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Analysis of the occurrence of adverse events after vaccination

Análisis de la aparición de eventos adversos después de la vacunación

Análise das ocorrências de eventos adversos pós-vacinação

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Abstract

The aim was to analyze the notifications of adverse events after vaccination of the last five years in a city in the interior of Ceará, characterizing the occurrences of adverse events post-vaccine notified, as well as the identification and classification of cases. Retrospective documentary study with a quantitative approach, carried out between January and December 2018. 41 notification forms of adverse events after vaccination (AEFI) from January 2014 to June 2018 were used, provided by the municipality's epidemiological surveillance. The data were analyzed using simple descriptive analysis. The findings show that the age group most affected by PVAE were children aged 0 to 6 months and 29 days, female, mixed race and in routine vaccination. The pentavalent vaccine was the immunobiological one with the highest notification in cases of AEFI. Non-serious and local reactions were the most described manifestations. It was also observed non-conformities in filling out the notification forms, showing incomplete information and errors in filling in the fields, which can cause compromise of the real situation of adverse events after vaccination, in addition to difficulty in distinguishing which events are not associated with vaccines. It is necessary to constantly train health professionals on EAVP notification and its importance, to reduce errors and underreporting.

Descriptors: Immunization; Immunization Programs; Notification; Drug-Related Side Effects and Adverse Reactions.

Resumén

El objetivo fue analizar las notificaciones de eventos adversos posteriores a la vacunación de los últimos cinco años en una ciudad del interior de Ceará, caracterizando las ocurrencias de eventos adversos post-vacuna notificados, así como la identificación y clasificación de casos. Estudio documental retrospectivo con enfoque cuantitativo, realizado entre enero y diciembre de 2018. Se utilizaron 41 formularios de notificación de eventos adversos posvacunación (AEFI) desde enero de 2014 a junio de 2018, proporcionados por la vigilancia epidemiológica del municipio. Los datos se analizaron mediante un análisis descriptivo simple. Los hallazgos muestran que el grupo de edad más afectado por PVAE fueron los niños de 0 a 6 meses y 29 días, mujeres, mestizos y en vacunación de rutina. La vacuna pentavalente fue la inmunobiológica con mayor notificación en casos de AEFI. Las reacciones locales y no graves fueron las manifestaciones más descritas. También se observaron no conformidades en el llenado de los formularios de notificación, mostrando información incompleta y errores en el llenado de los campos, lo que puede comprometer la situación real de eventos adversos luego de la vacunación, además de dificultad para distinguir qué eventos no están asociados a las vacunas. Es necesario capacitar constantemente a los profesionales de la salud sobre la notificación de EAVP y su importancia, con el fin de reducir errores y subregistro.

Descriptores: Inmunización; Programas de Inmunización; Notificación; Efectos Secundarios y Reacciones Adversas Relacionados con los Medicamentos.

Resumo

Objetivou-se analisar as notificações de eventos adversos pós-vacinação dos últimos cinco anos em um município do interior do Ceará, caracterizando as ocorrências de eventos adversos pós-vacina notificados, bem como a identificação e a classificação dos casos. Estudo documental, retrospectivo, de abordagem quantitativa, realizado entre janeiro a dezembro de 2018. Utilizou-se 41 fichas de notificação dos eventos adversos pós vacinação (EAPV) dos anos de janeiro de 2014 a junho de 2018 fornecidas pela vigilância epidemiológica do município. Os dados foram analisados por meio da análise descritiva simples. Os achados mostram que a faixa etária mais afetada pelas EAVP foram crianças de 0 a 6 meses e 29 dias, do sexo feminino, raça parda e na vacinação de rotina. A vacina pentavalente foi o imunobiológico com maior notificação nos casos de EAPV. Reações não graves e locais foram as manifestações mais descritas. Observou-se também inconformidades no preenchimento das fichas de notificação, evidenciando informações incompletas e erros no preenchimento dos campos, o que pode gerar comprometimento da situação real dos eventos adversos pós-vacinação, além de dificuldade em distinguir quais eventos não estão associados às vacinas. Faz-se necessário a capacitação constante dos profissionais de saúde sobre a notificação de EAVP e sua importância, para diminuir os erros e as subnotificações.

