Adherence to nursing practices in the safe care and administration of immunobiologicals: a cross-sectional study

Adesão de práticas de enfermagem no cuidado e administração segura de imunobiológicos: estudo seccional

Adherencia a las prácticas de enfermería en el cuidado y la administración segura de inmunobiológicos: estudio transversal

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RESUMO

Objetivo: avaliar a adesão de práticas de enfermagem segura no cuidado e administração de imunobiológicos nas salas de vacinação. **Método:** Trata-se de uma pesquisa quantitativa com delineamento seccional. O estudo foi conduzido nas salas de vacinação em um município da região nordeste do Brasil, com um tamanho amostral de 152 procedimentos. A coleta de dados foi realizada por meio do instrumento denominado Lista de Verificação de Segurança do Paciente em Sala de Vacina**. Resultados:** No domínio 1 os itens 4, 5, 7, 8 e 19 demonstraram baixa adesão. Já no domínio 2, a maioria dos itens apresentou 100% de adesão às boas práticas, os demais apresentaram frequências de não adesão abaixo de 50%. Por fim, o domínio 3, o item 30 não foi realizado de forma correta, tendo 17,1 % de não adesão. **Conclusão:** Evidencia-se uma lacuna considerável em diversos aspectos quanto às ações essenciais nas administrações de imunobiológicos. Logo, nota-se a fragilidade que perdura sobre a assistência de enfermagem nas salas de vacinas.
Descritores: Enfermagem; Imunização; Segurança do paciente..

ABSTRACT

Objective: To assess the adherence to safe nursing practices in the care and administration of immunobiologicals in vaccination rooms. **Method:** This is a quantitative study with a cross-sectional design. The study was conducted in vaccination rooms in a municipality in the northeast region of Brazil, with a sample size of 152 procedures. Data collection was performed using the instrument called the Patient Safety Checklist in Vaccination Rooms. **Results:** In Domain 1, items 4, 5, 7, 8, and 19 showed low adherence. In Domain 2, most items had 100% adherence to good practices, while the others had non-adherence rates below 50%. Finally, in Domain 3, item 30 was not performed correctly, with 17.1% non-adherence. **Conclusion:** There is a significant gap in various aspects concerning essential actions in the administration of immunobiologicals. Thus, the ongoing fragility in nursing care in vaccination rooms is evident.
Descriptors: Nursing; Immunization; Patient Safety.

RESUMEN

Objetivo Evaluar la adhesión a las prácticas de enfermería seguras en el cuidado y la administración de inmunobiológicos en las salas de vacunación. **Método:** Se trata de una investigación cuantitativa con un diseño seccional. El estudio se realizó en las salas de vacunación de un municipio en la región noreste de Brasil, con un tamaño muestral de 152 procedimientos. La recolección de datos se llevó a cabo utilizando el instrumento denominado Lista de Verificación de Seguridad del Paciente en Sala de Vacuna. **Resultados:** En el Dominio 1, los ítems 4, 5, 7, 8 y 19 mostraron baja adhesión. En el Dominio 2, la mayoría de los ítems presentó un 100% de adhesión a las buenas prácticas, mientras que los demás tuvieron frecuencias de no adhesión inferiores al 50%. Finalmente, en el Dominio 3, el ítem 30 no se realizó correctamente, con un 17,1% de no adhesión. **Conclusión:** Se evidencia una brecha significativa en varios aspectos respecto a las acciones esenciales en la administración de inmunobiológicos. Por lo tanto, es evidente la fragilidad persistente en la asistencia de enfermería en las salas de vacunas.
Descriptores: Enfermería; Inmunización; Seguridad del paciente.

