Research Article

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Adverse Events Following Immunization And Associated Factors Amongst Children 0-24 Months In An Urban Setting In, Cameroon

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1. Abstract

1.1. Background:
Evidence has shown that immunization is the most potent public health intervention of all time reducing morbidity and mortality from infectious diseases. In spite of the fact that vaccines have been proven to be safe and effective, it is sometimes associated with adverse reactions following immunization especially in children.This study set out to determine the prevalence and associated risk factors of Adverse Events following Immunization (AEFI) amongst children aged 0-24 months in the Bali Health District in 2021.

1.2. Methods:
A community-based cross-sectional study involving 136 children (0-24 months) from 7 health areas of the Bali Health District in Cameroon. Data on AEFI was collected using a self-administered structured questionnaire from parents/caregivers of the children. Logistic regression analysis was used to identify the independent predictors of AEFI.

1.3. Results:
The prevalence of adverse events was 34% in the Bali HD. Some of the Adverse Events reported included: Fever (31.1%), Local reaction (pain, swelling, redness at injection site) (51.1%), and Systemic reactions (irritability, malaise, loss of appetite (13.3%) In Bivariate analysis, indicated that being a male (AOR 2.8, CI 95% and being sick (AOR 3.3 and CI 95%). were significantly associated ($p < 0.05$) with the manifestation of AEFI. While, the Feeding method's, Nutritional status of the child, Vaccines contact and effects of socio-demographic factors were not significantly associated ($p > 0.05$) with the manifestation of AEFI. Multivariate analysis revealed that being a male child (AOR 10, 95%CI 1.96) and being sick (AOR 30, 95% CI xxxx) were independent predictors for the manifestation of adverse events following immunization.

1.4. Conclusion:
This study has demonstrated that amongst children 0 – 24 months in the North West region of Cameroon being a male child and being sick are more likely to develop adverse events following vaccination.

2. Keywords:
Children, Immunization, adverse events, North West Region, Cameroon

3. Background

Vaccines are considered the safest and cost-effective interventions in the prevention of infectious diseases [1]. Historically, vaccines have proven to reduce morbidity and mortality rates of some infectious diseases [2,3]. Expanding and keeping high immunization coverage is necessary to achieve and maintain low levels of communicable diseases in populations. However, expansion of vaccination coverage leads to the occurrence of adverse events following immunization (AEFI). This might be attributed to the fact that vaccines are pharmacological products which may affect some individuals adversely [1,3,4,5]. Adverse events following immunization consist of any undesirable effect following immunization, not necessarily having a causal relation with the use of a vaccine or other immune biological preparation. (Ref) Most AEFIs are mild, local and systemic, thus, surveillance actions are focused on moderate and severe events. These events could be due to type of vaccine and vaccine components, conditions of administration, and storage [5]. Moreover, the intensity, of AEFI may vary from mild such as local manifestation to moderate and severe events and rare cases, classified as unexpected

[1,4,6]. Considering the characteristics of the vaccines, children under the age of one are the most affected with adverse events following vaccination given that most vaccines are for this age group. Studies conducted in São Paulo and Teresina [6,7] showed that the distribution of AEFI in this age group was 80% compared to other age groups. It is therefore important to do screening and monitor children for adverse events following immunization so that AEFI are identified for timely intervention. This helps to maintain good quality of the vaccines, as well as the reliability of the immunization [1,7]. AEFI should be carefully investigated aiming at avoiding a mismatch of cause and effect with the immunization, especially in cases presenting the occurrence of transitory association of the complication with the immunization. On the other hand, confirmed cases of AEFI should be disclosed in order to enable health professionals to become aware of them and consequently adopt specific preventive measures, as well as prescribe immunizations with a higher level of safety [1,4,8].

