

# Prevalence and Pattern of Adverse Events Following Immunisation Among Under-Fives in Rural and Urban communities of Ekiti- State, Nigeria

Serifat Asabi BABALOLA

Department of Community Medicine, Afe Babalola University, Ado-Ekiti, Ekiti State, Nigeria

**Abstract— Introduction:** Adverse events following immunisation (AEFI) is a medical incident that takes place after immunisation. AEFI is a critical component of the immunisation program. <sup>1</sup>Whether the adverse event was truly caused by the vaccine or was merely temporally related is often difficult to determine. The study aimed at determines prevalence and pattern of presentation of AEFI. **Methods:** The study was comparative study design. A multi-stage sampling technique was used. Data were collected using pre-tested, semi-structured questionnaire. Data were collated and analyzed using SPSS version 20. Results were presented in table and figure. A p-value was set as < 0.05. **Results:** The mean age of the respondents was  $28.6 \pm 5.8$  years in the rural area, and  $30.5 \pm 6.1$  in the urban area, ( $p=0.001$ ). 96.7% of the respondents were female, 91.9% were married, and 79.1% are Yoruba tribe and 81.7% are Christians. The prevalence of AEFI was higher among the rural respondents (49.3%) than urban respondents (38.3%) with statistically significant p value of 0.018. Most AEFI occurred within 24 hours in rural groups, higher proportion occurred in between 2-7 days in urban group. Most cases of AEFI recovered fully in both groups. **Conclusions:** There is a need to educate the communities in the state on AEFI during immunisation services. There is also a need to train and retrain the health workers on AEFI and proper vaccine administration.

**Keywords—** Adverse events; Under Five children; Caregivers; Immunisation.

## I. INTRODUCTION

Immunisation constitutes a cost effective strategy to reduce both the morbidity and mortality associated with infectious diseases.<sup>2,3</sup> AEFI is defined as a medical incident that takes place after immunization and is believed to be caused by the immunisation.<sup>3</sup> It is only when the benefit vaccination outweighs the risk that a vaccine is considered safe.<sup>4</sup>

A descriptive retrospective study on AEFI in a tertiary health institution revealed that more than half of the AEFI cases reported were between 2-4 months of age constituting 57.9%, followed by between 5-7 months 19.3% and 8-10 months old infants (17.6%).<sup>6</sup> A study done in Enugu –State, Nigeria reported that the most commonly reported adverse reaction by these mothers were fever 199 (90.4%), pain/swelling 61 (27.7%), rashes and convulsion 6 (2.7%). Ulcer was reported by 2(0.9%) while collapse and paralysis were reported by 1(0.5%) each. The antigens mostly identified by the mothers were DPT 176 (80.0%).<sup>7</sup>

Similarly, a study in Kano north western Nigeria showed that the overall prevalence of AEFIs was 34.9%.<sup>8</sup> Study on determinants of uptake of pentavalent vaccine in Benin city, Southern Nigeria; shows the prevalence of 27.8% mostly following pentavalent vaccination.<sup>9</sup>

A study on active surveillance study of AEFI of the children in Czech republic in 2014 showed that the rate of AEFI was 209/100,000 doses. The most frequently reported reactions were fever and injection site reaction.<sup>10</sup>

Vaccine preventable diseases are known to account for approximately 22% of child death in Nigeria, amounting to over 200,000 deaths per year.<sup>13</sup> However, in Nigeria, as in some other low income countries, immunisation coverage, is very

low. AEFI is a major cause of vaccine rejection. Whatever the cause, an AEFI may upset people to the extent that they may refuse further vaccination for their children. This will lead to many children contacting vaccine preventable disease, become seriously ill, disabled, and risk death.<sup>16</sup> Population-based studies allow comparisons of AEFI rates by vaccination status, or by temporal period, which is not possible with passive surveillance. Given the uncertainty about the frequency of AEFI, particularly the less severe, it is important to conduct and compare more studies on the prevalence of AEFI in urban and rural communities.<sup>4,17</sup> The findings from this study will help the policy makers in designing programmes to combat AEFI and also designing programmes to improve immunisation coverage and service utilization. The study aimed at determine and compare the prevalence of adverse events following childhood immunisation in rural and urban communities of Ekiti State. The specific objectives include determining and comparing the prevalence and pattern of adverse events following immunisation among children in rural and urban areas of Ekiti State.

