

Research Article

Factors Associated with the Occurrence of Serious Adverse Events Following Immunization Following Administration of Nopv2 in Children Under Five Years of Age in Benin

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Abstract

Background: The new oral polio vaccine type 2 (nOPV2), authorized by WHO in November 2020, was deployed in Benin in 2025 as part of response campaigns against circulating vaccine-derived poliovirus type 2 (cVDPV2). The factors associated with serious adverse events following immunization (AEFI) reported after this campaign remain poorly documented in the French-speaking West African context. **Method:** We conducted a national case-control study that was conducted from August 2025 to November 2025 in the twelve departments of Benin. A total of 1067 children were included in the study. Cases (n=510) were children 0 to 5 years of age with severe AEFI following nOPV2 administration and controls (n=557) were nOPV2-vaccinated children without AEFI. The associated factors were searched for by multivariate logistic regression, after selection of candidate variables in univariate analysis. **Results:** In multivariate analysis, five independent determinants were identified. History of past malnutrition was associated with higher odds ratios of severe AEFI (aOR = 12.37; 95% CI: [1.51-18.10]; p = 0.019). Loss or unavailability of the vaccination record (ORa = 1.76; 95% CI: [1.11-2.78]; p = 0.016) and vaccine incompleteness (ORa = 1.77; 95% CI: [1.10-2.87]; p = 0.020) were also associated with higher odds. Conversely, the verification of the health record (ORa = 0.36; 95% CI: [0.26-0.50]; p < 0.001) and the question about the child's health status before vaccination (ORa = 0.64; 95% CI: [0.45-0.92]; p = 0.016) were associated with lower odds. Age, which was significant in univariate analysis, was no longer significant after adjustment (ORa = 1.01; 95% CI: [1.00-1.02]; p = 0.2). **Conclusion:** Our results suggest that the occurrence of severe AEFIs for nOPV2 in Benin is mainly associated with children's nutritional vulnerability, vaccination status and the quality of pre-vaccination practices. These associations do not allow a causal relationship to be established between the vaccine and the events observed.

Keywords

AEFI Severe, NOPV2, Malnutrition, Associated Factors, Pre-vaccination Practices, Benin

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1. Introduction

Polio remains a major global public health challenge. Circulating poliovirus derived from type 2 vaccine (cVDPV2) accounts for 90% of current global outbreaks, with 66 confirmed cases in 2025 according to GPEI [1]. In response, nOPV2, genetically more stable than the Sabin OPV2 vaccine with a 75 to 80% reduction in the risk of vaccine-derived poliovirus emergence [2-4], was authorized by WHO in November 2020 under registration for emergency use and administered in about 250 campaigns in 41 countries, representing about 1.3 billion doses, without evidence of an unexpected global safety signal [5]. However, these aggregated global data do not allow for the identification of individual and operational determinants specific to each deployment context, particularly in areas of high nutritional vulnerability in Africa where the immune response to live oral vaccines can be significantly impaired [6].

The occurrence of a post-immunization adverse event results from the interaction between the intrinsic characteristics of the vaccine, host-specific factors and the conditions of implementation of the vaccination. In children, immune status, nutritional status and pre-vaccination practices may influence the response to vaccination as well as the likelihood of adverse events occurring [7, 8]. Identifying these individual and operational factors is essential to strengthen the safety of vaccination campaigns while maintaining high vaccination coverage.

In Benin, on 21 June 2025, the Ministry of Health officially launched a national campaign to protect approximately 4 million children from poliomyelitis, in the context of the circulation of variant poliovirus type 2, based on the use of the oral polio vaccine nOPV2 [9]. Following this campaign, the national pharmacovigilance system recorded an unusual and massive notification of adverse events. A total of 569 cases of serious AEFI have been reported by health facilities across the country's 12 departments. To our knowledge, the available data on nOPV2 mainly describe its overall safety profile and surveillance systems, while the individual and operational factors associated with serious AEFIs remain poorly documented in French-speaking West Africa [10, 11].

The objective of this study was to identify the independent factors associated with the occurrence of serious AEFIs reported after administration of nOPV2 in children aged 0 to 5 years in Benin in 2025, in order to contribute to the improvement of the safety of polio campaigns in this context.

2. Methods

2.1. Type, Duration and Scope of the Study

This was a descriptive and analytical case-control study. The data was collected over a period of four months (04 months) from August 2025 to November 2025. The study was conducted in the twelve departments of Benin.

