CONSERVATION OF VACCINES IN PRIMARY HEALTH CARE: CONDITIONS IN A CAPITAL CITY IN NORTHEASTERN BRAZIL

ABSTRACT: The preservation of vaccines in Primary Health Care units in São Luís, a capital city in northeastern Brazil, is evaluated. Current descriptive, evaluative, cross-sectional quantitative approach was applied to a section of PAISSV 2.0 of the National Immunization Program with nursing professionals, between August 2016 and January 2017. Descriptive statistical analysis was employed. Forty-eight (92.3%) vaccine rooms were assessed. The complete absence of refrigerated chambers and the lack of monitoring and control instruments for temperature may be highlighted. In the case of the conservation process, not a single vaccine room distributed vaccines on shelves as recommended. Further, 43 vaccine rooms (89.6%) were classified as unsuitable and all were inappropriate. The vaccine conservation practice is still incipient, with inadequate structure and working process. These flaws may compromise the eradication and control of immunopreventive diseases.

KEY WORDS: Health services research; Immunization; Primary health care; Refrigeration; Vaccines.

CONSERVAÇÃO DE VACINAS NA ATENÇÃO PRIMÁRIA À SAÚDE: REALIDADE EM CAPITAL DO NORDESTE BRASILEIRO

RESUMO: O objetivo deste trabalho é avaliar a qualidade da conservação das vacinas em Unidades da Atenção Primária à Saúde em uma capital do Nordeste brasileiro. Trata-se de um estudo descritivo e avaliativo, transversal, com abordagem quantitativa. Aplicou-se parte do instrumento PAISSV 2.0 do Programa Nacional de Imunização, com profissionais da enfermagem entre agosto de 2016 e janeiro de 2017. Utilizou-se análise estatística descritiva. Avaliou-se 48 (92,3%) salas de vacinas. Na dimensão estrutura, destaca-se a ausência de câmaras refrigeradas e de instrumentos de monitoramento e controle da temperatura em 100% das salas avaliadas. Quanto ao processo de conservação, evidenciou-se que nenhuma das salas realizava a distribuição das vacinas nas prateleiras, conforme recomendações técnicas. 43 (89,6%) salas foram classificadas como não adequadas e nenhuma considerada adequada. A prática da conservação de vacinas ainda é incipiente, com inadequação da estrutura e processo de trabalho. Estas lacunas podem comprometer a erradicação e o controle das doenças imunopreveníveis.

PALAVRAS-CHAVE: Atenção primária à saúde; Avaliação dos serviços de saúde; Imunização; Refrigeração; Vacinas.
INTRODUCTION

Immunization is one of the most efficient strategies employed worldwide by Health Vigilance (HV) for the prevention, monitoring and eradication of immunopreventive diseases\textsuperscript{1-3}. It greatly impacts the National Health Service (SUS) through a decrease in morbomortality rates in the population and in costs through hospitalizations and treatments\textsuperscript{4-6}.

In 1973, the Brazilian Ministry of Health elaborated the National Immunization Program (NIP), henceforth responsible for the operationalization of the service with the extended routine vaccine supply; yearly immunization campaigns; behavior to cope with adverse events and blockage vaccines; establishment of targets, joint ventures and technological incentives in the national production of immunobiological agents (vaccine, serums and immunoglobulins)\textsuperscript{2,3}. Highlighted worldwide, NIP provides guidelines in all sections of its administration on the normative aspects for the maintenance of the Cold Chain (CC) characterized by a complex system of managing the temperature of perishable products in order to maintain quality and safety from the point of origin, conditioning, conservation, supply, and distribution up to the administration of vaccines to patients. It also comprises programming, evaluation and funding followed by the states and municipalities\textsuperscript{7,8}.

Safe vaccine comprises quality control of thermolabile product, or rather, their capacity and immunogenicity are conditioned to refrigeration at specific temperature, between +2°C and +8°C in the local instance or -20°C in the central instance\textsuperscript{3}. However, several research works have detected interference factors related to CC featuring flaws in conservation, storage, transport and stocking\textsuperscript{11}; in Permanent Health Education (PHE)\textsuperscript{12}, supervision of professionals working in the Vaccine Room (VR)\textsuperscript{13,14} and accessibility limits to immunization services\textsuperscript{15}.

There are one or two assistant nurses and a nurse in each VR whose technical responsibility (TR) comprises supervision of vaccine procedures, with competence ordained by the Federal Council of Nursing (COFEN), Resolution 302/2005\textsuperscript{16}. The relevance of the nursing team should be underscored with regard to the administration and dispensation of immunobiological agents and to the compliance of norms and procedures recommended by NIP\textsuperscript{14}. In other words, the team’s task is to maintain the products’ conservation and dispensing quality, coupled to the planning and establishment of efficient strategies to reduce risks in patients’ protection\textsuperscript{17}.

