

# The influence of nursing team's behavior in adverse event following immunization surveillance

*A influência das condutas da equipe de enfermagem na vigilância de eventos adversos pós-vacinação*  
*Influencia del comportamiento del equipo de enfermería en la vigilancia de eventos adversos posvacunación*

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## ABSTRACT

**Objectives:** to analyze the effects of nursing professionals' behavior in adverse event following immunization surveillance. **Methods:** a cross-sectional study of 384 participants who received vaccines. Information on vaccination history, administered vaccines and vaccination guidelines were analyzed. Descriptive and bivariate analyzes were performed using simple logistic regression (unadjusted *Odds Ratio*). **Results:** guidelines on events (PR=1.8; p=0.001) and conducts regarding their occurrence (PR=1.7; p=0.001) are activities that influence adverse event following immunization surveillance. More than half of participants did not receive guidance on the vaccines administered, the events and the conduct in case of an occurrence. Only 38.5% were instructed about the vaccines administered and 40.6% about adverse events. In the presence of an event, 29.9% reported that they sought services for notification. **Conclusions:** proper screening, providing guidance on vaccines and adverse events are essential preventive measures to strengthen adverse event following immunization surveillance.

**Descriptors:** Vaccination; Adverse Reactions; Primary Health Care; Watchful Waiting; Nursing.

## RESUMO

**Objetivos:** analisar os efeitos das condutas dos profissionais de enfermagem na vigilância de eventos adversos pós-vacinação. **Métodos:** estudo transversal, com 384 participantes que receberam vacinas. Analisadas informações de antecedentes vacinais, vacinas administradas e orientações sobre vacinação. Realizadas análises descritivas e bivariada, por meio de regressão logística simples (*Odds Ratio* não ajustada). **Resultados:** as orientações sobre os eventos (RP=1.8; p=0,001) e as condutas frente a sua ocorrência (RP=1.7; p=0,001) são atividades que influenciam a vigilância dos eventos adversos pós-vacinação. Mais da metade dos participantes não recebeu orientações sobre as vacinas administradas, os eventos e as condutas em caso de ocorrência. Somente 38,5% foram orientados sobre as vacinas administradas e 40,6%, sobre os eventos adversos. Na presença do evento, 29,9% relataram que procuraram os serviços para notificação. **Conclusões:** realizar triagem adequada, orientar a respeito das vacinas e dos eventos adversos são medidas preventivas essenciais para fortalecer a vigilância de eventos adversos pós-vacinação.

**Descritores:** Vacinação; Reações Adversas; Atenção Primária à Saúde; Vigilância Ativa; Enfermagem.

## RESUMEN

**Objetivos:** analizar los efectos del comportamiento de los profesionales de enfermería en la vigilancia de eventos adversos posvacunación. **Métodos:** estudio transversal con 384 participantes que recibieron vacunas. Se analizó la información sobre el historial de vacunación, las vacunas administradas y las pautas de vacunación. Se realizaron análisis descriptivos y bivariados mediante regresión logística simple (*Odds Ratio* no ajustada). **Resultados:** las guías sobre eventos (RP=1,8; p=0,001) y las conductas en cuanto a su ocurrencia (RP=1,7; p=0,001) son actividades que influyen en la vigilancia de eventos adversos tras la vacunación. Más de la mitad de los participantes no recibieron orientación sobre las vacunas administradas, los eventos y la conducta en caso de ocurrencia. Solo el 38,5% recibió instrucciones sobre las vacunas administradas y el 40,6% sobre los eventos adversos. Ante la presencia del evento, el 29,9% informó que solicitó servicios de notificación. **Conclusiones:** realizar un cribado adecuado, orientar sobre las vacunas y los eventos adversos son medidas preventivas fundamentales para fortalecer la vigilancia de los eventos adversos posvacunación.

**Descriptorios:** Vacunación; Reacciones Adversas; Atención Primaria de Salud; Espera Vigilante; Enfermería.

## INTRODUCTION

For a vaccine to be made available for the immunization of the population, it goes through a long process of development, until it obtains approval and sanitary registration<sup>(1)</sup>. After releasing the immunobiological for use, monitoring is maintained in order to identify and communicate reactions not observed during its development, such as the occurrence of adverse events following immunization (AEFI), due to the process of vaccine production and storage, the technique used in their administration and the characteristics of individuals vaccinated<sup>(2-5)</sup>.