2.2. Study Population and Selection Criteria

The primary population consisted of children aged 0 to 5 years vaccinated with nOPV2 during the national campaign in June 2025. Parents or guardians were the main source of additional information, while vaccinators and health facility managers were called upon to document certain operational conditions.

Cases were vaccinated children under five years of age with severe AEFI that met at least one of the WHO criteria for severity: death, life-threatening, hospitalization or prolonged hospitalization, or persistent or significant capacity [12]. Controls were children vaccinated with nOPV2 during the same campaign and who did not have any reported AEFIs.

Children whose parents were absent when the investigators visited, were unable to answer questions, or refused to participate in the study, and children with doubts about the development of AEFI post-campaign or without evidence of AEFI were excluded from the study.

2.3. Sampling and Sample Size

The field plan combined departmental stratification and selection in clusters at 4 levels: commune, arrondissement, village or district, then household. The distribution of participants took into account the demographic weight of each department and the departmental prevalence of AEFIs. Secondary targets (parents or guardians) and tertiary targets (vaccinators and health facility managers) were identified by reasoned choice.

The minimum height had been estimated at 502 children according to Kelsey's formula, with a power of 80% and an increase of 10%. We then set an operational target of 520 cases and 520 controls to include as many serious cases as possible. Eligible cases identified in the reporting system were sought for inclusion. Of the 569 reported, 49 deaths were recorded but not included in this study due to the recent nature of the events (the campaign and the collection took place in the same year) in order to respect the mourning of the families. It should be noted that these deaths are the subject of an ongoing investigation. At the end of the recruitment period, 510 cases were effectively enrolled, with the remaining 10 cases having been lost to follow-up. For the selection of controls, comparability was sought on age (± 6 months), sex, place of residence and vaccination period. The final base included 510 cases and 557 controls. As the final numbers do not constitute fixed complete pairs 1:1, the analysis was conducted on the entire database by unconditional logistic regression, with adjustment in particular for age.

2.4. Data Collection

Data collection was done through individual interviews with parents/guardians and a document review using a tally sheet. The data were extracted from the national notification database, notification and investigation forms, hospitalization

records, available health records, and supplemented by interviews with vaccinators and health facility managers.

2.5. Variables Studied

The dependent variable was the occurrence of serious AEFI reported after administration of nOPV2, coded 1 in cases and 0 in controls. Independent variables included sociodemographic data (age, sex, area of residence, parental education), anthropometric data (weight, current underweight), medical history (chronic diseases, prematurity, low birth weight, past malnutrition, previous hospitalizations), and variables related to pre-vaccination practices (health record check, pre-vaccination interview, vaccination status, information given to parents, the place of vaccination).

Current underweight was defined as a weight-for-age of less than -2 standard deviations according to the WHO growth standards. The history of past malnutrition was consistent with a previous history of malnutrition (occurring in the last twelve months prior to vaccination) identified from information available in health documents or reported during the interview with parents or guardians. Immunization history was classified into five categories: complete immunization record by age, lost or unavailable record, incomplete immunizations, children who had never been vaccinated in the past, and children who had previously received other vaccines outside the Expanded Programme on Immunization (EPI).

2.6. Statistical Analysis

The data was analyzed with the STATA software. The qualitative variables were described by their numbers and percentages; quantitative variables by their mean and standard deviations. Univariate analysis compared the proportions between

cases and controls by the Chi-square test or the exact Fisher test depending on the number of students, and the means by the Student test when its application conditions were met. The multivariate analysis used an unconditional logistic regression model retained after a top-down walkthrough, including all variables with $p \leq 0.20$ in univariate analysis. Adjusted odds ratios (ORa) and their 95% confidence intervals were estimated. The statistical significance threshold was set at 5%.

2.7. Ethical Considerations

A favourable ethical opinion from the National Ethics Committee for Health Research (CNERS) has been obtained as well as authorisation from the Ministry of Health. Informed consent was obtained from all participants. The data has been anonymized and used for research purposes only.

3. Results

3.1. Incidence of Serious AEFIs

During the 2025 NPP2 campaign in Benin, a total of 11,510 AEFIs were reported, of which 569 were of a serious nature, including 49 deaths. The overall crude incidence rate of serious AEFIs was 1.34 out of a total of 4,238,850 vaccinated children, representing 4.94% of all reported AEFIs.

The incidence varied considerably by department (Figure 1), ranging from 0.12 per 10,000 doses in Alibori to 3.16 per 10,000 doses in Littoral. The departments with the highest incidences were Littoral (3.16), Plateau (2.62) and Couffo (2.47). The lowest incidences were observed in the northern departments such as Alibori (0.12), Borgou (0.19) and Atacora (0.22).