Several investigations in Spain and the USA have pinpointed significant flaws in the conservation and storage of vaccines which may contribute towards a decrease in immunization efficaciousness and in an increase in disease rates\textsuperscript{14}. Research in Brazil has detected the bad functioning of refrigerators and thermometers\textsuperscript{1} due to lack of Preventive (PP) and Corrective Maintenance (MC) programs of equipments and accessories\textsuperscript{1} and flaws in the conditioning of reused cartridges\textsuperscript{14}, among the main weaknesses at local instances. A study from Fortaleza CE Brazil reveals the existence of damaged equipments, lack of temperature monitoring by professional, lack of updating in immunization activities and in biosafety norms\textsuperscript{18}.

Flaws occur within the local environment since the systematic monitoring of the process is of paramount important so that vaccine quality dispensed to the patient may be maintained without any health risks to the population\textsuperscript{15}. Due to the complexity of tasks in the VR\textsuperscript{8-12}, the evaluation of service quality on the structure and processing of the VR makes investigation on weaknesses, impairments, planning of activities capable of reordering the execution and quality supply of services highly relevant to attend to NIP recommendations\textsuperscript{18,19}. Assessment of health services becomes a necessary tool for the improvement of quality health assistance to patients\textsuperscript{8}, through information that would give solutions for decision taking and the planning of future activities towards a greater efficiency, efficaciousness and effectiveness\textsuperscript{9}.

There are very few national and local publications on the evaluation of structural, organizational and operational issues in VRs\textsuperscript{13,16}. Current analysis evaluates the quality of vaccine conservation in Primary Care units (UPAs) with regard to structure and processing in the northeastern city of São Luís MA Brazil.
METHODOLOGY

Current descriptive, evaluation, transversal and quantitative study on quality analysis was undertaken between August 2016 and January 2017, with nursing professionals in VRs in PCUs in São Luís, the capital city of the state of Maranhão, Brazil, with a population of approximately 1,094,667 inhabitants\(^2\). Units were selected according to the official list of the Coordination of Community Health which is the sector responsible for the administrations of PCUs within the Municipal Secretary of Health, featuring 54 PCUs out of which 52 had VRs.

PCUs inclusion criteria comprised health establishments including traditional Basic Health Units (BHUs), Family Health Units (FHUs), Health Centers (HCS) and joint units with APS teams within the model of the strategy of Health Community Agents (SHCAs), proper to the city of São Luís; with a VR and the presence of a professional nurse or an assistant nurse. The health professionals’ inclusion criteria included people 18 years old or over; nurse or assistance nurse of both genders. All BHUs, FHUs, HCs and joint units with SHCAs teams with no working VR were excluded.

The Theoretical Model for Vaccine Conservation in PHCUs\(^3\) was employed, associating the degree of conservation quality of vaccines and image-target which contemplates the attributes of structure and primordial process for the effective practice of vaccine conservation through basic materials, activities, results and expected impacts. Consequently, the evaluation of current study was based on the definition of three components, namely, monitoring of temperature, organization of refrigeration equipment and behavior to temperature changes\(^1\). The above logical model has been based on the Cold Chain Handbook\(^2\), with the necessary adaptations to attend to recommendations of the NIP Cold Chain Handbook\(^2\) and the Handbook and Procedures for Vaccination\(^2\).

Data were collected by a standard tool of the NIP Program for the Evaluation of Supervision Instrument for Vaccine Rooms (PAISSV 2.0)\(^4\), employing items 1 (Identification of VR) and IV (Cold Chain). Questionnaire was applied by two interviewers in 48 VRs of the municipality. Two VRs were under construction during the data collection period and the professional for interviewing in one VR was on leave. Researchers collected data during working hours (morning and afternoon) in the VRs of the PHCUs by interviews with nurses or assistant nurses of VRs and by observations of VRs and equipments. Responses of forty nurses and of eight assistant nurses were received.

Analysis and evaluation of quality indexes of VRs were performed by the adaptation of analysis and assessment matrix\(^1\). Adaptation was required due to new NIP technical guidelines on vaccine conservation. The following variables for structure were a) exclusive refrigeration equipment for vaccine storage; b) maximum-minimum thermometer; c) freezer with recyclable ice; d) lower segment with bottle filled with water; e) empty door; f) capacitated professional in the VR and cold chain.

