

## NURSING PROFESSIONAL KNOWLEDGE ABOUT THE NOTIFICATION OF ADVERSE EVENTS POST-VACCINATION

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### ABSTRACT

The occurrence of adverse events post-vaccination is a situation experienced by nursing professionals who work with immunization. The knowledge about the notification and adoption of appropriate measures before the cases, consists of a instrument to improve the quality of care. Objective: to analyze the Nursing professional knowledge about the adverse events after vaccination. It's a descriptive study, with a qualitative approach conducted in five Basic Health Units from Feira de Santana, Bahia. The data collection occurred by means of semi-structured interviews with fifteen professionals of the nursing team, eight nurses and seven technicians, between April and August 2011. The data were analyzed through the technique of Contents Analysis, being developed two categories of analyses: "Criteria for notification of adverse events post-vaccination" and "Professional responsibility by the notification of adverse events post-vaccination". The ethical aspects were respected. Just the events post-vaccination were notified, considered more serious, being sub-notifications and doubts about who is the professional responsible for the notification. It's necessary to practice the Nursing professionals who work in the immunization area, because the notification of adverse events post-vaccination is a premise in dangers prevention and in the care and treatment of involved.

**Keywords:** Immunization. Notification. Nursing.

### INTRODUCTION

The progress of biotechnology broadened the ability of identification of etiological agents of unknown disease and propitiated the development of vaccines of new generation, more effective and potentially safe. However, the occurrence of adverse events post-vaccination (AEPVs), which are understood as harms to health arising from vaccination, is not discarded, whereas vaccines are pharmaceuticals compounds by microorganisms, adjuvants, stabilizers and conservative substances<sup>(1,2)</sup>.

The AEPVs can be expected or unexpected. The expected are those relatively trivial, arising from the nature and characteristics of immune-biologicals. The unexpected comes from changes related to product quality as contamination of lots or improper content of endotoxin in certain vaccines<sup>(3)</sup>.

The post-vaccination adverse events reported

in the literature are: BCG vaccine (ulcer greater than 1 cm; hot or cold abscess; lymphadenopathy: voluminous axillary inguinal bubo, supra or infra-clavicular); Hepatitis B and Pentavalent (abscesses, intense local reactions, fever, headache, dizziness, fatigue and gastrointestinal discomfort); DTP (irritability, persistent crying, encephalopathy, intense local reactions); Poliomyelitis oral vaccine (motor deficit and flaccid paralysis) and Inactivated (intense local reactions, hyperesthesia, anaphylaxis, seizures and sudden deaths); Rotavirus (nausea, vomiting, abdominal pain, intense and persistent or abdominal distension); Tetra-viral (fever, seizures, anaphylaxis, local reactions, meningitis, herpes zoster, encephalitis, ataxia, multi-form erythema, Stevens-Johnson Syndrome, pneumonia, thrombocytopenia and Guillain-Barre Syndrome); Yellow Fever (fever, local pain and headache)<sup>(3,4)</sup>.

Study<sup>(2)</sup> performed in the Reference Center of Special Immune-biologicals (RCSI) of the

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municipality of Campo Grande has shown that the main adverse events reported were: pain, redness and heat (22.4%), indurate (18.4%); fever less than or equal to 39.5° (10.5%); in addition, appeared in smaller percentages respectively: hypotonic – hypo-responsive episodes, skin rash, lump, headache, febrile convulsion, hot abscess, myalgia, cold abscess, fever greater than or equal to 39.5°, difficulty of walking, Arthus reaction, arthralgia.

Although expected, some AEPVs may have a negative effect on the population causing fear of the event, larger than having the disease. This thought is worrisome, because with no continuity of the vaccination schedule can be resurgence of diseases already controlled. This fact justifies the actions of Epidemiological Vigilance at health services geared towards the analysis of possible risks in the use of an immune-biological, which requires the professional working in immunization room – nurse and nursing technician, technical and scientific knowledge in order to assure the population quality and the reliability of administered vaccines<sup>(5)</sup>.