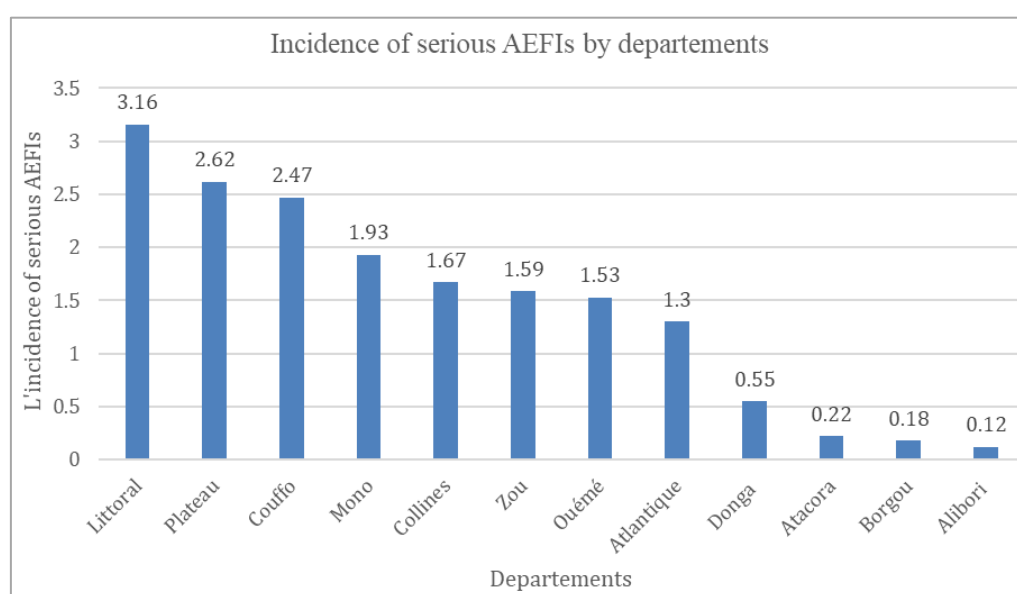


Figure 1. Incidence of serious AEFIs by department.

3.2. General Characteristics of the Study Population

A total of 1067 children were included: 510 cases and 557 controls. The mean age of the population was 23.5 months (standard deviation: 15 months). The sex ratio (M/F) was 1.04 with a slight male predominance (51.1%) compared to (48.9%) among girls. The level of education of parents was generally

low, with 35.9% of parents not attending school.

The mean age was 25.2 months in cases and 22.0 months in controls ($p < 0.001$). Sex, weight, current underweight and overall distribution by department were not significantly associated with the occurrence of severe AEFI in univariate analysis (Table 1). The parents' level of education was significantly associated ($p = 0.008$).

Table 1. Association between sociodemographic, anthropometric and the occurrence of serious post-nOPV2 AEFIs in children aged 0 to 5 years in Benin in 2025.

Variables	Serious AEFI, Yes (n=510)	Serious AEFI, No (n=557)	p-value
Average age	25.2 months	22 months	< 0.001
Gender			0.391
Male	268 (52.5%)	277 (49.7%)	
Female	242 (47.5%)	280 (50.3%)	
Average weight (kg)	10.5	10.1	0.215
Underweight			0.518
Yes	179 (35.1%)	184 (33.0%)	
No	331 (64.9%)	373 (67.0%)	
Area of residence (Departements)			0.159
Alibori	5 (1.0%)	17 (3.1%)	
Atacora	8 (1.6%)	9 (1.6%)	
Atlantique	84 (16.5%)	104 (18.7%)	
Borgou	12 (2.4%)	24 (4.3%)	
Collines	42 (8.2%)	41 (7.4%)	
Couffo	69 (13.5%)	69 (12.4%)	
Donga	17 (3.3%)	17 (3.1%)	
Littoral	68 (13.3%)	71 (12.7%)	
Mono	27 (5.3%)	42 (7.5%)	
Ouémé	73 (14.3%)	71 (12.7%)	
Plateau	55 (10.8%)	43 (7.7%)	
Zou	50 (9.8%)	49 (8.8%)	
Parents' level of education			0.008
Primary	166 (32.5%)	132 (23.7%)	
Secondary	146 (28.6%)	192 (34.5%)	
Superior	19 (3.7%)	29 (5.2%)	
Non-schoolchildren	179 (35.5%)	204 (36.6%)	

3.3. Medical History

Analysis of the medical history (Table 2): the history of past malnutrition was reported in 10 cases (2.0%) compared to 1 control (0.2%), i.e. a statistically significant association in univariate analysis ($p = 0.010$). Preterm birth was associated with

near the significance threshold ($p = 0.057$). Chronic disease, low birth weight, and history of hospitalization were not significantly associated with the occurrence of serious AEFI. Preterm birth had a significant borderline association ($p = 0.057$).

