



## Prevalence and pattern of adverse events following immunization among children in South-western state, Nigeria: a cross-sectional study among mothers attending immunisation clinics

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### Abstract

**Context:** Adverse Events Following Immunization (AEFI) contribute immensely to child morbidity and mortality as they often lead to low uptake of vaccines with consequent persistence of vaccine-preventable diseases. This study assessed knowledge, prevalence and patterns of adverse events following immunization among children attending immunization clinics in Osogbo, Osun State.

**Materials and Methods:** A descriptive cross-sectional study was conducted among 244 mothers of infant 0-24 years attending immunization clinics in Osogbo using a multistage sampling technique. Data were collected using a pre-tested, semi-structured, interviewer-administered questionnaire. Chi-Squared test and binary logistic regression model were used for inferential statistics at  $p < 0.05$ .

**Results:** One hundred and seventy-five (72.6%) children experienced one form of AEFI or the other before. Fever (103, 42.4%) was the most frequently mentioned AEFI. One hundred and forty-four (57.8%) respondents have poor knowledge of AEFI. Pentavalent vaccine (112, 46.9%) was the commonest antigen among respondents responsible for AEFI. Birth order of baby ( $p = 0.001$ ) and antenatal clinic attendance ( $p = 0.042$ ) were statistically significantly associated with knowledge of AEFI.

**Conclusion:** Knowledge of AEFI among respondents was sub-optimal. The need for continuous sensitization of mothers during antenatal and immunization clinics is strongly recommended as this will go a long way in early identification and prompt reporting of AEFI to the appropriate quarters for immediate management.

Keywords: Prevalence, Patterns, Adverse effect, Immunization, Children

### Introduction

Immunization stands as one of modern medicine's greatest achievements and arguably one of the most cost-effective public health interventions in history. It safeguards not only individuals and families, but entire communities against infectious diseases. More recently, its reach has expanded to include protection against certain non-communicable conditions, such as cancer and other chronic illnesses.<sup>1</sup> It is documented that immunization has the propensity to abate mortality in all age groups and currently, more than two million life-threatening diseases of childhood can be protected annually.<sup>2</sup> With all the beneficial outcomes linked with immunization in childhood, there are some occasional bouts of side effects,

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otherwise known as adverse events following immunization, (AEFI), manifestation of which may be mild while some may require urgent hospital admission. The grave consequence of adverse events following immunization has the propensity of eroding any gains attributed to immunization as well as increase childhood immunization hesitancy.

Adverse events following immunization (AEFIs) according to the World Health Organization, is known as any untoward medical occurrence that follows immunization and that does not necessarily have a direct or causal relationship with vaccine use. It may be any unintended sign or unfavorable, abnormal laboratory finding, or disease/symptoms.<sup>3</sup>

AEFIs could be classified into either serious or non-serious reactions which could manifest either locally or systematically. It could be reactions due to the vaccine product, or effects due to an alteration in the quality of the vaccine, or effect as a result of immunization errors or reactions due to anxiety on taking the vaccine or reaction that are just coincidental with the administration of vaccine.<sup>3</sup>

Manifestation of AEFI range from pain at injection site, skin rash, fever, irritability, skin rash, sores on a mild to moderate dimension while more severe AEFI could manifest as convulsion to difficulty in breathing, weakness of the limbs, encephalitis, aseptic meningitis, and even death.<sup>3,4</sup> Globally, AEFIs have been documented as a significant determinant of vaccine hesitancy which invariably lead to low vaccination coverage.<sup>5</sup>

Nigerian's current immunization schedule offers the Bacillus Calmette–Guérin (BCG), HBV, polio, PENTA/DPT, yellow fever, and measles vaccines. As at 2021, a report showed that immunization rates for BCG, polio vaccine, pentavalent vaccine, measles vaccine and yellow fever vaccines were 34%-51%.<sup>6</sup> The same report has it that more than two-third of children within the ages of 12 to 23 months old do not take the routine immunization. Furthermore, according to the report, the reason why 11% women will not allow their wards to be immunized was due to the fear of side effects, while 26% refused to get their children immunized because of fear and mistrust of the vaccine. Now, that there are even more recently introduced vaccines to the immunization schedule, the fear of AEFI is likely to increase with the consequent reduction of immunization coverage.<sup>7</sup> Reduction in immunization coverage leaves children vulnerable to diseases that would have been prevented with vaccines. Most often than not, parents are sometimes concerned about adverse effects that could result from immunization. It was exactly what happened in the Northern part of Nigeria when most

mothers refused to allow their children to be vaccinated because of the misconceptions and rumors about the efficacy of the vaccine.<sup>3,8</sup>

