Nursing practice in view of adverse events following vaccination

A PRÁTICA DA ENFERMAGEM FRENTE AOS EVENTOS ADVERSOS PÓS-VACINAÇÃO

LA PRÁCTICA DE LA ENFERMERÍA FRENTE A LOS EVENTOS ADVERSOS POST-VACUNACIÓN

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ABSTRACT

The objectives of this article are to identify the adverse events following vaccination, the focus if nursing practice, using the Post-Vaccination Adverse Events Information System database, and discuss on the nurses' practice on the surveillance for those events. Secondary data were those regarding the vaccines applied in the Brazilian public health system, in the period from 1999 to 2008, totaling 65,442 registers, 59,899 of which were confirmed and 1,403 were associated with another vaccine. The 16 nursing practice events totaled 21,727 registers. Although they account for 35.4% of the registers, the data do not reflect the reality, because their reliability depends on the knowledge network that comprises diagnosis, notification and inclusion in the system. Discussions were made on interventions for the most prevalent events: fever and local events. Most interventions established in the adverse events manual was in agreement with the literature, though there were differences in the content between conducts for the same event due to different vaccines.

DESCRIPTORS

Vaccination
Public health nursing
Information systems

RESUMO

Este artigo tem como objetivos identificar eventos adversos pós-vacinação, foco da prática da enfermagem, em base de dados do Sistema de Informação de Eventos Adversos Pós-Vacinação e discutir a atuação do enfermeiro na sua vigilância. Utilizaram-se dados secundários referentes às vacinas aplicadas na rede pública de saúde brasileira, no período de 1999 a 2008, totalizando 65.442 registros, sendo 59.899 confirmados e 1.403 associados com outra vacina. Os 16 eventos de atuação da enfermagem perfizeram 21.727 registros. Embora representem 35,4% dos registros, os dados não refletem a realidade, pois sua fidedignidade depende da rede de conhecimento que engloba diagnóstico, notificação e inclusão no sistema. Discutiram-se as intervenções para os eventos de maior prevalência: febre e eventos locais. A maioria das intervenções estabelecidas no manual de eventos adversos estava de acordo com a literatura, porém verificaram-se diferenças de conteúdo entre as condutas para um mesmo evento decorrente de vacinas diferentes.

DESCRITORES

Vacinação
Enfermagem em saúde pública
Sistemas de informação

RESUMEN

Este artículo objetiva identificar eventos adversos post-vacunación, foco de la práctica de enfermería, en base de datos del Sistema de Información de Eventos Adversos Post-Vacunación y discutir la actuación del enfermero en su vigilancia. Se utilizaron datos secundarios referentes a vacunas aplicadas en red pública de salud brasileña de 1998 a 2008, totalizando 65.442 registros, estando 59.899 confirmados y 1.403 asociados con otra vacuna. Los 16 eventos de actuación de enfermería completaron 21.727 registros. A pesar de representar el 35,4% de registros, los datos no reflejan la realidad, su veracidad depende de la red de conocimiento que engloba diagnóstico, notificación e inclusión en sistema. Se discutieron intervenciones para eventos de mayor prevalencia: fiebre y eventos locales. La mayoría de las intervenciones establecidas en el manual de efectos adversos concordaba con la literatura, sin embargo se verificaron diferencias de contenido entre las conductas para un mismo evento derivado de vacunas diferentes.

DESCRIPTORES

Vacunación
Enfermería en salud pública
Sistemas de información

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INTRODUCTION

The profile of morbidity and mortality in Brazil showed a marked change in recent decades, especially in relation to infectious and parasitic diseases due to control measures, among them immunizations[1]. However, as with any drug or medication, vaccines also require special attention because, though they are considered safe and beneficial to control diseases, they can trigger mild or even severe adverse events; some are expected while others may be unusual[2]. If such events are not identified, investigated and monitored, they can hinder adherence to immunization programs[3-4].

With the growth of the Brazilian population, the number of doses of applied vaccines has also increased and, consequently, the incidence of Adverse Events Following Immunization (AEFI)[5]. In such a context, the population may become even more concerned with AEFI than with the disease the vaccine is intended to prevent. This fact is one of the justifications used to add the Surveillance of Adverse Events Following Immunization (SAEFI) and continuing assessment of potential risks posed by vaccines to health services' actions, which requires technical-scientific knowledge on the part of professionals to make decisions and, especially, to ensure the quality of immunization programs and the service's reliability.