In this context, the National Immunization Program (NIP) implanted in 1992 the System of Epidemiological Vigilance of Adverse Events Post-vaccination (EV AEPV) to notify, investigate, monitor and standardize the appropriate conducts before the occurrences. Besides, elaborated manuals and protocols in order to train healthcare professionals to attendance, notification and investigation of cases of AEPVs. From the year 2000, the Information System of Epidemiological Vigilance of Adverse Events Post-vaccination (IS-AEPV) was impacted in an attempt to accelerate the analysis of reported cases and broaden the variables of the application forms used in the process<sup>(3, 5)</sup>.

In July 2005, the Ordinance n° 33, determined the compulsory notification of all suspected cases of AEPVs, allowing the EV AEPV to get a greater knowledge about these problems and, consequently, adopt appropriate interventions<sup>(3)</sup>. Thus, the vaccination-related events are logged in the application form of Notification and Investigation of Adverse Events post-vaccination, filled by health professional where the person received the immune-

biological. After filling, the application form is forwarded to other instances in local level, state and national and the client is forwarded to the customer service and follow-up according to the events presented<sup>(3)</sup>.

Despite the broad propagation of the IS-AEPV, the sub-notification, the poor quality of information and insufficient research are still frequent, hindering a specific conduct on the cases, favoring the disrepute of vaccination by the person who is vaccinated and health professionals own generating harm risks to health of the client<sup>(5, 6)</sup>.

Thereby, the notification of AEPVs to the National System of Vigilance of Adverse Events post-vaccination and frequency of training of health teams are of the utmost importance for it to be viable the development of research protocols and, consequently, to guarantee the quality and reliability of immune-biologicals<sup>(2)</sup>.

Another aspect that must be considered is the Family Health Strategy, a policy of improving the quality of Basic Care and materialization of the principles of the Unified Health System. Their practices are intended to promote health, prevent and cure diseases, to rehabilitate and develop the individual and collective leadership, including immunization in these respects.

Study<sup>(7)</sup> performed about the knowledge and practice of nursing assistant in immunization room, showed the importance of the interaction of professionals working in the Family Health Strategy, specifically of the nurse and nursing technique which develop activities in the immunization sector, and their knowledge and availability to provide guidance on the immune-biologicals, its effects and care when the AEPVs happen.

Given the above, this research had as its guiding question: "Which is the knowledge of nursing professionals about notification of adverse events post-vaccination?" and aimed to analyze the knowledge of Nursing professionals about the notification of adverse events post-vaccination.

## METHOD

Descriptive study of qualitative nature held in five Basic Health Units (BHU) of the municipality of Feira de Santana, Bahia. The

subjects were fifteen Nursing professionals, being eight nurses who acted in vaccine-room as supervisor and seven technical in Nursing acting exclusively in the industry, regardless of the time of performance.

The data were collected in the period from April to August 2011, through semi-structured interview. This kind of interview combines close and open questions that allow the interviewee to expatiate about the proposed topic, without answers or prefixed conditions by the searcher<sup>(8)</sup>.

The interviews were previously scheduled in the days, times and locations chosen by the professionals, usually in private room at BHU, in the afternoon. Were recorded with the aid of MP4 and had 10 to 30 minutes in duration. An interviewed did not accept the use of recorded and her interview was manually registered.

The collection instrument was an interview script composed of two parts: the first contained the demographic data of the participants and the second consisted of issues that attend the objective of the original study. In this article, will be analyzed the aspects involving only the question: Talk about the adverse events post-vaccination that you've already notified or would notify for the Epidemiological Vigilance.

The data were analyzed using the Content Analysis technique, constituted of three phases: a) the pre-analysis, which consisted in the organization of the material from the reading and the determination of registration units (keywords), units of context and cuttings; the decoding and construction of categories, as well as the more general theoretical concepts that guided the analysis; it was observed that the word notification was accompanied of the conception of serious adverse event post-vaccination, with examples of situations in which these occurred and were notified. It was noticed that not all adverse events were notified, some notifications were aimed at certain professionals and not a routine of all of them. In some cases there was afraid to notify an event resulting in sub-notification. With these two categories of analysis were elaborated: "Notification of adverse events post-vaccination" and "Professional who notified that the adverse events post-vaccination occurred"; b) The second phase - material analysis meant the moment that the *corpus* of information was

undergone to an in-depth study; (c) In the last phase, during the processing of the results, there was the unveiling of the latent content<sup>(8)</sup>.

