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ORIGINAL ARTICLE

STUDY OF THE PROCEDURES FOR CONSERVATION OF VACCINES OF THE NATIONAL IMMUNIZATION PROGRAM

ESTUDO DOS PROCEDIMENTOS QUANTO À CONSERVAÇÃO DAS VACINAS DO PROGRAMA NACIONAL DE IMUNIZAÇÃO

ESTUDIO DE LOS PROCEDIMIENTOS SOBRE LA CONSERVACIÓN DE LAS VACUNAS DEL PROGRAMA NACIONAL DE INMUNIZACIÓN

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ABSTRACT

Objective: to evaluate the conservation process of immunobiological agents of the National Immunization Program (NIP) in vaccination rooms of the urban area of Teresina-PI. ***Method:*** epidemiological and cross-sectional study conducted through *checklist* in 53 vaccine rooms in the period from September 2008 to February 2009. Data were processed in the *SPSS* version 17.0, presented in figures and tables. ***Results:*** the rooms have deficient equipment, do not work full time period, most of workers are unskilled, there are still rooms with incidence of sunlight and the cleanliness and organization of the refrigerator and the cold box were inappropriate according to recommendations of the NIP. ***Conclusion:*** in order to assure that vaccination activities achieve consistent results, it is necessary, in addition to high coverage, to train the professionals that work in vaccination rooms, organizing and equipping rooms, as well as to monitor the processes that involve the handling of these substances. ***Descriptors:*** Cooling; Immunization programs; Health evaluation.

RESUMO

Objetivo: avaliar o processo de conservação dos imunobiológicos do Programa Nacional de Imunização (PNI) nas salas de vacina da zona urbana de Teresina-PI. ***Método:*** estudo epidemiológico, transversal, realizado através de *checklist* em 53 salas de vacina, no período de setembro de 2008 a fevereiro de 2009. Os dados foram processados pelo *SPSS*, versão 17.0, e apresentados em figuras e tabelas. ***Resultados:*** as salas possuem deficiência em equipamentos, não funcionam em período de horário integral; boa parte dos funcionários sem capacitação, ainda há salas com incidência de luz solar e apresentaram a limpeza e organização do refrigerador e caixa térmica inadequadas em relação ao preconizado pelo PNI. ***Conclusão:*** para que as atividades de vacinação atinjam resultados coerentes, faz-se necessário, além das altas coberturas, capacitação dos profissionais que atuam em salas de vacina, organização e provisão de equipamentos para as salas, como também o monitoramento dos processos que envolvem a manipulação dessas substâncias. ***Descritores:*** Refrigeração; Programas de Imunização; Avaliação em Saúde.

RESUMEN

Objetivo: evaluar el proceso de conservación de los inmune-biológicos del Programa Nacional de Inmunización (PNI) en las salas de vacuna de la zona urbana de Teresina-PI. ***Método:*** estudio epidemiológico, transversal, realizado a través de *checklist* en 53 salas de vacuna, en el período de septiembre de 2008 a febrero de 2009. Los datos fueron procesados por el *SPSS*, versión 17.0, y presentados en figuras y cuadros. ***Resultados:*** las salas poseen deficiencia en equipamientos, no funcionan en período de horario integral; buena parte de los funcionarios sin capacitación, todavía hay salas con incidencia de luz solar y presentaron la limpieza y organización del refrigerador y caja térmica inadecuadas en relación al preconizado por el PNI. ***Conclusión:*** para que las actividades de vacunación tengan resultados coherentes, es necesario, además de las altas coberturas, capacitación de los profesionales que actúan en salas de vacuna, organización y provisión de equipamientos para las salas, como también el monitoreo de los procesos que envuelven la manipulación de esas sustancias. ***Descriptores:*** Refrigeración; Programas de Inmunización; Evaluación en Salud.

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INTRODUCTION

The results of the practice of vaccination for reducing the morbidity and mortality of the population in worldwide, collective and individual perspective, are incontestable proofs of its relevance for public health.