...the population may become even more concerned with Adverse Events Following Immunization than with the disease the vaccine is intended to prevent.

The work of nurses in the Single Health System (SUS) generates a growing demand for nursing consultations, requiring professionals to continually update their knowledge to improve the problem-solving capacity of their care delivery[6-8]. Nonetheless, knowledge concerning adverse events related to immunization is still incipient, which reflects difficulties in decision-making, with gaps both in the investigation of cases and in interventions, consequently posing a risk to the health of patients[9-10]. Nurses working in primary health care units show little interest in AEFI; they consider it very complex and limit their actions to vaccinations in the injection-area level, while referring the surveillance of events to nurses or other professionals from epidemiological surveillance[9].

An AEFI is defined as *any undesirable clinical event in an individual who received some immunobiological agent* [5]. Events can be systemic or related to the injection-area and are classified in relation to intensity: a) severe: hospitalization is required for at least 24 hours; there is significant and/or persistent dysfunction or impairment (sequelae), results in congenital anomaly, risk of death (requires immediate intervention to avoid death), or death; b) moderate: requires medical assessment, complementary exams and medical treatment; and c) no complementary exams or medical treatment required[5]. The latter is characterized as being within the scope of nursing practice.

An event can also be classified in relation to its cause: a) vaccine-induced: related to the characteristics of the vaccine's components, preparation of the vaccine and the recipient's individual response, which would not occur without the vaccination; b) aggravated by the vaccine: it would occur regardless of the vaccination but was precipitated by it; c) programmatic errors: related to the manner in which the vaccine was prepared, manipulated or administered; d) coincident: temporarily associated with the vaccine, the event already existed at the time of the immunization but had not been manifested or was not seen as significant[11].

An event may be temporarily associated with a vaccine though there will not necessarily be a causal relation with it. Most events, both those related to the injection-area and systemic events, are mild and self-limited. Surveillance actions give priority to moderate and severe events aiming to rule out causes improperly attributed to the immunization. Hence, the use of the term *adverse event* temporarily related to the immunization instead of *adverse reaction* is justified because the word *reaction* suggests a causal relationship with the vaccine, which is often confused with some disease coincident to the period of vaccination[5]. The use of appropriate and standardized nomenclature to characterize an adverse event is essential to avoiding ambiguous information that may result in inaccurate and imprecise interpretation, harming the event's assessment and follow-up[2].

Clarification provided to the population and health care providers concerning the safety of immunization during the 1980s and 1990s resulted in a decrease in the incidence of immunopreventable diseases due to improved immunization coverage. The cost-effectiveness analysis was favorable for immunization, however with a reduced number of diseases and growing number of doses applied the perception of people has changed and fear related to AEFI has emerged[12].

This problem also occurred in other countries besides Brazil and was partially solved with the implementation of AEFI epidemiological surveillance. A national system to report adverse events following immunization, the Vaccine Adverse Events Reporting System (VAERS), was created in the United States in 1986[13]. After its implementation in the USA and an equivalent system in England, in 1991 the World Health Organization (WHO) recommended the remaining countries adopt such a system.

In 1992, the Brazilian Ministry of Health (MH) jointly with the National Program of Immunization (NPI) launched the National Surveillance of Adverse Events Following Immunization (NSAEFI), which became effective in 1998 with the publication of the Manual for Epidemiological Surveillance of Adverse Events Following Immunization (ESAEFI)

[12]. This manual's main objectives were: regulate recognition and conduct in cases with suspicion of AEFI; identify new and/or rare events and encourage greater knowledge concerning the origin of AEFIs; establish or rule out, if possible, relations of causality to immunizations; enable the identification of immunobiological agents or batches that deviate in quality of production that results in increased reactogenicity and therefore requires a decision concerning its continued use or suspension[5].

The NSAEFI is put into operation through this manual, the list of reporting events, the reporting/investigation form, and the Information System of AEFI. All the cases suspected of being AEFI must be investigated and reported— reporting is mandatory— following the NPI/MH criteria and list of events according to decree nº 33/SVS/MS de 2005[5]. Even though the Brazilian system works regularly, similar to the American system, it is a passive system with various limitations. For example, the reporting of cases temporally related but with no causal relation to immunizations[12], which sometimes harms the quality of information generated by the information system.