The World Health Organization (WHO) mandates the systematic collection, analysis and evaluation of medically important adverse events following immunization (AEFI) for all immunization programs [9]. The major goal of this immunization safety surveillance is the "early detection and analysis of adverse events. This enables appropriate and quick responses to emerging AEFI issues in order to decrease the negative impact on the health of individuals and the immunization programme" [9]. In addition, vaccine safety surveillance allows signal identification and hypothesis generation. It also helps in the identification and rectification of gaps in the system to strengthen the Expanded Programme on Immunization (EPI programme) [9]. In Cameroon, there is limited data on the prevalence of AEFI and the factors associated with AEFI in children below twoyears[2]. Understanding the predictors of adverse events following vaccination in this vulnerable population will provide valuation information to guide targeted intervention in providing safe immunization and thus the control of immuno-preventable diseases. This study therefore set out to determine the prevalence of AEFI and to identify the factors associated with adverse events following vaccination in children0 -24 months in seven [7] health areas in the Bali Health District of the North WestRegion of Cameroon.

4. Materials and Methods

4.1. Study Participants

The study participants were parents with children 0-24 months living in Bali and Staff of the EPI in the different health units in Bali Health District.

4.2. Ethical Considerations

Approval to carry out this study was obtained from the Institutional Review Board (IRB) of The University of Bamenda (Ref No 2021/067H/UBaIRB). Administrative clearance was gotten from the Regional Delegation of Public Health for the North West Region (Ref No 21/00030/UBa/D-FHS/VD-RC). Written informed consent was obtained from all the quarter heads and parents/ caregivers/ guardians of the children before any data collection procedure started.

4.3. Data Collection

Data for this study was collected by the principal investigator and 4 trained field surveyors using a structured questionnaire which was pretested and modified for the purpose of this study. The questionnaire was administered at the health unit and at home. The questionnaire was divided into the following parts: Socio demographic and background information, clinical factors.

4.4. Socio Demographic And Background Information:

This included; For the Respondent: Age marital status, occupation, religion, level of education and area of residence

For the child: Age, sex and weight

Vaccines characteristics; vaccines and dose.

4.5. Clinical Factors Included:

Fever, headache, vomiting, excessive crying, cough, soreness (redness, swelling), mild rash, severe rash, swelling and tenderness of lymph nodes, any eye infections, infection at the side of the injection.

4.6. Statistical Analysis

To ensure data quality, data collected were been screen to eliminate incomplete or poorly filled questionnaires. The data was then coded before entry in to a pre-designed and tested data masque on Excel to ease analysis. Data for this study was analysed using SPSS for Windows version 25. Frequency distribution tables was used to summarize the descriptive characteristics as well as categorical variables while mean and standard deviation or median was used to represent continuous variables for the mother. Effects of socio-demographic variables on AEFI was assessed using Chi square test for categorical variables and student t-test for continuous variables respectively. The frequencies of potential risk factors of AEFI was estimated and this was followed by calculation of odds ratios (OR) using a univariate binary logistic regression analysis. Further, AOR was determine using a multivariate binary logistic regression analysis was performed to determine the independent risk factors of AEFI. A p-value of less than 0.05 was considered to be statistically significant.

5. Results

5.1. Sociodemographic Characteristics

From table 4 below, women less than 22 years represented 58.2% whereas those greater than 22 years represented 41.8%. Median age of mothers was 22 years and mean 23.2 years, youngest was 17 and oldest 35 years. 67.9% were married while 32.1% were not married. 19.4% were formally employed, 74.6% were self-employed while 6% were housewives. 7.5% attended at least primary education, 83.6% attended at least secondary education and 50% attended at least tertiary education.

Table 1: Socio-demographic characteristics of mother

Variable	Category	Frequency (%)

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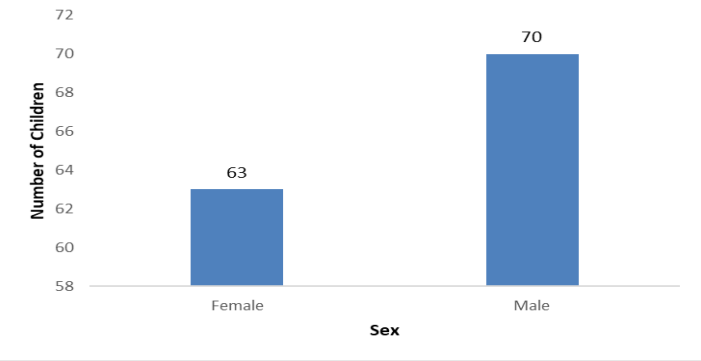
Age group	<22	78(58.2)
(year)	>22	56(41.8)
Marital status	Married	91(67.9)
	Single	43(32.1)
Occupation	Formally employed	26(19.4)
	Self employed	100(74.6)
	House wife	8(6)
Level of education	No formal education	2(1.5)
	Primary	10(7.5)
	Secondary	112(83.6)
	Tertiary	100(50.0)
	Rural	116(86.6)
Mothers residence	Urban	8(6)
	Semi urban	10(7.5)

