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INCIDENCE OF POST-VACCINATION ADVERSE EVENTS IN CHILDREN

INCIDÊNCIA DE EVENTOS ADVERSOS PÓS-VACINAÇÃO EM CRIANÇAS

INCIDENCIA DE EVENTOS ADVERSOS POST-VACUNACIÓN EN NINOS

Polyana Cristina Vilela Braga[1], Ana Elisa Bauer de Camargo Silva[2], Ludmila Bastos Mochizuki[3], Juliana Carvalho de Lima[4], Maiana Regina Gomes de Sousa[5], Ana Lúcia Queiroz Bezerra[6]

ABSTRACT

Objective: to analyze the Post-Vaccination Adverse Events (PVAE) in children under five years of age. ***Method:*** quantitative, cross-sectional study with analysis of 353 records of PVAE notifications. The data were collected with a structured instrument, analyzed statistically by the SPSS 19.0 program and, later, presented in tables and figure. ***Results:*** 373 PVAE were identified, 83.90% of which were Temporal Vaccine Adverse Events (TVAE) and 16.10% were immunization errors (IE). The most frequent occurred in male children and under one year of age. The highest incidences of TVAE were related to inactivated vaccines against Poliomyelitis and Pentavalente, and the incidences of IE with Yellow Fever and Oral or Poliomyelitis vaccines. The most frequent errors were wrong vaccine (26.7%) and administration outside the recommended age (18.3%). ***Conclusion:*** the reatogenicity of vaccines and systemic failures suggest the need to improve the vaccination system. ***Descriptors:*** Immunization; Vaccines; Surveillance; Patient Safety.

RESUMO

Objetivo: analisar Eventos Adversos Pós-Vacinação (EAPV) ocorridos em crianças menores de cinco anos de idade. ***Método:*** estudo quantitativo, transversal, com análise de 353 fichas de notificações de EAPV. Os dados foram coletados com um instrumento estruturado, analisados estatisticamente pelo programa SPSS 19.0 e, posteriormente, apresentados em tabelas e figura. ***Resultados:*** foram identificados 373 EAPV, sendo 83,90% eventos adversos temporalmente relacionados à vacina (EATV) e 16,10% a Erros em Imunização (EI). Os mais frequentes ocorreram em crianças de sexo masculino e menores de um ano de idade. As maiores incidências de EATV estavam relacionadas com vacinas inativadas contra a Poliomielite e à Pentavalente, e as incidências de EI com as vacinas de Febre Amarela e a Oral contra a Poliomielite. Os erros mais frequentes foram vacina errada (26,7%) e administração fora da idade recomendada (18,3%). ***Conclusão:*** a reatogenicidade das vacinas e as falhas sistêmicas sugerem a necessidade de aperfeiçoamento do sistema de vacinação. ***Descritores:*** Imunização; Vacinas; Vigilância; Segurança do Paciente.

RESUMEN

Objetivo: analizar los Eventos Adversos Post-Vacunación (EAPV) ocurridos en niños menores de cinco años de edad. ***Método:*** estudio cuantitativo, transversal, con análisis de 353 fichas de notificaciones de EAPV. Los datos fueron recolectados con un instrumento estructurado, analizados estadísticamente por el programa SPSS 19.0 y, posteriormente, presentados en tablas y figura. ***Resultados:*** fueron identificados 373 EAPV, siendo 83,90% eventos adversos temporalmente relacionados a la vacuna (EATV) y 16,10% a la Errores en Inmunización (EI). Los más frecuentes ocurrieron en niños de sexo masculino y menores de un año de edad. Las mayores incidencias de EATV estaban relacionadas con vacunas inactivadas contra a la Poliomielitis y a la Pentavalente, y las incidencias de EI con las vacunas de Fiebre Amarilla y Oral contra a la Poliomielitis. Los errores más frecuentes fueron vacuna equivocada (26,7%) y administración fuera de la edad recomendada (18,3%). ***Conclusión:*** la reatogenicidad de las vacunas y las fallas sistémicas sugieren la necesidad de perfeccionamiento del sistema de vacunación. ***Descriptores***: Inmunización; Vacunas; Vigilancia; Seguridad del Paciente.

