4%) and icepacks 16 (21.4%) were mainly used to treat the AEFI by the caregivers.
Conclusion: The common AEFI observed by the caregivers were fever and pain at injection sites, which mainly occurred following BCG, OPV and PENTA vaccines administration. Drugs and icepacks were used for treatment of AEFI. Health workers should continue to educate and reassure caregivers of the management of symptoms and signs that may occur following vaccination.

Keywords: Adverse Event Following Immunization (AEFI); Immunization Clinics; Infants; Treatment; Pattern; Nigeria.

Introduction

Immunization is an effective public health intervention to reduce childhood morbidity and mortality globally [1]. The proportion of the world's children who receive recommended vaccines has remained the same over the past few years with at least 123 countries achieving over 90% coverage of DTP3 vaccine [1]. Despite this global progress, Nigeria's vaccination coverage remains at a meager 31% among children aged 12 to 23 months while that of Edo State ranges between 48 to 59% [2]. Previous studies showed that low vaccination uptake was largely affected by age, maternal education, occupation, marital status, wealth, media access, place of delivery and fear of adverse event following immunization (AEFI) [3-5].

Although precise data on the risk and incidence of adverse effect following vaccination are relatively difficult to obtain, vaccines certainly compare favorably with other pharmaceutical agents in terms of adverse event [6].

AEFI can be categorized into five which include: vaccine product related reactions due to one or more of the inherent properties of the 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; 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 [7]. The commonly encountered AEFI include pain at the site of injection, swelling and redness of the injection site, fever, rash, excessive crying, drowsiness and irritability. Globally, the rate at which AEFI occur differ from country to country, with higher prevalence in developing countries [8]. World Health Organization (WHO) reports that on the average, the following prevalence rate of AEFI occur: Guillain-Barre syndrome (0.51 within 1 day, 3.58% within 7 days, and 21.5 within 6 weeks all per 10 million children vaccinated); optic neuritis (2.05 within 1 day, 14.4 within 7 days and 86.3 within 6 weeks all per 10 million children vaccinated); sudden death within one hour of any symptom (0.14 within 1 day, 0.98 within 7 days and 5.75 within 6 weeks all per 10 million children vaccinated). WHO report shows that fever is the commonest AEFI with prevalence rate of 14.1 per 100,000 children vaccinated and headache being the least common AEFI worldwide with a prevalence rate of 0.83 per 100,000 children vaccinated [9].

Reporting and proper management of AEFI is very important towards improving immunization outcome. A study carried out in Sokoto State, Nigeria showed that the overall reporting practice was appropriate in 224 (86.8%) of respondents. Of the 85 who had ever encountered an AEFI, 61 (71.8%) reported it routinely [10]. Another study carried out in 2015 in Kano State, Nigeria showed that majority of caregivers (96.1%) managed AEFI with paracetamol and/or tepid sponging, while the rest managed their infants by either taking the infant to the hospital/clinic, applying cold compress or temporarily stopping immunization [11].

In order to improve AEFI reporting and management, it is important to ascertain the prevailing pattern and management of AEFI, since it affects immunization uptake. This study was conducted to determine the pattern and management of AEFI in infants among caregivers attending immunization clinics in government-owned secondary health facilities in Benin City, Nigeria

Methods

This descriptive cross-sectional study was carried out among caregivers of infants attending immunization clinics in two state-owned secondary health facilities in Benin City, Nigeria namely: Central Hospital (CH)and Stella Obasanjo Women and Children Hospital (SOWCH), Benin City, Edo State, Nigeria. CH is a 434-bed hospital where 1073 children are immunized weekly, while SOWCH is a 159-bed hospital and offers immunization to approximately 550 children weekly [12].

Caregivers whose infants had received immunization at least once at the well-baby clinics in the health facilities were recruited for the study, in order to ensure previous exposure of the children to vaccines with possible AEFI experience. The sample size was calculated using the Cochran's formula [13] for descriptive cross-sectional study. A prevalence rate of 66.5% obtained from a study conducted in Kaduna State, Nigeria was utilized in calculating the sample size of 404 after adding the 10% non-response [14].