The Information System of Adverse Events Following Immunization (IS-AEFI) was implemented in 2000. It is a computer system aimed to speed up analysis of cases, compile the largest number of variables from the reporting and investigation forms, and moreover to promote the consolidation and analysis of AEFI data from the entire country in a single system[5]. It is installed in all the Brazilian states and is centralized in the State Departments of Health responsible for including AEFI in the system.

The IS-AEFI enables the consultation of databases and production of reports by patient or by immunobiological agent, city or regional health center, and by period of time previously defined. As opposed to the systems of other countries, the Brazilian system uses the number of applied doses as the denominator to compute the incidence of AEFI, which confers greater validity to the country's indicators[14].

Studies conducted in various countries indicate the high incidence of some adverse events, most frequently mild ones, especially related to the injection-area. The same is seen in studies conducted in Brazil where injection-site related events account for about 40%[14-16]; the causes of some of these are related to programmatic events such as incorrect procedures in the preparation and application of vaccines[14-15].

It is worth noting that the administration of medications, including vaccines, is among the responsibilities of nurses and requires responsibility, sound ethics, scientific knowledge and technical skills[17]. Also, the immunization program within SUS is mainly carried out through nursing actions that go from the application of the vaccine, care provided in the case of mild adverse events up to AEFI epidemiological surveillance[7]. However, there is underreporting of AEFI, in part due to the need to be specifically qualified in the field, poor quality of information, and insufficient investigation of suspicious cases, which in such cases, may result in inappropriate care delivery[10].

Given the preceding discussion, this study focuses on IS-AEFI events that are considered to be within the scope of nursing care and discusses the potential of nursing work within this domain.

OBJECTIVES

To identify the adverse events following immunization, within the scope of nursing practice, based on data from the Information System of Adverse Events Following Immunization and discuss the potential work of nurses in the surveillance of adverse events following immunization.

METHOD

This is a descriptive documental study with a quantitative approach. This investigation is based on the ESAEFI manual[5] and on secondary data collected from the IS-AEFI/NPI/MH that contains spontaneous reporting of adverse events following immunization concerning all the vaccines applied in the public health care network in Brazil, covering the period from 1999 to 2008.

The study was developed in three phases: collection of events prevalent in the IS-AEFI database; identification of events within the scope of nursing practice; and verification of the adequacy of the nursing interventions proposed by the ESAFI manual for such events.

After identifying the content of the IS-AEFI database, the variables of interest were selected for the study, that is, those variables that would enable the identification of the types of AEFI and their classifications. The following were selected: *Event* (type of adverse event) and *Closure* (classification of event as *confirmed*; *associated with another vaccine – confirmed, but not possible to specify which vaccine caused the event*; *undefined*; *under investigation*; and *ruled out*).

The database was then cleaned up with the elimination of non-used variables, typos were corrected, and the remaining data were stratified according to the outcome. Only the events classified as *confirmed* and *associated with another vaccine* were considered.

Because criteria to establish and report AEFI were updated in 2008, the events listed in the IS-AEFI database were compared to the list of mandatory-reporting events from the ESAEFI manual[5].

Afterwards, the conduct recommended for each event was verified in the manual (medical care, nursing care, or complementary exams) in order to classify the events either as within nursing or within medical care practice. The AEFI within the nursing domain were compared with the

reporting events from the manual[5] so that they were in accordance with the reporting events recommended by the NPI. In this case, the events reported as a set of symptoms such as *pain, heat and redness* were separated because in the manual these are considered independent symptoms.

The listed events were the basis for the verification of the adequacy of interventions defined by the NPI/MH. In this phase, each intervention from the ESAEFI manual was analyzed according to the nursing literature, checking the equivalence between both in order to discuss the potential of the work of nurses within this domain.

Data are quantitatively presented through charts and tables by absolute and relative frequency and discussed in light of the literature addressing the topic.

The research that originated this study was approved by the Ethics Research Committee at the Pontifical Catholic University of Paraná, No. 1298/07, according to the resolution 196/96, National Council of Health.

