

ORIGINAL ARTICLE

IMMUNOBIOLOGICAL ADMINISTRATION FAILURES: ROOT CAUSE ANALYSIS FALHAS NA ADMINISTRAÇÃO DE IMUNOBIOLÓGICOS: ANÁLISE DE CAUSA RAIZ FALLAS EN LA ADMINISTRACIÓN DE INMUNOBIOLÓGICOS: ANÁLISIS DE CAUSA RAIZ

Francisco Clécio da Silva Dutra¹, Patrícia Freire de Vasconcelos², Flávia Paula Magalhães Monteiro³, Vanessa Emille Carvalho de Sousa Freire⁴, Pedro Holanda Souza Neto⁵

Objective: to evaluate the immunobiological administration in vaccination rooms of the Basic Units of Family Health of a city in the Northeast of Brazil. Method: this is a quantitative, investigative, research-action type. The data were collected through systematic observation in a Basic Family Health Unit. The guidelines used were based on the recommendations of the Manual of Norms and Procedures for Vaccination of the National Immunization Policy. Results were presented by tables. Results: in 57.1% of the observations, the professional did not verify the appearance of the solution in the immunobiological vial and in 14.3% of the cases the expiration date was not verified. In none of the procedures, hand hygiene was performed. Conclusion: Based on the recommendations proposed by the National Immunization Policy, the practices involved in immunobiological administration are far from what is recommended. Failures involving appropriate techniques of immunobiological preparation, storage and preservation have been observed. Descriptors: Management; Vaccine; Administration; Primary Health Care; Conducts; Bias.

Objetivo: buscou-se avaliar a administração de imunobiológicos em salas de vacina de Unidades Básicas de Saúde da Família de um município do Nordeste brasileiro. Método: trata-se de um estudo quantitativo, investigativo, tipo pesquisa-ação. Coletaram-se os dados por meio da observação sistemática em uma Unidade Básica de Saúde da Família. Utilizaram-se roteiros a partir das recomendações do Manual de Normas e Procedimentos para Vacinação da Política Nacional de Imunização. Apresentaram-se os resultados por meio de tabelas. Resultados: constata-se que, em 57,1% das observações, o profissional não verificou a aparência da solução no frasco dos imunobiológicos e, em 14,3% dos casos, não foi verificado o prazo de validade. Salienta-se que em nenhum dos procedimentos foi realizada a higienização das mãos. Conclusão: percebe-se, com base nas recomendações propostas pela Política Nacional de Imunização, que as práticas envolvidas na administração de imunobiológicos se encontram distantes do que é preconizado. Observaram-se falhas envolvendo as técnicas adequadas de preparo, de armazenamento e de conservação dos imunobiológicos. Descritores: Manejo; Vacinas; Administração; Atenção Primária à Saúde; Condutas; Erros.

RESUMEN

Objetivo: evaluar la administración de inmunobiológicos en salas de vacuna de Unidades Básicas de Salud de la Familia de un municipio del Nordeste brasileño. Método: se trata de un estudio cuantitativo, investigativo, tipo investigaciónacción. Se recogieron los datos por medio de la observación sistemática en una Unidad Básica de Salud de la Familia. Se utilizaron guías a partir de las recomendaciones del Manual de Normas y Procedimientos para Vacunación de la Política Nacional de Inmunización. Se presentaron los resultados por medio de tablas. Resultados: se constata que, en 57,1% de las observaciones, el profesional no verificó la apariencia de la solución en el frasco de los inmunobiológicos y en 14,3% de los casos, no fue verificado el plazo de validez. Se salienta que en ninguno de los procedimientos fue realizada la higiene de las mãano. Conclusión: con base en las recomendaciones propuestas por la Política Nacional de Inmunización, que las prácticas envueltas en la administración de inmunobiológicos se encuentran distantes de lo que es recomendado. Se observaron fallas envolviendo las técnicas adecuadas de preparación, de almazenamiento y de conservación de los inmunobiológicos. Descriptores: Manipulación; Vacunas; Administración; Atención Primaria a la Salud; Conductas; Errores.