Descritores: Imunização; Programas de Imunização; Notificação; Efeitos Colaterais e Reações Adversas Relacionados a Medicamentos.

Introduction

Reducing the morbidity and mortality of vaccine-preventable diseases is the main objective of the vaccination program. In view of this statement, it is important to keep in mind that for the development of antibodies by vaccines, or for the defense of microorganisms (when it comes to serums and immunoglobulins), it is necessary to adopt adequate and safe measures before during and after manipulation and administration in the population[1]. As with any other drug, the administration of vaccines can cause unexpected adverse reactions. However, there is no way to predict who will be affected by adverse reactions, except for cases in which there are reports in the literature[2].

In 1992, following the guidelines of the World Health Organization (WHO), the National Immunization Program / Ministry of Health (MS), begins the structuring of the National Post-Vaccination Adverse Events Surveillance System (SNVEAPV), which has as a focus to unify the conduct of health professionals in the identification and management of suspected cases of Adverse Post-Vaccination Events (AEFI), making it possible to know the possible causes of AEFI and to investigate errors associated with transport, storage, handling or administration, as well possible immunization errors that result in adverse events[3].

According to the Manual of Standards and Procedures for Vaccination established by the Ministry of Health, the actions developed in the vaccination room are carried out by nursing professionals, in which they are trained in the procedures for handling, conservation, preparation and administration, registration and disposal of residues resulting from vaccination actions, and should standardize their actions according to the guidelines of the National Humanization Program (PNI), in order to offer the population a safe vaccination, with respect and responsibility, following the National Immunization Calendar[3].

In the event of adverse events, the nurse must identify the Event and proceed with the complete filling of the Post-Vaccination Adverse Events Notification / Investigation Form and forward it to local or municipal epidemiological surveillance[3,4].

An Adverse Post-Vaccination Event (AEFI) is characterized as "any unpleasant medical occurrence that follows immunization and that does not necessarily have a causal relationship with the use of the vaccine. If not treated quickly and effectively, it can undermine confidence in a vaccine and, ultimately, have dramatic consequences for immunization coverage and disease incidence"[5:1].

Thus, recognizing the importance of preventing adverse events, this research has the guiding question: What do the notification forms for adverse events post-vaccination point in the city of Sobral in the last five years? Regarding the development of the investigation, the importance of knowing the adverse events after vaccination is emphasized, investigating how the surveillance actions contribute to the safe use of immunobiologicals, since there is a need for specific and necessary care, following rules and guidelines for ensure the well-being of the vaccinated individual.

Thus, the objective is to analyze the notifications of adverse events after vaccination of the last five years in a city in the interior of Ceará, characterizing the occurrences of adverse events post-vaccine notified, as well as the identification and classification of cases.

Methodology

Documentary, retrospective study with a quantitative approach. The documentary study refers to research that uses data sources that have not been submitted to analytical treatment, or even those that can be submitted to a new organization according to the object of study[6].

The study was carried out in the epidemiological surveillance of a municipality located in the interior of Ceará from January to December 2018. The municipality in question has three levels of health care (primary, secondary and tertiary), being responsible for 55 municipalities that reference for this system. Primary Health Care has 36 Family Health Centers (urban and rural areas), all equipped with a vaccination room.

Notification forms for AEFIs from 2014 to June 2018 were used in the study, provided by epidemiological surveillance. Of the total of 42 records analyzed, in the pre-analysis phase, one was found to be inconsistent between the patient's birth date and the date of notification, thus being excluded, leaving 41 records for the sample. The selection of the sample followed the following inclusion criteria: Research forms / notification of adverse events after vaccination of the last five years. Forms that are still being processed by the team and that did not comply with the form were excluded. The collection was carried out by filling in a form adapted from the notification / investigation form of adverse events after vaccination by the Ministry of Health, filled in by professionals, notifiers in the public network.

