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Incidence of Serious AEFI Linked to Reactions to the Vaccine Product in Weakly Immunized Health Areas, Case of the ZS of Kabinda, Province of Lomami, DRC, November 2019

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Introduction- Vaccines are considered safe, effective in disease prevention and cost-effective [1, 2]. Reason for the need to expand and maintain high immunization coverage in order to maintain effective immunity [3-5]. But this vaccine leads to the likelihood of occurrence of adverse events following vaccination (AEFI), since vaccines are pharmacological products and are not exempt from causing adverse events in some people [1, 3-5].

AEFI consists of any undesirable effect following vaccination, which does not necessarily have a causal relationship with the use of a vaccine or other immunobiological preparation [1, 3, 4].

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I. Introduction

Vaccines are considered safe, effective in disease prevention and cost-effective [1, 2]. Reason for the need to expand and maintain high immunization coverage in order to maintain effective immunity [3-5]. But this vaccine leads to the likelihood of occurrence of adverse events following vaccination (AEFI), since vaccines are pharmacological products and are not exempt from causing adverse events in some people [1, 3-5].

AEFI consists of any undesirable effect following vaccination, which does not necessarily have a causal relationship with the use of a vaccine or other immunobiological preparation [1, 3, 4].

Five causes are inconvenient for the occurrence of AEFI, these are: 1) product-related reaction where the AEFI caused or precipitated by a vaccine emanates from one or more properties inherent in the vaccine product; 2) reaction related to a quality defect of the vaccine product where the AEFI caused or precipitated by a vaccine results from one or more quality defects of the vaccine product, including the administration device supplied by the manufacturer; 3) reaction related to a vaccination error where the AEFI caused is due to an error in handling, prescribing or administering the vaccine; 4) vaccine-related anxiety reaction where the AEFI caused resulting from anxiety about the vaccine and 5) a mere coincidence where the resulting AEFI is due to a factor other than the vaccine product, a vaccine error or anxiety associated with vaccination [6].

Most AEFIs are non-serious, local and systemic, therefore surveillance actions focus on moderate and severe events. These events are linked to several factors, such as the type of vaccine, the conditions of administration, the storage and the characteristics of the vaccinees. However, their intensity can vary from non-serious and expected effects such as local manifestation to moderate and severe events and rare cases, classified as unexpected [1, 3, 4].

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Given the characteristics of the vaccinated, children under one year of age represent the group most affected by AEFI. The highest concentration of vaccine offered and doses applied occur in this age group. Studies worldwide have shown that the distribution of AEFI in this age group is approximately 80% compared to other segments of the population [4, 7]. In this sense, it is important to carry out screening and surveillance after vaccination in order to identify AEFI and adopt timely intervention measures, allowing the maintenance of the quality, the safety of the vaccinees and the preservation of vaccine reliability. Immunization [1.7].

AEFI should be carefully investigated to avoid a cause-and-effect lag with vaccination, especially in cases with a transient association of the complication with vaccination. On the other hand, confirmed cases of AEFI should be disclosed in order to allow health professionals to become aware of them and therefore to adopt specific preventive measures, as well as to prescribe vaccinations with a higher level of safety. [1, 2, 3]. Considering the relevance of information on AEFI for public health, safe vaccination and sustaining advances in the control of immunopreventive diseases, the objective of the present study was to determine the incidence of AEFI in patients. children during the measles vaccination campaign in Lomami province.

II. Patients and Methods

Cross-sectional descriptive study. The database included data collected during reporting of adverse events identified after mass measles vaccination campaign. The study sample included the total AEFI cases that occurred in children after this mass measles vaccination campaign between October 31 and November 3, 2019.

All vaccinated children with AEFI requiring hospitalization of less than 24 hours were included in this study. AEFI treated at home was not included in our study.

The data were collected by vaccination site health workers and confirmed by a team made up of

EPI, Pharmacy and Drug Management and WHO officers using an AEFI investigation form.

The adverse event following vaccination was chosen as the dependent variable, classified according to the options contained in the notification form. In this context, the most recurring events have been taken into account in this study.

The independent variables were those related to the vaccine (sex, age - depending on the interval, hereditary and personal children's history, batch number, vaccine expiration date, co-infection); time (interval between immunization and onset of adverse event - elapsed time); and the outcome of the case related to the intensity of the event, the course adopted and the progress of the case.