¹State University of Ceará/UECE. Fortaleza (CE), Brazil. ORCID : https://orcid.org/0000-0002-3451-1664 E-mail: cleciouece@gmail.com 2,3,4,5 Universidade da Integração Internacional da Lusofonia Afro-Brasileira/UNILAB. Redenção (CE), Brazil. ORCID : https://orcid.org/0000-0002 6158-9221 E-mail: patriciafreire@unilab.edu.br ORCID : https://orcid.org/0000001-9401-2376 E-mail: flaviapmm@unilab.edu.br ORCID https://orcid.org/0000-0003-3571-0267 E-mail: vsousa@unilab.edu.br ORCID https://orcid.org/0000-0002-9006-925X pedrohsn2016@gmail.com

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INTRODUCTION

Immunization is one of the most effective measures in the prevention of diseases, promoting reduction of morbimortality immunopreventable diseases. Diseases that affected the country, such as poliomyelitis, smallpox and human rabies have been eradicated or are under control due to the adoption of specific immunization throughout However, measles, a disease once considered eradicated, is in an epidemiological outbreak. The disease virus was reintroduced in the country in 2013, and 1200 cases were confirmed, all in the states of Ceará and Pernambuco.² The gaps were opened for this virus to be re-circulated.

It is necessary the standards of conservation are observed and complied to ensure the effectiveness of the vaccines, which are thermolabile products. In this sense, there are prerogatives that show flaws involving safe practice, both in the preparation and in the administration of immunobiological, and also in the adequate vaccination coverage. The monitoring of the processes that involve the manipulation of immunobiologicals by the supervisors of the Basic Health Units, especially the professional of Nursing and the manager is fundamental since it provides the safety and the viability of immunobiological for the population and society.³

The mechanistic work performed by the professionals, the high number of immunobiologicals in the routine scheme and the insufficient number of human resources fully trained in vaccination rooms can contribute to the occurrence of errors in the administration of immunobiologicals, as well as may justify the fact that the greatest number of errors occur with vaccines administered routinely, that is, in a daily and everyday way.⁴

The responsibility of managing the activities performed by staff working in the vaccination room is defined as the intrinsic role of the nurse professional, such as: guiding and assisting patients with safety, responsibility, and respect; provide, periodically, material immunobiological needs; maintain the ideal for the conditions preservation immunobiologicals, keep the equipment in good working order; monitor the doses of vaccines administered according to the goal; search for defaulters: disseminate the available immunobiological data and systematically evaluate and monitor vaccination coverage within the territory.⁵ Therefore, the Nursing actions in the vaccine room are decisive, since they contribute the control and eradication of possible avoidable failures, making feasible practice.6

In the vaccination room, it should include activities to be developed by a trained Nursing

team for the handling, conservation, and administration of immunobiologicals.⁵

In this context, Patient Safety is a priority in the promotion of care as one of the dimensions of quality, because it has a cross-cutting character and is a branch of knowledge encompassing several disciplines, providing knowledge that promotes good health care. It is up to the professional nurse to be trained in vaccination and to emphasize that other professionals (auxiliaries and technicians) will not only be vaccine administrators, but also conscientious professionals who take care of the health of millions of people.

Therefore, the rationale for this study lies in the need to evaluate the possible errors involving the conservation and administration of immunobiologicals, proving to be relevant, since the recurrent errors in these situations cause serious problems, disagreeing with the performance of safe attitudes advocated by PS.

OBJECTIVE

• To evaluate the immunobiological administration in vaccine rooms of the Basic Health Units of the Family Health in a city in the Northeast of Brazil.

METHOD

The study is characterized by a quantitative, descriptive, research-action type study. This type of approach seeks to describe meanings that are considered as inherent to the objects, so it is defined as objective and has the characteristic of allowing a focused, punctual and structured approach, using quantitative data. The data collection was carried out in a Basic Health Unit (BHU) of the municipality of Acarape, State of Ceará. The unit was chosen because it is the only BHU to present an immunization room in which a Nursing technique is responsible for the conservation, preparation, and administration of immunobiologicals.