A systematic sampling technique was used to select the respondents based on the weekly attendance at the immunization clinics in the health facilities. The study centres had an average daily attendance of 325 [215+110] caregivers. Data collection was scheduled for 2 weeks with a target of administering 40 questionnaires daily. After calculating a sampling interval of 4, simple random sampling technique using balloting was used to select the first respondent from each of the sampling frames. Subsequently, every 4th caregiver 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 caregivers were given health education on the importance of routine vaccination and reporting of AEFI.

The data collected for the study were analyzed using IBM SPSS version 20.0. Data were presented as prose and frequency tables.

Results

Majority 338 (83.7%) of the caregivers were in the age group of 25-34 years and 389 (96.3%) of them were married. Almost all of them 388 (96.0%) had at least secondary level of education. A majority of the infants, 366 (90.6%) were in the age group of 1-6 months. More than half of the infants, 219 (54.2%) and 230 (56.9%) were females and in at least the 2nd birth order respectively (Table 1).

Faulty method of vaccine administration and non-viable vaccines were the common causes of AEFI mentioned by 128 (31.8%) and 91 (22.6%) of the caregivers respectively. Few of the caregivers 17 (4.2%) reported that illness of infants prior to vaccination could cause AEFI (Table 2). Fever was the commonest AEFI reported following vaccination with yellow fever (60.0%), OPV (32.6%), PENTA (31.8%), measles (25.0%) and BCG (20.0%) vaccines respectively ((Table 3). Pain at the injection site occurred following administration of yellow fever (40.0%), PENTA (27.2%), measles (25.0%) and BCG (20.0%) vaccines. Boils were reported by 20.8% of the caregivers following BCG administration, while 0.4%

said convulsion occurred after PENTA vaccination was given (Table 3).

Table 1: Socio-demographic characteristics of caregivers and infants

Variable	Frequency (n=404)	Percent
Age group (in years)		
15-24	31	7.7
25-34	338	83.7
35-44	35	8.6
Marital status		
Ever Married	389	96.3
Never Married	15	3.7
Level of education		
Primary	16	4.0
Secondary	152	37.6
Tertiary	236	58.4
Age group of infants (in months)		
1-6	366	90.6
7-12	38	9.4
Sex of infants		
Male	185	45.8
Female	219	54.2
Birth order of infants		
1	174	43.1
≥2	230	56.9

Table 2: Causes of AEFI mentioned by the caregivers

Cause of AEFI*	Frequency (n=402)	Percent
Faulty method of vaccine administration	128	31.8
Expired/ non-viable vaccine	91	22.6
Wrong vaccine	60	14.9
Vaccines are potentially harmful	54	13.4
Overdose of vaccine	31	7.7
Illness prior to vaccination	17	4.2

Table 4 shows that though, 381 (94.3%) of the caregivers mentioned that it was important to report AEFI, only 37 (9.2%) ever reported an AEFI. Immunization clinics and hospital were the places AEFI were reported by 16 (43.2%) and 14 (37.8%) of the caregivers respectively. The major AEFI reported by the caregivers include: pain at the injection site 10 (27.0%); boils 10 (27.0%) and fever 9 (24.3%) respectively. The time of reporting AEFI by the caregivers was mainly days after the onset of symptoms 16 (43.4%) and when the symptoms worsen 14 (37.8%).

Drugs were used for the treatment of AEFI by 58 (77.4%) of caregivers following vaccination with PENTA 27 (36.0%), BCG 14 (18.7%), OPV 9 (12.0%) measles 5 (6.7%) and yellow fever 3 (4.0%) vaccines respectively. Ice pack was used for treatment of 14 (18.7%) and 2 (2.7%) of AEFI following PENTA and BCG vaccination (Table 5).

Discussion

Fever and pain at the injection site were the most common AEFI observed by the caregivers of infants in this study, which corresponds to findings from studies conducted in Kano {11} and Kaduna {14} in Nigeria, Mysuru, India [15] and Zhejiang Province, China [16]. There was no reported case of anaphylactic reaction or death following vaccination and all the children recovered fully without hospitalization. This was similar to findings from a study done in Australia [17]. This may be due to fact that majority of the caregivers reported the AEFI at the healthcare facility with possible prompt medical intervention by trained health professionals. It is commendable that most of the caregivers reported the AEFI to the health workers at the health facilities, indicating good healthcare-seeking practice. Cases of death were reported in children admitted in hospitals following measles vaccination in Bangladesh and Pakistan [18,19]. Such negative consequences of AEFI could undermine the success of any immunization programme.