The content of the AEFI forms were analyzed and the data necessary for the study were recorded on the data collection instrument. To conduct the analysis, a simple descriptive analysis was adopted. This is described by study[7] such as the use of numerical and graphical methods to show the pattern of behavior of the data, to summarize the information in a convenient way. It is a way of synthesizing a series of values of the same nature, allowing an overview of the variation of these values, organizing, and describing the data.

For the grouping of the forms, the Google Docs tool was used, after this first step, the Microsoft Office Excel 2010 program was used for data tabulation. Respecting the ethical precepts of Resolution No. 466/2012[8], the present study was submitted to the Ethics and Research Committee (CEP), having a favorable opinion, with CAAE: 79154117.9.0000.81344, under opinion No. 2,374,560.

Results

In view of the analysis of the 41 forms, there was a higher rate of notifications in 2017, with 15 notifications

made (36.6%), followed by 2015 with 11 (26.8%). In 2016, eight notifications were made (19.5%), 2018 had four (9.8%) and 2014 were 03 (7.3%).

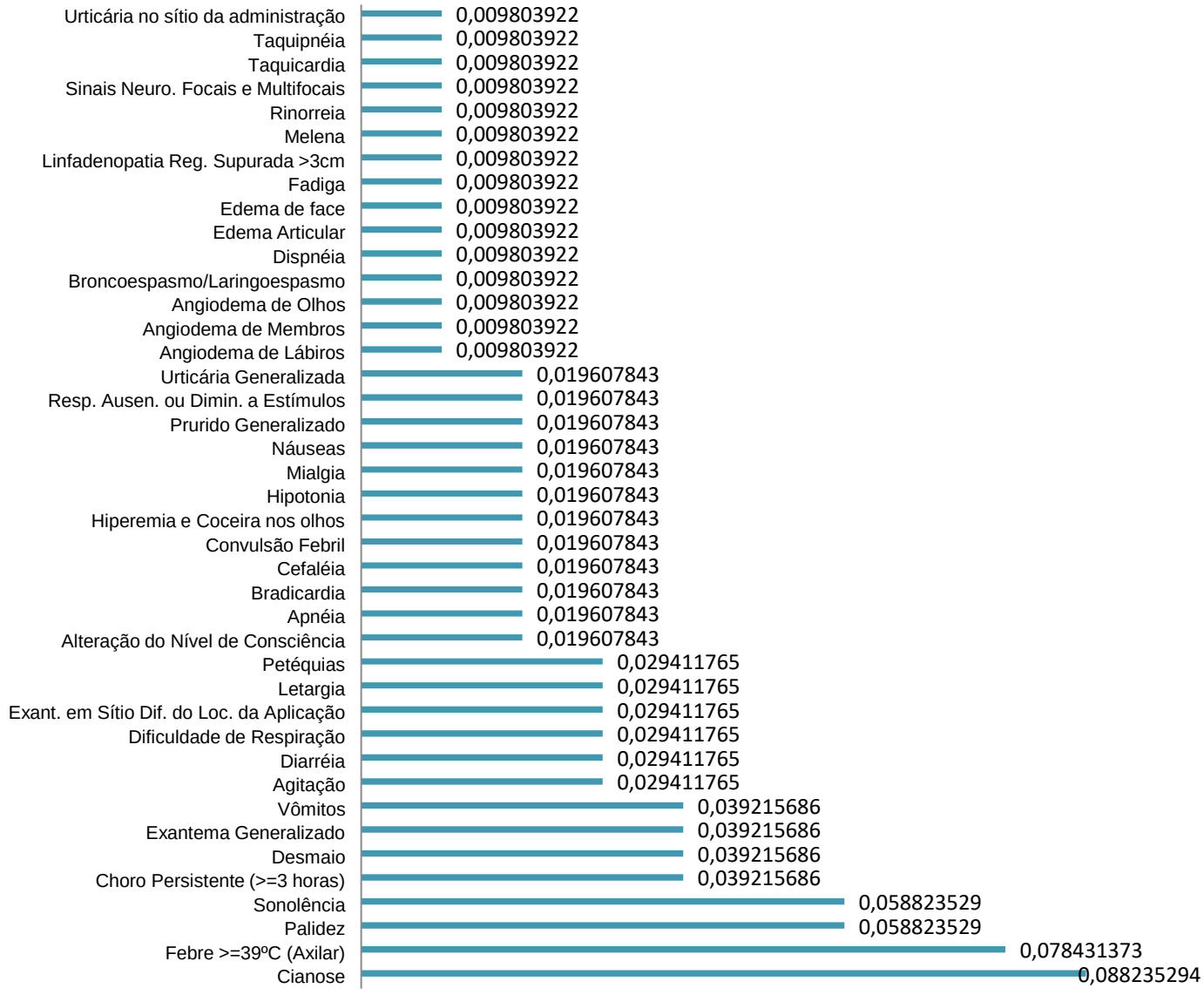
In the analysis of the age group of people who presented adverse events after vaccination, 21 users (51.3%) were up to seven months old, five (12.2%) were seven months old and one day to one year, seven (17.1%) from one year and one day to two years, three (7.3%) from 10 years to 19 years, three (7.3%), 20 years to 59 years. The age group of two to five years was responsible for one case (2.4%), and one case in individuals aged 60 or over (2.4%). No cases were registered in the age group of five to nine years, during the studied period. Os motivos que levaram os usuários a buscarem pela vacinação descritos nos casos foram em vacinação de rotina (63,3%), campanha (9,8%) e em outras duas situações tratava-se de recomendação médica (4,9%). Chama a atenção a alta taxa de respostas ignoradas (22%) na ficha de notificação.