There were three variables for the process, with the respective quality indexes: a) organization of the refrigeration equipment (I – correct distribution of vaccines according to shelves for the refrigeration chamber where specific distribution/for refrigerator is not required, with the absence of vaccines on the first shelf and in the lower compartment; II - correct distribution of vaccines on shelves for refrigerating chamber where the specific distribution/for refrigerator is not required, with viral or bacterial vaccines conditioned on the second and third shelves; III – cleaning and de-freezing according to period recommended by NIP; IV – preventive and/or corrective maintenance for the refrigeration equipment); b) monitoring temperature (I – reading and register of temperature at the start and end of day; II – conditioning of reused cartridges; III – monitoring/control of temperature of the thermal box for daily use); c) behavior in the wake of changes in temperature (I – immediate communication of temperature changes to a higher authority; II - filling the form Registration of Occurrences for different changes (quality deviation) in immunobiological agents; III – maintenance of doubtful vaccines at the recommended temperature (between +2ºC and +8ºC), until further order from higher authority.

Maximum marks at 35 were distributed as follows: 10 marks for structure (refrigeration equipment exclusive for vaccine storage – 1.0 mark; maximum-minimum thermometer – 3.0 marks; freezer with recyclable ice –
1.0 mark; lower section with bottle filled with water – 1.0 mark; empty door – 1.0 mark; professional specialized in vaccine room and cold chain – 3.0 marks) (Figure 1); 25 marks for process (activities for temperature monitoring – 5.0 marks; activities for the organization of the refrigerator – 10.0 marks; activities related to events with temperature changes of the refrigeration equipment – 10.0 marks).

The sum of marks of indexes in each dimension under analysis provided scores which were converted into relative rates, with 100% as maximum score. Quality degree scores were undertaken taking into account two stages: (1) determination of rates (Σ of marks of indexes) and the calculation of quality degrees (Σ observed / Σ of maximum marks X 100) for each component; (2) sum of components to calculate total quality degree. After the determination of scores for quality level in vaccine conservation, categories were defined at the following classification: “adequate” (90% - 100%); “inadequate” (60% - < 90%); and “critical” (< 60%).

Data were transferred on a Microsoft Excel® 2010 sheet with double digitation for the analysis of external consistency. Questions on the questionnaires were categorized in a code book together with the sheets to decrease systematic errors. Data were transferred to Stata®14.0 for descriptive analysis.

The Health Education Sector of the Municipal Health Secretary of São Luís (Semus) gave its consent after several meetings on the presentation and awareness on the research to PHCUs agents of the municipality during the meetings of the Regional Inter-administration (RIC). The study was also approved by the Committee in Ethics for Research of the Universidade Ceuma, by Protocol 1.570.456/16. Free Consent Term (TCLE) was signed by all participants following Resolution 466/2012.

RESULTS

Forty-eight (92.3%) vaccine rooms within 52 PHCUs in São Luís were evaluated. Table 1 provides data that reveal the structure and organization of VRs under analysis.

Table 2 provides data on the evaluation of the work process in VRs. All the 48 (100%) rooms distributed incorrectly (contrary to NIP recommendations) vaccines on the shelves.

Further, 43 (89.6%) of rooms were classified as inadequate from the point of view of results related to total quality degree of conservation of VRs, while 5 (10.4%) were considered critical. No room reached the adequate score band (Table 3). Mean quality degree of the 48 VRs evaluated reached 70.1 marks, varying between 67.2 and 72.9, and deviation at approximately 1.4 marks (data not shown in the Tables).
### Table 1. Description of the structure and organization of VRs of PHCU's, São Luís MA Brazil, 2017 (n = 48)

<table>
<thead>
<tr>
<th>Variables</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Refrigeration equipments, type domestic refrigerator</td>
<td>48</td>
<td>100</td>
</tr>
<tr>
<td>Storing of items/substances in the door of the refrigeration equipment</td>
<td>9</td>
<td>18.8</td>
</tr>
<tr>
<td>Ice recyclable cartridges in the freezer at the recommended number</td>
<td>45</td>
<td>93.8</td>
</tr>
<tr>
<td>Bottles with colored water in the lower segment of the refrigerator</td>
<td>47</td>
<td>97.9</td>
</tr>
<tr>
<td>Maximum-minimum thermometer</td>
<td>44</td>
<td>91.7</td>
</tr>
<tr>
<td>Refrigerated chambers, laser infrared thermometer, thermometer with graphic registration, data loggers, electronic freezer register and freezing gauge</td>
<td>0</td>
<td>100</td>
</tr>
<tr>
<td>Capacitation of interviewees in VR* within the last 5 years</td>
<td>41</td>
<td>85.4</td>
</tr>
<tr>
<td>Capacitation of interviewees in CC** during the last 5 years</td>
<td>34</td>
<td>70.9</td>
</tr>
<tr>
<td>Capacitation of interviewees in VR and CC during the last 5 years</td>
<td>27</td>
<td>56.2</td>
</tr>
</tbody>
</table>

Note: *VR: vaccine room; **CC: cold chain.

