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Original article

ADVERSE EVENTS FOLLOWING IMMUNIZATION OF THE ELDERLY

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ABSTRACT: The aim of this study was to analyze the occurrence of adverse events following immunization of the elderly, in Brazil, from 2004 to 2013. This is a descriptive, retrospective, quantitative study with data from the National Information System on Adverse Events Following Immunization, related to vaccines against diphtheria and tetanus, hepatitis B, pneumococcal 23-valent, yellow fever and influenza, in Brazil, collected in April 2015. Data were analyzed with descriptive statistics using Microsoft Excel 2013® and Epi Info® 7.1.4. A total of 2,692 adverse events were found, 97.91% were not severe. Of these, 37.11% involved pain, heat and flushing, prevalent in influenza (42.64%) and diphtheria, and tetanus (39.64%) vaccines. The elderly from 60-69 years (71.65%) and females (76.19%) were the most affected. Of the cases, 59.32% did not receive care in health services. It was concluded that this population is affected by adverse events, especially with no severity, but that require the attention from healthcare professionals to maintain their trust and adherence to vaccination.
DESCRIPTORS: Health of the elderly; Immunization; Adverse event; Nursing.

OCORRÊNCIA DE EVENTOS ADVERSOS PÓS-VACINAÇÃO EM IDOSOS

RESUMO: Este estudo objetivou analisar a ocorrência de Eventos Adversos Pós-Vacinação em idosos, no Brasil, de 2004 a 2013. Estudo descritivo, retrospectivo, quantitativo, com dados do Sistema de Informação de Eventos Adversos Pós-Vacinação, relacionados às vacinas difteria e tétano, hepatite B, pneumocócica 23 valente, febre amarela e influenza, no Brasil, coletados em abril de 2015. Análise realizada com estatística descritiva, utilizando *Microsoft Excel* 2013® e *Epi Info*® 7.1.4. Encontrados 2.692 eventos adversos, 97,91% não graves, deste 37,11% dor, calor e rubor, predominantes nas vacinas influenza (42,64%) e difteria, tétano (39,64%). Os idosos de 60 a 69 anos (71,65%) e do sexo feminino (76,19%) foram os mais atingidos. 59,32% dos casos não receberam atendimento nos serviços de saúde. Concluiu-se que este grupo populacional é acometido por eventos adversos, principalmente sem gravidade, mas que exigem atenção dos profissionais de saúde, para manter sua confiança e adesão à vacinação.
DESCRITORES: Saúde do idoso; Imunização; Reação adversa; Enfermagem.

OCURRENCIA DE EVENTOS ADVERSOS POSTVACUNACIÓN EN ANCIANOS

RESUMEN: Se objetivó analizar ocurrencia de Eventos Adversos Postvacunación en ancianos, en Brasil, entre 2004 y 2013. Estudio descriptivo, retrospectivo, cuantitativo, con datos del Sistema de Información de Eventos Adversos Postvacunación relativos a las vacunas contra difteria, tétanos, hepatitis B, neumocócica 23 valente, fiebre amarilla e influenza, recolectados en abril de 2015. Análisis realizado por estadística descriptiva, utilizando Microsoft Excel 2013® y Epi Info® 7.1.4. Fueron encontrados 2.692 eventos adversos, 97,91 no graves, de ellos 37,11% expresaron dolor, calor y rubor, predominando en vacunas contra influenza (42,64%), difteria y tétanos (39,64%). Los ancianos de 60 a 69 años (71,65%) y sexo femenino (76,19%) fueron los más afectados. El 59,32% de casos no recibió atención en servicios de salud. Se concluye en que este grupo poblacional es afectado por eventos adversos, particularmente sin gravedad, que requieren atención de los profesionales de salud para mantener la confianza y adhesión a la vacunación.
DESCRIPTORES: Salud del Anciano; Inmunización; Efectos Colaterales y Reacciones Adversas Relacionados con Medicamentos, Enfermería.

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INTRODUCTION

The aging process involves many changes in the human body, among them changes in the immune system, which makes the elderly more susceptible to diseases, including those that can be prevented with vaccination[1].

Studies have shown the occurrence of vaccine-preventable diseases in the elderly, such as pneumonia, influenza[2], tetanus[3] and hepatitis B[4]. Many cases identified had incomplete or nonexistent immunization schedules[5], demonstrating the need to improve access to vaccination for this population group.