[1,5]Nurse, Master, Post-Graduate Program of the School of Nursing, Federal University of Goiás / UFG. Goiânia (GO), Brazil. E-mail: polyanacvb@hotmail.com; maianaregina@gmail.com; [2,6] Nurse, PhD, Associate Professor, School of Nursing, Federal University of Goiás / UFG. Goiânia (GO), Brazil. E-mail: anaelisa@terra.com.br; analuciaqueiroz@uol.com.br; [3,4]Nurses, Master's students, Post-Graduate Program in Nursing, School of Nursing, Federal University of Goiás / UFG. Goiânia (GO), Brazil. E-mail: ludmilabm@hotmail.com; julianafen@hotmail.com

INTRODUCTION

The use of vaccines is among the greatest advances observed in the health area. In Brazil, vaccines are available to the community through private services and the Unified Health System (UHS). In the UHS, the vaccination actions are coordinated by the National Immunization Program (NIP).

The NIP is a governmental instrument designed to protect the Brazilian population against diseases that can be prevented, controlled and eradicated through the use of immunobiological agents, including vaccines. This program is, admittedly, one of the most successful public health initiatives in Brazil.[1]

The various strategies adopted over the years in the country have eradicated urban yellow fever, smallpox and polio, controlled measles, neonatal tetanus, severe forms of tuberculosis, diphtheria, accidental tetanus and pertussis.[1]

In 2016, Brazil was certified rubella and measles elimination.[2] However, as the perception of risk of vaccine-preventable diseases declines, the number of doses of vaccines applied increases, and consequently the complexity of the vaccination system and the incidence of Post-Vaccination Adverse Events (PVAE).[3]

PVAE are any undesirable medical occurrences after vaccination and that, not necessarily, have a causal relationship with the use of immunobiologicals. They can be classified into five categories: a) reaction to the composition of the vaccine; b) coincident - temporarily associated with the vaccine; c) potentiated by the vaccine; d) events of unknown causes and e) errors in immunization.[4]

PVAE affects, mainly, children, during which time the human being receives the largest number of vaccines, besides being a phase of immunological immaturity, in which they are most vulnerable.[5]

In this sense, this study aims to analyze Post-Vaccination Adverse Events in children under five years of age.

METHOD

Quantitative, descriptive, cross-sectional, retrospective study of secondary data, performed in the city of Goiânia / GO, Brazil. Data collection took place from May to September 2013, with the souce of data being, reports of post-vaccine adverse events reporting. These records were filled out by Nursing professionals from the vaccine rooms and sent to the Immunization Division of the Municipal Health Department of Goiânia, from July 2012 to June 2013.

Of the total of 502 adverse event notification cards, 149 were excluded, which provided information about out-of-term occurrences, from other States and municipalities, in children over five years of age and in the private network. Thus, 353 notifications forms were considered valid.

The content of the notifications was analyzed and the information was recorded in a data collection instrument prepared by the researcher, previously, analyzed, by a group of specialists in the area.

The study variables were related to the users (age, gender), the vaccination process (number and type of vaccines involved and the reported clinical manifestations) and their consequences.

In some reports, it was not possible to identify which vaccine caused the temporal vaccine-related adverse event (TVAE), since administration was simultaneous with other vaccines. In these cases, for the purpose of calculating the incidence of TVAE, an event was considered for each vaccine that the individual received.

The incidence calculation was obtained by the number of cases of adverse events reported by the number of doses of routine vaccines applied in children under five years, corresponding to the study period, multiplied by 10 thousand. The number of doses applied per vaccine was obtained through the information contained in the Immunobiological Application Evaluation System (SI-API), a program used by the Immunization Division to record the doses applied in the routine by age group and vaccine.

It is noteworthy that the calculation of the incidence of TVAE was performed only for vaccines with routine doses, due to the lack of information regarding the number of doses applied in children under five in the field. Statistically different incidences were considered when confidence intervals did not overlap.