No que tange ao sexo e raça dos usuários notificados por EAVP, a maioria foram pardos (51,2%) e do sexo feminino (63,4%). No entanto, no quesito raça, seis fichas tiveram essa informação ignorada (14,6%).

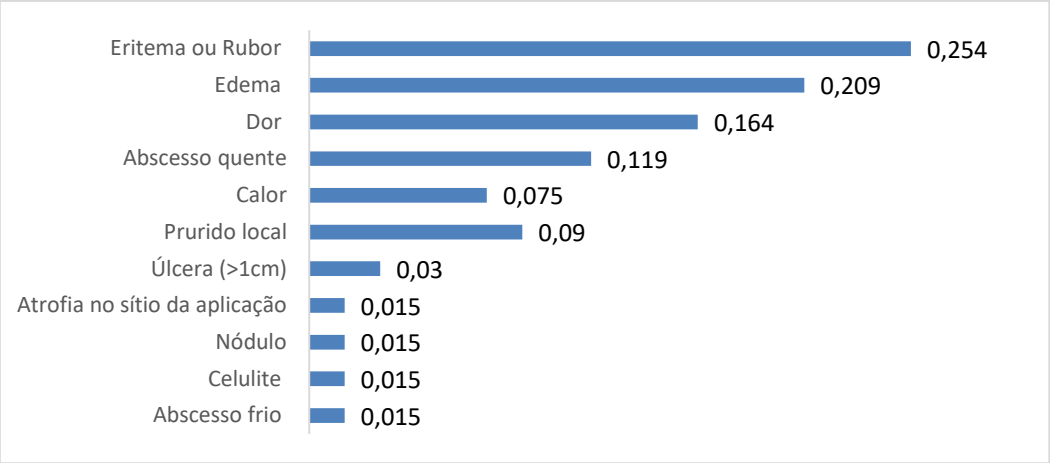
Além disso, analisou-se os imunobiológicos aplicados no dia da reação adversa, tendo em vista que muitos dos clientes receberam mais de uma vacina, não há como definir qual vacina causou os eventos adversos, pois a quantidade de vacinas é superior à quantidade de notificações. Contudo, as vacinas mais citadas foram a Pentavalente em treze registros (31,3%), a VIP em cinco (13,4%), Rotavírus Humano foi citada em quatro fichas (10,4%) e Tríplice viral e DPT em três registros (7,5%). Os imunobiológicos pneumocócica 10V, DTpa, Hepatite B, Tetra Viral e Dupla Adulta não foram citadas em nenhumas das notificações analisadas nessa pesquisa.

