Original article

# Adequacy assessment of immunobiological agent conservation in the Western Health macro-region of Minas Gerais State, Brazil: a descriptive study, 2017*

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## Abstract

**Objective:** To describe the adequacy of immunobiological agent conservation in vaccination rooms in the municipalities of the Western health macro-region of the state of Minas Gerais, Brazil. **Methods:** This was a descriptive study, based on a validated scale, with a maximum score of 15 points. A descriptive analysis and an association test between the scores obtained by the municipalities and variables of the external context were performed. **Results:** 275 out of a total of 295 existing vaccination rooms were evaluated. Immunobiological agent conservation in the West macro-region obtained an average score of 4 points (standard score, 0 to15). There was a poor availability of immunization supplies aimed at immunobiological agent conservation, and work processes, that require improvement. Small municipalities presented better immunobiological agent conservation (p=0.011). **Conclusion:** Immunobiological agent conservation in vaccination rooms in the Western health macro-region of Minas Gerais State was considered inadequate.

**Keywords:** Vaccines; Immunization; Refrigeration; Descriptive Epidemiology.

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## Introduction

Immunobiological agent conservation influences on vaccine effectiveness and, consequently, the success of the National Immunization Program (PNI).[1-3] During the process, the cold chain is the system for storing and transporting immunobiological agents from the manufacturer's point of origin to users in vaccination rooms, public or private, requiring adequate storage and transportation to guarantee the recommended temperature.[4,5] According to the recommendations of the World Health Organization (WHO), at the municipal level, immunobiological agents should be transported and stored at temperature between +2 ºC and +8 ºC; 6 at the national and state levels, it is worth mentioning that some immunobiological agents can be stored at temperature between -25 °C and -15 °C.[5]

> *The inadequate temperatures to which immunobiological agents are exposed, provides evidence of the failure in the maintenance of the cold chain and may result in a reduction of protection of individuals against vaccine preventable diseases, in addition to the possibility of causing undesirable adverse events, interfering negatively in the adherence of the population to vaccination.*

The adequacy of the cold chain aims to ensure the immunogenicity of immunobiological agents, sensitive to temperature changes.[7,8] High temperature impacts on the reduction of immunobiological agent quality, while freezing can irreversibly damage these produts.[9,10] The inadequate temperatures to which immunobiological agents are exposed, provides evidence of the failure in the maintenance of the cold chain and may result in reduction of protection of individuals against vaccine preventable diseases, in addition to the possibility of causing undesirable adverse events, interfering negatively in the adherence of the population to vaccination.[6] A large amount of financial resources has been invested to maintain the cold chain, in order to provide effective immunobiological agents and thus ensure safety for users.[7,11] In some countries in Africa, Asia and Europe, however, these chains do not work as they should, and a common event is observed: failure to maintain the cold chain,[1,3,12] as it also occurs in Brazil.[13-16]

As such, we highlight the need to conduct studies that systematically evaluate the adequacy of the cold chain in order to provide safe and effective immunobiological agents to the population. This study aimed to describe the adequacy of immunobiological agent conservation in vaccination rooms in the municipalities in the Western health macro-region of Minas Gerais.

## Methods

This was a descriptive study to evaluate the adequacy of immunobiological agent conservation in vaccination rooms in urban Primary Healthcare Centers (PHC) in the Western health macro-region of Minas Gerais State Minas Gerais, in 2017 (Figure 1).

Located among the Central, South and Upper Paranaíba regions, with a territorial extension of 28,136.5 km², the Western health macro-region of Minas Gerais has an average human development index (HDI) of 0.70 and a population of 1,280,907 inhabitants. It is divided into eight micro-regions, considered from their respective polo municipalities: (i) Bom Despacho, with seven municipalities; (ii) Campo Belo, seven municipalities; (iii) Divinópolis, eight municipalities; (iv) Formiga, eight municipalities; (v) Itaúna, four municipalities; (vi) Lagoa da Prata/ Santo Antônio do Monte, five municipalities; (vii) Oliveira/Santo Antônio do Amparo, six municipalities; and (viii) Pará de Minas, with eight municipalities.[17]

In the 53 municipalities of the Western health macro-region, there are 295 vaccination rooms belonging to the public health network, inserted in the Family Health Strategy (FHS) or distributed among PHCs, polyclinics and hospitals. Immunization activities are performed by the nursing team, under the supervision of a nursing professional.

All immunization rooms inserted in the urban PHCs were eligible for the study, excluding those located in the rural area and/or which only served as support points to health teams during their work in rural areas, whose limited access and/or lack of physical structure is recognized.