ORIGINAL

Introdução

Patient safety is a topic discussed worldwide and applied as a priority by the World Health Organization (WHO). The Ministry of Health (MH) of Brazil has established the National Patient Safety Program (PNSP), which aims to contribute to the qualification of health care in all health establishments in the national territory, both public and private, according to the priority given to patient safety in health facilities on the political agenda of the WHO member states.[1]

The provision of safe patient care transcends the hospital environment, extending to the various levels of health care, including Primary Health Care (PHC). In view of this, vaccination rooms are places with high numbers of incidents and adverse events, which can be prevented by using safety protocols.[2]

One study pointed out that the safety of individuals exposed to immunobiologicals is influenced by multiple factors such as attention to the expiration date, manufacturing conditions, care during transport, storage, and temperature control, as well as the organization and preparation of vaccinators from administration to the observation of adverse events.[3]

In line with this, problems in the work process, lack of collaboration and communication from the team, lack of inputs, reduced number of professionals, inadequate structure, lack of encouragement from managers, excessive workload, are conditions that can cause failures and expose patients to unsafe care and consequently to adverse events.[4]

Therefore, the knowledge of the professional responsible for vaccination directly interferes with the immunization process, as success does not depend only on the individual's immune system or on the vaccine.[5] To this end, certain precautions must be taken when administering a vaccine, namely: body composition of the vaccinated individual, needle size, volume to be administered, correct route, among other precautions. Also, passing on the appropriate information and forms of prevention to the population about post-vaccine effects can also minimize unwanted reactions.[6]

A study conducted in Brazil showed that adequate vaccination screening, training, and health education are specific and important actions to minimize errors during vaccination and ensure the quality and safety of immunization.[7] In this sense, seeking to improve safe practice in vaccine rooms and ensure quality care for users, studies are needed to investigate whether safe patient care in the vaccine room is being performed. Therefore, this study aims to contribute to the adoption of safer practices for users.

Based on the above, the objective of this study is to evaluate the adherence of safe practices in the procedures for administering immunobiologicals in patients in the vaccine room.

Method

This is a cross-sectional study with a quantitative approach. It was developed in eight vaccine rooms in a municipality in northeastern Brazil. Which are distributed in the basic health units that make up primary health care, 06 of these in the urban area and 01 in the rural area.[8]

The inclusion criteria were: Vaccination rooms located in the urban area of the municipality. This decision is because the vaccination room located in the rural area of the city presents difficulties for access, such as long distances on inadequate roads and an unstable mobile network for filling out the questionnaires, which would constitute a limitation for the development and scope of the study. Vaccination procedures performed daily, including all age groups and routes of administration, were also included. Procedures that were not routine, such as vaccination campaign days, were excluded.

To calculate the sample size, the local database was considered, and the data were collected in 2023. The vaccination rooms that participated in the study perform a total average of 1440 vaccinations per month. For the sample calculation, a prevalence of adherence to good vaccination practices of 90.0%,2 a margin of error of 5% and a finite population of 1440 were considered, based on data provided by the city's municipal health department, resulting in a sample of 126 procedures. A loss of 20% was also considered, thus defining a sample of 152 vaccination procedures.

For data collection, the instrument called the Vaccine Room Patient Safety Checklist (LVSPSV) was used. The instrument is validated and its elaboration was based on the recommendations of the Manual of Standards and Procedures for Vaccination of the Ministry of Health, in addition to other recommendations, such as notes and technical reports, ordinances and updated vaccination calendar.[2]

The LVSPSV instrument is divided into two parts: characterization and aspects of immunization. The first part includes identifying the vaccination room, the person to be vaccinated, and the vaccine to be administered. The second part consists of 31 items that address the recommendations to be carried out in each vaccination procedure, constituting the good practices of the Ministry of Health, to ensure patient safety in the vaccination room.

The data were obtained through systematic observation of the vaccination procedure, avoiding the interference of the researcher. The researchers approached the individuals who would be vaccinated or their legal guardian, explained about the objectives of the research and ethical issues, with the individual's permission, obtained the signature of the Informed Consent Form (ICF). Data collection took place during the month of January 2024.

The LVSPSV was inserted into an electronic questionnaire (google forms) to operationalize data collection, then migrated to the Microsoft Office Excel program for organization. After organization, the data were sent and analyzed using the Statistical Package for the Social Science (SPSS) for Windows version 22. For the analysis of categorical variables, descriptive analysis was used, such as absolute and relative frequencies, while for quantitative variables, mean and median. For the analysis of adherence to good practices in the vaccination room, it was necessary to calculate the adherence score. The total score of adherence to safety was determined by counting positive answers (yes) of the total items of the instrument, according to the following formula: [number of

yes / (number of valid items – number of items that do not apply) *100].2 The adherence score for each domain was also calculated using the following formula: [Domain Yes No. / (No. of valid domain items – No. of items that do not apply in the domain) *100].