Dentre as manifestações clínicas/sistêmicas, revelou-se cianose (8,8%), seguido de febre axilar >39^{0}C (7,8%), palidez (5,9%) e sonolência (5,9%). Exantema generalizado, choro persistente, vômito e desmaio também foram notificados (3,9% dos casos, cada um).

Graph 1. Analysis of the notified clinical / systemic manifestations. Sobral, CE, Brazil, 2018



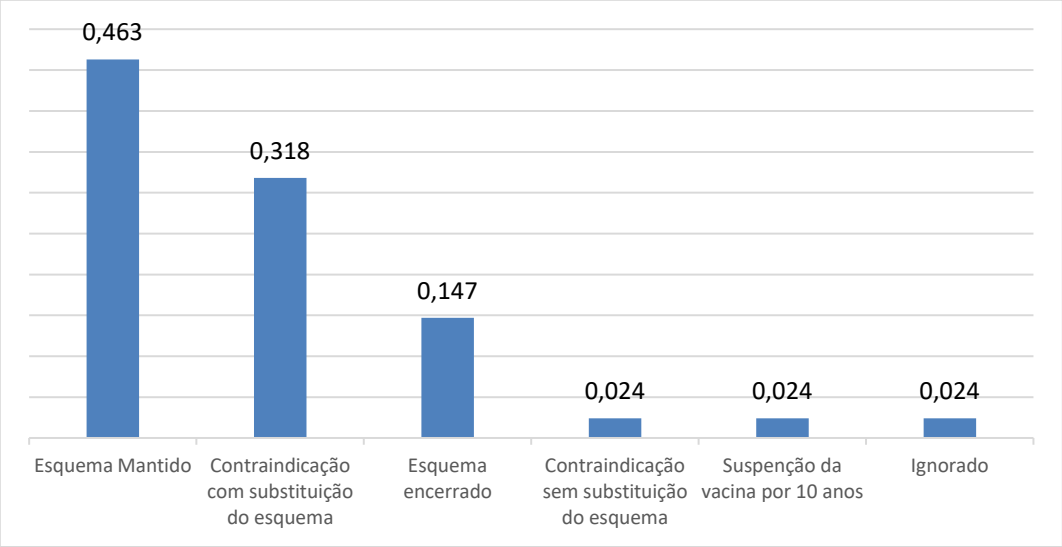
Graph 2. Local clinical manifestations. Sobral, CE, Brazil, 2018



Rash at a different site than the application site, petechiae, difficulty in breathing, diarrhea, lethargy, and agitation were the most recurrent (2.9%), followed by generalized urticaria, hyperemia and itching, generalized pruritus, apnea, change in the level of consciousness, febrile seizure, absent or decreased response to stimuli, hypotonia, bradycardia, nausea, apnea, headache, and myalgia (2.0%). Lip angioedema, limb angioedema, angioedema in the eyes, suppurated regional lymphadenopathy (> 3cm), tachycardia, bronchospasm / laryngospasm, dyspnea, rhinorrhea, tachypnea, sneezing, neurofocal and multifocal signs, melena, joint erythema, fatigue, and edema of face (fatigue and edema of face) 1.0%), as shown in Graph 1.

It is not uncommon the considerable frequency of Hypotonic Hyporesponsive Episode (EHH) in studies related to the theme, however, during the data analysis of this research it was found that there was only one EHH diagnosed. There was no record of this event due to the lack of this variable in the notification form used by the public network of the municipality under study.

Graph 3. Conduct regarding the vaccination scheme (%). Sobral, CE, Brazil, 2018



Among local manifestations, most cases presented erythema or flushing (25.4%), followed by edema (20.9%) and pain (16.4%). Hot abscess was recorded eight times (11.9%), heat in place in five records (7.5%), local itching with six reports (9%) and ulcer (> 1 cm) with two reported cases (3%). Cold abscess, nodule, cellulite, and atrophy at the application site, each with a registered notification (1.5%), as shown in Graph 2.