For the child, the proportion of male children recruited in our study was 70 (52.2) % while the proportion female children stood at 63 (47.8%).

Figure 1: Distribution of children by sex in Bali Health District



5.2. Distribution Of The Different Vaccines Received By The Children

From table 2, most of the children recruited in our study received the fifth contact dose (35.1%) according the Cameroon vaccination calendar followed by the fourth contact with 27.6%. for the first, second, third and sixth contact, the percentage of children were 3.7%, 3.7%, 10.4% and 19.4%, respectively.

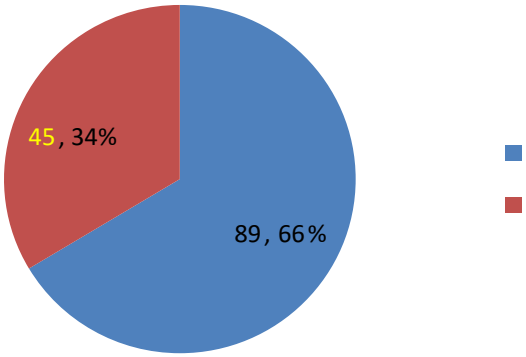
Table 2: Distribution of different vaccines received and their frequency

Contact	Frequency	Percentage
BCG, OPV 0	5	3.7
Penta 1, Pneumo 1, Rota 1 OPV 1	5	3.7
Penta 2, Pneumo 2, Rota2 OPV 2	14	10.4
Penta 3, Pneumo 3, OPV 2 = 3	37	27.6
MR1, YFV	47	35.1
MR2 = 5	26	19.4
Total	134	100.0

5.3. Prevalence of AEFI

As concern the frequency of AEFI, from figure 2, 34% of all children recruited in this study presented a case of an AEFI after vaccination at the different contact levels of the vaccination calendar.

Figure 2: Frequency of AEFI recorded



of the above AEFI after vaccination was least with 4.4% recorded.

5.4. Types of AEFI

From table 3, local reactions such as pains, swelling, redness at injection site predominated the list of AEFI presented by children after vaccination in our study with a percentage of 51.1%. Also, fever was presented in 31.1% of the children while systemic reactions involving irritability, malaise and loss of appetite was seen in 13.3%. The number of children who presented at least two of the above AEFI after vaccination was least with 4.4% recorded.

Table 3: Types of AEFI and their frequency

Type of AEFI	Frequency	Percentage
Fever	14	31.1
Local reaction (pain, swelling, redness at injection site)	23	51.1
Systemic reactions (irritability, malaise, loss of appetite	6	13.3
6 = Two or more of above symptoms	2	4.4
Total	45	100

5.5. Distribution Of AEFI By Sex Of Child

As seen in table 4, males were more males (44.3%) presented with AEFI compared to 22.2% in the female sex (OR=1.303, p=0.01).

5.6. Distribution Of AEFI By Sex Of Child

As seen in table 4, males were more males (44.3%) presented with AEFI compared to 22.2% in the female sex (OR=1.303, p=0.01).

Table 4: Distribution of AEFI by sex

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Sex of child	Unusual signs after vaccination	Total	Odd Ratio (CI=95%)	P value	
	Yes	No			
Male	31(44.3%)	39(55.7%)	70	2.782(1.3 035.939)	0.01
Female	14(22.2%)	49(77.8%)	63		
Total	45(33.8%)	88(66.2%)	133		

5.7. Distribution Of AEFI According To The Different Contact Vaccines

As seen on table 5, the greatest number of children presented with AEFI is observe after the first contact (60%) and the least during the second contact (20%). During the third contact, 50% of children presented an AEFI after vaccination while 27%, 29.8% and 38.5% for the fourth, fifth and six contacts respectively presented an AEFI after vaccination.