The independent variables of the study that were selected defined two categories for the studied municipalities: population size (less than or equal to 10,000 inhabitants; greater than 10,000 inhabitants);[18]

and FHS coverage (less than or equal to 80%; greater than 80%).[19] The Primary Health Care Information System (SIAB) database, under the national coordination of the Ministry of Health, was used to collect data on population size and FHS coverage. Regarding the variables selected for the vaccination rooms, their insertion or not in the FHS was analyzed. As for nursing professionals working in these rooms, the professional category (nurse; nursing technician; nursing assistant) and professional formation (level of study: Technical; Graduation; Specialization; Master's degree; PhD) were investigated.

The Immunobiological Agent Conservation Assessment Scale (EACI) was adopted,[20] validated for the Brazilian context, aimed at measuring the conservation of immunobiological agents at the local level, specifically in vaccination rooms. The EACI enables the identification of weaknesses in the context in which the vaccination rooms are inserted, and also the implementation of interventions to improve the cold chain. The EACI is comprised of five items, which use a Likert scale (it shows the level of agreement with an affirmation) as an option of answers, organized in an ordinal scale, with opposite and symmetric extreme points, and the following possibilities are in between: never (0); almost never (1); almost always (2); always (3). The score obtained by the EACI represents 15 points, stratified into: 0 - 9 points the immunobiological agent conservation is 'inadequate', and 10-15, 'adequate'. The five evaluation items include: (i) the availability of batteries or generators, in case of power grid failure; (ii) the existence of other temperature measurement instrument in addition to maximum and minimum thermometer (instantaneous temperature reading); (iii) the existence of a refrigerated chamber for immunobiological agent storage; (iv) air conditioned vaccination room (between +18 ºC and +20 ºC); and (v) the transportation from the municipal facilities (immunobiological agent center) to the vaccination rooms, in refrigerated vehicles. In addition to these items, there are seven more, of descriptive nature, for an optimization of the evaluation of vaccination rooms: (i) use of polyurethane cooler boxes; (ii) the exclusivity of the vaccination room for vaccination-related activities; (iii) updating of the professional working in the room, in immunization training; (iv) the occurrence of direct sunlight or other heat source close to immunobiological agent storage equipment; (v) the replacement of reusable ice coils after the expiration date; (vi) preventive maintenance for immunobiological agent conservation equipment; and (vii) keeping the professional working in the room informed on immunization updates available.

The application of the EACI was performed by one of the researchers, in person, in a reserved room in a PHC, with a nursing professional who was the technical responsible for the vaccination room; or with a nursing technician or assistant working in the same room. The interview was conducted after the research participant received guidance on the objectives of the study and signed a Free and Informed Consent Form. It is worth mentioning that an identification code was assigned to each of the participants, respecting their anonymity.

Data were collected during the second half of 2017, during visits to all vaccination rooms in the 53 municipalities in the Western health macro-region of Minas Gerais, when the EACI was applied, in addition to direct observations made by the researchers that enabled the elaboration of a field diary.

Descriptive analysis of the variables related to the characterization of the municipalities, vaccination rooms and the professionals working in these rooms was performed, in addition to the items related to the EACI and respective scores obtained by the immunization rooms. Pearson's chi-square test was used to verify the association between the scores obtained by the municipalities and external context variables (population size; FHS coverage). All analyses were performed by adopting a significance level of 5%. Data were processed using EpiData software (version 3.1) and analyzed in Epi Info™ (version 7.2).

The study project was approved by the Human Research Ethics Committee of the Federal University of São João del-Rei. Opinion No. 2134434, issued on September 16, 2015, and Certificate of Submission for Ethical Appraisal (CAAE) No. 47997115.2.0000.5545.

## Results

Of the 295 public vaccination rooms in the Western health macro-region of Minas Gerais State, 275 were evaluated; 20 were excluded because they did not meet the eligibility criteria. Of the 275 professionals interviewed, who worked in the vaccination rooms, 156 (56.7%) were nursing technicians; 85 (30.9%),

nurses; and 34 (12.4%), nursing assistants. Regarding education level, of the 275 professionals, 190 (69.0%) had medium or technical level, 42 (15.3%) had a degree in nursing; 42 (15.3%) had a specialization degree; and one (0.4%) had a Master's degree.