As for the final classification of AEFIs, most cases were considered non-serious (43.9%), followed by serious adverse events (7.4%), unclassifiable events (2.4%) and immunization errors (2.4 %). It is noteworthy a significant expressive number of forms with this item ignored by the professionals who completed the notification (43.9%). Regarding the category of the event, most cases were characterized as vaccine reaction (90.3%), followed by ignored cases (4.9%), reaction at the application site (2.4%) and those reported as errors programmatic (2.4%).

Regarding the conduct regarding the vaccination schedule after the adverse reaction, in most cases the schedule was maintained (46.3%), contraindicated with replacement of the schedule (31.8%), closed (14.7%), ignored filling out the notification (2.4%), contraindicated without replacing the scheme (2.4%) and suspension of the vaccine for 10 years (2.4%), as shown in Graph 3.

Regarding the evolution, 23 cases evolved to cure without sequelae (56.1%), four were an event associated with BCG with the indication of Izoniazida (9.8%), one presented a cure with sequelae (2.4%), one was still undefined (2.4%) and twelve of the notifications had this item ignored (29.3%).

As for the professionals who notified the AEFV, the most were nurses (80.5%), doctors (12.2%) and nursing technicians (4.9%). The other forms did not contain records of the professional responsible for the notification (2.4%).

Discussion

This study shows an increase in AEFI notifications in 2015, followed by a 7.3% drop in 2016. However, there was a 17.1% increase in 2017. With notification records until June, the 2018 had a percentage of 9.8%.

Such growth is also reported in a study[9] when referring that the occurrence of AEFI due to immunization error has grown in recent years, with an upward trend until 2018, as indicated in the linear regression model. This finding hypothesis reflects the improvement of surveillance, but it can reveal weaknesses in the practice of nursing staff who work in the vaccination room.

Regarding the age group, the group aged up to seven months had the highest rate of adverse event records. For this age group, a higher occurrence of records is expected due to the concentration of doses in this period. Corroborating this finding, research conducted in Teresina and Campo Grande, revealed that 63.5% of the reported cases were in children up to one-year old[10,11].

In addition to these, between 2009 and 2013, the State Immunization Program of Pernambuco, which registered 1,167 cases of AEFI, of which 810 (69.4%) were in children under one year of age. Of the 810 registered cases, 20.5% occurred with children under three months old, 49.2% of the cases corresponded to individuals aged three to less than six months, 23.1% represented children aged six months to less than nine months and 7.2%, from nine months to one year[12].

The high frequency of adverse events in the first year of life, in relation to the others, is possibly related to immunological immaturity, greater number of vaccines administered, in addition to corresponding to a period with the occurrence of infectious events that are often confused with AEFI.

Regarding race filling, authors[13] emphasize in a study that race / color is relevant in notification, as it provides specific characteristics important for determining actions that determine policies for this population.

Considering this correlation between sex and adverse events, a study[13] pointed out that AEFV notifications between the years 2014 and 2016, with a higher prevalence of adverse events in women (58.5%) compared to men (41.5%). So, another study[14] in Oman, in the Middle East, which pointed to a high number of AEFIs in women and still claims, that females generally develop antibody responses and experience more adverse reactions after vaccination than males.

Regarding the immunobiologicals responsible for the highest number of notifications, authors[15] report that in Cuba, between January 2006 and December 2007, 852 adverse events after vaccination were reported. Sequentially the vaccines that had the highest number of notifications were DTP, hepatitis B and Pentavalent.

In a research carried out in France[16], the highest AEFI rates were observed with the Bacille Vaccine of Calmette and Guérin (BCG) (482.3 per 100,000 doses), diphtheria and inactivated tetanus and poliovirus with acellular pertussis vaccine (dTap-IPV) (106.1 per 100,000 doses) and meningococcal quadrivalent glycoconjugate vaccine (MenACWY-CRM) (39.3 per 100,000 doses).