Previous studies have found wide disparities in the reported rates of AEFIs in different parts of Nigeria, which could be attributed to vaccine-related issues in different geopolitical zones of the country, inequalities in socioeconomic factors as well as some other contextual differences.<sup>7</sup> Therefore, this study is targeted at determining the prevalence as well as patterns of AEFIs among children in Osogbo, South West Nigeria, to bridge the contextual gap for evidence-based programming and planning related to AEFIs that can assist policy makers in enacting relevant policies.

## Materials and Methods

**Study area:** This study was carried out at Osogbo, the administrative headquarters of Osogbo and Olorunda Local Government Areas (LGAs) and the capital of Osun State, Nigeria Study Area. The survey was conducted between 12 January 2024 and 27 January 2024 in three LGAs of Osun State namely, Olorunda, Ede-North and Osogbo (the capital city of Osun State, Nigeria). Osun State is one of the six states in the South-Western part of Nigeria, it lies between latitude 7°77" and 7°48" north of the equator and between longitude 4°33" and 4°35" east of the Greenwich Meridian.[20] Osogbo has a population of 731,000 according to the National Population Commission of Nigeria (2021). The people of Osogbo are predominantly Yorubas. The LGAs each have major healthcare facilities for administering immunizations.

## 3.2 Study Design

A descriptive cross-sectional study design was employed for this research.

## 3.3 Study Population

The study population consists of children aged less than 24 months who attended immunization clinics regularly in Osogbo. This population is considered at risk of experiencing AEFI due to their exposure to vaccines for childhood immunization.

## 3.4 Sample Size Calculation

Prevalence of AEFI of 10% (0.1) based on previous studies was used in determining the sample size.

The formula for calculating the sample size for a prevalence study is:

$$n = (Z^2 \times p \times (1 - p)) / e^2$$

Where:

n = required sample size

Z = the standard normal variate at the desired confidence level (for 95% confidence, Z = 1.96)

p = estimated prevalence of AEFI (assumed 0.1 based on previous studies)

e = desired margin of error

Desired margin of error of 5% (0.05).

Substituting the values, we get:

$$n = (1.96^2 \times 0.1 \times (1 - 0.1)) / 0.05^2$$

$$n = (3.8416 \times 0.09) / 0.0025$$

$$n = 138.7$$

Assuming a 20% non-response rate, the final sample size was increased to 167.

### Sampling Technique

This study utilized a multi-stage sampling design. Wards were first chosen from Osogbo's two Local Government Areas, and health facilities within those wards were then selected via simple random sampling. Respondent numbers per facility were proportionally allocated according to each clinic's average patient volume, as reported by the head matron. Data collection proceeded using systematic sampling: on each visit day, the first mother was recruited, and every other woman who walked in was included until the predetermined facility quota was reached.

### Data Collection and Measurements

Data collection involved the use of a semi-structured interviewer administered questionnaire given to mothers who brought their children for immunization at Osogbo clinics. Data collection was done with the help of research assistants, who were trained on how to administer the questionnaires so as to have a shared understanding of the questions.

### Data Analysis

Data collected from questionnaires were sorted, coded, entered into a database, and analyzed using SPSS version 24. Descriptive statistics, including frequencies, percentages, and means and standard deviations, were used to describe the prevalence and patterns of AEFI. Inferential statistics, such as chi-

square tests were employed to examine associations between variables.

### Ethical Consideration

Ethical approval was gotten from Primary Health Care Review Board, Osogbo. Confidentiality and data protection measures were implemented to safeguard participants' privacy throughout the research process. Additionally, participants were assured of their right to withdraw from the study at any time without consequences.