AEFI, defined as any undesirable and unintentional event that an individual may develop when receiving a dose of an immunobiological agent, can be localized and/or systemic, severe and non-severe, differing in its intensity and severity and the type of demand for clinical treatment<sup>(4,6)</sup>. In most cases, localized AEFI can cause hyperemia, pain, erythema, edema, abscess, itching, among others, at the application site and are considered mostly non-severe events<sup>(7-8)</sup>. Among the systemic events, the most frequent are fever, diarrhea, anaphylaxis, persistent crying, convulsion and hypotonic hyporesponsive episode (HHE)<sup>(9-11)</sup>.

Surveillance and monitoring of these events, or any other issue related to vaccination, is essential so that the risks do not exceed the benefits already achieved by immunization programs<sup>(11-13)</sup>. In order to reduce the occurrence of events, it is important to emphasize professionals' role in AEFI surveillance. Knowledgeable health professionals are able to inform the population about the importance and benefits of vaccination, the possible risks and the presence of AEFI<sup>(14-15)</sup>.

Among the conducts performed in the immunization room, we highlight the reception, procedures prior to immunobiological administration, use of correct techniques for administration, guidance and clarification of possible doubts related to the administered products and specific guidance on AEFI<sup>(4)</sup>.

Welcoming is characterized by actions that favor the construction of a relationship of trust and commitment of users with the team and the health service and configures an attitude of inclusion<sup>(16)</sup>. Before administering the immunobiological itself, it is necessary to obtain information about individuals' health status, evaluate the user's vaccination history, carry out the identification and presentation of vaccines to be administered, provide guidance on the importance of vaccines and their contraindications, and schedule the necessary returns. It also includes activities regarding immunobiological verification, their characteristics, batch number, expiration date, route of administration and dosage and registration in the immunization information system<sup>(16)</sup>.

As for the specific guidelines on AEFI, it is important to explain to the vaccinated what the AEFI are, inform about the possible occurrence of these events, their frequency, care to be taken and thus guide the user to return to the health unit, in case of any adverse event<sup>(13)</sup>.

In the presence of AEFI, professionals must carry out notification and investigation that contributes to health surveillance and leads to a safe vaccination practice<sup>(17)</sup>. Studies assume that carrying out vaccine screening, continuous training of vaccinators and health education are specific measures to increase AEFI notification and to ensure vaccination quality and safety<sup>(10,18-20)</sup>.

The literature points to underreporting of AEFI<sup>(8,21-23)</sup>; however, there is no evidence on the effects of the conducts performed

in the immunization room that can reduce underreporting. At a time when the Covid 19 pandemic has exposed several concerns about the quality and safety of immunobiological agents, as well as the importance of AEFI surveillance, epidemiological studies on this topic are important and necessary.

It is assumed that the behaviors adopted by nursing professionals in immunization services have an effect on the notifications of adverse events.

## OBJECTIVES

To analyze the effects of nursing professionals' behavior in AEFI surveillance.

## METHODS

### Ethical aspects

This project is part of a larger project entitled "*Eventos adversos pós-vacinação: um estudo de coorte*", approved by the Institutional Review Board of the *Universidade Federal de São João del-Rei* (IRB/UFSJ).

### Study design

This is a cross-sectional epidemiological study guided by the STROBE tool, developed through a survey in PHC, in a regional hub municipality of Minas Gerais.

The study had as its setting the immunization services inserted in 32 units of Family Health Strategy and 11 Traditional Health Units. These units are distributed in 10 health regions: Central, Northwest, West, Southeast, Southwest, Northeast, Far Northeast, Far Northwest, Far Southeast, Far Southwest<sup>(24)</sup>. For this study, the health regions of the city were grouped considering their proximity, resulting in 6 major health regions. Subsequently, six health units were selected by simple cluster sample, stratified by the six health regions. The units were selected considering their strategic location and due to their large flow of assistance, which ended up favoring the opportunity to find users available for the survey. Participants were distributed proportionally to the size of each established health region.

To calculate the sample size, the criteria<sup>(25)</sup> were adopted using the estimated proportion of 50% for a given characteristic, a value that provides the largest sample size for a finite population ( $n=187,030$ ), setting the significance level at 5% (alpha or type I error) and the sampling error at 5%. Applying a rate of 11% to recompose the sample, assuming that 10% of it will be lost during the research, the final sample size was at least 384 participants.