It was opted for the qualitative method, because this is concerned with the universe of meanings, beliefs, conceptions that pervade the human relations that cannot be quantified<sup>(8)</sup>; the study of the knowledge about notification of adverse events post-vaccination is inserted in this context, since the participants in the survey did not expressed only the scientific conceptions about the topic, but subjective aspects that influenced in their daily practices.

During all phases of the study, was considered the Resolution n° 196/96, today repealed and substituted by 466/2012, of the National Health Council, which deals with the research involving humans beings. Both incorporate references of bioethics, such as autonomy, non-maleficence, beneficence, justice and equity, guaranteeing the rights and preventing damage to the participants of the survey. The risks of the study were related to the possibility of embarrassment in answering any questions or don't know to answer them, but this risk was minimized with anonymity, privacy and confidentiality of information. In this sense, it was used the NUR01 and NUR15 codes to refer to lines according to the order of interviews.

The project was approved by the Research Ethics Committee (REC) of the State University of Feira de Santana – Bahia, under Protocol No 184/2011, CAAE 002.0.059.000-11.

## RESULTS AND DISCUSSION

Study participants were all female, being eight nurses and seven nursing techniques, aged between 36 to 46 years. As regards to the ongoing participation of updates and training on immunization, almost all stated to have performed it, only a professional did not held it. The nurses ' training occurred in 2010 and nursing techniques in 2011. In the area of immunization being a complex theme and constantly changing due to the research and introduction of new immune-biologicals, in the vaccination calendar, becomes relevant the permanent education of these professionals to ensure that their actions with the clientele is efficient and safe.

Therefore, Article 14° of the Code of Ethics of Nursing Professionals (CENP) brings that these workers should enhance technical knowledge, scientific, ethical and cultural, to the benefit of the person, family and community and development of the profession<sup>(9)</sup>.

It is added that the knowledge of professionals must cover the composition of vaccines, conservation, routes of administration, age of onset, number of doses and intervals between doses, adverse events and their conduct, availability to explain to the client all these aspects, clarify doubts, in addition to practical training. In this context, the procedures related to the dilution of different vaccines are included, read and filling out the vaccination book and correct marking of the return.

Study<sup>(10)</sup> about the knowledge of nursing professionals in the conservation of vaccines showed flaws with regard to proper temperature, defrost of the refrigerator and mistakes as to the time of use of the vaccine against yellow fever, pointing the importance of investment in education of these professionals and their subsequent improvement, since vaccination norms are in constant change and the introduction of new immune-biologicals in the vaccine calendar is frequently.

It stresses that, in any area, knowledge can become obsolete very quickly, due to the dynamism of science, the emergence of new technologies and appearance of new technologies and propagation of information through the media, facts which show the need for frequent update of immunization professionals.

Another study about vaccination of premature children showed flaws in the guidelines given to responsible regarding the age of onset of vaccines, because now the professionals considered the weight of the baby, now age; and in filling out the immunization booklet, highlighting wrong age in the administration of the vaccines against poliomyelitis, break between doses and incorrect return or not convoked. These occurrences let customers insecure and expose children to immune-preventable diseases due to the delay of their vaccination schedule<sup>(11)</sup>.

Soon, the permanent education of the professionals responsible for immunization is an

initiative with the potential of change required, so the Nursing staff can ensure the quality of vaccines available to the population, as well as exercise their activities with increased security and free of technical flaws<sup>(10)</sup>.

### **Criteria for notification of adverse events post-vaccination**

The notification of AEPVs aims to optimize the analysis of the cases, to promote the consolidation and analysis of AEPVs data occurring in real time, and enable continuous measurement of safety of a certain vaccine in the population, providing to professionals, update information about adverse events<sup>(3, 12, 13)</sup>.