The reported difficulties of these individuals' compliance include lack of knowledge about the vaccines[6], fear of possible adverse events following immunization (AEFI)[7-8] and lack of access to healthcare services[6].

An adverse event following immunization is any unwanted medical occurrence following vaccination, even if it has no causal relationship to the use of an immunobiological. In Brazil, this is mandatorily notifiable throughout the national territory[9].

The increase in vaccination coverage contributed to the control of many infectious diseases responsible for high morbidity and mortality. With the increase of the quantity of doses of vaccines given, adverse events have become more evident. Paradoxically, the population felt protected from these diseases, but was afraid of immunobiologicals, because they could cause unwanted reactions[10]. This situation was observed in England, France and other countries, where the low coverage led to increased incidence of vaccine-preventable diseases, causing deaths[11].

Vaccines are safe biological products, but can cause AEFI that are mostly not severe, due to factors related to the immunized individual, the vaccine and its administration, with local and/or systemic manifestations. These are expected or unexpected and classified as severe (requiring hospitalization for at least 24 hours, can cause sequelae, congenital anomaly, risk of death and death) and not severe, such as pain, heat, flushing, headache, fever, and myalgia (those not included in the severe criteria)[9].

Nursing is the profession that is most involved with immunization, but there are still gaps in their knowledge about adverse events[12-13], which may hinder their approach to the user. It is therefore crucial that healthcare professionals working in this area know the immunobiologicals available to seniors and their AEFI deeply, in order to guide them before, during, and after vaccination, as well as assisting them safely.

It is noteworthy that users who are informed about the importance of prevention of vaccine-preventable diseases and the whole vaccination process feel safer and accept vaccines better[13].

Given this scenario, it is important to identify and analyze AEFI that affect the elderly resulting from vaccines provided by the National Immunization Program (NIP). The research results will contribute to safe vaccination and the practice of nursing in this field, with new knowledge that will assist in the formulation of strategies to improve the elderly compliance to vaccination and the quality of care provided. Thus, this study aimed to analyze the occurrence of adverse events following immunization of the elderly, in Brazil, between 2004 and 2013.

METHOD

This is a descriptive, retrospective study with a quantitative approach, carried out in Brazil from 2004 to 2013. The definition of the study period was established considering the limitations of the database of the Adverse Events Following Immunization (ISAEFI), provided by the NIP, regarding the available period. The sample consisted of 3,772 AEFI records of elderly individuals (people aged 60 years or over)[14]. The immunobiologicals indicated for this group were identified in the National Schedule of Immunization of the Elderly, and on bulletins of national immunization campaigns[15]. Cases resulting from hepatitis B (Hep B), yellow fever (YF), tetanus, diphtheria vaccine (Td), influenza (Flu) and pneumococcal polysaccharide vaccine (PPSV23) vaccines were selected, resulting in 3,168 records.

Of these, 2,692 cases that were confirmed and/or associated with other vaccines were included, which composed the study sample. Inclusion criteria were adverse events in the elderly, resulting from Td, YF, hep B, Flu and PPSV23 vaccines, confirmed and/or associated with other vaccines. The exclusion criteria were

records containing no information of one of the variables, or those with errors.

Data collection took place in April and May 2015, using a Microsoft Excel® 2013 spreadsheet containing the variables: age, sex, immunobiological, year of administration, dose, event, and attendance. Ages were stratified by age groups.

Data were organized in tables and graphs, and analyzed with descriptive statistics, aided by softwares Epi Info® 7.1.4 and Microsoft Excel® 2013. The results were presented as absolute (N) and relative (%) frequencies, with confidence intervals (CI) of 95%, and analyzed in the light of the literature available on the subject.

This research is a subproject of the study "Immunization Errors and Nursing Practice", approved by an ethics committee under number 527.288/2014.

RESULTS

The most frequent AEFI was the inflammatory triad of pain, heat and flushing (37.11%), whereas other adverse events did not exceed, individually, 0.55% to 7.20%. Two types of AEFI stood out for their specificity and severity: other severe and unexpected events (5.5%), including cases of Guillain Barré Syndrome (5), post-YF vaccine acute viscerotropic disease (4), anaphylactic shock (2), and death (1); and hypersensitivity for up to 2 hours (1.33%) (Table 1).