Statistical analysis was performed by the SPSS program, version 19.0 for Windows. A descriptive analysis was performed with absolute and relative frequency measures presented in tables and figures.

This study had the research project approved in the Research Ethics Committee under CAAE: 14151713.4.0000.5078, obeying the regulatory norms of Resolution No. 466 / 2012.[6]

RESULTS

The study identified 373 FADS, 313 (83.90%) of which were temporally related to the vaccine (TVAE) and 60 (16.10%) errors in immunization (EI).

Of the 313 TVAEs, 279 (89.10%) were due to vaccinations occurring within routine vaccination schedules, 33 (10.50%), due to vaccines administered during the vaccination campaign against H1N1, with the Influenza vaccine, and one (0.30%), due to a vaccination done from a medical recommendation.

The characterization of the children showed that TVAE were more frequent in male children (56.23%) and in children less than one year old (78.60%).

Of the total of 313 TVAE, 44.10% were due to the administration of only one vaccine, mainly Pentavalente (20.76%) and Influenza (10.54%). However, it was observed that the administration of three vaccines at the same vaccine opportunity accounted for 10.20% of the total TVAE, and the administration of four vaccines at the same vaccine opportunity accounted for 31.95% of the TVAE, combination of the Pentavalent, Rotavirus, VIP and Pneumo10 vaccines, responsible for 23.96% of the total TVAE.

Regarding the clinical manifestations observed in children due to VTE, 14 types were identified and totaled 671 reports, of which 214 (68.38%) manifestations were considered local and 165 (52.71%), systemic. Most of the local manifestations were self-limited and of spontaneous resolution, requiring no medical intervention, as opposed to systemic manifestations, which tend to be more serious.

Among the systemic reactions, the most frequent were fever (32.93%), persistent crying (18.62%) and altered level of consciousness / hypotonia / lethargy (11.92%), as presented in table 1.

Table 1. Systemic clinical manifestations post-vaccination presented by children under five years. Goiânia, Goiás, July 2012 - June 2013.

Systemic manifestations	N	%
Fever	221	32.93
Persistent crying	125	18.62
Change in level of consciousness / hypotonia / lethargy	80	11.92
Nausea / vomiting	61	9.10
Pallor	42	6.25
Cyanosis	34	5.06
Decreased response to stimuli	30	4.48
Diarrhea	28	4.18
Dyspnea	27	4.02
Convulsion	14	2.09
Angiodema	4	0.60
Stools with blood	2	0.30
Bronchospasm	2	0.30
Paresis	1	0.15
Total*	671	100

* There was more than one type of clinical manifestation by TVAE identified

The association of the vaccines with the clinical manifestations showed that most of the manifestations were related to the administration of the recommended vaccines for the 2nd, 4th and 6th months of the child, especially the combination of Rotavirus, VIP, Pentavalent, Pneumo10 (31 , 60%) and for the administration of pentavalent alone (25.00%). The presence of feces with blood at the time of vaccination with the BCG vaccine, an unexpected event, is emphasized.

Six cases of seizure were observed, related to the administration of the Pentavalent vaccine were isolated, and one with Tetravalente, also isolated; six cases of seizure in which these vaccines were administered associated with others and one case of seizure after the vaccination against Febre Yellow.

The calculation of the incidence of TVAE occurred on the 279 TVAEs that occurred during routine vaccination and the total number of doses of vaccines administered within the routine in Goiânia, and are presented, in table 2, by type of vaccines.

Table 2. Incidence of vaccine-related adverse event in children under five years of age. Goiânia, Goiás, July 2012 - June 2013.

Vaccine	Applied doses	TVAE*	Incidence of TVAE
	N	N	(x10.000)
VIP	21.240	98	46.13
Pentavalent	50.073	206	41.13
Rotavirus	40.027	113	28.23
Tetravalent	3.625	10	27.59
Pneumo 10	58.536	140	23.92
VOP	45.698	44	9.63
Meningo C	42.843	25	5.84
DTP	32.420	17	5.24
BCG	23.094	11	4.76
Yellow fever	20.818	4	1.92
Triple Viral	46.586	5	1.07
Hepatitis B	34.729	3	0.86

* TVAE was considered for each vaccine given at the vaccine opportunity.