Table 3: Reported AEFI following administration of vaccines to infants

	Vaccine administered to infants				
Adverse event*	**BCG (n =255)**	**OPV (n=236)**	**PENTA (n=239)**	**Measles (n=8)**	**Yellow fever (n=5)**
Fever	51 (20.0)	77 (32.6)	76 (31.8)	2 (25.0)	3 (60.0)
Pain at injection site	51 (20.0)	-	65 (27.2)	2 (25.0)	2 (40.0)
Diarrhoea	30 (11.8)	28 (11.9)	32 (13.4)	1 (12.5)	-
Rashes	17 (6.6)	-	37 (15.5)	1 (12.5)	-
Cough	-	9 (3.8)	10 (4.2)	-	-
Catarrh	-	28 (11.9)	5 (2.1)	-	-
Sneezing	-	6(2.5)	5 (2.1)	-	-
Breathlessness	-	15 (6.4)	-	2 (25.0)	-
Weakness	-	50 (21.2)	8 (3.3)	-	-
Boils	53 (20.8)	-	-	-	-
Vomiting	53 (20.8)	23 (9.7)	-	-	-
Convulsion	-	-	1 (0.4)	-	-

Table 4: Report of AEFI by caregivers of infants

Variable	Frequency (n)	Percent (%)
Importance of reporting AEFI (n=404)		
Important	381	94.3
Not important	23	5.7
Ever reported an AEFI (n=404)		
No	367	90.8
Yes	37	9.2
Place of reporting AEFI (n=37)		
Immunization clinic	16	43.2
Hospital	14	37.8
Patent medicine store	7	19.0
AEFI reported (n=37)		
Pain at the injection site	10	27.0
Boils	10	27.0
Fever	9	24.3
Rashes	5	13.5
Cough	3	8.1
Time of reporting AEFI (n = 37)		
Immediately the symptoms were noticed	5	13.5
Few hours after onset of symptoms	2	5.4
Days after onset of symptoms	16	43.3
When symptoms got worse	14	37.8

Fever was commonly reported following administration of BCG, Pentavalent vaccine, OPV, measles and yellow fever vaccines. Pain at the injection site was also commonly mentioned by all the vaccines mentioned above excluding OPV. Pentavalent vaccine yielded the most cases of fever as AEFI reported by the caregivers of infants in this study. This is however expected because of the multiple constituents of antigens which could be associated with minimal discomfort that is self-limiting and would resolve without complication, thus, should not be a contraindication to future vaccination. Other reported AEFI in this study included: boils (BCG); rashes (BCG, Pentavalent and measles vaccines); breathlessness (OPV and measles vaccine) and convulsion (reported to have occurred following pentavalent vaccine administration). AEFI following measles and yellow fever vaccines administration were few probably because most of the children were in the age group of 1-6 months and the vaccines are administered at the age of 9months. This corresponds to findings documented in literature from studies conducted by WHO [20,21]. Health workers should capitalize on the good health-seeking practice of caregivers to give health education on the importance of immunization and the content of the health education session should include possible signs and symptoms that may occur following vaccination and how they can be managed promptly.