Most local or systemic events is mild and self-limited such as fever, local hyperemia, especially after application of tetra vaccine, DPT and hepatitis B, which should be notified to the customer by the vaccinator, as well as interventions to be taken according to the event<sup>(5)</sup>.

Thus, all vaccinated people who submit adverse events and return to the health unit spontaneously should be evaluated in order to check whether the event is foreseen, reportedly in literature or in the manual of AEPVs or notify it and investigate it. The following reports show that considered serious events were reported by the professional who answered the client.

We already notified the Arthus reaction. (NUR07)

We notified unusual reactions, a hyperthermia above 39° we already considers for notification, in this case, if it exists a syndrome [...], there are people who have reactions of Guillain Barre syndrome, so in these cases, we notify to the Secretariat. (NUR 04)

The Arthus reaction is characterized by emergence of pain, edema and redness at the local of application of the vaccine and may extend to the member. The peak of evolution lies between four and six hours, being self-limited, benign and progressing well after a few days. In some cases, the infiltrator reaches the deep tissues and may cause necrosis. There is the emergence of vesicles with serosity and pustules that develop into scabs that, when fall off, leaving a deep ulcer<sup>(3)</sup>. In this case, the vaccinated person should be forwarded to follow-up with infectious physician in order to receive specific treatment.

Another serious event cited is the Guillain Barre Syndrome, which is characterized by an acquired neuropathy, peripheral, acute ascending with albuminous-cytological dissociation in the liquor, i.e. it happens the paresthesia, a motor deficit, and consequent paralysis<sup>(3, 14)</sup>. So, faced with the gravity that can be referred to the adverse event, is emphasized the need for dialogue with vaccinated people and, when children, with parents or guardians and with a detailed history about vaccine background and reactions to each dose, as well as the provision of guidance about what is expected/unexpected so that the AEPV can be identified and treated quickly.

Some reports have shown that light events usually are not notified.

We generally notify systemic reactions, reactions that are out of the ordinary [...], because there are those that we consider common, for example, a headache. (NUR 04)

[...] severe adverse events schedule then I notify, the ideal is to notify all [...]. (NUR 07)

In the second report it is verified the ambivalence as the interviewed recognizes that must notify and did not notified. This demonstrates that the sub-notifications happen often because the nursing professionals, mostly technicians who work in vaccine, they think the symptoms presented by the child are mild, not requiring notification. It is added that, the non-notification of an adverse event could compromise the health of both the customer who presented symptoms as others, in the case of a problem of greater reactogenicity of administered immune-biological.

Study about medication errors showed the concern to involve the team in the notification of occurred events, discussing their causes in formal meetings, so that preventive actions were discussed and deployed increasing client security<sup>(15)</sup>.

Thus, it is considered that the solution to the problems of preventable adverse events is not simple, but its analysis allows to recognize the weaknesses of the sector and propose actions aimed at prevention, being from the revision of the working process, training of professionals or creation of protocols, maximizing the benefits of immunization to the customer and minimizing the damage.

In this context, it is clear that the reason for the notification is recommended in cases of AEPV that return to health services consists in the perception and control of outbreaks, being considered outbreak, the increased occurrence of an injury to health above expected levels<sup>(16)</sup>.

The appearance of an outbreak may indicate the presence of a lot more reactogenic of vaccines or avoidable errors in storage and dilution, and the technique of application, resulting in contamination, there the need to notify cases that return to the unit with a complaint regarding any symptoms for that decision, as to its use or suspension, be taken safely<sup>(3, 17)</sup>. It should be noted that the preferred notification of cases of greater gravity not only decreases the sensitivity of surveillance, which is the detection of all true cases of AEPV but also its representativeness<sup>(18)</sup>.

In Brazil, when the AEPVs cases are confirmed, will be registered in the IS-AEPV and forwarded monthly to the NIP. The electronic storage of these data aims to elaborate standards for the identification and standardization of conducts in front AEPV cases; to analyze the information nationwide relating to AEPV; to identify the lots more reactogenic and decide about the best action to be taken; in addition to maintaining the reliability of immune-biologicals used in the NIP by the population and health professionals<sup>(3, 18)</sup>.