The VIP and Pentavalent vaccines presented the highest incidence of TVAE. Although the incidence with the VIP vaccine was the highest, it is noted that, on all occasions, it has always been associated with the Pentavalent vaccine.

The Pentavalent vaccine was present in 206 cases of TVAE, and, in 142, it had been administered along with other vaccines, and at 65, it appears as the sole responsible for the identified reaction.

Figure 1, shows the incidence (x 10,000) of TVAE in children under five years of age with the respective 95% confidence intervals.

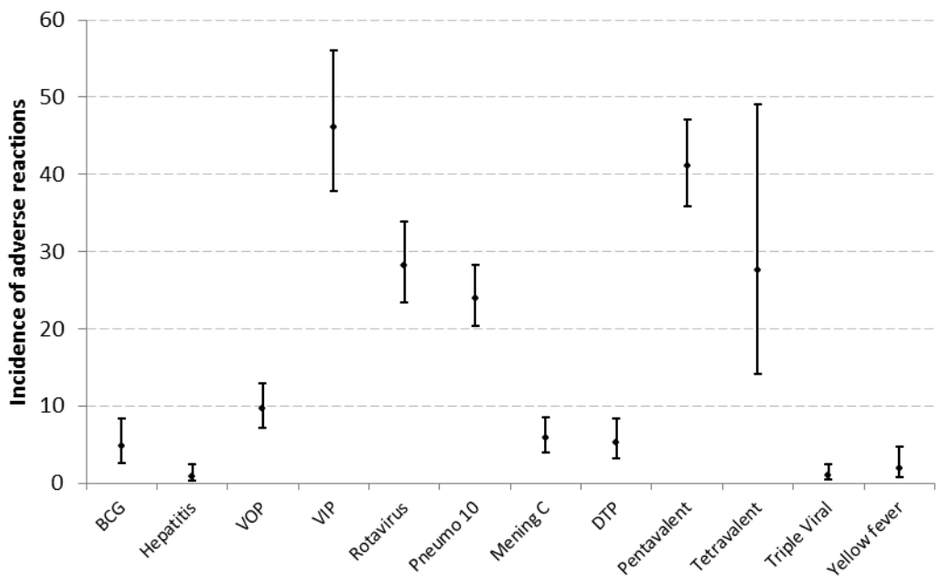

Figure 1. Incidence of adverse events temporally related to the vaccine in children under five years. Goiânia, Goiás, July 2012 - June 2013.

Of the 60 identified immunization errors, 86.67% occurred with children younger than one year of age, mainly, involving, errors in the administration of yellow fever vaccine and OPV. The types of errors and vaccines involved in immunization errors are described in table 3.

Table 3. Errors in immunization occurring in children under five years of age. Goiânia, Goiás, July 2012 - June-2013.

Type of immunization error	Vaccines administered	N	%
Wrong vaccine administration	VOP	16	26.70
	Subtotal	**16**	**26.70**
Vaccine given out of recommended age	Rotavirus	4	6.66
	Yellow fever	3	5.00
	Meningococcal C	2	3.33
	DTP	1	1.67
	Influenza	1	1.67
	Subtotal	**11**	**18.31**
Vaccine applied with expired expiration date	BCG	1	1.67
	Yellow fever	9	15.00
	Subtotal	**10**	**16.67**
Inadequate interval between doses	BCG	1	1.67
	Yellow fever	1	1.67
	Hepatitis B	1	1.67
	Meningo C	1	1.67
	Rotavirus	1	1.67
	VOP	1	1.67
	Subtotal	**6**	**10.02**
Vaccine applied in wrong place	Yellow fever	3	5.00
	Triple Viral	3	5.00
	Subtotal	**6**	**10.00**
Vaccine administered in wrong way	Yellow fever	2	3.33
	BCG	1	1.67
	Triple Viral	1	1.67
	Subtotal	**4**	**6.65**
Error in administration technique	BCG	1	1.67
	DTP	1	1.67
	Yellow fever	1	1.67
	Pneumo10	1	1.67
	Subtotal	**4**	**6.65**
Extra dose	BCG	1	1.67
	Pentavalent	1	1.67
	Subtotal	**2**	**3.33**
Overdose	BCG	1	1.67
Subtotal	**Subtotal**	**1**	**1.67**
TOTAL		**60**	**100**