The research followed the recommendations of Resolution 466/12 and was evaluated by the research ethics committee, being approved under number 74835323.0.0000.5568.

Results

No total, 152 vaccination procedures were observed during the research. Regarding the proportional distribution of procedures in the vaccination room, data were collected in 06 vaccination rooms, the amount of vaccines observed in each unit had a proportional distribution, with 27 (17.7%) vaccination procedures in unit A, 30 (19.7%) in B, 29 (19.0%) in C, 25 (16.4%) in D, 24 (15.7.0%) in E and 23 (15.1%) in F.

Regarding the age group of those vaccinated, a higher concentration of vaccination procedures was observed among children under one year of age (n=34; 22.4%) and between 1 and 4 years of age (n=48; 27.2%). The age group in the elderly had lower vaccination (from 60 years n=6; 3.6%). Regarding immunobiologicals, the most administered vaccines were: MMR (n=15; 9.9%), Pneumococcal (n=11; 7.2%), hepatitis B (n=11; 7.2) and double adult (n=10; 6.6%). In addition to these, 41 (27%) vaccines were also registered that entered as "other", equivalent to field vaccines, which are influenza and the vaccine against COVID-19. Regarding dosage, the most administered dose was the 1st dose of the schedule of all vaccines analyzed.

Tables 1 to 3 show the descriptive data regarding the adherence of the domains. Regarding the score of adherence to good practices in the vaccination room, the total score (involving all domains of the instrument) was equivalent to 80.3%, with the maximum score being domain 3 (91%) and the lowest score being domain 1 (70.2%). Domain 2 had a score of 74.9% of adherence to good practices.

Regarding the performance of procedures prior to the administration of the immunobiological, Domain 1 (Table 1) showed low adherence in some items, as observed below.

Table 1 - Distribution of frequency of adherence to recommendations in procedures prior to the administration of the immunobiological (Domain 1). Santa Cruz, RN, Brazil, 2024. (n=152)

	Adhesion					
	Yes		No		Yes	
Items	N	%	N	%	N	%
Item 1 – Verified the age of the vaccinated person through the date of birth	93	61,18%	57	37,5%	2	1,32
Item 2 – Identified the vaccine to be administered through the vaccine card	151	99,3%	1	0,7%	-	-
Item 3 – Verified the age and interval between doses, recommended for the vaccine	140	92,1%	2	1,3%	10	6,6%
Item 4 – Investigated the occurrence of adverse events after vaccination to the previous dose (when having a previous dose)	24	15,7%	99	65,13%	29	19%
Item 5 – Obtained information about the user's health status, evaluating contraindications	43	28,3%	108	71,1%	1	0,7%
Item 6 – Mentioned the name of the vaccine to be administered	144	94,7%	9	5,2%	-	-
Item 7 – Mentioned against which disease(s) the vaccine generates protection	41	27%	111	73%	-	-
Item 8 – Provided guidance on the benefits of vaccination	21	15%	131	85,0%	-	-
Item 9 – Provided guidance on the importance of completing the vaccination schedule (when necessary)	61	41%	62	40%	29	19%
Item 10 – Personal data	121	79,6%	11	7,2%	20	13,2%
Item 11 – Name of the vaccine	152	100%	-	-	-	-
Item 12 – Application date	152	100%	-	-	-	-
Item 13 – Lot number	152	100%	-	-	-	-
Item 14 – Producing laboratory	131	86,2%	21	13,8%	-	-
Item 15 – Vaccination unit	134	82,8%	18	11,8%	-	-
Item 16 – Name of the vaccinator	152	100%	-	-	-	-
Item 17 – Performed the scheduling in pencil (when necessary)	106	69,7%	12	7,89%	34	22,36
Item 18 – Provided guidance on the date of return (when necessary)	76	50%	29	32,2%	27	17,8%
Item 19 – Provided guidance on possible adverse events after vaccination	54	35,5%	98	64,5%	-	-

Regarding the performance of the procedures, during the administration of the immunobiological, Domain 2 (Table 2), most of the items presented 100% adherence to good practices, the others presented frequencies of non-adherence below 50%, demonstrating good practices on the part of the professionals.