Table 1 – Distribution of number and percentage of the types of adverse events following immunization of the elderly. Brazil, 2004-2013

Adverse event following immunization	N	%	95% confidence interval	
			ll (%)	ul (%)
Pain, flushing and heat	999	37.11	35.28	38.93
Fever below 39.5 C	194	7.20	6.23	8.18
Induration	168	6.24	5.33	7.15
Headache	152	5.64	4.77	6.52
Myalgia	151	5.60	4.74	6.48
Other severe or unexpected event *	147	5.46	4.60	6.32
Other local reactions**	126	4.68	3.88	5.48
Hypersensitivity reaction after 2 hours	125	4.64	3.85	5.44
Hot subcutaneous abscess	114	4.23	3.47	5
Fever higher than or equal to 39.5 C	104	3.86	3.14	4.59
Arthralgia	64	2.37	1.80	2.95
Generalized rash	56	2.08	1.54	2.62
Nodule	54	2.08	1.48	2.54
Headache and vomiting	50	1.85	1.35	2.37
Arthus' reaction	40	1.48	1.03	1.94
Hypersensitity reaction up to 2 hours	36	1.33	0.90	1.77
Intense local reactions**	28	1.04	0.66	1.42
Nonsupurated lymphadenomegalia	20	0.74	0.42	1.07
Paresthesia	17	0.63	0.33	0.93
Difficulty ambulating	17	0.63	0.33	0.93
Cold subcutaneous abscess	15	0.55	0.28	0.84
Generalized hives	15	0.55	0.28	0.84
Total	2692	100	100	100

Source: ISAEFI/NIP/Ministry of Health
Notes: ll= lower limit; ul= upper limit

* variable to notify severe and/or unexpected events not listed on the Investigation Form of AEFI (IFAEFI). They were grouped in this category: Guillain Barré Syndrome, post-YF vaccine acute viscerotropic disease, anaphylactic shock, apnea, atrophy on site of application, encephalitis, acute encephalopathy, other paralysis, and death.
** other local reactions (edema, etc.) and intense local reactions (heat and flushing on the site of vaccine, with great extension) are variables to register local events not listed on the IFAEFI.

By linking AEFI to the vaccines given, it was observed that Td was responsible for the largest percentage of Arthus' reaction (70%), induration (53.57%), difficulty ambulating (52.94%), nodules (51.85%), pain, heat and flushing (49.95%), and other local reactions (swelling, and others) (44.44%). Influenza presented the highest prevalence in the events: hypersensitivity reaction for up to 2 hours (72.22%), generalized rash (71.43%), other severe and unexpected events (including five cases of Guillain Barré Syndrome) (65.31%), arthralgia (60.94%), fever higher than or equal to 39.5 C (53.85%), headache (53.29%), myalgia (49.01%), headache and vomiting (48%), fever lower than 39.5 C (47.94%), hypersensitivity reaction after 2 hours (42.98%), and generalized hives (42.64%). Intense local reactions were mainly related to PPSV23 (46.43%). It is noteworthy that, despite the low incidence of nonserious adverse events after YF, such as myalgia (17.3%), pain, heat, flushing (13.4%), and headache (12.6%), four acute cases of viscerotropic disease were also registered (2.4%).

Among the vaccines studied, Flu and Td had records of the highest frequencies of AEFI (Table 2).

Table 2 - Distribution of the percentage of adverse events following immunization of the elderly, per immunobiological. Brazil, 2004-2013

Immunobiological	Adverse events following immunization		95% Confidence Interval	
	N	%	ll (%)	ul (%)
Flu	1148	42.64	40.78	44.51
Td	1067	39.64	37.79	41.48
PPSV23	326	12.11	10.88	13.34
YF	122	4.53	3.75	5.32
Hep B	29	1.08	0.69	1.47
Total	2692	100	100	100

Source: ISAEFI/NIP/Ministry of Health
Note: ll= lower limit; ul= upper limit

In the years studied there was a variation in AEFI notification, with significant increase of events for Flu, Td and PPSV23 in 2007, followed by a sharp drop of Td until 2011, and a significant rise until 2013. The reported reduction of adverse events in 2010 and great elevation of Flu in 2011 (Figure 1) were noteworthy.