Table 2. Association between medical history and occurrence of serious post-nOPV2 AEFIs in children aged 0 to 5 years in Benin in 2025.

Variables	Serious AEFI, Yes (n=510)	Serious AEFI, No (n=557)	p-value
Past malnutrition			0.010
Yes	10 (2.0%)	1 (0.2%)	
No	500 (98.0%)	556 (99.8%)	
Previous hospitalization			0.358
Yes	24 (4.7%)	19 (3.4%)	
No	486 (95.3%)	538 (96.6%)	
Prematurity			0.057
Yes	7 (1.4%)	1 (0.2%)	
No	503 (98.6%)	556 (99.8%)	
Low birth weight			1.00
Yes	5 (1.0%)	5 (0.9%)	
No	505 (99.0%)	552 (99.1%)	

3.4. Pre-vaccination Practices

Analysis of pre-vaccination practices (Table 3): Health record verification was less frequent in cases (43.5%) than in controls (67.0%) ($p < 0.001$). Similarly, questioning about the

child's health status before vaccination was reported in 72.7% of cases and in 86.4% of controls ($p < 0.001$). Information given to parents about the vaccine and its effects was also less frequent in cases (54.3%) than in controls (67.0%) ($p < 0.001$). Incomplete vaccination status was more common in cases (10.6%) than in controls (6.5%) ($p < 0.001$).

Table 3. Association between pre-vaccination practices and the occurrence of serious post-nOPV2 AEFIs in children aged 0 to 5 years in Benin in 2025.

Variables	Serious AEFI, Yes (n=510)	Serious AEFI, No (n=557)	p-value
Health record check			< 0.001
Yes	222 (43.5%)	372 (67.0%)	
Variables	Serious AEFI, Yes (n = 510)	Serious AEFI, No (n = 557)	p-value
No	288 (56.5%)	185 (33.2%)	
Vaccination location			0.496
Door-to-door	498 (97.6%)	538 (96.6%)	
Health Center	11 (2.2%)	16 (2.9%)	
Fixed location	1 (0.2%)	3 (0.5%)	
Informed parents			< 0.001

Variables	Serious AEFI, Yes (n=510)	Serious AEFI, No (n=557)	p-value
Yes	277 (54.3%)	373 (67.0%)	
No	233 (47.5%)	184 (33.0%)	
Questioning about the child's health			< 0.001
Yes	371 (72.7%)	481 (86.4%)	
Not	139 (27.3%)	76 (13.6%)	< 0.001
Vaccination status			
Complete vaccination record according to age	365 (71.6%)	464 (83.3%)	
Lost / unavailable notebook	76 (14.9%)	41 (7.4%)	
Incomplete vaccinations	54 (10.6%)	36 (6.5%)	
Never vaccinated in the past	5 (1.0%)	2 (0.4%)	
Other non-EPI vaccines	10 (2.0%)	14 (2.5%)	

3.5. Associated Factors in Multivariate Analysis

After the non-significant variables (5% cut-off) were phased out by a top-down step-by-step procedure, five factors independently associated with the occurrence of a serious AEFI were retained (Table 4). History of past malnutrition was associated with higher odds of severe AEFI (aOR = 12.37; 95% CI: [1.51-18.1]; p = 0.019). This estimate is based on a very small number of exposed children (10 cases and 1 control) and should therefore be interpreted with caution. Compared to children with a complete vaccination record by age, those

whose record was lost or not available had a 76% higher odds of serious AEFIs (ORa = 1.76; 95% CI: [1.11-2.78]; p = 0.016), and those with incomplete vaccinations of the 77% higher (ORa = 1.77; 95% CI: [1.10-2.87]; p = 0.020). Checking the health record was associated with 64% lower odds (ORa = 0.36; 95% CI: [0.26-0.50]; p < 0.001) while the question about the child's health status before vaccination was associated with 36% lower odds (ORa = 0.64%; 95% CI: [0.45-0.92]; p = 0.016). Age was no longer significantly associated after adjustment (aor = 1.01; 95% CI: [1.00-1.02]; p = 0.2) and was retained in the model as an adjustment variable.