Vaccines are among the safest organic products with proven efficacy, low cost, high impact on the health status of a community and are available to the entire population as target group of immunization programs. However, it is imperative that the vaccination activity be surrounded by care, adopting proper procedures before, during and after administration of these products in the population.[1]

In most public health systems, immunization is structured in the form of a program. In 1973, the Ministry of Health (MOH) established the National Immunization Program (NIP), active until the present day. This program coordinates immunization activities carried out routinely in the network of health services, defines the mandatory vaccines, the standards for each one of them, as well as the procedures, is responsible for the acquisition, quality control, distribution of all immunobiological agents (vaccines and serums), and for providing technical advice and operational and financial support to executive organs of vaccination.[2]

The development of the NIP is guided by technical standards nationally established concerning conservation, transport and management of immunobiological agents, as well as aspects related to schedule and evaluation.[3]

As a key point for ensuring the quality of products, the NIP invests in central Cold Chain (CC), a logistic system comprising a qualified technical team, standardized equipment and procedures for the receipt, storage, conservation, handling, distribution and transport of immunobiological substances under appropriate conditions of temperature and protected from light, from the manufacturer to the moment of use.[4]

The advance of NIP intensified the use of immunobiological substances and brought with it the need to ensure the quality of products used by both the program and by other immunization activities, particularly with respect to the conservation of vaccines. Among the essential equipment and materials for the conservation of vaccines is the storage chamber, within which vaccines are stored at 2°C to 8°C until moment of use. Maintain the temperature at 5°C offers greater safety against possible oscillations.[5]

The form of preservation of organic products must be the as most appropriate as possible because the temperature can affect both the effectiveness of the vaccine the possibility of post-vaccination local reactions. High temperatures also affect bacterial antigens, breaking them and causing release of endotoxins. Storage at lower temperatures than indicated, or the process of freezing, may compromise the effectiveness of biological products. Antigens from inactivated (dead) bacteria or virus are the most affected. Adjuvants are affected with extreme heat or cold. The aluminum hydroxide, a common immunity adjuvant, precipitates in the form of flakes when frozen or, if stored at a temperature of 0°C, can cause local reactions (nodule, pain and edema).[6]

The stability of vaccines varies according to the characteristics of each product. Vaccines of attenuated virus are more sensitive to heat and light. Vaccines containing aluminum derivatives as adjuvant, toxoids and inactivated vaccines or subunit vaccines tolerate better higher temperatures, but freezing below zero degrees can inactivate them. Some immunobiological agents are also sensitive to light, whether natural or fluorescent.[7]

In this context, the heating of vaccines is a major problem and the most common mistake when it comes to the conservation of vaccines is the exposure of the inactivated to freezing temperature. It is worth mentioning that in the state of Piauí, especially in Teresina, due to low relative humidity, wind chill reaches 40°C and the average annual temperature is 35°C. In Brazil, the consequences of the influence of high temperatures on the quality of vaccines are amplified by the bad condition of the existing cold chain and the lack of knowledge about the norms for storage and application of these immunobiological substances by the professionals involved.

OBJECTIVE

- To evaluate the conservation process of immunobiological agents of the National Immunization Program (NIP) in vaccination rooms of the urban area of Teresina-PI.

METHOD

This study was part from the master's thesis presented to the Graduate Program in Pharmacology of the Federal University of Ceará/UFC << *Study of the procedures for*

conservation of vaccines in the national immunization program in Teresina-PI, in 2011 >>.

This is an epidemiological and transversal research, conducted in vaccine rooms in the urban area of the municipal public service of Teresina. The Unified Health System (SUS) in the municipality is managed by Municipal Health Foundation (MHF), which has currently 71 vaccine rooms, 18 of these are located in rural areas and 53 in urban areas, distributed by Regional of Health, as follows: 20 in the central-north area, 19 on the south area and 14 on the east side.

The study included all vaccine rooms of the public municipal system in the urban area, registered in the SUS, regardless of time-length of its operation. Vaccine rooms of private or charitable institutions and the rooms of the rural public system were excluded.

The main variables of interest were: physical structure, equipment and supplies of vaccine rooms, vaccine packaging, thermometer use, temperature monitoring, handling of the vaccine conservation equipment, and specific training of professionals working in the vaccine rooms.