### **Professional responsibility for notification of adverse events post-vaccination**

It is the responsibility of the professionals to be attentive not only to the application of immunobiologicals, but to the notification and follow-up of expected and unexpected adverse events, ensuring the vaccinated person a Nursing care free of damage due to malpractice, negligence and recklessness as calls for the Code of Ethics of the profession<sup>(9)</sup>.

It is observed that the concern with the notification of adverse events is not exclusive of the Brazilian health system; study points out that in Spain the health authorities have emphasized the commitment of health care professionals to notify the adverse reactions to drugs and vaccines.

Healthcare professionals should report adverse the adverse effects that may be related to the administration of a medicament. So they have the

system of spontaneous Notification of Adverse Reactions, or "Yellow card", which consists of a prepared form for collecting the notifications of suspected adverse reactions. It relies on the voluntary reporting by health professionals, of any suspected adverse Reaction observed in relation to the use of drugs. This form contains all the information necessary to analyze each suspected adverse reaction (17:136). Health professionals must communicate the solution that adverse could be in relation to the administration of a medicine. For this have the Notification system of Spontaneous adverse Reactions "Yellow card", which consists on a prepared form to the notifications of suspected reactions adverse. If based on the voluntary notification, by health professionals, any suspicion of reaction observed Adverse in relation to the use of medicament. In this form it gathers all the information necessary to analyze each adverse reaction suspected (17:136).

Accordingly, in Brazil, is not only the Nursing professional who must carry out the notification of AEPVs, but any healthcare professional with high school and higher education; however, the investigation of cases should only be performed by the higher-level professional<sup>(19)</sup>.

It was verified that some respondents unaware that high school professionals can also notify AEPVs. As noted below, a BCG vaccine adverse event was not notified because the nurse of the period was not present at the time the child attended the unit.

[...] at the time the mother had been here, had no nurse so it wasn't notified. (NUR 15)

[...] the employee believes that is a lightweight frame and end up not passing to the nurse make the notification. (NUR 07)

The loss of the opportunity of notifying adverse events post-vaccination becomes a problem that spans not only the child who stops being properly attended and accompanied by a team of competent health professionals, but also brings about a problem of public health since the symptoms are not being tallied, making it impossible for a reliable evaluation of the reactogenicity of the applied vaccines.

This occurrence showed that there was no proper care of the customer, because there was no notification, neither the return orientation to the unit in the time that had a nurse. It should be

noted that is the nurse responsible, the ethical and legal coordination of nursing staff and, consequently, the supervision of immunization activities carried out, however, in daily practice, one realizes that a professional performs a large number of administrative and vigilance activities in its work process, away from the direct assistance in vaccine, therefore, more detailed monitoring of adverse events.

In this context, it stresses that the permanent education of the Nursing staff can be an instrument of improvement in adverse event notification process post-vaccination. The search for knowledge is a commitment of each professional, but the managers involved in the National Immunization Policy should promote opportunities for the permanent education in health. The service learning start from the problematization, participation and critical reflection through educational spaces in multi-professional meetings, as well as through technical and scientific update activities<sup>(20)</sup>.

## FINAL CONSIDERATIONS

It was noticed that there is gap in the knowledge of Nursing professionals with regard to the notification of adverse events post-vaccination, because they considered the need to notify only the serious events. The training of professionals is one of the strategies proposed by the NIP, policy whose theoretical structure shows satisfactory, but in implementation of the actions related to immunization, still faces challenges, ranging from the sufficient supply of immune-biological, permanent education in service until notifications of AEPVs in some localities. The positive impact that the program has achieved over the years in preventing immune-preventives diseases could be extended from these three aspects.

Therefore, it is suggested the periodic training of professionals who develop activities in the area of immunization, due to the need for competent performance in favor of the improvement of public health services and the provision of a coherent assistance to individual needs when faced with cases of adverse events post-vaccination.