Fonte: Dados da pesquisa.

### Table 2. Description of the process in VRs of PHCU's, São Luís MA Brazil, 2017 (n = 48)

<table>
<thead>
<tr>
<th>Variables</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Distribution of vaccines on the shelves according to NIP’s technical recommendations</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>Viral and bacterial vaccines on the first shelf</td>
<td>46</td>
<td>95.9</td>
</tr>
<tr>
<td>Viral or bacterial vaccines on the second and third shelves</td>
<td>45</td>
<td>93.8</td>
</tr>
<tr>
<td>Viral and bacterial vaccines together on the second and third shelves</td>
<td>39</td>
<td>81.2</td>
</tr>
<tr>
<td>Thawing and/or cleaning procedures according to recommended periodicity</td>
<td>16</td>
<td>33.3</td>
</tr>
<tr>
<td>Preventive and/or corrective maintenance of refrigeration equipments</td>
<td>1</td>
<td>2.1</td>
</tr>
<tr>
<td>Reading and register of temperature of refrigeration equipment at the start and end of the day</td>
<td>40</td>
<td>83.3</td>
</tr>
<tr>
<td>Rate maps inconsistent with recommended standard</td>
<td>3</td>
<td>7.5</td>
</tr>
<tr>
<td>Environmental adequacy of the box used daily</td>
<td>24</td>
<td>50.0</td>
</tr>
<tr>
<td>Temperature monitoring and control of the box used daily</td>
<td>23</td>
<td>47.9</td>
</tr>
<tr>
<td>Immediate communication to higher authority when temperature changes occur</td>
<td>48</td>
<td>100</td>
</tr>
<tr>
<td>Filling and sending of immuno-biological forms with quality deviations to higher authority</td>
<td>15</td>
<td>31.2</td>
</tr>
<tr>
<td>Doubtful vaccines kept at recommended temperature till guidelines by higher authority</td>
<td>38</td>
<td>79.1</td>
</tr>
</tbody>
</table>

Fonte: Dados da pesquisa.
Several studies in Brazil also show good practices in the use of refrigeration equipments. Whilst one study evaluated 223 VRs, of which 51 (23.0%) had refrigerated chambers, another from the mid-western and southern regions of the municipality of São Paulo showed that 100% of BHUs evaluated already had specific chambers for the conservation of vaccines. Most had even more than one equipment.

Domestic refrigerators were not projected for the conservations of vaccines due to the absence of homogeneity of thermal distribution and the incapacity of maintaining internal temperature at a minimum when a fall in electrical energy occurs. They should therefore be replaced by refrigerated chambers recommended by the World Health Organization. In fact, they have capacity to maintain the same positive temperature between +2ºC and +8ºC throughout the equipment and thus preserve the vaccines from extreme temperatures. The above may interfere in immunogenicity where vaccines composed of aluminum-containing adjuvants submitted to temperature below may have a permanent fall in capacity. Another issue deals with alterations in their physical and chemical characteristics and the possibility of causing adverse post-vaccination events (EAVP).

The lack of thermometers in some refrigerators and in fifty percent of boxes for daily use cannot be permitted. One should underscore the basic requirement of the thermometer to monitor the refrigerator and the vaccine thermal box, and thus avoiding administering vaccine with the certificate of adequate conservation.

The standard reading of temperature twice a day is not sufficient to guarantee the quality of vaccine conservation. The employment of digital temperature data logger or thermographs is the best. International research work concerned with vaccine quality within the cold chain network have investigated new tools and approaches underscoring control and monitoring of vaccine temperature, focusing on thermal stability, freezing, development of regulations and protocols.

Most professionals admitted temperature reading and registration at the start and end of the day. The procedure does not necessarily imply in the correct maintenance of temperature since registers outside the recommended band were identified. Reading and

### Table 3. Distribution of total quality degree of VRs of PHCUs, São Luís MA Brazil, 2017 (n = 48)

<table>
<thead>
<tr>
<th>Classification</th>
<th>N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adequate</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Inadequate</td>
<td>45</td>
<td>89.6</td>
</tr>
<tr>
<td>Critical</td>
<td>5</td>
<td>10.4</td>
</tr>
<tr>
<td>TOTAL</td>
<td>48</td>
<td>100</td>
</tr>
</tbody>
</table>

Fonte: Dados da pesquisa.