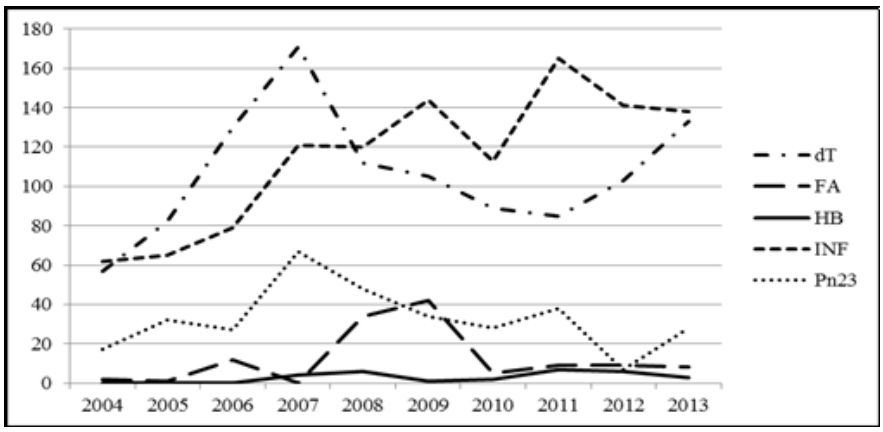

Figure 1 – Distribution of percentages of adverse events following immunization of the elderly, per year and immunobiological. Brazil, 2004-2013. Source: SIAEFI/NIP/Ministry of Health

Cases of AEFI found were predominant in females (76.19%) and in the age group from 60 to 69 years (78.34%) (Table 3).

Table 3 - Number and percentage distribution, with confidence interval, of adverse events following immunization of the elderly, by age and sex. Brazil, 2004-2013

Age group	Female				Male				Total	
	N	%	95% CI		N	%	95% CI		N	%
			ll (%)	ul (%)			ll (%)	ul (%)		
60 to 69 years	1490	78.34	76.49	80.19	412	21.66	19.81	23.51	1902	100
70 to 79 years	412	72.79	69.13	76.46	154	27.21	23.54	30.87	566	100
80 to 89 years	149	66.52	60.34	72.7	75	33.48	27.3	39.66	224	100
Total	2051	76.19	74.58	77.8	641	23.81	22.2	25.42	2692	100

Source: SIAEFI/NIP/Ministry of Health
Note: CI= Confidence Interval; ll= lower limit; ul =upper limit

Of the 2,692 AEFI identified, 1,597 (59.32%) belonged to elderly individuals who did not seek care in healthcare facilities during the event, notifying them later. Of those receiving care (1,095), most went to a basic health unit (Table 4).

Table 4 - Percentage distribution, with its respective confidence interval, of adverse events following immunization, by place of care. Brazil, 2004-2013

Place of care	N=1095	95% CI	
	%	ll (%)	ul (%)
Basic health unit	74.98	73.34	76.61
Emergency unit	17.44	16.01	18.88
Nursing ward	6.39	5.47	7.32
Others*	0.73	0.41	1.05
Intensive care unit	0.46	0.2	0.71
Total	100	-	-

Source: SIAEFI/NIP/Ministry of Health
Notes: CI= Confidence Interval; ll= lower limit; ul= upper limit
*the variable "others" of the Investigation Form of AEFI grouped places of care that were not mentioned, such as private practices and pharmacies.

By linking AEFI to the number of vaccine doses that the user received, it was found that 62.67% (95% CI, 60.84 to 64.49) of the adverse events occurred in the first dose; 31.10% (95% CI, 39.35 to 32.85) in the second dose; 15.16% (95% CI 13.8 to 16.51) in the third dose; 29.70% (95% CI 27.98 to 31.43) in the first booster, and 11.50% (95% CI 10.29 to 12.70) in the second booster or more doses.

DISCUSSION

The progressive aging of the Brazilian population led to the need for establishing public policies aimed at the elderly, including the Elderly Statute (2003), the National Social Care Policy (2004), and the National Health Policy for the Elderly (2006), foreseeing that protective actions and care to the elderly should have the participation of the State, society and family. In this perspective, the State provides elderly immunization to protect them[16].

Reporting AEFI is very important for safe vaccination, because it contributes to the monitoring of the quality of immunobiologicals and vaccination, allowing studies to reduce the reactogenicity of their products, the identification of possible causes, and improving the quality of care.