RESULTS AND DISCUSSION

A total of 65,442 AEFI records were found in the IS-AEFI database according to the variable *Closure*; 59,899 of these were classified as *confirmed* and 1,403 were *associated with another vaccine*, which corresponded to 93.6% of the total records (Figure 1); these are the quantitative basis of analysis.

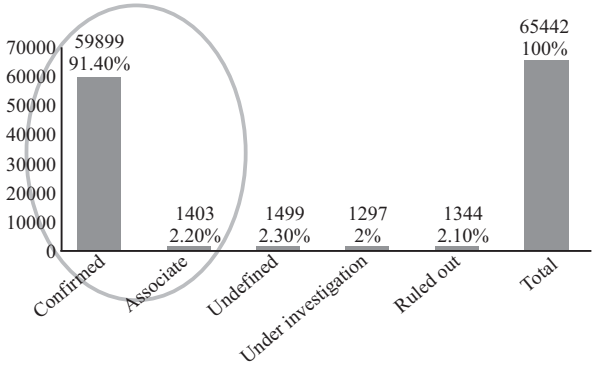
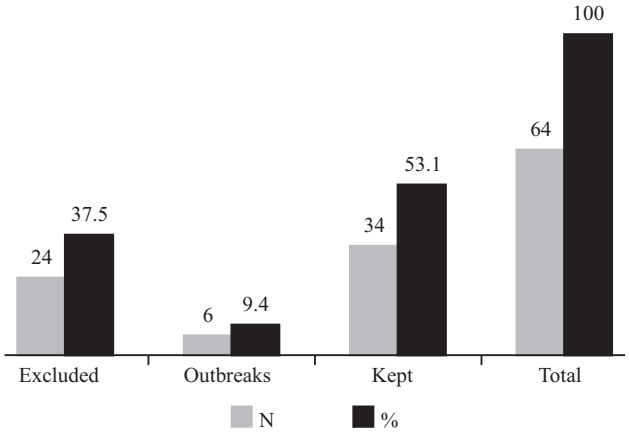


Figure 1 – Frequency of adverse events following immunization in the IS-AEFI according to the variable *closure* – Brazil – 1999 to 2008

Since the database's temporality is not compatible with the current manual given the updates of compulsory-reporting events, we needed to compare the events from the database with those contained in the ESAEFI manual to determine whether the nursing declarations were formulated according to the recommendations of the NPI/MH. Of the 64 types of events contained in the database: 24 were excluded, six were retained because they reported outbreaks, and 34 were kept for mandatory reporting (Figure 2). It is worth noting that nine new events were included in the manual update.



Source: IS-ESAEFI/NPI/MH

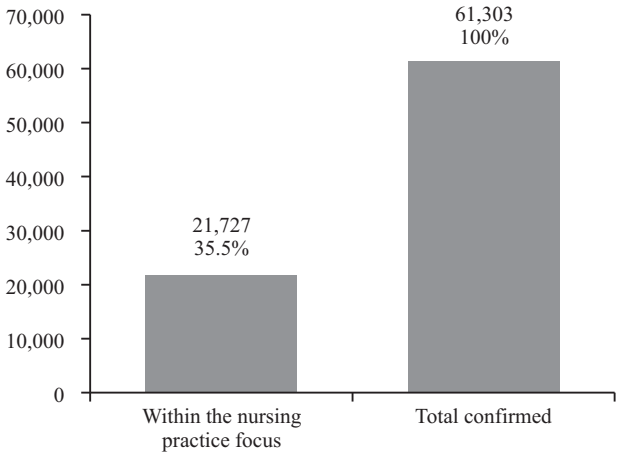
Figure 2 – Comparison between events reported in the IS-ADFI and the mandatory-reporting events according to the ESAEFI manual – Brazil -2009.

The events from the IS-AEFI and those listed in the EASEFI manual were classified either as events within the medical care scope or events within the nursing care scope. The results indicated there were 16 AEFI within the domain of nursing care with 21,727 records corresponding to 35.4% of the IS-AEFI database (Table 1 and Figure 3).