### Population

The survey included 384 participants who received vaccines in selected immunization services and who are part of the target audience of the vaccination schedules contemplated by the Brazilian National Immunization Program (PNI - *Programa Nacional de Imunizações*) (children aged 0-10 years accompanied by their parents, adolescents between 11 and 19 years old, accompanied or not of parents, pregnant women, adults, elderly people with preserved cognitive capacity). The inclusion of the entire target

audience covered by the PNI is justified, as the AEFI is an uncommon outcome among those vaccinated. As exclusion criteria, all participants of any age who attended the services to receive special immunobiological agents due to previous AEFI were considered.

### Study protocol

Data collection took place from September 2017 to June 2018, within the primary health care units selected for the survey. A semi-structured questionnaire was used, adapted from the AEFI notification/investigation form of the Brazilian Epidemiological Surveillance System. Some fields on the form (Past Pathological History and Complementary Laboratory Information) were not used in this research and therefore were excluded from the questionnaire used in the survey. The questionnaire covers a set of items related to sociodemographic identification (gender, age group, ethnicity); health information and vaccination history (self-reported pre-existing diseases, self-reported known allergies, use of analgesics/antipyretics), information about vaccines (administered vaccines, number of doses administered, type of adverse event), and guidance on vaccination (guidance on administered vaccines; guidance on AEFI; guidance on conduct in the event of AEFI). As for the presence of AEFI, verbal information on the occurrence of the event was considered, with onset of symptoms within 72 hours, the period with the highest prevalence of the occurrence of the adverse event<sup>(4)</sup>. At the time of data collection, the researchers identified the professional category that performed vaccination at the health unit. To avoid possible information and selection biases, training of researchers was carried out on the application of the instrument and selection of respondents according to the sample calculation.

### Analysis of results, and statistics

In data analysis and treatment, the variables present in the questionnaire were analyzed using Stata version 14.0. For all analyses, a significance value of 5% was adopted. The relative frequency distribution was calculated for categorical variables and median for the age group variable. Bivariate analysis was conducted to investigate the association between the variables present in the instrument and the status of AEFI presence, using simple logistic regression (Odds Ratio value - unadjusted OR).

## RESULTS

The study was conducted with 384 participants, aged between 0 and 83 years (median 28.5 years), with 54.4% being female and 52.6%, white. Regarding the most mentioned pre-existing self-reported diseases, it was observed that heart diseases (18.5%) were the most frequent, followed by diabetes and lung diseases (5.7%). And 8.4% reported drug allergy and 1.8% lactose allergy, in addition to the use of analgesics/antipyretics (3.1%) (Table 1).

On vaccination activities, it was identified that most vaccines were administered by nursing assistants/technicians 97.7% and the others by nurses and undergraduate nursing students. Among the interviewees, only 38.5% received guidance on the vaccines administered, 40.6% received guidance on possible AEFI and 30.5% guidance on conducts in the event.

**Table 1** - Characteristics of participants vaccinated in immunization services, Divinópolis, Minas Gerais, Brazil, 2017 - 2018

Variables	n	%
Sex		
Female	209	54.4
Male	175	45.6
Age group		
< 1 year	48	12.5
1 to < 7 years	90	23.4
7 to < 20 years	27	7.0
20 to <60 years	155	40.4
> or = 60 years	64	16.7
Ethnicity		
White	202	52.6
Mixed ethnicity	132	34.4
Black	47	12.2
Yellow	3	0.8
Self-reported pre-existing diseases		
Diabetes	26	6.8
Heart diseases	71	18.5
Pulmonary diseases	22	5.7
Other diseases	28	7.3
Self-reported known allergies		
To medication	32	8.4
To lactose	7	1.8
Use of analgesic/anti-thermal		
No	372	96.9
Yes	12	3.1

Regarding the number of vaccines received, 62.2% received only one vaccine, 18.5% (n=71) received two vaccines, 12.8% received three and 6.5% received four or more vaccines. The most used route of administration was intramuscular, (87.8%) followed by subcutaneous (24.5%), oral (9.6%) and intradermal (3.6%).