The prevalence of the inflammatory triad of pain, flushing and heat, identified in this study, corroborates the findings of other studies[10,17] and the frequency estimated by the NIP[9]. These events occur as a result of the introduction of the needle and product, especially in the muscle tissue, associated with reactive vasodilation, which potentiates their absorption. They are expected, self-limiting, with benign evolution, and the most incident in vaccines available for the public. Diphtheria and tetanus vaccine was the most commonly involved immunobiological in this kind of event, the reaction of which is associated with aluminum hydroxide adjuvant that promotes an inflammatory reaction to aid in the immune response. This situation is enhanced in the subsequent doses of the vaccine, and can reach up to 85% of those vaccinated with booster doses[9].

Fever, usually below 39.5 C, is frequent after vaccination, reaching up to 58% of those vaccinated[9], higher than that obtained in this study. This is a physiological response caused by the administration of an antigen, which produces inflammatory cytokines that release prostaglandins, and increase body temperature, thereby contributing to the immune response[18]. It has an average duration of 24 to 48 hours, and its persistence for more than 24 hours requires investigation of an infectious disease in progress[9]. Especially in the elderly, this situation requires attention from healthcare professionals, caregivers and family members, because due to immunosenescence, changes occur in the immune response, making it more susceptible to infectious reactions. In this case, low fever can be unduly attributed to the immunobiological, exposing the elderly to risk of complications.

Influenza was the vaccine with the highest percentage of this AEFI, higher than that found in another study[19]. This finding may be related to the behavior of some people when they fear the presence of fever, which they associate with the occurrence of diseases, and seek care in healthcare services[18].

It is worth noting the reporting of severe adverse events, such as hypersensitivity reaction for up to 2h, and acute viscerotropic disease after YF vaccine, which may occur due to an error of prescription or indication of an immunobiological[9]. The lack of a detailed investigation before vaccination about vaccination history, risk factors and the individual's health status, does not reveal indicative situations of delay or nonapplication of the vaccine and exposes certain users to damage risk[20-21]. Therefore, to avoid preventable events, the vaccinator should question the elderly on pre-existing conditions; use of immunosuppressive drugs; adverse events in previous doses, specifying the type and treatment; allergy to any component of the immunobiologicals, inactivated or attenuated; severe allergy to eggs and immunosuppression, for the attenuated[9].

Another important factor to be evaluated is the user's age, because the primary vaccination with YF in people aged 60 or over should be made only after evaluation of the benefit/risk, according to the epidemiological situation, due to the high incidence of acute viscerotropic disease in the elderly. This risk is due to immunosenescence, where immunosuppression cannot control vaccine replication and triggers the disease, with clinical features similar to wild yellow fever. Although the percentage of acute viscerotropic disease identified in this study is lower than that estimated by the NIP, this adverse event requires close monitoring due to its severity and high mortality in the elderly[21]. The YF vaccine also caused nonsevere AEFI, with percentages that were higher than those reported by the NIP[9], probably due to the increased sensitivity of epidemiological surveillance[22].

Although the hot subcutaneous abscess presented a low frequency, its occurrence causes concern because it indicates deviation from the quality, which interferes with patient safety and causes error of immunization, a preventable event that can cause or lead to inappropriate use of immunobiologicals, or cause harm to a patient, while the product is under the control of health professionals[9]. One of the most frequent errors involves the immunobiological administration technique, with contamination due to lack of proper hand hygiene[23]. In the United Kingdom, a study found that more than half of the errors occurred during the preparation of the vaccine, including material contamination[24]. The presence of infection at the injection site reinforces the importance and the need to establish good practices of vaccination, as well as to increase awareness of vaccinators in this area.

The AEFI regarding PPSV23 are usually mild, self-limited and restricted to the injection site, with a prevalence of pain. There may also be severe local reactions, such as Arthus' reaction, often in early revaccination. This immunobiological is indicated by the NIP for people aged 60 years or more, residents in long-term institutions for the elderly, nursing homes, with a single dose regimen and a booster after five years. The administration of more than two doses is not recommended, because they do not induce booster effect, and increase the probability of intense local events[9]. Therefore, investigating the number of previous doses

prior to vaccination will contribute to the prevention of moderate and severe reactions. The results of this research support studies in the United States[25], Brazil[17] and frequencies presented by the NIP[9].

Over the study period, wide variations were observed in the percentage of notifications, with rises and falls, which may indicate underreporting of cases, and adoption of strategies to encourage vaccination, such as campaigns. On these occasions, many doses are administered over a short period of time, increasing the sensitivity of epidemiological surveillance and the likelihood of adverse events[22]. The information provided in basic health units, and especially in the media[26], make the population more aware of possible reactions, and lead them to seek healthcare services, which also have a more sensitive surveillance[27].