Though most of the caregivers indicated that it was important to report AEFI, just a few of them ever reported AEFI. This might be because they perceived that the signs and symptoms that presented following vaccination were not serious to warrant visitation to the hospital, thus resulting to self-care with simple interventions like tepid sponging, use of ice-packs including medications to relieve fever and pain like analgesics [11]. A study carried out in Uganda revealed that almost two-thirds of caregivers 63.9% administered no form of treatment for AEFI because they perceived the AEFI were self-limiting [22]. Another study done in Enugu revealed that more than half of caregivers, 57.4% administered paracetamol for treatment of AEFI [23]. This was further buttressed by the fact that in this study, the treatment for the AEFI reported in the children did not require hospitalization. However, there was poor timing of reporting the AEFI as observed in the study, where caregivers reported days after onset of symptoms and when the symptoms got worse, possibly because they felt it could be managed at home without requiring services of health professionals. Occurrence of AEFI was reported within 24 hours of onset of signs and symptoms in a study conducted in Ghana in 2015 [24]. Timely reporting of AEFI will enhance the documentation at the health facility and assist in surveillance. Also, prompt and appropriate treatments could be given in order to prevent further complications of the AEFI. It is also commendable that most of the caregivers that reported AEFI did so at the health facility, this was similar to findings from a study done in Australia [25]. The reason for presentation of some of the reported AEFI at the patent medicine store could be because of proximity and financial constraints as more than a third of the caregivers have secondary level of education that might not correspond with financial empowerment that will enhance easy access to healthcare delivery.

Table 5: Treatment of AEFI in infants

Treatment	PENTA	BCG	OPV	Measles	Yellow Fever	Total
	Frequency [n=75] (%)					
Drugs	27 (36.0)	14 (18.7)	9 (12.0)	5 (6.7)	3 (4.0)	58 (77.4)
Icepack	14 (18.7)	2 (2.7)	-	-	-	16 (21.4)
Oil	-	1 (1.2)	-	-	-	1 (1.2)
Total	41 (54.7)	17 (22.6)	9 (12.0)	5 (6.7)	3 (4.0)	75 (100.0)

Faulty method of vaccine administration was the major cause of AEFI mentioned by 128 (31.8%) of the caregivers of infants in this study, followed by administration of expired/non-viable vaccine (22.6%). A study done in Jos, Nigeria revealed that 44.5% of respondents felt that AEFI were due to inappropriate handling of the vaccine and 40.3% thought that AEFI was due to the chemical content of the vaccine [26]. It is possible that this information was obtained and reinforced during health education sessions at the health facility during antenatal and immunization clinic, which is quite commendable. Illness prior to vaccination was also mentioned by few respondents as causes of AEFI. This is also a possibility because various bacterial and viral infections can affect children that might not be related to vaccination but the signs and symptoms manifested about the vaccination period leading to the perception that they are AEFI.

Limitations of the study

The cross-sectional design of the study may have resulted in a limitation of the study which relied on the self-reported information provided by the caregivers that is limited to errors that may have been introduced by them either due to recall bias or language or prejudice. The caregivers were counseled against this and questions were repeated at times for clarity in order to get appropriate responses. Also, viral and bacterial illnesses are very common in developing countries among children which can result in signs and symptoms which are similar to those seen following immunization. To overcome this, caregivers were asked if their children were sick two to three days' prior vaccination.

Conclusion

Although only a few of the caregivers ever reported AEFI, the most common AEFI reported among the caregivers were fever and pain at the injection sites, which occurred mainly due to administration of BCG, OPV and PENTA vaccines. Drugs and icepacks were used for treatment of AEFI. The timing of reporting and treatment of AEFI among the caregivers was poor, although most of them knew the importance of reporting and treatment of AEFI. Health workers should continue health education of caregivers of infants on the importance of immunization and also reassure them of effects that can occur following vaccination and how they can be managed.

List of abbreviations

AEFI: Adverse Event Following Immunization; BCG: bacillus Calmette-Guerin; OPV: oral polio vaccine; PENTA: pentavalent vaccine.

Declarations

Ethics approval and consent to participate

Ethical approval to carry out the study was obtained from the Ethics and Research Committee in the Edo State Ministry of Health. Institutional permission was obtained from the Edo State Hospital Management Board. Verbal informed consent was obtained from the caregivers of the infants after explaining the purpose and possible benefits of the study before administering the questionnaire.

Consent for publication

Not applicable.

Availability of data and materials

The data and materials used in this study are available from the corresponding author on request.

Competing interest

No conflict of interest is associated with this work.

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Contribution of authors

We declare that this work was done by authors named in this article and all liabilities pertaining to claims relating to the content of this article will be borne by the authors. VYA conceived and designed this work, drafted the manuscript, EDO collected and analysed the data and also participated in drafting the manuscript while FIO and OI also took part in data collection and reviewed the literature while OI. All authors reviewed and approved the manuscript for publication.

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