The data were collected from July 31 to August 25, 2017, through systematic observation for 20 days at the BHU. Each observation day lasted four hours. The observation was guided by the scripts based on the recommendations of the Manual of Norms and Procedures for Vaccination of the National Immunization Program.⁷

Regarding the checklists, the first one (Organization and Functioning of the Immunization Room) was applied in a timely manner, as it was based on the physical verification of the room, both physically as for the presence of inputs; and the second one (Conservation of Immunobiologicals) contemplated the conditions of the immunobiological ones in relation to their conservation and storage in refrigerators or thermal boxes. This instrument was applied once a

day, totaling 20 completed checklists. The third one (Preliminary Procedures for Administration of Vaccines and Serums) was used in advance of each procedure, totaling 39 checklists. The fourth, fifth, sixth and seventh checklists were each destined for different routes of administration. The fourth was to be checked for intradermal administration. However, no procedure involving this route was done. The fifth checklist (Oral Administration) presented a total of seven vaccines administered. Four procedures were performed in the sixth checklist (Subcutaneous Administration) and in the seventh checklist (Intramuscular Administration), a quantitative of 28 procedures were performed. All comments were added, resulting in a total of 99 checklists applied.

The data obtained in a Microsoft Office Excel® 2007 spreadsheet were tabulated and organized. A descriptive analysis of the main independent and dependent variables of the study was carried out, considering their peculiarities and observing the absolute and relative frequency distributions.

The analysis model used in this study was the Ishikawa diagram. The purpose of this method is not only to find root causes but to try to solve the fact, preventing new episodes from happening, that is, other errors. This diagram is presented as a graphical representation of an organized list of possible causes, factors that may be at the origin of a consequence and data that relate to each other. The diagram and its root causes were produced in a meeting with all the primary care nurses in the city, where the first data of the study were exposed and then, in consensus, the main causes of the failures observed during the research were scored.

The project was submitted to the analysis of the Research Ethics Committee (CEP) of the Universidade da Integração Internacional da Lusofonia Afro-Brasileira (UNILAB) and approval was obtained under CAAE: 62673716.6.0000.5576. The individuals who participated in the study had

The individuals who participated in the study had access to the Informed Consent Term, in compliance with ethical principles, according to Resolution 466/12 of the National Health Council.¹²

RESULTS

The first checklist looked at issues related to immunization room facilities. Among the findings, an outlet for each of the equipment and the absence of direct sunlight were highlighted, factors considered necessary for the optimal immunobiological conservation; however, regarding the independent entry and exit, the unit did not contemplate this recommendation.

In the presence of inputs and equipment, the extensor cable thermometer, enough plastic perforated trays, plastic bottles with water, 0.2 ml graduated syringes and the 25x8 and 30x8 size needle, both for dilution, the disposable vaccine protection cup and the paper towel for hand hygiene.

After the application of the second checklist, which evaluated the immunobiological conservation behaviors, the diluents were not located on the third shelf. On eight days' observation, the shelves were not completely cleaned and organized, the jars were not arranged in a linear fashion and many products of distinct compositions were close to each other.

Table 1. Preliminary procedures for the administration of immunobiologicals. Acarape (CE), Brazil, 2017.

Variables	Yes n (%)	No n (%)
The immunobiological to be administered was checking		
As indicated on the Child Card	28 (73.7)	11 (26.3)
As another registration document	11 (26.3)	28 (74.7)
The product was examined		
Observing the appearance of the solution	23 (59)	16 (41)
Observing the expiration date	21 (53.8)	18 (46.2)
Observing the route of administration	37 (94.8)	2 (5.2)
Observing the dosage	36 (92.3)	3 (7.7)
Performed handwashing before handling	- (-)	39 (100)

When analyzing the preliminary procedures for the administration of immunobiologicals, categorized in table 1, there was a considerable percentage of failures on the hand hygiene item among the items analyzed by the third checklist: at no time was this practice performed.

On the index of verification of the shelf-life before opening a packaging 46.2% was not opened.

In the procedures subsequent to the administration of immunobiologicals, the care

guidelines were not provided in approximately 70% of all procedures.

Table 2. Subsequent processes to the administration of immunobiologicals. Acarape (CE), Brazil, 2017.