The significant increase of cases arising from Td and PPSV23 in 2007 may be related to the inclusion of these vaccines in the national vaccination campaign against influenza, which present similar local reactogenicity, mainly Td, which reaches up to 85% of those vaccinated. The decline recorded in the following years may indicate, in particular, cases of underreporting, but also the reduction of susceptible people, since the campaign is selective and follow the regimen recommended by the NIP. In 2011 and 2013, a further increase was observed in PPSV23, probably by the administration of the booster doses of previous years.

The appearance of cases of wild yellow fever in Brazil in 2008 and 2009 triggered vaccine intensification in several states, resulting in an increase of the doses applied and, consequently, of AEFI notifications.

The reduction of notifications is emphasized in 2010, probably because of the campaign against pandemic influenza[27], with large mobilization of the population and intensified surveillance, because it was a new vaccine that could cause unexpected events.

This study found that older women showed more AEFI than men, similar to the findings of another study[8], however, a difference in vaccine reactions between the genders was not found in the literature. This may be related to the aging process, especially the feminization of old age, attributed to lower exposure of women to certain risk factors compared to men, disease coping and disability and longevity[28].

Historically, women seek healthcare services more often than men, they care more for their health and show greater adherence to preventive actions, because they feel responsible for other people in their families[8].

Men, on their turn, seek these services less often, because they consider them places frequented by women[8]. Because of the cultural male construction, they identify themselves as strong, and to seek care means to show weakness; in addition, they report fear of a diagnosis of a serious illness, which leads them to opt for not attending the basic health unit[29]. Men's low compliance is also related to the hours of operation of these units, because most of them coincide with the periods users work, including the elderly who continue working[8].

The age group that is most affected by AEFI was those within 60-69 years old, also described in other studies[8,17]; this is probably related to ease of access to health services, due to little impairment of autonomy and independence.

Most adverse events were seen in basic health units, probably because of the most prevalent nonsevere events that can be resolved at this location. However, more than half of reported cases did not seek care in health services, perhaps for lack of information or access. It is understood that access is associated with a person's ability to seek care, and to the facilities or difficulties for their displacement, as observed in the elderly[20].

Another factor that interferes with elderly compliance is the lack of embracement by professionals at basic health units, and often the quality of care[6]. It is important to emphasize that the elderly may have cognitive impairment, with difficulty to understand the guidelines on vaccines and adverse events, requiring more attention to preserve their safety.

FINAL CONSIDERATIONS

The study achieved its objective of analyzing the occurrence of AEFI in the elderly, and revealed aspects that are relevant to safe vaccination, such as the occurrence of preventable events caused by deviations from best practices as the cause of infectious abscesses, and lack of assistance to adverse events, possibly due to difficult access.

It was concluded that this population is affected by adverse events, especially nonsevere events, but they require attention from health professionals to keep their confidence and compliance to vaccination.

The findings showed that nonsevere adverse events were the most common, with a prevalence of the inflammatory triad of pain, heat and flushing, usually in the first dose of the vaccine. It was also found that the elderly have been affected by severe AEFI that require immediate intervention in healthcare services, and that the age group of 60-69 years was the most affected. The highest percentage of AEFI was recorded with the Flu and Td vaccines, and most cases assisted sought care at basic health units.

The percentage of users with AEFI who did not seek care in healthcare services in a timely manner stands out. Elderly people who are not informed about adverse events, when facing some signs and symptoms after vaccination, may think they are natural, assign them to the product and do not seek care, putting themselves at risk of severe AEFI or disease coincident with vaccination, without receiving appropriate treatment.

Thus, it is necessary that healthcare professionals working with immunization have knowledge and skills in this area, including continuing education activities, essential to qualify them, keep them updated and, consequently, assist with quality and safety.

It is believed that the share of healthcare services with universities is essential for proper care. The inclusion of the AEFI subject in lessons about immunization will contribute to professional training, so that graduates have technical and scientific conditions to perform activities in this area.

The study had limitations because it was based on ISAEFI data, subject to underreporting and poor quality of records, as it performs passive surveillance. However, it proved to be very useful in gaining new knowledge about the profile of AEFI in the elderly.

For future research, the development of studies to analyze the risk of AEFI and their tendency in this population group is recommended.

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