Vaccine rooms surveyed in the three regions of Teresina were investigated for organization of immunobiological substances in the refrigerator, if the gelox is properly stored, if there are bottles placed at the bottom of the refrigerator, the refrigerator is washed every two weeks, and as to the setting of the gelox, it is read and recording temperature, at least twice a day, and if there monitoring coolers. The organization of immunobiological substances in the storage chamber and cleaning of the vaccine room were checked, and also if the refrigerator is located 20 cm away from the wall and away from any heat source and direct sunlight and if the walls are free from posters and others.

Data were obtained through interviews and non-participant observation technique carried out by the researcher in all rooms of vaccine from September 2008 to February 2009, by using a pre-tested instrument, consisting of a systematic observation and an interview form essential aspects related to the process of conservation of vaccines.

After collection, data were typed and processed using the *software Statistical Package for Social Sciences* (SPSS®) 17.

The research project was approved by the Ethics Committee of the Federal University of Ceará (UFC) under opinion nº 152/08 in line with Resolution of the National Health Council (CNS) in 196, of October 10, 1996.

RESULTS

Table 1 shows us aspects related to physical infrastructure, furniture and equipment and operating hours of vaccines rooms according to the zone. Some aspects deserve highlights.

As for the physical structure of Teresina vaccine rooms, we found a result that urges be reviewed by health authorities, because it is essential that they have hygienic conditions for the conservation of vaccines and to prevent infections.

Another factor is the lack of beds for application of vaccines, which forces children to take vaccines lying on their mothers' lap, prompting possible errors in the application, such as drilling of a blood vessel.

According to MHF, the time established for functioning of vaccines rooms is divided into two shifts: the morning shift from 7h to 13h and the afternoon shift from 13h to 19h. It was observed that vaccinations do not happen full time in most of health units.

Table 1. Distribution of aspects related to physical infrastructure, furniture and equipment and operating hours of vaccine rooms according to the zone. Teresina - PI, 2008-2009.

Physical structure	Vaccination room by region							
	Central-North (n=20)		South (n=19)		East (n=14)		Total (n=51)	
	f	%	F	%	F	%	f	%
Stainless steel countertop	12	60	5	26.3	7	50	24	45.3
Size of the room	12	60	7	36.8	14	100	33	62.3
Washable walls	17	85	10	52.6	10	71.6	37	68.8
Characterization of vaccine rooms regarding furniture and equipment								
Beds	7	35	6	32	6	43	19	35.9
Air conditioning	19	95	19	100	14	100	52	98.1
Gelox in enough amount	18	90	19	100	14	100	51	96.2
Tables and chairs	20	100	18	95	14	100	52	98.1
Cabinets	19	95	15	79	13	93	47	88.7
Polystyrene in enough amount	19	95	18	95	14	100	51	96.2
Thermometers	19	95	19	100	14	100	52	98.1
Opening hours of vaccine rooms								
Full-time	1	5	2	10.5	5	36	8	15.5
Incomplete	19	95	17	85.5	9	64	45	85

Another aspect inevstigated was the behavior of professionals with regard to conservation of immunobiological agents (Table 2). According to obtained responses, it turns out that among the 53 (100%) surveyed health units of Teresina, only 4 (10.0%) in the central-north zone and 1 (5.3%) on the south did not have proper organisation of materials in the refrigerator; 6 (30.0%) in the central-north and 4 (21.1%) in the south kept the refrigerator away from heat and sunlight; only 1 (5%) in the central-north does not keep the refrigerator at a distance of 20 cm from the wall; only 1 (5.3%) room on the south did not use bottles in the bottom of the refrigerator; cleaning the refrigerator is not made every 15 days in 5 (26.3%) rooms in the south and 1 (7.1%) room on the east; the ambiance with gelox is performed on all units surveyed; the organization of immunobiological agents in the cold box is not performed in 1 (5.0%) unit in the central-north zone, 6 (31.6%) in the south and one on the east; monitoring the temperature of the cold box is held in all units of the central-north and south. However, monitoring is not carried out in 10 (71.4%) units of the east zone; only 2 units do not perform adequate cleaning of the vaccine room, 1 (5%) located in the central-north zone and one (7%) on the east zone; The majority of units maintain the walls of the vaccine rooms free from posters and others.