Variables	YES n (%)	NO n (%)
guidance on necessary care was provided	12 (30.8)	27 (69.2)
Immediate reactions were observed The registration document was rubricated in the proper space		31 (79.4)
		1 (2.6)
The due date was checked when necessary	36 (92.3)	3 (7.7)
Guidelines, especially the due date for the return were reinforced	34 (87.1)	5 (12.9)
Disposable material was put in a suitable container	38 (97.4)	1 (2.6)
His hands were washed at the end of the procedure	- (-)	39 (100)

Other factors analyzed were the records and the presence of files inherent to the immunization room. This information is listed in Table 3. Cases, where the vaccination records were not filled, were noted.

For the analysis of the main causes that culminated in the presence of observed failures, the theoretical reference of the type causes root was used.

The root cause analysis model is constituted by different techniques, which include the analysis of

barriers, the analysis of changes, the Pareto analysis, the causes trees, the Ishikawa diagram, among others, to elaborate the chain causal, starting from an undesired final event, to find the root cause.¹³ The instrument used in this study was the Ishikawa diagram.

In the assembly of the diagram, the causes were grouped into six categories: Personal Factors; Organizational or Service Factors; External Factors; Patient Factors; Factors of Work or the Environment and Other Factors.¹⁴

Table 3. Record of activities and files of the immunization room. Acarape (CE), Brazil, 2017.

Variables		NO
Variables	n (%)	n (%)
Child Records Verification	29 (74.3)	10 (25.7)
Adult Record Verification	3 (7.7)	36 (92.3)
Checking the Pregnant Woman Record	8 (20.6)	31 (79.4)
Unit Control Record	35 (89.7)	4 (10.3)
Daily Vaccination Newsletter	36 (92.3)	3 (7.7)
Monthly Bulletin of Applied Doses of Vaccines	28 (71.8)	11 (28.2)
Map for daily temperature control	33 (84.3)	6 (15.4)
The monthly movement of immunobiologicals and inputs	29 (74.3)	10 (25.7)

DISCUSSION

The absence of perforated boxes for the storage of bottles inside the refrigerators, of maximum and minimum thermometers in the immunization rooms of some units, were found in research and the extensor cable thermometer was not found in any unit. 15 The presence of at least a maximum and minimum type thermometer is an indispensable resource for adequate and accurate monitoring of circulating temperature refrigerators.⁷ A study carried out in 11 Health Centers Family bound to the Regional Executive Secretariat I of the city of Fortaleza (CE), a similar result when analyzing the physical structure of 11 immunization rooms.¹⁵

In 100% of the cases, considering that hand hygiene has not been carried out in 100% of cases, the non-adequate antisepsis of the hands can cause a series of cross-infection in professional-patient, patient-patient or professional professional. This failure is a very serious and critical aggravating factor since, in different monitoring, the percentages of handwashing were 90% to 100%. 4,16 Another concern was the index of validity before the opening of packaging: in about 46.2% of the time, this fact did not occur, which

generates concern regarding the nonestablishment of safe work routines.⁷

It is suggested, by evidence, 6,16-7 that the low incidence of the provision of guidelines and information on the occurrence of possible adverse effects ends up contributing to the development of hypersensitivity reactions to the components in the immunobiological composition, precisely due to the absence important information and data. Due to the observed results, the educational moments are probably devalued by the professionals in their work process. Thus, the guiding power of education in the dissemination of good health practices is reduced. 17

There is a need for proper control and registration of vaccination appointments within the vaccine registries and in the archives of the vaccine room, so there is a systematic control of the activities performed.

It is important to mention the need for continuing education in the training of immunization professionals, and to the Nursing, team ensures the quality of the immunization offered to the population.⁶ It is considered necessary to systematically implement activities of supervision, monitoring, and evaluation of the

vaccine room since there are few Brazilian productions with this theme.⁶

In the first category called Personal Factors, in the construction of the Ishikawa diagram, the main causes that compromised patient safety were inefficient training, excessive self-confidence (automaticity), lack of knowledge and lack of professional autonomy in the performance of their duties. In the National Immunization Policy, there are questions about the need for preventive attitudes and behaviors to be adopted by health professionals who work with vaccination, precautionary measures that must be routinely within the sector and, technicalprofessional improvement as a permanent behavior.⁷