During the research period, 628 doses of vaccines were administered, with Influenza (29.7%), Hepatitis B (28.6%) and combined adult (23.7%) being the most administered, followed by measles mumps and rubella (11.5%), yellow fever (10.7%), among others (36.3%).

Regarding AEFI occurrence, 33.1% of those vaccinated self-reported the presence of some type of adverse event, with local events, pain, erythema and edema, being the most mentioned (Table 2). Fever was the most reported systemic reaction; of these, only 29.9% sought health services, including primary care units, Emergency Care Units, hospitals and offices.

**Table 2** - Self-reported post-vaccination adverse events by vaccinated participants, Divinópolis, Minas Gerais, Brazil, 2017 - 2018

Variables	n	%
Type of reported reactions		
Localized events	71	55.9
Systemic events	17	13.4
Concomitant localized and systemic events	39	30.7
Localized reactions		
Pain	90	23.4
Erythema	30	7.8
Edema	22	5.7
Tightening	14	3.6
Systemic reactions		
Fever > or = 37.5°C	23	6.0
Headache	9	2.3
Persistent crying	6	1.6
Nausea	4	1.0
Diarrhea	4	1.0
HHE (diagnosed by doctor)	2	0.5

HHE - hypotonic hyporesponsive episode.

**Table 3** - Percentage distribution of self-reported adverse events following immunization according to sociodemographic characteristics and health history of vaccinated participants, activities performed in immunization services and applied vaccines, Divinópolis, Minas Gerais, Brazil, 2017 - 2018

Variables	%	Self-reported AEFI (%)		rOR <sup>1</sup> (IC95%) <sup>2</sup>	p value <sup>3</sup>
		Yes	No		
Sex					
Female	54.4	34.4	65.6	1.0	0.531
Male	45.6	31.4	68.6	0.9	
Age group					
< 1 year	12.5	45.8	54.2	1.2	
1 to < 7 years	23.4	33.3	66.7	0.9	0.001
7 to < 20 years	7.0	40.7	59.3	1.1	
20 to < 60 years	40.4	37.4	62.6	1.0	
≥ 60 years	16.7	9.4	90.6	0.3	
Ethnicity					
White	52.6	33.2	66.8	1.0	0.967
Non-white	47.4	33.0	67.0	1.0	
Self-reported pre-existing diseases					
No	31.3	23.3	76.7	1.0	0.006
Yes	68.8	37.5	62.5	1.6	
Use of analgesic/anti-thermal					
No	96.9	32.3	67.7	1.0	0.059
Yes	3.1	58.3	41.7	1.8	
Guidelines on administered vaccines					
No	78.1	35.3	64.7	1.0	0.075
Yes	21.9	25.0	75.0	0.7	
Guidelines on AEFI					
No	59.4	24.6	75.4	1.0	0.001
Yes	40.6	45.5	54.5	1.8	
Guidelines on conducts in AEFI occurrence					
No	69.5	27.0	73.0	1.0	0.001
Yes	30.5	47.0	53.0	1.7	

<sup>1</sup>rOR - Raw Odds Ratio; <sup>2</sup>95%CI - 95% confidence interval; <sup>3</sup>p-value - probability of statistical significance set at  $p \leq 0.05$ ; AEFI - adverse events following immunization.

Regarding the time of occurrence of adverse reactions, 20.5% occurred in the first hour after vaccine administration; 40.2% occurred after one hour; and 39.3% in more than 12 hours, according to participants' reports.

In the bivariate analysis, an association was identified between guidelines on AEFI ( $p < 0.001$ ) and guidelines on conducts in AEFI occurrence ( $p < 0.001$ ) with self-reported AEFI. Receiving guidance on adverse events and conducts to be followed in the presence of this, increases the chances of identification of AEFI by vaccinated individuals. Age group ( $p < 0.001$ ) and self-reported pre-existing diseases ( $p < 0.006$ ) were also associated with occurrence of self-reported AEFI. Children under one year are 20% more likely to have AEFI compared to adults between 20 and under 60 years of age. Participants with self-reported pre-existing diseases are 1.6 times more likely to have AEFI compared to those without diseases (Table 3).