Table 2. Distribution of vaccine rooms studied according to the conduct of professionals toward conservation of immunobiological agents. Teresina - PI, 2008-2009.

Conduct of professionals	Vaccination room by region							
	Central-north (n = 20)		South (n = 19)		East (n = 14)		Total (N = 53)	
Proper organization of supplies in the refrigerator	f	%	f	%	f	%	f	%
	18	90	18	94.7	14	100	51	96.2
Refrigerator away from heat and incidence of sunlight	6	30	4	21.1	00	0	10	18.8
Refrigerator 20 cm away from the wall	19	95	19	100	14	100	52	98
Bottles placed at the bottom of the refrigerator	20	100	18	94.7	14	100	52	98
Cleaning the refrigerator at least every 15 days	20	100	14	73.7	13	93	47	88.6
Ambiance with gelox	20	100	19	100	14	100	53	100
Organization of immunobiological agents inside the cold box	19	95	13	68.4	14	100	46	86.7
Monitoring of temperature inside the cold box	20	100	19	100	4	4/ 112	43	81.2
Proper cleaning of the vaccine room	19	95	19	100	13	93	51	96.2
Walls free from posters and others	17	85	9	47.4	9	64.3	33	62.2

It was found that professionals from most of the surveyed units who handle vaccines had received training more than two years ago. However, four (21.1%) units of the south had four professionals working in vaccination room in the area who had not received training, raising doubts on the quality of vaccine conservation (Figure 1).

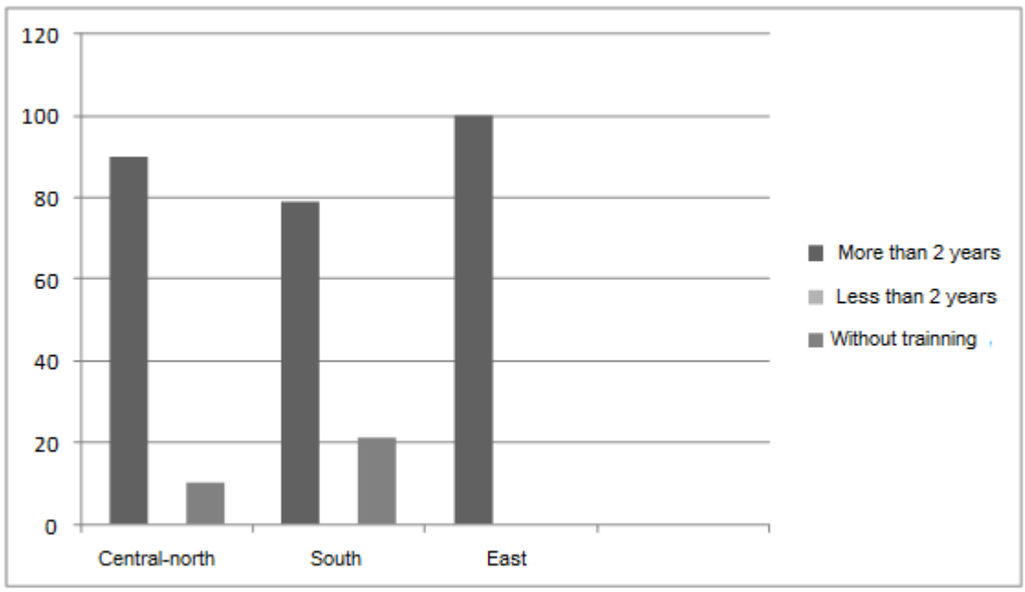

Figure 1. Professional training of workers in vaccine rooms in recent years by zone. Teresina - PI, 2008-2009.

Figure 2 shows the percentage of professionals per zone who underwent specific training in BCG, cold chain and post-vaccination adverse events. Overall, approximately 19 (36%) had received no training on BCG, 43 (93%) on cold chain and adverse effects. A large number of workers was found to lack specific training on BCG, particularly, 11 (57.9%) professionals of vaccines rooms of the south. It is noteworthy, too, that most of professionals working in the surveyed vaccines rooms did not received training on cold chain, corresponding to 19 (100%) of the southern zone, 18 (95%) of the cental-north and 13 (93%) of the east side. Recent training in the area, less than two years ago, happened in the case of only 1 (7%) worker of the east zone and 1 (5%) of the central-north region. In addition, 13 (93%) of nurses who work in the vaccines rooms of the east, 17 (89.5%) of the south and 16 (80%) of the central-north did not receive any training on adverse effects.