## II. METHODS

The study was a community-based, comparative, cross-sectional study design. The study population consist of the consented caregivers of previously immunised under- five children. Caregivers whose children are critically sick were excluded from the study.

The study was carried out in Ekiti State, South western Nigeria. The headquarters located in Ado-Ekiti. It has 16 Local Government Areas (LGAs). Ekiti state has three senatorial districts: Ekiti Central, Ekiti South and Ekiti North senatorial districts. Out of the 16 LGAs, four are predominantly urban, while five LGAs are predominantly rural, the remaining LGAs

are semi-urban.<sup>18,19</sup> Research approval with reference number ERC/2017/06/02/75A, was obtained from the Ethics and Research Review Committee of the Federal Teaching Hospital, Ido-Ekiti. Permission was taken from the local government chairman and was granted evidently by his signature. Also informed consent was obtained from the respondents before questionnaire was administered and maximal level of confidentiality was used to treat respondent's data. All consented caregivers that has been living in the community for at least six months were included and caregivers that are sick are excluded from the study.

Sample size of 250 was derived and used for the study using appropriate formula while Multistage sampling method was used to select the local government areas, settlements, wards and households for the study. Proportional allocation of questionnaires was used; consented and eligible respondents within the chosen communities were interviewed. Data was collected using a validated 21 – item structured, interviewer administered questionnaires. Data collation and editing were done manually. Data entry and analysis were done using Statistical Package for the Social Sciences (SPSS) version 20 software package. P-value was set at <0.05.

### III. RESULTS

The variable of the study were analysed, where most of the respondents were aged 30-39 years.

The proportion less than 20 years of age was higher in the rural than urban communities. Most of the respondents were female, Yoruba by ethnicity and of Christian religion (Table 1).

More than half of the respondents had tertiary education in both groups. Most of the respondents' income level is below poverty line, 67.8% in the rural and 58.6% in the urban groups. There is statistically significant difference in education level, occupational status, occupation, income earned and income level of the respondents ( $p = 0.006, 0.002, 0.007, 0.001$  and  $0.041$  respectively).(table 2)

The prevalence of AEFI was higher among the rural respondents (49.3%) than the urban respondents (38.3%). The is a statistically significant difference in the prevalence of AEFI between the groups (figure 1).

Most AEFI occurred within 24 hours in the rural groups, higher proportion occurred between 2-7 days in the urban group. Most cases of AEFI are mild, need no medical intervention and recovered fully in both groups. (table 3 and 4)

### IV. DISCUSSION

The urban caregivers were slightly older. The proportion of females was higher in both groups; 96.5% in the rural group and 96.9% in the urban group, and this could be because females are directly more involved in taking care of the children especially in relating to immunisation. The prevalence of AEFI was statistically significantly higher in the rural group (49.3%) than the urban group (38.3%). The prevalence of AEFI in this study is higher than some previously published studies.,<sup>21,22,23,24</sup>

Most of the respondents reported fever in both groups; this was followed by local swelling, especially in the rural group (41.1%). Local swelling is higher in the rural group because of the practices of applying all sort of thing like local concoctions

on the injection site. Other reported forms of AEFI are persistent crying, irritability, convulsion, vomiting, diarrhea and anaphylaxis. Most AEFI were reported with pentavalent vaccines, 80.4% in the rural groups and 73.6% in the urban group. This was followed by BCG, hepatitis, PCV, IPV, OPV and yellow fever vaccines. Most cases recovered fully 92.9% rural and 95.4% urban group, few recovered with disability 3.6% in rural group and 2.3% in the urban group, few proportion did not recover at all in both groups..

These finding were similar to previously published studies from the United State, India and China.<sup>25,22,10</sup> Ekwueme *et al.* in Enugu reported similar findings.<sup>7</sup>

### V. CONCLUSIONS

This study revealed a higher prevalence of AEFI in rural and urban communities in Ekiti state. Slight differences were noted in the pattern of AEFI among the studied groups. The study recommends for the recommendations adequate health education or the caregivers on AEFI before immunising their children provide. The government should facilitate the process of making the ROTA vaccine available for the citizens. Community members should be encouraged to report cases of moderate to severe AEFI to health facilities and avoid self medications.