Table 2 - Distribution of frequency of adherence to recommendations in the procedures during the administration of the immunobiological (Domain 2). Santa Cruz, RN, Brazil, 2024. (n=152)

	Adhesion					
	Yes		**No**		**Not applicable**	
Items	**N**	**%**	**N**	**%**	**N**	**%**
Item 20 – The applying professional evaluated the vaccine card and re-identified the vaccine to be administered	152	100%	-	-	-	-
Item 21 – Sanitized your hands with correct technique	129	84,9%	23	15,1 %	-	-
Item 22 – Examined the product	144	94,7%	8	5,3%	-	-
Item 23 – Carried out the preparation properly (when necessary)	148	97,4%	-	-	4	2,6%
Item 24 – Labeled the vaccine with the date and time of opening the vial (when necessary)	48	31,5%	35	23,0 %	69	45,3%
Item 25 – Regarding the application, it was carried out in the correct dosage	152	100%	-	-	-	-
Item 26 – Regarding the application, it was carried out in the correct route of administration	152	100%	-	-	-	-
Item 27 – Regarding the application, it was carried out with correct materials	152	100%	-	-	-	-
Item 28 – Regarding the application, it was carried out in the correct place	152	100%	-	-	-	-
Item 29 – Regarding the application, it was performed with correct technique	152	100%	-	-	-	-

Regarding domain 3, referring to procedures after the administration of the immunobiological, this domain has only two items, Item 30 – Hand hygiene with correct technique, 17.1% of the procedures were not performed correctly, however most of the procedures had good adherence to good practices. Item 31 - Fed the National Immunization Program Information System (SI-PNI) or the equivalent system, had 100% adherence.

Table 3 - Distribution of frequency of adherence to recommendations in procedures after the administration of the immunobiological (Domain 3). Santa Cruz, RN, Brazil, 2024. (n=152).

	Adhesion					
	Yes		No		Not applicable	
Items	N	%	N	%	N	%
Item 30 – Sanitized your hands with correct technique	125	82,2%	26	17,1%	1	0,7 %
Item 31 – Fed the National Immunization Program Information System (SI-PNI) or the equivalent system	152	100%	-	-	-	-

Discussion

The total score of adherence to good practices had a positive result, especially in relation to domain 3. Therefore, overall, the results of the study were positive. However, it is necessary to observe which non-adherence items are not being followed.

Regarding adherence to the recommendations of the Ministry of Health in the vaccination procedures present in the LVSPSV instrument in domain 1, referring to procedures prior to the administration of the immunobiological, it was noted an excellent adherence of the items, namely: 1- verified the age of the vaccinated person through the date of birth (61.18%), 2- identified the vaccine to be administered through the vaccine card 99.3%, 3- verified the age and interval between doses recommended for the vaccine 92.1%, item 6 - mentioned the name of the vaccine to be administered 94.7%, item 9 - was guided about the importance of completing the vaccination schedule (when necessary) 41%, item 10 - personal data 79.6%, items 11 - name of the vaccine, 12 - date of application, 13 - batch number obtained 100% adherence, item 14 - producing laboratory 86.2%, item 15 - vaccination unit obtained 82.8%, item 16 - name of the vaccinator 100%, item 17 - performed the pencil scheduling (when necessary) 69.7% and item 18 - provided guidance on the return date (when necessary) 50%.

Based on the results, it is clear that good adherence to the items described contributes to a safe care environment, in which the treatments and services provided do not cause damage, injuries or complications, in addition to those arising from the course of the patient's own health condition. In addition to this, they also add the construction of a vaccination room that promotes maximum safety for the user, in which the use of immunobiologicals must be based on their indications, contraindications, dosages and storage conditions.[9]

On the other hand, an item that deserves to be highlighted is the investigation of the occurrence of adverse events after vaccination to the previous dose (item 4), which showed 65.13% of non-adherence, considered worrying. Failure to question previous adverse reactions exposes the vaccinated

person to the risk of a more severe reaction than before, and the nursing team is responsible for vaccination activities and responsible for its consequences.[10]

In addition, data on information on the user's health status, evaluating contraindications (item 5), showed 71.1% of non-adherence on the part of the vaccinators. This result is in line with the recommendations recommended by the Ministry of Health, which guides the professional when obtaining information about the user's health status and observing with specificity the indications and contraindications of each immunobiological.[11]

It is essential that the professional who will administer the immunobiological pass on as much information as possible. In view of this, another result found in this study was related to information about vaccines. Item 7 - mentioned which disease(s) the vaccine generates protection against, obtained 73% of non-adherence and item 8 - was oriented on the benefits of vaccination, 85.0%. It is understood that the professionals in the vaccine room provide guidance on which vaccine they are administering, but there is a failure when it comes to saying against which diseases these vaccines will generate protection and what the benefits of vaccination will be.