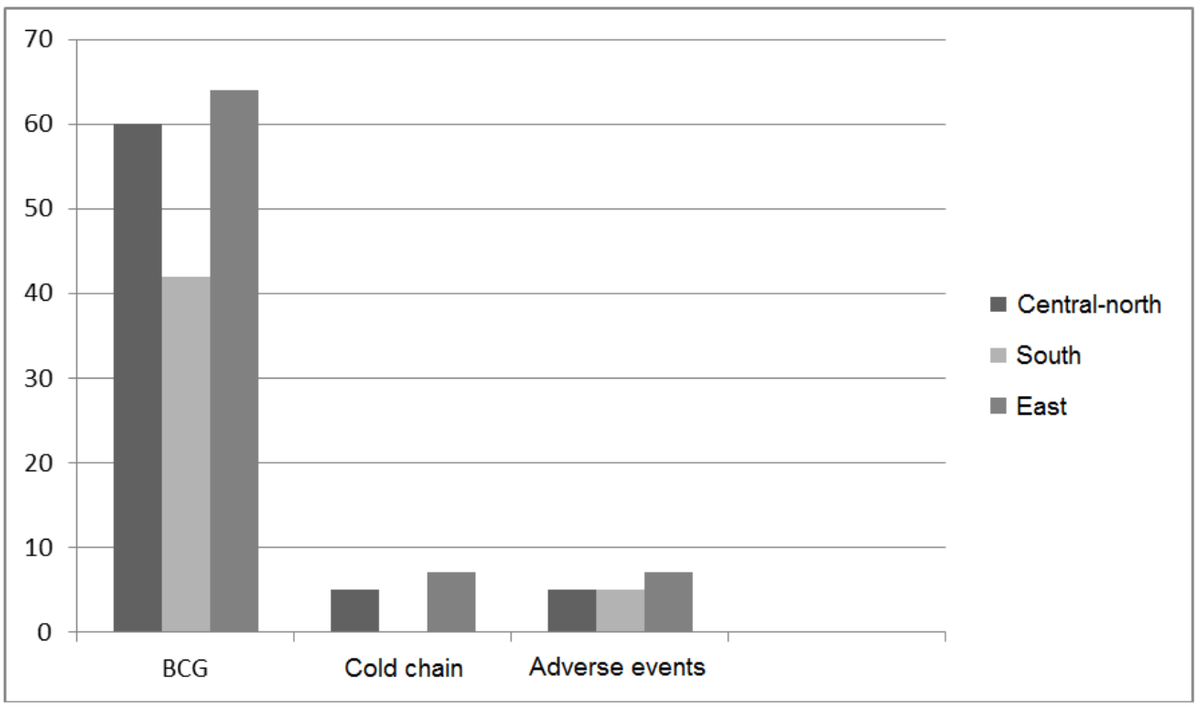

Figure 2. Specific training of Professional in vaccine rooms in recent years by zone. Teresina - PI, 2008-2009.

DISCUSSION

Regarding the physical structure, a rough calculation of the size of vaccine rooms through observation and estimation was made and found that 8 (40%) vaccine rooms of the central-north zone and 12 (63.2%) of the south zone do not have adequate size. Some are so small that do not even have capacity to lodge the equipment needed as bed and cabinets, and make it difficult for professionals and the patient to move around in the room,

precluding thereby the correct application of immunobiological agents.

It is noteworthy that all vaccine rooms located on the east side (wealth area of the capital of Piaui) have adequate size, that is, a minimum size of 6m^2, as standardized by the NIP.[1]

Importantly, the hygiene of rooms where immunobiological agents are administrated is essential, and washable walls free from posters and stainless steel countertops are indispensable aspects to facilitate the process of cleaning and disinfection, avoiding thus infections and providing favorable conditions for handling and conservation of vaccines.[1] Unfortunately, this was not the structure found in most study areas, mainly in the southern zone vaccine rooms.