It is observed that the most frequent error was the administration of the wrong vaccine (26.70%), when VOP was administered instead of the recommended VIP.

The 11 errors related to the application of vaccines outside the recommended age, according to the basic vaccination schedule adopted in Brazil, related to four errors involving Rotavirus; three, the Yellow Fever vaccine, two, errors involving the Meningococcal C vaccine; one, the dT vaccine and one the Influenza vaccine.

Of the ten cases in which the vaccines were expired, nine involved the Yellow Fever vaccine and one, the BCG vaccine and all occurred in the same health unit.

The overdose error refers to the application of the BCG vaccine at a dosage five times higher than that recommended.

The calculation of the incidence of errors in immunization occurred on the 59 errors identified after vaccination occurred within the routine and with the total number of doses of vaccines administered within the routine in Goiânia, and is presented in table 4, by type of vaccines.

Table 4. Incidence of immunization errors occurring in children under five years of age. Goiânia, Goiás, July 2012 - June 2013.

Vaccines	Applied doses	Immunization errors	Incidence rate of immunization errors
	N	N	(x10.000)
Yellow fever	20.818	19	9.12
VOP	45.698	17	3.72
BCG	23.094	6	2.59
Rotavirus	40.027	5	1.24
Triple Viral	46.586	4	0.85
Meningo C	42.843	3	0.70
DTP	32.420	2	0.61
Hepatitis B	34.729	1	0.28
Pentavalent	50.073	1	0.19
Pneumo 10	58.536	1	0.17

It should be noted that the highest incidence of immunization errors were related to Yellow Fever and OPV vaccines, and the Yellow Fever vaccine presented an incidence 2.45 times higher than the OPV.

The results show the rate of 140 immunization errors per million doses of vaccine administered in children under five years of age.

Of the 60 reports of errors, only 14 (23.33%) reported the occurrence of damage, the most common damage being those related to local manifestations.

DISCUSSION

Adverse events related to the vaccine (TVAE) occurred, more frequently, in children less than one year of age. An investigation of post-vaccine adverse events in children under seven years of age, conducted in Rondônia, found that young children (≤ one year of age) were the most susceptible to VAP and these occurred, most of the time, in the six (54.20%) after vaccination.[7]

In a study conducted in Campo Grande, it was identified that 53.60% of reports of adverse events were related to children younger than ten years of age. Of these, 31.70% occurred in children less than one year of age, confirming the high frequency of adverse events in this age group when compared to the others, which, may be, related to the still immature immune system and the greater number of vaccines recommended for this age.[8-9]

In addition, children less than one year of age return to health facilities more often, either to be vaccinated or to monitor their growth and development, providing an opportunity for research on the occurrence of post-vaccine adverse events and notification.[8]

MALE children were the most affected by TVAE, a discordant result of a study conducted in Rio de Janeiro, in which the highest incidence was in female children (61%). [9] In the CDC study, in relation to children , notifications occurred in the same proportion for both sexes.[5]

Most of the TVAEs identified in this study were related to the simultaneous administration of two or more vaccines, although this is a recommendation of the Ministry of Health, due to the advantage of reducing the number of vaccinations and the possibility of immunizing the child against various diseases at the same vaccination opportunity. The most representative combinations involved Pentavalent, Pneumococcal 10-valent, VIP or VOP and Rotavirus vaccines, ie vaccines given at two, four and six months of age, as recommended by the Ministry of Health.[10]