Effective communication is a milestone that influences greater adherence to immunization practices by patients. Therefore, it becomes necessary to provide information through a good welcome and a relationship of trust and affection with the vaccinated, this is important to ensure adherence to vaccination, especially for those parents or guardians who have difficulty accepting vaccination. The lack of dialogue, discrimination and errors in the dissemination of false contraindications are elements that enhance non-immunization.[12]

Guidance on the adverse effects of vaccines is essential. Related to item 19 (guidance on possible adverse events after vaccination), there was 64.5% non-adherence, and it was inferred that the professionals advised that some type of adverse reaction could occur after vaccination, but did not inform the vaccinated or guardians that if any reaction occurred, they should seek the health unit for notification.

Study points out that the lack of guidance about post-vaccination adverse events compromises patient safety, which aims to reduce unsafe acts in care processes and the use of best care practices, reduce the risks of unnecessary damage associated with health care and manage persistent risks over time.[13]

With regard to domain 2, it is relevant to highlight items 20, 25, 26, 27, 28, 29, which obtained maximum adherence during the performance of the procedures and correspond, respectively, to: The applying professional evaluated the vaccine card and identified again the vaccine to be administered, the application was performed in the correct dosage, in the correct route, with the right materials, in the right place and with the right technique. A study shows that in order to avoid errors during the preparation and administration of any medication, it is relevant that the nursing professional develops a broader view of the procedure, evaluating from the user's arrival at the health unit to their departure.[14]

In line with this, it is imperative that health professionals in the context of PHC develop strategies to prevent errors in nursing care. Among these strategies, the involvement of the patient as a co-participant in the care, double checking before the administration of the immunobiological, adherence to the

right nine and confirmation of identification data through the user and/or their companions stand out.[15]

Despite a significant adherence to domain 2, it is still worth highlighting item 24, equivalent to the labeling of the vaccine, with the date and time of opening of the vial, as a practice that has not been properly followed, when necessary, by all vaccinators in the municipality involved. Recommendations from the Brazilian Society of Pediatrics (SBP) point out that the identification of vials of multidose vaccines with an opening date and time is essential, so that there is no improper administration of immunobiologicals after the deadline.[16]

The last two items of the instrument, present in domain 3, which covers the procedures after the administration of the immunobiological, is Item 30 – Hand hygiene with correct technique, presented 17.1% of non-adherence, showing that the procedures were not performed correctly.

Contaminated hands are the most common route of transmission for the spread of infections, so their hygiene is crucial to prevent the spread of infection. This is a simple but effective measure, and to be effective it must be carried out with adequate frequency and quality.[17]

Regarding the limitations of this study, data collection was carried out in an observational and systematic way in the vaccination rooms, and the presence of the researcher is considered an influence for the professionals in these places to develop more detailed care, as they understand data collection as an evaluation process of the performance of their duties. In view of this, there is a need to carry out a prospective follow-up study.

Although in the results found in this study, many items follow the adherence to good vaccination room practices, it is necessary to understand which points and practices need to be improved in order to qualify and update professionals, considering that it is relevant to favor the quality of care provided and maintain patient safety in PHC.

Conclusion

The analysis of the data obtained is able to reveal a considerable gap in several aspects regarding the essential actions in the administration of immunobiologicals. Fundamental points, such as knowledge about the patient's previous status, surveillance in the face of adverse events after vaccination to the previous dose, guidance on the benefits of vaccines, diseases that offer immunity, and potential adverse effects after vaccination, were largely neglected by vaccinating professionals. In addition, it is highlighted that the non-labeling of immunobiologicals and the non-hygiene of hands with the correct technique, both with significant results of non-adherence, emerge as risk factors for the harm to the health of PHC users.

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