Table 1 – Frequency of adverse events following immunization considered to be within the nursing care domain – Brazil – 1999 to 2008

AEFI IS-AEFI	Absolut Frequency	%	Relative Frequency (%) N= 61.302
Cold local abscess	803	3.70	1.30
Arthralgia	468	2.14	0.76
Arthritis	14	0.06	0.02
Headache	923	4.20	1.50
Difficulty walking	600	2.90	0.98
Pain, redness and heat	6094	28.00	9.94
Induration	1391	6.40	2.27
Generalized rash	2518	11.60	4.10
Fever below 39.5 ºC	4551	21.00	7.42
Non-suppurative lymphadenitis > 3 cm	465	2.10	0.75
Suppurative lymphadenitis	272	1.24	0.44
Suppurative lymphadenitis > 3 cm	160	0.70	0.26
Non-suppurative lymphadenopathy	1008	4.61	1.64
Myalgia	920	4.23	1.50
Nodule	1009	4.62	1.64
Ulcer larger than 1cm post BCG	545	2.50	0.88
TOTAL	**21.727**	**100**	**35.40**

Source: IS-EAFI/NPI/MH

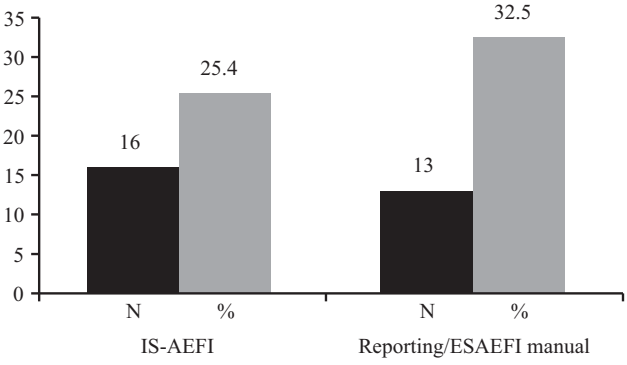


Source: IS-AEFI/NPI/MH

Figure 3 – Absolute and relative frequency of adverse events following immunization considered to be within the nursing practice focus, IS-AEFI – Brazil – 1999 to 2008.

After the initial selection of AEFI considered to be the within the nursing practice domain, we verified that the manual did not recommend medical care when there was *fever equal or greater than 39°C* but mentioned the risk of febrile seizures in children three months to six years old, hence, this event was excluded from the initial list, and only fever below 39°C remained because it was considered to be within the domain of nursing care.

Even though the protocol from 2008[5] had reduced the number of AEFI for which reporting was mandatory (Figure 2), the events from the nursing care domain proportionally increased from 25.4% to 32.5% (Figure 4), showing the possibility of nurses working in this domain, which is reinforced by data from IS-AEFI in which 43.5% of the events were considered to be injured-area events (Table 1): cold abscess, difficulty walking, pain, heat, redness, induration, non-suppurative lymphadenitis, suppurative lymphadenitis; ulcers larger than 1cm. Many of these are related to failures in the technique of administering immunizations[5].



Source: IS-AEFI/NPI/MH

Figure 4 – Comparison between frequency of adverse events following immunization considered to be within the domain of nursing practice in the IS-AEFI and in the ESAEFI manual – Brazil – 2009.

In comparing the events from the IS-AEFI with those from the ESAEFI manual[5], we observed the use of terms or phrases that can generate confusion and ambiguity concerning the meaning of events and consequently hinder their assessment and the implementation of actions necessary to monitor and care for the patient, impairing even the reporting of events[2]. For instance, the manual uses three terms to describe the same injection-area event in distinct vaccines: redness, flushing and erythema, hindering a rapid and objective search for symptoms during care provided to an AEFI, because it may be erroneously interpreted and result in inappropriate reactions such as counter-indication of subsequent doses or replacing by another type of vaccine[10].

In relation to the interventions established by the ESAEFI manual[5] for events considered to be within the nursing practice domain, most were in accordance with what is recommended by the nursing literature. However, for events common to various vaccines, differences among practices were found, in addition to the fact that information is more complete in some cases than in others. We observed that the manual indicates only symptomatic medication and observation in the case of fever following yellow fever vaccination while the information *offer maternal milk and/or water* is added in the case of the tetravalent (DTP+Hib) vaccine.