### Results

**Table 1: Sociodemographic characteristics of respondents**

| Variables                 | Frequency(n=244) | Percentage |
|---------------------------|------------------|------------|
| <b>Mother's age</b>       |                  |            |
| <20                       | 22               | 9.0        |
| 21-30                     | 138              | 56.6       |
| 31-40                     | 77               | 31.6       |
| 41-50                     | 6                | 2.5        |
| >51                       | 1                | 0.4        |
| <b>Marital status</b>     |                  |            |
| Single                    | 20               | 8.2        |
| Married                   | 222              | 91.0       |
| Cohabiting                | 2                | 0.8        |
| <b>Child's Sex</b>        |                  |            |
| Male                      | 124              | 50.8       |
| Female                    | 120              | 49.2       |
| <b>Educational status</b> |                  |            |
| No formal                 | 6                | 2.5        |
| Primary                   | 15               | 6.1        |
| Secondary                 | 101              | 41.4       |
| Tertiary                  | 122              | 50.0       |
| <b>Occupation</b>         |                  |            |
| Unemployed                | 62               | 25.4       |
| Unskilled                 | 16               | 6.6        |
| Semi-skilled              | 41               | 16.8       |
| Skilled                   | 125              | 51.2       |
| <b>Ethnicity</b>          |                  |            |
| Yoruba                    | 228              | 93.4       |
| Igbo                      | 7                | 2.9        |
| Hausa                     | 9                | 3.7        |

One hundred and thirty-eight (56.6%) mothers were within 21 and 30 years of age, 222(91.0%) of mothers were married. One hundred and twenty-two (50.0%) have tertiary level of education and 125 (51.2%) are skilled workers. Two hundred and twenty-eight (93.4%) are Yoruba by tribe.

Ninety-five (38.9%) of the index child are first born while 74 (30.3%) are second born. One hundred and sixty-five (67.9%) have between one or two children while 72 (29.6%) have either three or four children. Two hundred and thirty (94.3%) attended antenatal services and 225 (92.2%) delivered this

index baby in a health facility while 19 (7.8%) delivered at home.

**Table 2: Birth history of index child**

| Variables                          | Frequency(n=244) | Percentage |
|------------------------------------|------------------|------------|
| <b>Birth order</b>                 |                  |            |
| First born                         | 95               | 38.9       |
| Second                             | 74               | 30.3       |
| Third                              | 47               | 19.3       |
| Fourth                             | 23               | 9.4        |
| >Fourth                            | 5                | 2.0        |
| <b>Number of children</b>          |                  |            |
| 1-2                                | 165              | 67.9       |
| 3-4                                | 72               | 29.6       |
| 5-6                                | 6                | 2.5        |
| <b>Antenatal clinic attendance</b> |                  |            |
| Yes                                | 230              | 94.3       |
| No                                 | 14               | 5.7        |
| <b>Place of delivery</b>           |                  |            |
| Healthcare facility                | 255              | 92.2       |
| Home                               | 19               | 7.8        |

**Table 3: Knowledge of AEFI among respondents.**

| Variables                                        | Frequency | Percentage |
|--------------------------------------------------|-----------|------------|
| <b>Definition of AEFI</b>                        |           |            |
| Right                                            | 237       | 97.1       |
| Wrong                                            | 3         | 1.2        |
| No idea                                          | 4         | 1.7        |
| <b>Causes of AEFI</b>                            |           |            |
| Chemical in vaccines                             | 100       | 41.2       |
| Infection from inappropriate handling of vaccine | 81        | 33.3       |
| Fear of vaccination                              | 66        | 27.2       |
| Coincidental event                               | 39        | 16.0       |
| <b>Forms of AEFI you know</b>                    |           |            |
| Fever                                            | 141       | 58.0       |
| Pain                                             | 136       | 56.0       |
| Swelling                                         | 104       | 42.8       |
| Convulsion                                       | 17        | 7.0        |
| Ulceration                                       | 4         | 1.7        |
| Generalized rashes                               | 15        | 6.2        |
| Difficulty in breathing                          | 3         | 1.2        |
| Weakness of the limb                             | 21        | 8.6        |
| Continuous high-pitched cry                      | 61        | 25.1       |
| Sudden collapse                                  | 4         | 1.6        |
| <b>Awareness on the need to report AEFI</b>      |           |            |
| Yes                                              | 198       | 82.5       |
| No                                               | 46        | 17.5       |
| <b>Ever received health education on AEFI</b>    |           |            |
| Yes                                              | 226       | 93.4       |
| No                                               | 18        | 6.6        |
| <b>Overall Knowledge</b>                         |           |            |
| Poor                                             | 144       | 57.8       |
| Good                                             | 100       | 42.2       |

Two hundred and thirty-seven (97.1%) gave correct meaning of AEFI. One hundred (41.2%) identified that AEFI is often caused by chemicals in the vaccine given, 81 (33.3%) said AEFI is as a result of infection from inappropriate handling of vaccine.