In a study conducted in Campo Grande, there were also reports of adverse events occurring in simultaneous vaccination, with 17.10% being adverse events in the application of two vaccines and 4.80% in the administration of three vaccines. These results indicate a possible relationship between the occurrence of adverse events and the number of vaccines administered simultaneously.[8]

The Pentavalent vaccine is associated, in this study, with adverse events temporally related to the vaccine. DPT / Tetravalent / Pentavalent vaccines have, in their compositions, the combination of diphtheria and tetanus toxoids and inactivated Bordetella pertussis, with aluminum hydroxide or phosphate as an adjuvant and thimerosal as a preservative. They can cause many adverse events, but, of little seriousness, being the majority in the first 48 hours that follow the application of the vaccine.[4]

The Pentavalent vaccine was introduced in the basic calendar of the child's vaccination in the second half of 2012, to replace the Tetravalente vaccine. These two vaccines have practically the same composition, protecting against the diseases: diphtheria, tetanus, pertussis and meningitis by Haemophilus influenzae B, and, in the case of Pentavalent vaccine, hepatitis B is added.[11]

Among the most severe systemic manifestations related to Pentavalent, however, very rare are the hyporesponsive hypotonic episode, whose clinical characteristic appears in the first 48 hours, after the vaccine application, lasting for minutes or days, followed by pallor, disappearance of the muscle tone and lack of response to stimuli. Most children are followed with irritability and fever.[9]

Information provided by Pentavalent vaccine manufacturers points to febrile seizure in a ratio of one episode to every 12,500 doses applied or 0.8 / 10 thousand doses applied. In this study, six cases of seizure related to the Pentavalent vaccine, administered alone, were identified, a ratio of 1.19 / 10, thousand doses applied, that is, a frequency 1.48 times higher than expected, according to the information of the vaccine manufacturers. [12]

Regarding the systemic clinical manifestations, a study carried out in the State of São Paulo, from 1984 to 2001, obtained similar results to that found in this study, in which a fever less than or equal to 39.5 ° C (52.60%) and hypotonic-hyporresponders episode (EHH) (57.00%) predominated, respectively, among the most reported mild and severe manifestations related to the DPT vaccine.[13]

This study allowed the estimation of a rate of 140 immunization errors per million doses of vaccines administered in children under five years of age, a rate 12.72 times higher than that found in a study carried out in Greece which estimated an incidence of 11 errors per million doses of immunization.[14]

Errors in the application of the wrong vaccine and beyond the recommended age were also the most frequent in a study conducted in the United States, after analysis of reports from the period 2000 to 2013.15 Many cases occur because commercial and generic names are similar in sound, and in writing, or by having similar packages / jars.[16]

It is worth noting that the cases where the use of the wrong vaccine took place occurred in a transition period from the old oral polio vaccine scheme and the sequential scheme with the VIP / OPV vaccines at the time of the VIP vaccine. For the introduction of this vaccine, the Ministry of Health adopted a four-dose sequential (VIP / VOP) scheme for children under one year of age who were initiating the vaccination schedule. In the year 2016, there were changes in the poliomyelitis scheme. The VIP is administered at two months (1st dose), four months (2nd dose), and six months (3rd dose) and 15 months of age, and four years with VOP.17-18 Changes in vaccine schedules may predispose to errors, especially, complex schemes like the one indicated. The training provided often takes place short and, quick at the time of the introduction of new vaccines and is often, not enough to remedy any doubts that may arise in practice and sometimes does not allow the participation of all those involved in the vaccination process.[19]

The "received vaccine expired" error has been identified, which can reduce its efficacy and have consequences for users, who will not have the expected immune response and become susceptible to vaccine-preventable diseases.[20]

A study carried out in Paraná, Brazil, aimed to identify adverse events that occurred with the VORH vaccine, and identified that 81 immunization errors, of which 69.20% were "out-of-age vaccination (inadvertently vaccinated)"; 28.40%, expired validity "; 1.20%," administration of vaccine diluent only "and 1.20%," reapplication of vaccine after regurgitation / vomiting ".[21]