### DISCUSSION

In current study, data analysis evaluated vaccines’ conservation quality on the basis of structure and process, and evidenced that most VRs were classified as inadequate (89.6%) according to NIP’s technical norms. One should underscore that some VRs had a critical score (10.4%) and none was adequate (0%).

Several studies have shown frequent flaws at local instances with regard to adequacy of the structure-process sequence and to the quality supply of vaccination activities. Most PHCUs were classified as inadequate when degree of total quality of vaccine conservation was evaluated. None reached the adequate score mark. Findings bring many concerns. They are very similar to results collected in the western region of the state of Minas Gerais where 83% of VRs were classified as inadequate, with 77.6 and 80.3% rates for structure and process, respectively, albeit different from those in the northern region of the same state in 2015 where most VRs were classified as good/very good.

All VRs in current study had domestic refrigeration equipments, more than half of which were frost free. Similar results were also provided by other municipalities of the southeastern and northeastern regions of Brazil. However, the replacement of this type of refrigeration by refrigerated chambers has already been recommended in Brazil and abroad since it improves the quality of handling of immune-biological agents, with a significant decrease of losses. International studies undertaken in Germany, India, Australia and New Zealand have shown significant concern on storage and adequate thermal distribution of vaccines to guarantee their efficiency and tolerance through the use of chambers, besides the continuous training of the teams.
registration of temperature in PHCUs are undertaken to merely comply with protocols rather than a guide for the preservation of the quality in vaccine conservation. Vaccines stored outside the recommended temperature band may have a loss in immunogenic quality with damage ranging from the impairment of the stimulus of immunologic response, with low or no protection, to the loss of products with severe financial burden.

With regard to the use of domestic refrigerators, NIP established that vaccines should not be placed on the first shelf and on the lower compartment (drawer) of the equipments. They should rather be organized by type (viral or bacterial) and conditioned in the second and third shelves, placing the vaccines with a shorter expiring date in front of the others with a longer. In most rooms, the commonest disposition featured yellow fever vaccines and oral vaccine against child paralysis (VPO) on the first shelf and the others distributed, without any criterion, on the second and third shelves.

Results suggest that the organization of the work process by PHCU nurses has many deficiencies where the VR administration is not performed systemically focusing on daily supervision. In fact, the administration of immune-biological agents is a rather complex activity. However, one should never underestimate the experience acquired in the professional service of the assistant nurse within the improvement of quality. In spite of everything, one should understand that nurses exercise an important task within the work environment, planning nursing assistance, education, capacitation and development of the nursing team through evaluations of periodic activities.

Distancing of care tasks is perhaps related to the nurses’ day to day assistance activities, characterized by simultaneous performance as VR administrators and technical agents, with excess of labor impairing care planning, supervision and team guidance within the perspective of permanent follow-up and education.

Current study is limited by the fact that in the immunization field the PAISSV is an instrument indicated by the Ministry of Health to evaluate VRs. However, the most recent version was made available in 2004 and never updated. Results indicate the need of reorganizing the infrastructure and the work process of PHCUs and the adoption of promotion of safe practices in VRs. Consequently, information may be employed and discussed in the professional practice of nursing with emphasis on immunization activities and the degree for efficaciousness, efficiency and effectiveness of the service and, thus, a more quality care in HCU.

CONCLUSION

Current analysis has shown that the quality of vaccine conservation is not adequate in most PHCUs. Results indicate the lack of equipments in the form and technical quantity suggested by NIP, lack of capacitization and awareness of nursing professionals with regard to the recommended tasks, especially the control and monitoring of vaccine temperature and the performance of proper behavior in the wake of possibilities of the products’ quality deviation. Discussions and resolution strategies are required without disregarding the small investments that weaken the Brazilian Health System (SUS).

Data show the importance of the nursing team within the process of decision-taking related to the day to day care in VRs and the promotion of safe practices in immunization. They also enhance the capacities and fragilities in the quality of vaccine conservation in PHCUs in the capital city of the state of Maranhão and underscore the challenges to be coped with in the systematization of supervision, monitoring and evaluation of health services.

CONFLICT OF INTERESTS

The authors declare that no conflict of interest exists.

REFERÊNCIAS


2. Pereira DDS, Neves EB, Gemelli M, Ulbricht L. Análise da taxa de utilização e perda de vacinas no