The list of vaccines involved with AEFV due to immunization error. The BCG vaccine had the highest rates (57%), followed by diphtheria, tetanus, pertussis and Haemophilus influenzae type b (DTP / Hib) vaccines (7.3%) and DTP / hepatitis B (HB) / Haemophilus influenzae type b (DTP / HB / Hib) (6.6%)[9].

As for the clinical / systemic manifestations, analyzes highlight fever, present in 344 reported cases and hypotonic hyporesponsive episode with 67 records, followed by irritability (102), vomiting (54), drowsiness (44), rash (46) and cyanosis (27)[17].

Regarding the public, these are children up to five years old, whose most common manifestations were fever (32.9%), followed by persistent crying (18.6%) and altered level of consciousness / hypotonia / lethargy (11.9%)[18]. It is important to note that the factors predisposing to EHH are unknown, having the diagnosis based on the clinical description, and the signs related to this reaction are pallor, loss of muscle tone and consciousness in the first 48 hours[17].

When it comes to local reactions, authors[17] observed in the period from 2003 to 2013, in Brazil, that local AEFIs were frequent in all vaccines. Pain (2.5 / 10,000 doses) and nodule (2.1 / 10,000 doses) were the most common local reactions.

Of the 329 adverse events analyzed per study[19] in two health centers in the state of Rio de Janeiro, local reactions were the most significant. Pain, redness, heat, induration, edema, and erythema were frequent in almost all reports.

Regarding local reactions, it is important to note that they may appear in the first 24 hours, evolving to spontaneous resolution in approximately two days, with no sequelae. However, in some cases an abscess may develop at the site where the vaccine was performed, which may be a cold abscess, which may have originated because of the introduction of the inherent agent of the vaccine by intramuscular application, hot abscess, which has pus,

because of secondary bacterial infection[3].

Among the classifications of AEFI cases, the highest percentage of cases evolved as non-severe. Similar finding in a survey conducted in the United States, which shows that 94.6% of non-serious events were reported between the years 2012 to 2016[20]. Authors[13] complement by stating that the higher occurrence of non-serious events is in line with the findings of other studies carried out in several countries.

The Post-Vaccination Epidemiological Surveillance Manual for Adverse Events defines the classification of adverse events according to severity. The adverse event is considered serious considering sequelae, risk of death, death, or hospitalization for more than 24 hours. The non-serious adverse event (EANG) is any other event that is not included in the criteria for serious adverse event (EAG). As for the immunization error, it is difficult to identify, due to the various factors that are linked to its definition, as they encompass the failures that occur in the production process, in the cold chain and handling and / or administration of immunobiologicals[3].

Study[21] reports that most adverse events are mild, local, and self-limiting, requiring only supportive and follow-up measures in these circumstances with follow-up to the vaccination schedule. For example, the use of a cold compress to reduce local pain, edema, and induration.

There were notifications regarding the immunization error, but it is known that this variable can be confused with a programmatic error, which may be due to failures in transport, storage, or handling. Such records can also be mistakenly associated with temporal symptoms that are unrelated to the vaccine.

It draws attention to the high rate of non-fulfillment of this item compared to the previous items of the form, which prevents the generalization of this finding. The hypothesis of knowledge deficit about the AEFI classification is raised, since the answer requires the notifier to understand the factors that define the classification.

Nursing professionals are primarily responsible for immunization actions, but there is still limited knowledge of the nursing staff about AEFIs, which makes it difficult to make decisions regarding events and causes underreporting of adverse events that have occurred[9].

A study carried out in Albania with primary care professionals in 2017 showed low levels of professionals' knowledge about AEFI. This research found that barriers to notification included lack of interest, unclear definition of AEFI and lack of awareness of what to report[22].

In a study carried out in Spain[23], it is noteworthy that the surveillance systems of AEFI have limitations that lead to underreporting and insufficient information in case reports. However, this surveillance provides important information, such as trends and signals that can be detected even with an incomplete report.