## DISCUSSION

As observed in the results, the conducts adopted by professionals operating in immunization rooms greatly influence AEFI surveillance. There is evidence that guidelines on the importance and safety of immunobiological agents, contraindications for vaccination, types of adverse events and conducts in the presence of events are essential activities for AEFI surveillance<sup>(26-27)</sup>. However, our findings indicate that more than half of participants did not receive guidance on the vaccines administered, the AEFI and the conducts in the occurrence of these events.

Receiving guidance on AEFI and conducts to be followed in the presence of the event increases the chances of identifying some type of reaction after vaccine administration. This finding shows that when well guided, users are more closely related to signs and symptoms and follow the guidance of professionals to return and/or inform the services about possible adverse events. This communication is necessary for notification and investigation of the case, contributing to the reduction of AEFI underreporting<sup>(28)</sup>. From the moment the user receives guidance on the vaccine applied and the adverse events caused by it, these become more adept at vaccination<sup>(17,27,29)</sup>.

Fear of adverse events caused by vaccines is evident in the population and the fear of these reactions is an important factor that influences the decision to receive vaccine or not<sup>(12,17,30)</sup>. Therefore, the nursing team needs to build care practices and guidance in immunization rooms, since these guidelines received in health services have great influence on vaccinated individuals' conduct<sup>(31-32)</sup>. Carrying out an adequate assessment to verify possible contraindications and the need to postpone or not a vaccine, use the correct technique of conservation, handling and administration of the immunobiological, provide guidance about vaccines and AEFI are specific measures that prevent AEFI and contribute to the adherence of users to the vaccination calendar<sup>(14,26-27)</sup>.

However, it is assumed that the lack of guidance, as seen in our results, is due to a set of factors that permeate insufficient training of professionals for care in the immunization room, lack of supervision of immunization activities by nurses and overload of services in health units<sup>(33)</sup>. Professionals who are sure of their knowledge are able to guide those vaccinated about conducts in the face of AEFI occurrence<sup>(34)</sup>.

Therefore, it is very important that nurses increase supervision in the immunization room and seek alternatives that generate safe care practices for users<sup>(35-36)</sup>. Continuing education, for example, is a strategy that enables professionals' work, in a process of significant learning to aggregate knowledge and update immunization practices<sup>(26,37)</sup>.

As observed in our study, the informed user has more possibility to identify and report an AEFI to health services, which decreases underreporting. The events most reported by the participants of this research were pain, erythema and edema. Localized reactions are the most frequent events, and may be a reaction of the body to vaccine elements that induce the inflammatory reaction to aid the immune response. They can occur between two and 48 hours, being self-limited, with benign evolution, and only symptoms<sup>(10-11,38-39)</sup> must be followed and treated.

Children younger than one year were the ones most likely to have AEFI according to the results of this study. This trend may be related to the still immature immune system and the higher concentration of vaccines offered and doses applied to this age group<sup>(10,40)</sup>. Another factor that can contribute to the high number of notifications is that children under one year of age return more often to health units, either to be vaccinated or to monitor their growth and development, opportunistic research on the occurrence of adverse events after vaccination<sup>(40)</sup>.

On the other hand, it was observed in this study that participants with self-reported pre-existing diseases are more likely to have adverse events. This finding requires further studies to analyze the relationships between comorbidities and the presence of AEFI. Patients with certain previous pathologies, especially those affecting the immune system, are more susceptible to adverse events after vaccination<sup>(4)</sup>.

## Study limitations

The study presents as limitations AEFI self-report occurrence due to lack of accuracy of information, which can cause bias in the results. To minimize this limitation, only one in which symptoms were approached by a suspected case of AEFI or diagnosed by a medical professional was accepted as an adverse event. Another limitation was the inclusion of all age groups in the identification of an event, making it difficult to compare the results with scientific literature, since most AEFI happens in children and the publications are more comprehensive for this target audience.

## Contributions to nursing, health, and public policies

The study contributes to highlight the importance of nursing professionals' conduct in the immunization room, such as vaccination screening and guidelines for occurrence and conducts through the presence of AEFI. The performance of such conducts may impact on adverse event surveillance and consequently on underreporting reduction.

## CONCLUSIONS

The conducts performed by nursing professionals such as adequate screening, guidelines on vaccines and adverse events and actions regarding the occurrence of some AEFI influence AEFI surveillance, an indispensable tool for the control of vaccine, professional and user safety.

Our findings may provide support for implementation of good practices in immunization services.

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