Sixty-six (27.2%) however said AEFI is borne out of fear while 39 (16.0%) said its often as a result of coincidental event. One hundred and forty-one (58.0%) identified fever as one of the manifestations of AEFI, 136 (56.0%) knew pain to be a form, 104 (42.8%) however picked swelling. One hundred and ninety-eight (82.5%) are aware that they should report any AEFI witnessed and 226 (93.4%) have received health education on AEFI before. One hundred and forty-four (57.85) have poor knowledge of AEFI while 100 (42.2%) have good knowledge.

**Table 4: Pattern of and response to AEFI among children of respondents**

| Variables                                | Frequency | Percentage |
|------------------------------------------|-----------|------------|
| <b>Child ever experienced AEFI</b>       |           |            |
| Yes                                      | 175       | 72.6       |
| No                                       | 69        | 27.4       |
| <b>*Type of AEFI (N=175)</b>             |           |            |
| Fever                                    | 103       | 42.4       |
| Pain                                     | 98        | 40.5       |
| Swelling                                 | 72        | 29.6       |
| Irritability                             | 32        | 13.3       |
| Convulsion                               | 10        | 4.1        |
| Weakness of limb                         | 20        | 8.3        |
| Diarrhea                                 | 2         | 0.8        |
| Vomiting                                 | 14        | 5.7        |
| Rash                                     | 18        | 7.5        |
| <b>Site of AEFI reported</b>             |           |            |
| Local                                    | 122       | 69.7       |
| Generalized                              | 53        | 30.0       |
| <b>Time of onset</b>                     |           |            |
| <6                                       | 65        | 37.5       |
| 6-12hours                                | 66        | 37.7       |
| 13-23                                    | 12        | 6.8        |
| >24 hours                                | 32        | 18.3       |
| <b>*Vaccines linked with AEFI(n=175)</b> |           |            |
| BCG                                      | 35        | 14.7       |
| Pentavalent vaccine                      | 112       | 46.9       |
| Pneumococcal conjugate vaccine           | 34        | 14.2       |
| Oral polio vaccine                       | 16        | 6.7        |
| Inactivated polio vaccine                | 8         | 3.3        |
| Measles vaccine                          | 26        | 10.9       |
| Yellow fever                             | 22        | 9.2        |
| <b>*Response to the AEFI reaction</b>    |           |            |
| Reported to the hospital within 24hrs    | 90        | 42.1       |
| Reported to the hospital after 24hrs     | 18        | 8.4        |
| Gave home treatment                      | 86        | 40.2       |
| Didn't do anything                       | 20        | 9.3        |

\*Multiple responses

One hundred and seventy-five (72.6%) mothers have experienced AEFI on their wards at one time or the other, fever having happened in 103 (42.4%) children, followed by pain at injection site, then swelling in 72 (29.6%) children. One hundred and twenty-five (70.2%) reported that their children witnessed a localized AEFI while 53 (29.8%) said theirs was generalized. Sixty-five (36.5%) AEFI

happened less than 6hrs after administration of vaccine while 66 (37.1%) began between 6 and 12hrs of receiving the vaccine. However, 35(19.7%) however indicated that AEFI started more than 24 hours after receiving the vaccine. One hundred and twelve (46.9%) identified pentavalent vaccine as the AEFI experienced while 35 (14.7%) said BCG was the cause of AEFI experienced. However, 8 (3.3%) said their wards experienced AEFI after the administration of inactivated polio vaccine. Ninety (42.1%) reported AEFI within 24 hours of onset and 86 (40.2%) gave home treatment. Twenty (9.3%) however didn't take any action.