In a study carried out in China, between the years 2008 to 2013, about 1% of AEFI were identified as programmatic errors, related to measles, mumps and rubella vaccination and BCG[24].

Authors[9] point out that for a diagnosis and correct classification of adverse events resulting from post-vaccination, there must be a sharp clinical examination, requiring the skill of the assistant professional. In this way, inexperience can weaken the recognition of the problem, and consequent underreporting of the AEFI.

Study[21] stresses that vaccines cause some expected reactions, such as fever, pain, edema, and flushing, which does not need to be notified and investigated. These events are largely due to programmatic errors, and it is necessary to emphasize the use of the incorrect technique in preparation and administration, with emphasis on the incorrect dilution of the immunobiological, lack of hand washing, erroneous delimitation of the application area and rapid injection of the content vaccination, favoring the appearance of local events such as irritation, inflammation, and warm local abscess. They emphasize that the route of administration and the place to administer each vaccine must be strictly respected, if this does not occur, there may be a greater number of adverse events.

Interventions by professionals regarding the vaccination scheme were analyzed in a study, in which it was found that 20% of the actions performed were inadequate, disagreeing with the recommendations of the Ministry of Health[11].

Study results[25] refer to the clinical evolution of people who were notified with AEFV, showing that almost the entire sample studied (99.3%) evolved to cure without sequelae. Only one individual, despite having obtained a cure, presented a sequel related to intestinal invagination. It is noteworthy the occurrence of one death due to febrile seizures and five others that were designated as 'ignored' and / or 'without evolution'. Thus, from AEFV notifications, 40.2% were closed as confirmed, 58.9% were classified as undefined and 0.9% as discarded.

Other studies have also found a high number of notifications without closure, which leads to the conclusion that there are important weaknesses in filling in the data in the SI-EAPV, such inconsistencies are associated with typing errors, absence in filling in the fields present in the form and in the flow of information[13,25].

No records were found in the literature that highlighted the professionals notifying the AEFV. However, a study conducted in Juiz de Fora found that most adverse events are reported by nurses. The author also reports that the underreporting of events occurs mainly due to the lack of knowledge about what constitutes harm to the patient and the team's lack of perception of the event for notification[26].

Sharing the occurrence of events is essential to obtain information that is the basis for the implementation of prevention mechanisms to guarantee patient safety. It is essential that nurses identify and notify events that occur in nursing practice, with a view to increasing patient safety[27].

Final Considerations

Although immunization is safe and effective, AEFIs can lead to unpleasant symptoms and, consequently, loss of public confidence in immunization programs. Its vigilance is extremely important for the formulation of health strategies

that provide reliability and safety to users who follow the schedule, as well as minimizing risks and injuries.

The percentage of people affected by these events in relation to the number of people vaccinated in the same period in the study macro-region corresponds to a safe number of reactions recorded in the literature, thus reinforcing that the benefits of this preventive measure are greater than the risks offered.

The people most affected by PVAE in this study were children aged 0 to 6 months and 29 days, female, mixed race and in routine vaccinations. This profile corroborates with the national and international studies found. Knowing the characteristics of these people is important for the formulation of prevention and alert strategies against these events.

It is noteworthy that in the results found, DTP, VIP, and Rotavirus vaccines as immunobiologicals were more involved in cases of AEFI, contrasting national and international studies, which cite the Penta vaccine and BCG as responsible for adverse events. However, most of the cases were considered non-serious and required only suspension of the regimen. The most common reactions were related to fever, edema / flushing, and pain, characterized as systemic reactions.

The limitations found in the study are related to the use of secondary sources, being verified fields with incomplete information, in addition to errors in filling in the fields, generating compromise in the understanding of the real situation of adverse events after vaccination, but its importance is also seen for being an information capture tool for a short-term retrospective assessment.

There was also a difficulty in distinguishing which events are not associated with vaccines, and it is not clear or unfilled in the evolution of the case. It is necessary to check the knowledge of health professionals about the notification of PVAE and its importance, to reduce errors and underreporting.

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