*Conflict of Interest:* NO

*Limitation of the study:* AEFI following ROTA vaccine could not be assessed because the vaccine is not available in the state but can be received at the neighbouring state after payment

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LEGENDS:

Table 1. Socio-demographic characteristics of the respondents.

Variable	Rural n (%) N = 227	Urban n (%) N = 227	X <sup>2</sup>	p-value
<b>Age group (in years)</b>				
< 20	17 (7.5)	5 (2.2)	17.210	<b>0.001</b>
20 – 29	94 (41.4)	85 (37.4)		
30 – 39	114 (50.2)	122 (53.7)		
40 – 49	2 (0.9)	15 (6.6)		
Mean ± SD	28.6 ± 5.8	30.5 ± 6.1	3.413	<b>0.001</b>
<b>Sex</b>				
Male	8 (3.5)	7 (3.1)	0.069	0.793
Female	219 (96.5)	220 (96.9)		
<b>Religion</b>				
Christianity	188 (82.8)	184 (81.1)	0.519	0.771
Islam and others	39 (17.2)	43 (18.9)		
<b>Ethnicity</b>				
Yoruba	188 (82.8)	171 (75.3)	4.531	0.210
Igbo	22 (9.7)	27 (11.9)		
Hausa and others	17 (7.5)	29 (12.8)		
<b>Marital Status</b>				
Single	16 (7.0)	12 (5.3)	3.352	0.187
Ever married	211 (93.0)	215 (94.1)		

Table 2: Socio-demographic characteristics of the respondents. (continued)

Variable	Rural n (%) N = 227	Urban n (%) N = 227	X <sup>2</sup>	p-value
<b>Highest level of education</b>				
No formal education	18 (7.9)	3 (1.3)	12.276	<b>0.006</b>
Primary education	34 (15.0)	29 (12.8)		
Secondary education	47 (20.7)	55 (24.2)		
Tertiary education	128 (56.4)	140 (61.7)		
<b>Occupation Status</b>				
Employed	149 (65.6)	178 (78.4)	9.194	<b>0.002</b>
Unemployed	78 (34.4)	49 (21.6)		
<b>Occupation</b>				

Civil servant	70 (30.8)	86 (37.9)	14.163	<b>0.007</b>
Trading	54 (23.8)	48 (21.1)		
Artisan	16 (7.0)	25 (11.0)		
Farming	9 (4.0)	19 (8.4)		
House wife	78 (34.4)	49 (21.6)		
<b>Monthly Income (in Naira)</b>				
≤10,000	103 (45.4)	81 (35.7)	17.754	<b>0.001</b>
11,000 – 20,000	51 (22.5)	52 (22.9)		
21,000 – 30,000	38 (16.7)	50 (22.0)		
31,000 – 40,000	9 (4.0)	29 (12.8)		
41,000 and above	26 (11.5)	15 (6.6)		
<b>Income</b>				
Below poverty line	154 (67.8)	133 (58.6)	4.177	<b>0.041</b>
Above poverty line	73 (32.2)	94 (41.4)		

Table 3: Rural – Urban comparison of AEFI pattern

Variable	Rural n (%) N = 227	Urban n (%) N = 227	X <sup>2</sup>	p-value
<b>child ever experienced an AEFI</b>				
Yes	112 (49.3)	87 (38.3)	5.592	<b>0.018</b>
No	115 (50.7)	140 (61.7)		
<b>Onset</b>	<b>n = 112</b>	<b>n = 87</b>		
Within 24 hours	63 (56.2)	33 (37.9)	11.082	<b>0.004</b>
2 – 7 days	46 (41.1)	43 (49.4)		
2 – 3 weeks	3 (2.7)	11 (12.6)		
<b>Description of AEFI</b>				
Mild	72 (64.3)	45 (51.7)	5.903	0.052
Moderate	31 (34.8)	37 (42.5)		
Severe	1 (0.9)	5 (5.7)		
<b>Medical attention needed</b>				
Yes	28 (25.0)	28 (32.2)	1.989	0.370
No	84 (75.0)	59 (67.8)		
<b>Duration of the event</b>				
1 – 2 days	56 (50.0)	45 (51.7)	4.861	0.182
3 – 4 days	36 (32.1)	18 (20.7)		
5 – 6 days	11 (32.1)	18 (20.7)		
7 days and above	9 (8.0)	6 (6.9)		
<b>Outcome</b>				
Recovered fully	104 (92.9)	83 (95.4)	0.560	0.756
Recovered with disability	4 (3.6)	2 (2.3)		
Did not recover	4 (3.6)	2 (2.3)		