**Table 5: Association between sociodemographic characteristics and knowledge of AEFI**

| Variables                          | Knowledge |          | Total     | Statistics                                 |
|------------------------------------|-----------|----------|-----------|--------------------------------------------|
|                                    | Poor      | Good     |           |                                            |
| <b>Marital status</b>              |           |          |           |                                            |
| Single                             | 15(10.6)  | 20(8.4)  | 20(8.4)   | $\chi^2=2.296$<br>df= 2<br>p-value=0.317   |
| Married                            | 125(88.7) | 91(93.8) | 216(90.8) |                                            |
| Cohabiting                         | 1(0.7)    | 1(1.0)   | 2(0.8)    |                                            |
| <b>Educational level</b>           |           |          |           |                                            |
| No formal                          | 3(2.1)    | 3(3.1)   | 6(2.5)    | $\chi^2=3.555$<br>df= 3<br>p-value=0.314   |
| Primary                            | 8(5.7)    | 6(6.2)   | 14(5.9)   |                                            |
| Secondary                          | 65(46.1)  | 33(34.0) | 98(41.2)  |                                            |
| Tertiary                           | 65(46.1)  | 55(56.7) | 120(50.4) |                                            |
| <b>Occupation</b>                  |           |          |           |                                            |
| Unemployed                         | 29(20.6)  | 32(33.0) | 61(25.6)  | $\chi^2=7.346$<br>df= 3<br>p-value=0.062   |
| Unskilled                          | 12(8.5)   | 4(4.1)   | 16(6.7)   |                                            |
| Semi-skilled                       | 29(20.6)  | 12(12.4) | 41(17.2)  |                                            |
| Skilled                            | 71(50.4)  | 49(50.5) | 120(50.4) |                                            |
| <b>Birth order</b>                 |           |          |           |                                            |
| First born                         | 65(46.1)  | 28(28.9) | 93(39.1)  | $\chi^2=23.178$<br>df= 4<br>*p-value=0.001 |
| Second                             | 49(34.8)  | 23(23.7) | 72(30.3)  |                                            |
| Third                              | 17(12.1)  | 28(28.9) | 45(18.9)  |                                            |
| Fourth                             | 7(5.0)    | 16(16.5) | 23(9.7)   |                                            |
| Fifth                              | 3(2.1)    | 2(2.1)   | 5(2.1)    |                                            |
| <b>Antenatal clinic attendance</b> |           |          |           |                                            |
| Yes                                | 130(92.2) | 95(97.9) | 225(94.5) | $\chi^2=3.666$<br>df= 1<br>*p-value=0.042  |
| No                                 | 11(7.8)   | 2(2.1)   | 13(5.5)   |                                            |

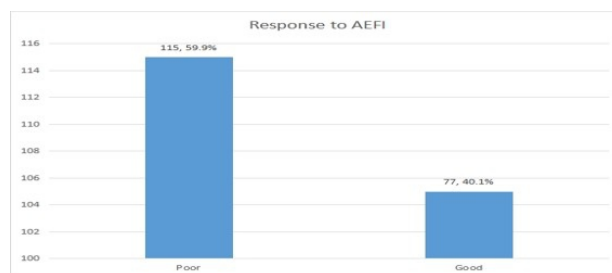
\*=Significant p value

There is a statistical association between knowledge of AEFI and birth order of child and mothers' antenatal attendance.

**Table 6: Association between knowledge of AEFI and maternal response to AEFI**

|                  | Response to AEFI |          | Total     | Statistics                            |
|------------------|------------------|----------|-----------|---------------------------------------|
|                  | Poor             | Good     |           |                                       |
| <b>Knowledge</b> |                  |          |           |                                       |
| Poor             | 58(52.3)         | 49(63.6) | 107(56.9) | $\chi^2=2.403$ df= 1<br>p-value 0.136 |
| Good             | 53(47.7)         | 28(36.4) | 81(43.1)  |                                       |

There is no statistical significant association between knowledge of AEFI and respondents' response to it.



**Figure 1: Response to AEFI**

This shows that one hundred and fifteen (59.9%) responded poorly to AEFI while 77 (40.1%) responded well to AEFI.