Table 5: Distribution of AEFI according to the different contact vaccines

Type of vaccines received	**Unusual signs after vaccination**	**Total**	**Odd Ratio (CI=95%)**	**P value**
	Yes	No		
BCG, OPV 0	3(60%)	2(40%)	5	
Penta 1, Pneumo 1,	1(20%)	4(80%)	5	
Rota 1 OPV				
Penta 2, Pneumo 2,	7(50%)	7(50%)	14	1.918	0.42
Rota2 OPV 2				
Penta 3, Pneumo 3,	10(27%)	27(73%)	37	
OPV 2 = 3				
MR1, YFV	14(29.8%0	33(70.2%)	47	
MR2 = 5	10(38.5%)	16(61.5%)	26	
Total	45	89	134	

5.8. Effects Of Socio-Demographic Factors On AEFI

As shown on table 6, it can be seen that mother <22 years of age have a greater risk of their children developing AEFI after vaccination with 37.2% of their children presenting with an AEFI with an odd ratio of 1.5 and p value of 0.2 which is not statistically significant. 33.6% of children from rural residence presented with AEFI after vaccination which is similar to the situation in urban residence (33.3%). Mothers with tertiary level of education presented the highest number of children with AEFI after vaccination (40%) second by secondary education with 34.8% of children and lastly, primary education with 16.7% of children presenting an AEFI after vaccination. Based on the occupation, 32.5% of employed women had children who presented an AEFI after vaccination compare to 50% in employed women.

Table 6: AEFI and socio-demographic factors

Socio-demographic characteristics	**Category**	**Number examined**	**Number of AEFI**	**Odd Ratio** (CI=95%)	**P value**
Mothers age	<22 years	78	29(37.2%)	1.48 (0.706-3.1)	0.197
	>22 years	56	16(28.6%)		
Residence	Rural	116	39(33.6%)	1.013 (0.353-2.903)	0.98
	Urban	18	6(33.3%)		
Level of education	Primary	12	2(16.7%)		0.406
	Secondary	112	39(34.8%)		
	Tertiary	10	4(40%)		
Occupation	Employed	121	41(32.5%)	0.482(0.115-2.026)	0.3
	Unemployed	8	4(50%)		

5.9. Association Of Clinical Factors To AEFI

From table 7, it can be seen that 58.8% of all the children who were sick before vaccination presented an AEFI after vaccination with an odd ration of 3.3 which is statistically significant with p value of 0.004. For the feeding methods, 45% of children under exclusive breastfeeding developed AEFI while only 25% of children complementary feeding method notably cerelac develops AEFI after vaccination. Also, among those children on other feeding method (neither exclusive breastfeeding nor cerelac), 33.3% developed an AEFI after vaccination.

Table 7: Relationship between AEFI and clinical factors

Clinical factors	**Category**	**Number examined**	**Number of AEFI**	**Odd Ratio** (CI=95%)	**P value**
child's state of health before vaccination	Sick	31	17(58.8%)	3.3 (1.418-7.459)	0.004
	Not sick	103	28(27.2%)		

Feeding method's	Exclusive breastfeeding	33	15(45.5%)		0.2
	cerelac	36	9(25%)		
	Others	63	21(33.3%)		
Nutritional status	Good	116	37(31.9%)	0.6 (0.214-1.605)	0.298
	Bad	18	8(44.4%)		

5.10. Predictors Of Adverse Events Following Immunization

Overall, gender, employment status, being trained, and recent AEFI encounter to elicit training were predictors of AEFI reporting.