The occurrence of an overdose error with the BCG vaccine was also identified, administered in dosage five times higher than that recommended. Errors of overdose, especially with the BCG vaccine, may predispose the individual to adverse reactions, including severe local ulceration, injection site abscess, and regional lymphadenitis.[22] A study conducted in the database of the post-vaccination adverse event information system of Brazil, comprising the period from 1999 to 2008, found a relationship between immunization errors and the appearance of clinical manifestations with the BCG vaccine. Most of the clinical manifestations were due to incorrect vaccine preparation or application techniques.[23]

The immunization errors identified relate to the timing of vaccine administration, however, studies have pointed out that errors also occur in the transport, storage, handling and preparation of vaccines.[23-24] It is believed that there is underreporting of post-vaccine adverse events, leading to ignorance of other types of errors. Notification of post-vaccination adverse events is imperative for

the discovery of gaps that need to be addressed by the service in order to improve the quality of work done to patients.[25]

Many professionals are afraid to report mistakes in care for fear of reprisals and punishments. In this context, developing a safety culture, in which practitioners are reassured to report occurrences, aware that notifications will be used to build a more secure vaccination system, will contribute to more notifications and more transparency in reporting, making it possible to elucidate the possible causes that are generating post-vaccination adverse events, with the targeting of improvement measures for the vaccination system.[26]

Interventions to increase safety in vaccination are advocated, such as: adoption of protocols, step-by-step on situations to avoid and standards to be observed; existence of up-to-date consultative materials available to professionals; continuing education on a systematic basis, on new vaccines included in the calendar and in the campaigns; open and transparent discussion of immunization errors; the use of only one brand of vaccine, as different brands may have different recommendations, such as validity of the bottle after open, indications of ages, among others. The stock of multiple brands of the same vaccine can lead to personal confusion and greater vulnerability to making mistakes.[19]

The organization of the stock refrigerator and the work carton can also contribute to the occurrence or not of errors. It is important to organize the inventory and always look at the expiration date of all vaccines, at the time of use, to avoid the administration of expired vaccines.19 When arranging the refrigerator, vaccines with similar names should be placed apart from one another , in order to avoid confusion when choosing the bottle. Another recommendation is to put the vaccines with bottles or similar names in containers of various colors to alert the professional, in addition to the external identification of the vaccine.[19]

CONCLUSION

The results of this study showed that post-vaccine adverse events were composed of adverse events that were temporally related to the vaccine and immunization errors that mainly affected children under one year of age.

Most TVAE have occurred with the administration of more than one vaccine. The vaccine with the highest incidence of TVAE was the Vaccine against Inactivated Poliomyelitis (VIP), followed by the Pentavalent vaccine, both analyzed separately. However, it can be seen that the VIP vaccine had been administered simultaneously with the Pentavalent vaccine, which proved to be the most reactogenic in all situations.

The most common errors identified were misuse of immunobiology and vaccine administered beyond the recommended age.

Although the data based on notifications present the inherent limitations of passive surveillance, the results found in this study suggest the reatogenicity of the vaccines.

Some considerations deserve attention regarding the limitations of this study. Because it was a study with a secondary data source, the analysis depended on the quality of the information contained in the PVAE files, which are filled by the professionals who work in the vaccination rooms. In this way, some analyzes have run counter to the lack or insufficiency of information in the records of PVAE notifications that made it difficult to deepen the investigation.

This study was pioneered in the State of Goiás, GO, Brazil, with the proposed objective. Therefore, it is necessary to invest in other studies, to deepen the investigations in order to evaluate the causal factors, to evaluate the occurrence of post-vaccination adverse events during campaigns, to analyze the consequences of the occurrence of post-vaccine adverse events for the and evaluate the structure and processes in the vaccine rooms, in order to guarantee continuous improvements and maintain the reliability of the NIP.

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Corresponding Address

Ana Elisa Bauer de Camargo Silva
Universidade Federal de Goiás
Faculdade de Enfermagem
Rua 227, s/n, Qd. 68
Setor Leste Universitário
CEP: 74605-080 – Goiânia (GO), Brazil