## Discussion

Active watchfulness for AEFI is the pillar to the attainment and maintenance of quality immunization services in any region of the world. Of note is that the high level of suspicion of looking out for AEFI lies in the in-depth knowledge and reporting practices by mothers of under five children to the healthcare workers who subsequently report to the appropriate quarters. In this study, seven out of ten under-five children were reported by their mothers to have had an AEFI at one point or the other. This prevalence gotten here is far much higher than the rates reported in Jos,<sup>4</sup> and Brazil<sup>9</sup>. It is important to state that the differences in the prevalence of AEFI observed in studies across different locations and countries could be attributable to the fact that the studies were conducted in different settings and level of health care services provision.

Also, pentavalent vaccine was the antigen most frequently identified as the cause of AEFI the child had, followed by BCG. Similar result of pentavalent vaccine was gotten in another study in Cameroon<sup>10</sup>, Kano<sup>11</sup> and Ile Ife<sup>12</sup>. The attribution of AEFI to specific vaccines may reflect the mothers' interpretations of vaccine safety and efficacy based on their social contexts and experiences. This has the propensity of debarring mothers from taking wards for the subsequent doses.

Four in ten of respondents mentioned fever as the most common AEFI experienced, which was supported vehemently by findings from Poland<sup>13</sup> and another Nigerian study<sup>4</sup> Other forms AEFI experienced in the study were pains and swelling as

well as convulsion which were also in close association with what was observed in another Nigerian study.<sup>14</sup> Appropriate actions following AEFI were taken by less than a quarter of the mothers in this study.

The findings suggest that mothers whose children are third born and downwards have good knowledge about AEFI compared to mothers nurturing either the first or second born. This is actually a pointer to the fact that experience about nurturing a child goes a long way in helping mothers identify AEFI in subsequent child births. Firstborn children may have different levels of knowledge regarding AEFI compared to mothers of second-born or subsequent children. This difference could stem from various factors, such as increased parental attention and information-seeking behavior for firstborn children. Furthermore, it was found out that mothers who did not attend antenatal clinics as appropriate were found to have poor knowledge of AEFI. This association between mothers' antenatal attendance and knowledge of AEFI highlights the role of healthcare interactions and information dissemination in shaping maternal awareness and understanding of vaccination-related risks.

The findings suggest that mothers who attend antenatal services may have greater access to health education and information on AEFI, leading to higher levels of knowledge compared to those who do not attend such services. Moreover, the statistical association between knowledge of AEFI and mothers' antenatal attendance underscores the importance of healthcare interventions in promoting maternal awareness and understanding of vaccination-related risks.

The lack of a statistically significant association between knowledge of Adverse Events Following Immunization (AEFI) and respondents' response to it shouldn't rule out an important point to note. Mothers who had good knowledge about AEFI tend to react well to such compared to those with poor knowledge. The findings imply that individuals' responses to AEFI may be influenced by factors beyond their knowledge level, such as cultural beliefs, trust in healthcare systems, and previous experiences with vaccination. The need for continuous sensitization of mothers as regarding signs of AEFI at every immunization visit cannot be overemphasized.

If this chain of reporting is maintained, it goes a long way in determining if an immunization program will succeed or not. This also in the long run boosts the confidence mothers have in the vaccines they take for their children. With the introduction of new vaccines to the national immunization schedule, more frequent vaccinations to meet national targets, and exposure to more vaccine antigens, there is an increased likelihood of AEFIs.

## Conclusion

This study showed that less than half of respondents have good knowledge of AEFI. A high prevalence of AEFI was noted among children of respondents with fever as the most common pattern amongst others like pain at injection site, swelling. This study found high prevalence of AEFI among under-five children, with pentavalent vaccine being the most commonly identified *ca.* Mothers' antenatal visits and experience with previous children are significant factors that influence knowledge of AEFI among mothers. There is need for policy makers to implement policies that will improve attendance of pregnant women at antenatal clinic where sensitization and health education on childhood immunization, its adverse effect and early reporting of AEFI are discussed. It is also recommended that continuous health education to mothers during antenatal clinics and immunization clinics should be promoted in healthcare facilities to increase immunization coverage and enhance better outcome in AEFI management.

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**Literature review:** ORI, OM

**Analysis:** ORI

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