Standardizing interventions according to the characteristics of the vaccine and AEFI is necessary as is adding other actions such as non-pharmacological care and instructions to return to the health service in case of any intercurrence. It is known that care provided during the initial clinical manifestations favors an early diagnosis and the necessary interventions being implemented, thus reducing the risk of complications. Lack of guidance to patients concerning the potential AEFI immediately after vaccination may be associated with severe events, especially in higher risk groups, as observed in the tetravalent vaccine, in which 75% of the events occur in the first six hours[14].

We especially take note of the interventions concerning AEFI related to the prevalence of fever (21%) and injection-area events (43.5%), in which programmatic errors are concentrated. Interventions in the case of fever indicated by the manual agree with those found in the nursing literature: rest in a cool environment, drink water and other fluids, keep breastfeeding, and use antipyretics recommended by the institutional routine. Such actions should be complemented with the inclusion of non-medication techniques such as ice packs, cold compresses and warm baths[18].

For most of the injection-area events, the manual[5] recommends interventions limited to epidemiological surveillance and medication therapy with little emphasis on other non-pharmacological actions, such as the use of cold compresses on the vaccine injection site to relieve pain and/or redness. Consequently, these interventions are not prescribed to the patient, nor is the one administering the vaccine so instructed[16].

Fever and injection-area events include situations related to programmatic errors, which most of the time, accrue from incorrect technique during preparation and application[5]. This fact is corroborated by the results of a study conducted in a health unit, which reported failures in the vaccination process involving lack of hand washing, incorrect dilution of immunobiological agents, wrong delimitation of the injection area, and rapidly injecting the vaccine content, leading to the onset of injection-area events such as irritation, inflammation, granuloma and tissue necrosis[16] in addition to warm local abscess (infection) caused by contamination.

A study addressing medication errors[19] estimates that only 25% of cases are reported and 40% of the events are not reported because of a negative connotation that is attributed to the incident, in addition to the reports required. It also states that underreporting is caused by: lack of knowledge concerning what a medication error really is, which interventions should be implemented, and concern over one's professional future.

The relationship between failure in the application of vaccine and programmatic errors is verified in AEFI related to the BCG vaccine, which represent 14.9% of the total events that occur within the nursing care domain (Table 1). These could be avoided because they are, in most cases, triggered by incorrect technique during the preparation of the vaccine and its application. Studies addressing errors in administering medication discuss nurses' lack of knowledge concerning basic issues related to the administration of medication, which increases the incidence of errors[17,19]. Concomitantly, health institutions do not show interest in identifying the causes of errors, since nursing management tries to solve the problem through punishment[17], which indirectly promotes underreporting.

Even though the AEFI that are within the nursing practice domain represent 35.4% of the IS-AEFI records, it is known that the data do not reflect the real situation due to operational failures, since the reliability of information depends on a network of knowledge, which includes the professional who makes the diagnosis and reports the EAFI to the individual who introduces the event into the information system[20].

In analyzing the professional interventions implemented in cases of AEFI, we verified that 20% on average were not in accordance with the recommendations of the NPI[10] Considering that 50% of technical knowledge in any field becomes obsolete within five years given the dynamics of science, new technology and rapid diffusion of information[17], we verify the urgent need to provide education in the domain of adverse events following immunization.

CONCLUSION

Currently, the need to ensure the quality of care delivery with the lowest risk possible in both the case of preventive and curative actions has highlighted pharmaco-surveillance, including the AEFI. Even though the IS-AEFI is a passive system with limitations, it enabled us to identify the profile of the EAFI in Brazil and, more importantly, to identify the possibility of nurses working in this domain, since this information is relevant not only for nurses but also to update standards that promote the safety and reliability of NPI and, consequently, maintain a high immunization coverage.

This study confirmed that nurses have a significant participation in this domain, though there are still gaps in their knowledge, which reflect on the incidence of evitable events. This problem can be solved through sensitizing managers and the nurses themselves concerning the need for human resources education, with the implementation of continuous education in health services. It is also worth noting the urgent need to sensitize nurses concerning their legal and ethical responsibility as coordinators of the nursing team, since immunization actions are performed by their team, under their supervision. It is extremely important that nursing schools, both vocational schools and universities, become involved in the discussion concerning EAFI and programmatic errors, so that the professionals they graduate have technical and scientific knowledge in order to occupy the wide space available in this domain for nursing practice.

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