Vaccination room is the place for administration of immunobiological agents. Thus, it is necessary that facilities meet the following minimal conditions: walls and floors must be washable; sinks and switches must be available for the exclusive use of each electrical equipment; the room must be ventilated and clear, avoiding, however, the incidence of direct sunlight. Moreover, it is important to keep it in good hygienic conditions. Ideally, the vaccination room must be exclusive for the administration of immunobiological agents and have, if possible, have an independent entrance and exit.[1,4,7]

Vaccine rooms should be furnished with equipment, such as thermometers, polystyrene, cabinets, table, chairs, gelox, air conditioning and beds, essential factors for handling and maintaining the proper conservation of vaccines and patient comfort. However, in this study, remarkable lack of beds was observed in most of the studied areas, favoring the occurrence of errors during the administration of the vaccine, causing disorder and damage to the assisted clientele consonant with the result found in a research conducted in Pernambuco.[7]

The vaccine room must also be cooled with air conditioning, since the temperature can not be higher than the cold box, otherwise it will cause the entire surface of the box to be affected due to the heat penetration through the its walls, and the heat is very harmful because it accelerates the inactivation of substances in the composition of the products.[5]

Facilities must have two refrigerators, one for vaccines in stock and another for daily use. All vaccines rooms studied have a refrigerator dedicated exclusively to the conservation of immunobiological agents. However, most units do not have another refrigerator for vaccines in stock, and the daily process of opening and closing the door of the refrigerator contributes to raising the internal temperature of the refrigerator, consequently compromising the effectiveness of vaccines.[1]

The conduct of workers on vaccine rooms studied, concerning handling, packaging and conservation of immunobiological agents, still leaves much to be desired. It is important to consider that the succession of small flaws may compromise the credibility that immunobiological agents have gained in recent decades and instructing professionals and monitoring the processes that involve the handling of these substances by supervisors of units and municipal health managers is essential to keep this credibility.[6]

Even developed countries are not free from fails. A survey conducted in the United States raised the possibility that failures in the storage of vaccines at local health units may have contributed to a recent increase in whooping cough rates in the country.[8]

Despite the standard rules established by the NIP[1], 6 (30%) vaccine rooms of the central-north and 4 (21.1%) of the southern zone do not keep the refrigerator away from heat and direct sunlight, as well as 1 (5%) of refrigerators in rooms in the central-north zone was not at a distance of 20 cm from the wall. This may cause huge losses for efficacy and vaccine potency due to the exposure of immunobiological agents to high temperatures.

It is necessary to highlight the importance of the use of bottles with water in the bottom of the refrigerator, because in case of power outages, these help to maintain the temperature suggested by NIP (2°C to 8°C), avoiding temperatures above 8°C. It turned out that 1 (5.3%) refrigerator of the vaccine rooms in the south do not have bottles of water inside the refrigerator and this can negatively affect the vaccine conservation process, since there is a lot of oscillation of energy in this area.

The cleaning and the refrigerator defrosting is also an important technical practice for maintenance of ideal conditions for vaccines.[1] In 5 (26.3%) of the south zone vaccine rooms, and 1 (7.1%) of the rooms of the east side, lack of proper cleaning of refrigerators was observed. Some of the staff reported that, often, it takes more than a month to wash the refrigerator, hindering thus the conservation of immunobiological agents, maybe freezing them. According to the norms of NIP, defrost and internal cleaning of the

domestic refrigerator should be performed every 15 days or when the layer of ice reaches 0.5 cm.[1]

Ambiance with gelox is a technical procedure of great importance for the conservation of immunobiological agents, and should be performed whenever vaccines are to be put in cold boxes at different instances, including for daily use in vaccine room. All nursing staff working in vaccine rooms reported that they perform the ambiance of ice packs before putting them in the cold box. It is worth mentioning that this report is not consistent with the practice of these professionals often due to the day-to-day rush and even by misinformation, take the gelox from the freezer and place them immediately in the cold box, or simply put under running water to remove excess external ice, as noted. A different practice was observed to be adopted in a study carried out in the Basic Health Units (BHU) of a municipality in the Midwest region of Minas Gerais.[9]

This detection is serious, since if ice coils are removed from the freezer, they are with temperature of nearly -7 ° C (seven degree Celsius) and are immediately placed in the box with immunobiological agents, without temperature control, these vaccines are exposed to the risk of freezing.