It was still noted in this study, a mistake regarding the responsibility of these

professionals in the notification process, since some reported that this procedure rests solely with the nurse, demonstrating that, although acting on vaccine room, still unaware of the magnitude of their actions.

Being the nurse, the professional responsible for the Nursing staff and qualified

for epidemiological vigilance, is essential to its exclusive presence in the operating room vaccine so that it can supervise the whole process of work involving the immune-biological and promote continuing education with the technicians, as well as act on prevention, occurrence and notification of adverse events.

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## CONHECIMENTO DOS PROFISSIONAIS DE ENFERMAGEM SOBRE A NOTIFICAÇÃO DE EVENTOS ADVERSOS PÓS-VACINAIS

### RESUMO

A ocorrência de eventos adversos pós-vacinais é uma situação vivenciada por profissionais de enfermagem que atuam na área de imunização. O conhecimento acerca da notificação e adoção de medidas oportunas diante dos casos consiste em um instrumento para melhoria da qualidade da assistência. Objetivo: analisar o conhecimento dos profissionais de Enfermagem sobre a notificação de eventos adversos pós-vacinais. Estudo descritivo de abordagem qualitativa realizado em cinco Unidades Básicas de Saúde de Feira de Santana, Bahia. A coleta de dados ocorreu por meio de entrevistas semiestruturadas com quinze profissionais da equipe de enfermagem, oito enfermeiras e sete técnicas, transcorrendo entre abril e agosto de 2011. Os dados foram analisados mediante a técnica de Análise de Conteúdo, sendo elaboradas duas categorias de análise: "Critérios para notificação de eventos adversos pós-vacinais" e "Responsabilidade profissional pela notificação dos eventos adversos pós-vacinais". Os aspectos éticos foram respeitados. Notificaram-se apenas os eventos pós-vacinais considerados mais graves, havendo subnotificações e dúvidas acerca de quem é o profissional responsável pela notificação. É necessário treinar os profissionais de Enfermagem que atuam na área de imunização, pois a notificação de eventos adversos pós-vacinais é uma premissa na prevenção de agravos e no cuidado e tratamento dos envolvidos.

**Palavras-chave:** Imunização. Notificação. Enfermagem.

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## CONOCIMIENTO DE LOS PROFESIONALES DE ENFERMERÍA SOBRE LA NOTIFICACIÓN DE EVENTOS ADVERSOS DESPUÉS DE LA VACUNACIÓN

### RESUMEN

La ocurrencia de eventos adversos post-vacunación es una situación vivida por profesionales de enfermería que trabajan en el área de la inmunización. El conocimiento acerca de la notificación y adopción de medidas adecuadas frente a los casos consiste en un instrumento para mejorar la calidad de la atención. Objetivo: analizar el conocimiento de los profesionales de Enfermería sobre notificación de eventos adversos post-vacunación. Estudio descriptivo, de enfoque cualitativo realizado en cinco Unidades Básicas de Salud de Feira de Santana, Bahia. Los datos fueron recolectados por medio de entrevistas semiestructuradas con quince profesionales del equipo de enfermería, ocho enfermeras y siete técnicas, transcurriendo entre abril y agosto de 2011. Los datos fueron analizados mediante la técnica de Análisis de Contenido, siendo elaboradas dos categorías de análisis: "Criterios para notificación de eventos adversos post-vacunación" y "Responsabilidad profesional por la notificación de los eventos adversos post-vacunación". Los aspectos éticos fueron respetados. Se notificaron sólo los eventos post-vacunación, considerados más graves, habiendo sub-notificaciones y dudas sobre quién es el profesional responsable por la notificación. Es necesario entrenar a los profesionales de Enfermería que actúan en el área de inmunización, puesto que la notificación de eventos adversos post-vacunación es una premisa en la prevención de agravios y en el cuidado y tratamiento de los involucrados.

**Palabras clave:** Inmunización. Notificación. Enfermería.

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**Submitted:** 13/08/2013

**Accepted:** 12/02/2014