Table 4. Factors associated with the occurrence of serious AEFIs for nOPV2 (Multivariate Analysis).

Variables	Serious AEFI		p-value
	Adjusted OR	IC 95%	
Age (months)	1.01	[1.00-1.02]	0.2
Past malnutrition	12.37	[1.51-18.10]	0.019
Lost / unavailable notebook	1.76	[1.10-2.78]	0.016
Incomplete vaccinations	1.77	[1.10-2.87]	0.020
Checking the child's notebook	0.36	[0.26-0.50]	<0.001
Health Questioning	0.64	[0.45-0.92]	0.016

4. Discussions

This study highlights several main results. First, a history

of past malnutrition was significantly associated with the occurrence of serious AEFI reported after nOPV2 administration, but this exposure in a very small number of exposed children. Second, loss or unavailability of the vaccination record and vaccine incompleteness were associated with higher odds of

severe AEFIs. Third, checking the health record and questioning the child's health status before vaccination were associated with significantly lower odds.

The overall incidence of 1.34 serious AEFIs per 10,000 doses is higher than the data from the first nOPV2 campaign in Nigeria [10]. This discrepancy likely reflects the increased sensitivity of the surveillance system set up in this study, the nutritional vulnerability of the population and the high burden of intercurrent diseases. The north-south disparity in departmental incidences likely reflects inequities in monitoring and reporting capacity between landlocked urban and rural areas, a well-documented phenomenon in sub-Saharan Africa [13, 14].

The mean age was higher in cases in univariate analysis (25.2 months versus 22.0 months; $p < 0.001$) but this association did not persist after adjustment. This result suggests that the crude association with age could be explained, at least in part, by other individual, vaccine or contextual characteristics taken from the model. No significant association was observed between sex and the occurrence of serious AEFIs. The slight male predominance (51.1%) suggests potentially different immunity in boys and girls, due to biological, genetic and functional differences in the immune system [11, 15, 16].

Multivariate analysis highlighted the history of past malnutrition as the factor with the strongest association with the occurrence of severe AEFI (aOR = 12.37). The estimate suggests a potentially important association, but its stability needs to be confirmed over larger numbers. The literature shows that malnutrition causes alterations in mucosal barriers and innate and adaptive immune functions, which can alter the response to vaccination [6, 7, 17, 18]. Compared to children with a complete record by age, loss or unavailability of the record or incompleteness of vaccination was associated with higher odds of serious AEFIs. A child who has not completed his or her vaccination schedule has less complete specific immune protection, due to insufficient exposure to the doses necessary to acquire and maintain seroprotection [19]. Also, an incomplete or absent vaccination status deprives the vaccinator of essential information about the child's history, increasing the risk of vaccinating a child who is temporarily ineligible or has undetected vulnerability factors.

Health record check and pre-vaccination interview were associated with lower odds of severe AEFI. These practices can promote better knowledge of the history, a more reliable identification of situations requiring clinical evaluation and a better traceability of the vaccination act. Work in Ghana and other African contexts has also highlighted the challenges of training, compliance with pre-vaccination precautions and the quality of AEFI surveillance [8, 20-22].

It is important not to turn these results into unfounded contraindications. Malnutrition and minor ailments alone are not general contraindications to vaccination, and WHO recommendations emphasize the risk of missed opportunities due to

false contraindications [23]. For nOPV2, the main contraindications include immune deficiencies or immunosuppression [24]. The results of this study therefore support the strengthening of pre-vaccination assessment, documentation and clinical guidance where necessary, and not the systematic exclusion of malnourished or benign children.

5. Conclusion

This national case-control study identified several features associated with the occurrence of serious AEFIs reported after administration of nOPV2 in children aged 0 to 5 years in Benin. A history of past malnutrition was associated with significantly higher odds, but this estimate was based on a very small number of exposed children. Loss or unavailability of the vaccination record and incompleteness of vaccination were also associated with higher odds. Conversely, checking the health record and questioning the child's health status were associated with lower odds. Age was not significantly associated after adjustment. These results argue for strengthening the quality of pre-vaccination assessment, documentation of vaccination history and status, as well as training of agents.

Abbreviations

CNERS	National Research Ethics Committee
cVDPV2	Vaccine-Derived Poliovirus Type 2
GACVS	Global Advisory Committee On Vaccine Safety
nOPV2	Novel Oral Polio Vaccine Type 2
MAPI	Manifestation Adverse Post-Immunisation
WHO	World Health Organization

Author Contributions

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Conflicts of Interest

The authors declare no conflicts of interest.

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