\*Multiple responses

Table 4: Rural – Urban comparison of AEFI pattern (continued)

Variable	Rural n (%) N = 227	Urban n (%) N = 227	X <sup>2</sup>	p-value
<b>Form (s) of AEFI</b>				
Pain/ Local swelling	46 (41.1)	29 (33.3)	1.249	0.264
Cellulitis	19 (17.0)	13 (14.9)	1.148	0.700
Fever	<b>51 (45.5)</b>	<b>37 (42.5)</b>	0.180	0.672
Convulsion	7 (6.3)	3 (3.4)	0.805	0.370
Paralysis of the limbs	4 (3.6)	2 (2.3)	0.271	0.603
Persistent crying	10 (8.9)	7 (8.0)	0.049	0.825
Irritability	6 (8.9)	4 (4.6)	0.059	0.808
Diarrhoea	3 (2.7)	1 (1.1)	0.581	0.446
Rashes	14 (12.5)	21 (24.1)	4.575	0.032
Vomiting	4 (3.6)	2 (2.3)	0.271	0.602
Anaphylaxis	2 (1.8)	1 (1.1)	0.134	0.716
<b>Vaccine they thought was responsible for the reaction*</b>				
BCG	39 (34.8)	37 (42.5)	1.232	0.267
Oral polio vaccine	20 (17.9)	31 (35.6)	8.117	0.004
Hepatitis	55 (49.1)	37 (42.5)	0.852	0.356
Pentavalent	<b>90 (80.4)</b>	<b>64 (73.6)</b>	1.292	0.256
PCV	38 (33.9)	33 (37.9)	0.342	0.559
IPV	43 (38.4)	33 (37.9)	0.004	0.947
Yellow fever	22 (19.6)	25 (28.7)	2.244	0.134

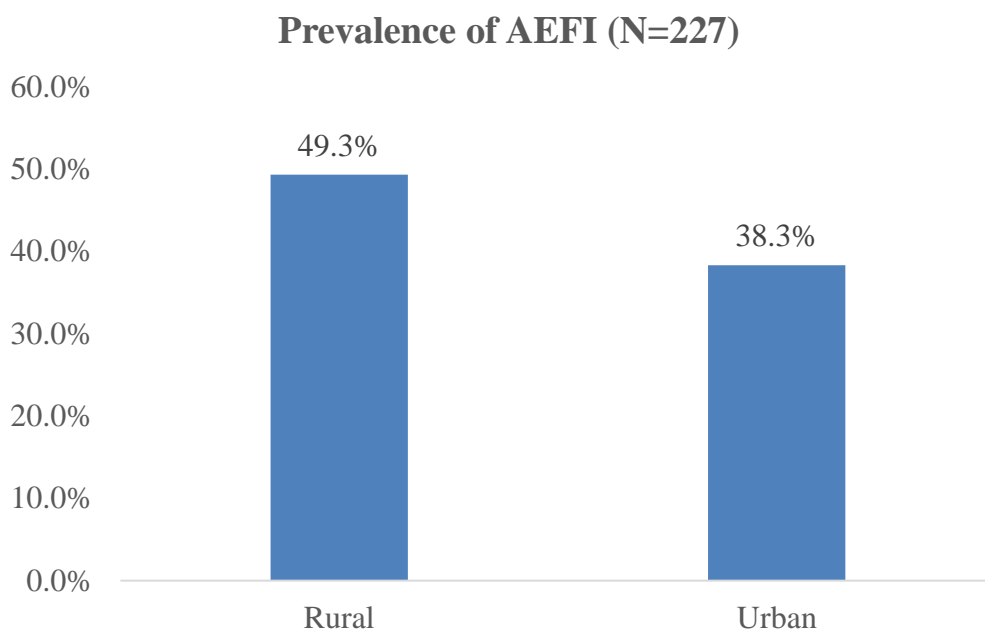


Figure 1: A bar chart showing the prevalence of AEFI in both rural and urban communities ( $X^2 = 5.592$ ,  $p = 0.018$ )