The freezing, as we know, can inactivate vaccines such as BCG, DPT and tetravalent. The precipitation of a vaccine may occur due a temperature below 0°C (zero degrees Celsius) for a period of time of several days, or accumulation of partial periods of time.[3]

Ten (71.4%) nurses from vaccine rooms of the east of Teresina perform the monitoring of temperature of the thermal boxes everyday, watching if it is between 2 and 8°C, influencing thus the effectiveness of vaccine, to avoid that the vaccination loses, as well, causing post-vaccination local reactions, thus putting in doubt the quality of these products.

Regarding cold boxes, it was found that most of them had proper condition of sealing and were free from solar light and far from heat sources, as recommended by the NIP Cooling Manual.[3] However there are still 10 (19%) rooms that do not meet the recommendations and need to adapt.

A study conducted in São Paulo State that evaluated the standardization of vaccines rooms attributed a satisfactory concept, despite of a few rooms with inadequate situations. Regarding the general aspects of vaccination rooms, the following critical points stand out: most of the rooms was not exclusive to vaccination; no one room had temperature kept between 18 and 20°C; most lacked adequate protection against direct sunlight; and more than half had decorative objects; and they did not have ideal conditions of cleanliness and conservation.[10]

An important technical conduct for the maintenance of optimal conditions of vaccines is also cleaning and defrosting the refrigerator. The rules of NIP recommend that defrosting and internal cleaning of the domestic refrigerator should be performed every 15 days. The study revealed that six units do not follow this standard. A divergent reality was found in Pernambuco, where 82% of the evaluated rooms perform defrosting and cleaning of the refrigerator every 15 days or when the ice layer exceeds 0.5 cm.[11]

Another observation was the opening hours of vaccine rooms in healthcare facilities. Employees in general do not obey the opening hours determined by the MHF, that is, the process of vaccination is not offered full-time (7am to 13h and 13h to 19h), which contributes to Loss of Opportunity for Vaccination (LOV). Full-time service happens in only 5% of the rooms of the central-north, 10.5% of the south and 36% of the east side. In São Paulo, one vaccine room works less than six hours a day and this is considered a critical point.[10]

Regarding the training of nursing professionals in vaccine room, it was noted that most employees were trained to work with vaccines more than two years ago and some have never received any training. Most do not have specific training in BCG and vaccine adverse effects.

It is noteworthy that the best strategy for the conservation of vaccines is the training of professionals who handle them because it is known that immunization is one of the most effective measures on disease prevention, reducing morbidity and mortality from vaccine-preventable disease.

A survey conducted in Piauí in 2012 that evaluated the knowledge and professional practices on vaccine conservation pointed out that the professionals working in vaccination rooms have inappropriate knowledge and practice and that many of the problems identified in this study persist until the present day.[12]

Despite the good level of information that technicians and nursing assistants researched in this study have, failures in the internal organization of the refrigerator were still observed, and these may compromise the quality of immunobiological agents. A strategy that could be adopted to minimize such a

situation would be the adoption of the nursing supervision process in vaccine room done by the nurse, which allows for more effective monitoring of immunization activities, avoiding the occurrence of failures in the procedures that can lead to reflection on the quality of immunobiological agents, made available to the public.[13]

CONCLUSION

This study reflected a worrying and relevant setting for the management, as some flaws in vaccine conservation process have been found, as well as deficiency in the training of nursing professionals in vaccine rooms in every sense.

Therefore, it is important to consider that the occurrence of small failures can compromise the credibility that immunobiological agents have gained in recent decades. The following aspects are essential to maintain this credibility: the specific training of professionals; monitoring of the processes that involve the handling vaccines, by supervisors of units and municipal health managers; and change of attitude on the part of managers.

A reflection is needed, as nursing professionals represent the technical team responsible for the conservation and management of immunobiological agents in the public health system, allowing thus the maintenance of effectiveness of vaccines in the service.

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