In the following category, the causes of Organizational or Service Factors were: punitive culture; lack of feedback; the absence of a standard operating protocol and the excess of print as barriers to the adoption of safe practices in the care provided. These and other aspects related to safe vaccination need to be based on guidelines, regulations, and protocols, whose formulation should be led by the national sphere of the National Immunization Policy, in an articulated and agreed manner with the other spheres supported with studies, research and the expertise of institutions and organizations.⁷

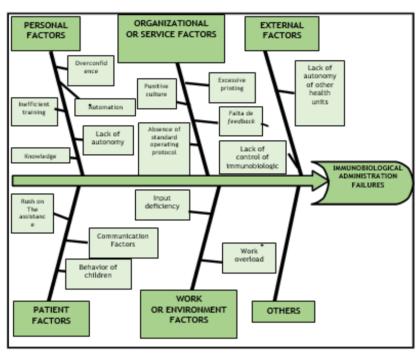


Figure 1 - Ishikawa diagram on the organization, conservation, and administration of immunobiologicals. Acarape (CE), Brazil, 2017.

Regarding the punitive culture, a study in the literature identified the feelings experienced by nursing professionals who made mistakes. Panic, despair, fear, guilt, and shame are among the most quoted feelings.¹⁸

In this analysis, in addition to the fear of being reprimanded by the managers of the service, the greatest punishing agent is the very conscience of the individual who made the mistake. According to the same study, the strategies of coping adopted by the individuals were: to share the problem; communicate the error and seek information. Thus, the institutions should not neglect errors, but make it a motive for programming and implementing preventive strategies.

In the third category, External Factors, the lack of autonomy of other health units (dependence), lack of control of the immunobiological agents attributed to the lack of a specific room for the storage and handling of vaccines were found. According to the National Immunization Policy, the concept of safe vaccination, in a wide and comprehensive manner, involves a differentiated set of aspects related to the vaccination process, which is still initiated in the scope of the

production process and in the acquisition of the immunobiological within the specifications and with the required quality, followed by its distribution in the appropriate conditions, from the producing laboratory to the vaccination room, highlighting, in this way, the efficiency of the cold network.⁷

In the fourth category, Patient Factors, the peculiar behavior of children (restlessness and restlessness), communication factors automation through care were found. A complex network of services should be incorporated, capable of efficiently using, when necessary, massive, rapid-range operations with maximum possible supply of products intended for that target population.⁷ Effective communication between professionals of the same team is paramount to service efficiency. 18-19

The security culture of an organization is understood as the values shared among its members about what is important, and this sharing will only be possible with the presence of active and permanent communication. Their opinions on the functioning of the unit, the interaction of the work team and with organizational structures and

systems will cause behavioral norms to be produced for the safe promotion of the unit completely.

In the fifth category, Labor or Environment Factors, assumptions such as the lack of inputs and the overload of work as barriers to the activities of the unit were inserted, compromising the adoption of safe practices and conduits. Also related to these circumstances, there are the conditions of the work environment which, according to the National Immunization Policy, should include measures to be taken when accidental contact with vaccine fluids or when there is a sharp accident with the material used in vaccination.⁷⁻¹⁹

Through the use of the Ishikawa diagram, it was possible to determine the probable causal factors for the occurrence of an incident, as well as the needs for improvement, management performance, training, technical/professional improvement, resources in a cohesive way and the permanent training of teams.

CONCLUSION

A number of events have been observed that have formed into errors or failures involving appropriate techniques of preparation, storage and optimal preservation of immunobiologicals. Such failures may culminate in the occurrence of adverse events, both for the patient of the health unit that receives care in the vaccine room and for the professional who performs the procedures. These obstacles can also have an impact on the efficacy of the vaccine, compromising its immune potential when not administered properly.

Based on the recommendations proposed by the National Immunization Policy, there are practices in the vaccination ward that are in discrepancy with the premises brought by such policy. Therefore, it is necessary a constant technical-professional improvement of all the members of the team that make up Primary Care of the locality observed and of any Brazilian locality, given the predominant scenario in the management and control of immunobiological.

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Immunobiological administration failures...

Dutra FCS, Vasconcelos PF de, Monteiro FPM et al.

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Correspondence

Francisco Clécio da Silva Dutra E-mail: cleciouece@gmail.com



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