6. Discussion

The overall prevalence of AEFI in this study was at 34%(15). It is higher than 8.2% reported in a study conducted by J.G. Breugelmans, et al on behalf of the YF AEFI group 2007 to 2010 on adverse events following yellow fever preventive vaccination campaigns in eight African Countries (Benin, Cameroon, Guinea, Liberia, Mali, Senegal, Sierra Leone, and Togo). However, these same results were found to be very similar to 33.7% prevalence rate reported in a descriptive record-based review of adverse events following immunization (AEFI) carried out in Oman using the national database for the period 1996–2005 [24,25]. Discrepancies in results perhaps could be explained by the fact that the studies were carried out in different study populations. Another similar study carried out in Spain on trends of Adverse Events Following Immunization (AEFI) Reports of Human Papillomavirus Vaccine in the Valencian Community Spain (2008–2018) [24], reported a general prevalence of 54.9% of surveillance AEFI-reporting rate in human papillomavirus (HPV) vaccine administered in the Valencian Community, Spain [18]. Prevalence of AEFI is generally expected to be higher in children who are sick than children who are not sick before taking the vaccines as seen in these studies. Similar prospective active vaccine safety surveillance study enrolled eligible children in the age group 0–5 years receiving vaccination from the immunization center at JSS Hospital, Mysuru [28], study bivariate analysis identified neonates, toddlers low birth weight and very low birth weight as predictors for development of AEFIs, irrespective of the vaccine administered [29]. In the study, male children were more likely to have an AEFI than females (44% Vs 23%, p= 0.010). This is similar to findings of Alexandra-Hendry-2122875840, Aditi-Dey-4, FrankBeard, Gulam-Khandaker and Kristine-K-Macartney December 2006, in Australia where 58% of BCG AEFI reports were for male children. In another study by Juny Sebastian, Parthasarathi Gurumurthy, Mandyam Dhati Ravi, and Madhan Ramesh November 2019, participants with AEFIs, 1380 (52.5%, CI: 50.60–54.40) were boys and 1248 (47.5%, CI: 45.60–49.40) were girls. As concerns, limitation of the study, one of the most commonly reported AEFI was fever (31%); the number may be an overestimation as the cause of fever was not analyzed. Secondly, the age group was limited to 0-24 months which could have given low prevalence compared to ages 5 to 13 years and women of child bearing ages who are usually also vaccinated in the EPI program.

7. Conclusion

The prevalence of AEFI in the Bali health district is 34% (CI: 95%) in children between 024 months enrolled in the EPI program for the year 2021. Male children were more likely to developed AEFI after vaccination than female children (44% vs 23%, p=0.010). Also, children who were sick before vaccination were more likely to develop AEFI compared to those who were not sick (58.5% vs 27.2%, AOR 3.3 CI 95%, P 0.004).

- There is a high prevalence of AEFI (34% (45) CI: 95%) in Bali in children 0-24 months in 2021.
- From this study, males were more likely to have an AEFI than females (44% Vs 23%, p= 0.010).
- The study identifies sick children more likely to have AEFI than children who were not sick. (58.8% Vs 27.2%, AOR 3.3 95%, p 0.004)

8. Abbreviations : AEFI: Adverse Event Following Immunization ; BCG:

Bacillus Calmette-Guerin - vaccine for tuberculosis (TB) ; BDHS: Bali District Health Service ; CHDR: Child Health Development Record ; CIOMS: Council for International Organizations of Medical Sciences ; DT: Diphtheria-tetanus vaccine; DTaP: Diphtheria-tetanus-pertussis (acellular) vaccine ; DTwP: Diphtheria-tetanus-pertussis (whole-cell) vaccine ; EPI: Expanded Programme on Immunization ; Hib: Haemophilus influenzae type b vaccine ; IPV: Injectable polio vaccine ; MMR: Measles-mumps-rubella vaccine ; MOH: Medical Officer of Health ; MR: Measles-rubella vaccine ; NIP: National Immunization Program ; NRA: National Regulatory Authority ; OPV: Oral poliomyelitis vaccine ; PHI: Public Health Inspector ; PHM: Public Health Midwife ; PHNS: Public Health Nursing Sister ; PMS: Post Marketing Surveillance ; PvV: Pentavalent (DTP-HepB-Hib) vaccine ; RDHS: Regional Director of Health Services RE: Regional Epidemiologist ; Td: Adult tetanus-diphtheria vaccine ; VAPP: Vaccine associated paralytic poliomyelitis ; VPD: Vaccine Preventable disease ; WHO: World Health Organization

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