The variable intensity of AEFI was classified as A if the AEFI has a coherent causal link with vaccination in this case we can have class A1: reaction linked to the vaccine product (in accordance with the published literature); A2: reaction linked to a vaccine quality defect; A3: reaction linked to a vaccination error or A4: reaction linked to anxiety linked to vaccination. Or like B if the cause is undetermined. In this case, we can have class B1: proven temporal relationship, but insufficient evidence to implicate the vaccine in the event (it could be a new event associated with the vaccine) or B2: examination of the These factors show contradictory trends, whether or not in the direction of a causal relation with vaccination or even as C if the causal link is inconsistent with vaccination or is a simple coincidence. And finally, we can have unclassifiable MAPI.

a) Statistical analyzes

Statistical analyzes of the data were performed using SPSS for Windows version 22 software. Descriptive analyzes performed are the median and extremes for non-Gaussian distributed data and proportions for categorical data. Pearson's chi-square test or Fisher's exact test as appropriate was performed to compare the proportions. The p-value <0.05 was the threshold of statistical significance.

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III. Results

A total of 24 children had presented serious AEFI during vaccination against VAR in the province of LOMAMI, in Kabinda. Their median age was 29.6 months with the extremes ranging from 9 to 51 months, 54.2% were girls, sex ratio 1H / 1F. 79.2% of these children received their 2nd dose. Two lots of vaccine were identified under number 0049F001 in 58.3% and 0049F047 (41.7%). The majority of these children had a history of AEFI related to this vaccine. The median time to investigation of AEFI and to hospitalization of children was 1 day, respectively.

Table 1: General characteristics of children

Variables	Effectifs (n=24)	Pourcentage
Age		
Médiane (extrêmes) (mois)	29,6 (9-51)	-
<12 mois	7	29,2
12-59 mois	17	70,8
Sexe		
Garçon	11	45,8
Fille	13	54,2
Dose		
1ère	5	20,8
2ème	19	79,2
Numéro de lot		
0049F001	14	58,3
0049F047	10	41,7
Antécédents		
MAPI vaccin	6	25,0
Allergie à un vaccin	2	8,3
Patient sous traitement	9	37,5
HF allergie	1	4,2
Delai d'investigation (jours)	1 (1-20)	-
Délai d'hospitalisation (jours)	1 (1-28)	-

Type of AEFI investigated

Prolonged fever, convulsion, incessant crying, vomiting and generalized rash were the most common AEFI during the measles campaign in this Kabinda locality. The difference was not statistically significant between girls and boys in the occurrence of AEFI.

Table II: Distribution of serious AEFI observed

MAPI	Tous (n=24)	Garçon (n=11)	Fille (n=13)	p
Fièvre	21(87,5)	10(90,9)	11(84,6)	0,565
Convulsion	17(70,8)	8(72,7)	9(69,2)	0,605
Pleurs incessants	11(45,8)	6(54,5)	5(38,5)	0,353
Vomissement	6(25,0)	3(27,3)	3(23,1)	0,590
Eruption cutanée	4(16,7)	1(9,1)	3(23,1)	0,363
Diarrhée	3(12,5)	1(9,1)	2(15,4)	0,565
Abcès	3(12,5)	1(9,1)	2(15,4))	0,565
Frisson	3(12,5)	2(18,2)	1(7,7)	0,435
Anémie	2(8,3)	2(18,2)	0(0,0)	-

Comorbidity associated with AEFI and treatment initiated

Malaria was the most common comorbidity during the onset of AEFI (70.8%). Most of the treatment started was paracetamol (62.5%), artezunat (54.2%) and diazepam (29.2%).

Table III: Comorbidity associated with AEFI and treatment initiated

Variables	Effectifs (n=24)	Pourcentage
Comorbidités		
Accès palustre	17	70,8
Méningite	3	12,5
Abcès hyatrogène	1	4,2
Traitement instauré		
Paracétamol	15	62,5
Artésunat	13	54,2
Diazépam	7	29,2
cloxaciline	5	20,8
Acide folique	2	8,3
Pansement au dakin	1	4,2

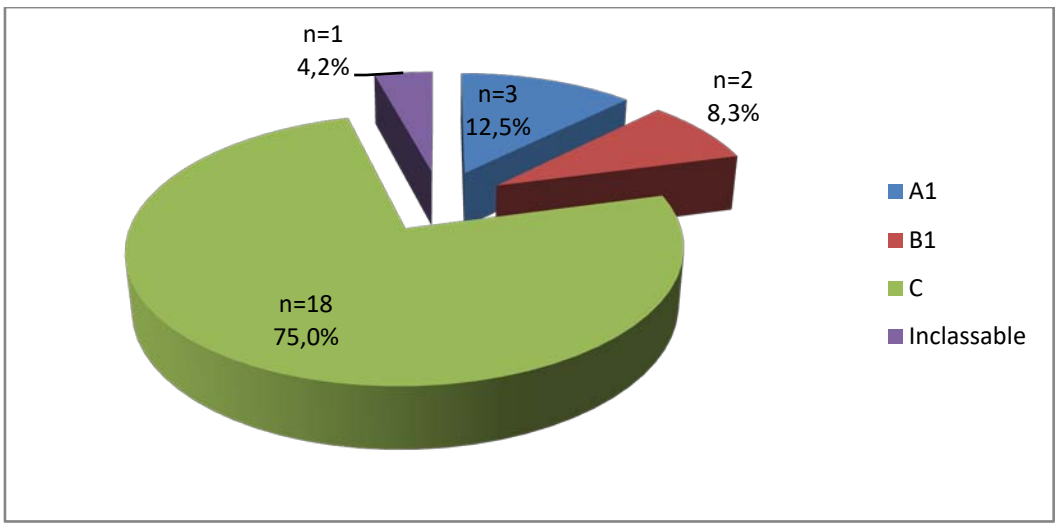

Figure 1: Classification of AEFI

A1: Reaction linked to the vaccine product (according to published literature)
B1: Proven temporal relationship, but insufficient evidence to implicate the vaccine in the event (it could be a new event associated with the vaccine)
C: Coincidentally, underlying or emerging condition (s), or condition (s) caused by exposure to anything other than the vaccine
The majority of AEFIs noted were coincidental (75%); 12.5% of AEFI were vaccine-related reactions and 8.3% were AEFI with a proven temporal relationship. One unclassifiable AEFI case was noted.

Figure 2: Illustration of AEFI

This figure shows the case of generalized skin rashes in a vaccinated child

IV. Discussion

The discussion of the risks of vaccination should be balanced by recognition of the already well-established benefits in preventing disease and disability and death caused by infectious diseases. In this sense, the identification of AEFI helps improve the health care routine for children and contributes to interventions aimed at vaccine safety because passive surveillance of AEFI can be considered useful in monitoring related safety. to vaccines [1, 2, 4].

The nursing team plays a leading role as vaccinators and supervisors of immunization rooms, overseeing technical and operational aspects, and in screening and monitoring the immunization status of users, particularly in healthcare primary. Therefore, studies on AEFI can help identify opportunities to improve the actions developed in immunization rooms. In addition, they can help reduce wasted vaccination opportunities, as decisions about vaccination screening and post-vaccination follow-up will be made more safely [3, 8, 9].

Specific measures to prevent AEFI, including appropriate screening to check for possible contraindications or the need to postpone vaccines, continuing training of vaccinators and health education can contribute to the quality and safety of the vaccine. immunization, thus ensuring the verified progress in the eradication and control of vaccine-preventable diseases. It is important to mention that the evidence for the safety and efficacy of vaccines in routine immunization in children and adults is significantly favorable [1, 9, 10].

The high frequency of AEFI in children under one year of age found in this study has also been demonstrated in other studies [4, 5, 11]. This study highlights that in this age group, the concentration of vaccines is higher and the immune system is still immature, increasing the likelihood of infectious processes, allergies and clinical alterations that may be associated with vaccination [10, 12-14].

The present study demonstrated the predominance of AEFI in children aged 1 to 5 months. Cases of AEFI have also been reported in children aged 9 to 12 months, during which time there are no specifically recommended doses of the vaccine, suggesting immunization of children with a late vaccination schedule.

Despite the slight predominance of women, no statistically significant difference in AEFI was observed between the sexes. A CDC study [9] with children found the same proportion of notifications between the sexes. A study carried out in Uruguay [15] found a higher frequency for men aged 2 months to 5 years, and a study carried out in Brazil found a predominance of girls [11]. Information on vaccine safety, contraindications and possible cases of AEFI is needed to control immunopreventable diseases. Public ignorance can compromise product reliability and vaccine coverage, as was observed for the influenza vaccine in 2012 [15, 16].
In view of the above, the present study suggests the improvement of surveillance actions in relation to AEFI, the precision in the filling of the notification form, and the continuous training in the health services in order to update the professionals. working in vaccination rooms and guiding the population on the subject of increasing the reliability, quality and safety of vaccination [1, 17].

The present study has limitations that are certainly linked to the use of secondary data. There may be an underreporting of AEFI cases, as well as insufficient filling out of the investigation form, which leads to a bias in the information collected. Nevertheless, given the importance of notified cases, the results of the study provide important information.

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