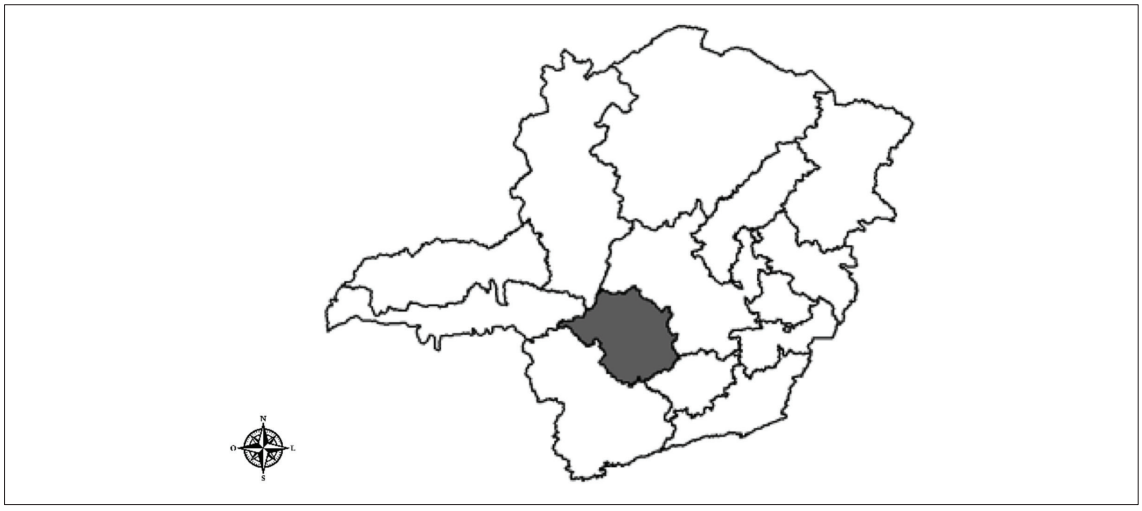
The West health macro-region presented an average of 95.0% coverage of FHS, 46 (86.8%) of its municipalities presented a coverage higher than 80%. Most vaccination rooms were inserted in the FHS (n=261; 95.0%), and located in municipalities with more than 10,000 inhabitants. (n=235; 85.4%) (Table 1).

The majority of the vaccination rooms did not have electric power generators, UPS (Uninterruptible Power Supply) or refrigerated chambers with available batteries in good conditions, in case of a power outage (n=206; 74.9%); and there were not other temperature measurement instruments apart from the maximum and minimum thermometer (n=185; 67.3%). Most rooms had neither refrigerated chambers for immunobiological agent storage (n=182; 66.2%), nor air conditioners in order to maintain indoor room temperature between +18 ºC and +20 ºC (n=199; 72.3%) (Table 2).

Most rooms were exclusively used for vaccination-related activities (n=167; 60.7%) and kept their refrigeration equipment away from the occurrence of sunlight or other heat sources (n=211; 76.7%). However, a regular preventive maintenance of most refrigeration equipment was not carried out, as recommended by the Brazilian PNI (n=214; 77.8%); and in several vaccination rooms, reusable ice coils were not replaced after the expiration date (n=134; 48.7%) (Table 2).

Immunobiological agent conservation in the vaccination rooms in the Western health macro-region was classified as inadequate, based on the EACI, reaching an average score of 4 points, ranging between 1 and 7 points according to their micro-regions (Table 3). There was a lack of supplies for immunobiological agent conservation; and the work processes required improvement. It is worth highlighting that only 13 (24.5%) municipalities carried out adequate immunobiological agent conservation. Moreover, in the analysis among micro-regions, four municipalities stood out as 'extreme points', i.e., two for reaching the maximum Score of the EACI (located in 2 and 4 microregions), and two for not scoring on any items of the EACI (located in 3 and 8 micro-regions).

A better adequacy of immunobiological agent conservation was observed in small municipalities, with up to 10,000 inhabitants. In the association analysis, it could be seen that the population size was statistically associated with the scores obtained by the municipalities related to immunobiological agent conservation: p=0.011. The FHS coverage was not associated with the scores achieved: p=0.667 (Table 4).



Source: Minas Gerais State Department of Health, 2021.
Note: On the map, the health macro-regions of the state of Minas Gerais are showed. The region highlighted in gray indicates the location of the West health macro-region.

**Figure 1 – Health Macro-regions of Minas Gerais State, Brazil, 2021**

**Table 1 – Characterization of municipalities and vaccination rooms (n=275), Western health macro-region, Minas Gerais State, Brazil, 2017**

| External context variables | Municipalities n (%) | Vaccination rooms n (%) |
|---|---|---|
| **Insertion in the Family Health Strategy** | | |
| Yes | - (0.0) | 261 (95.0) |
| No | - (0.0) | 14 (5.0) |
| **Family Health Strategy coverage** | | |
| ≤80% | 7 (13.2) | 72 (26.2) |
| >80% | 46 (86.8) | 203 (73.8) |
| **Population size (inhabitants)** | | |
| ≤10,000 | 24 (45.3) | 40 (14.6) |
| >10,001 | 29 (54.7) | 235 (85.4) |

**Table 2 – Adequacy of immunobiological agent conservation in vaccination rooms (n=275), Western healt macro-region, Minas Gerais, Brazil, 2017**

| Items | n (%) | | | |
|---|---|---|---|---|
| | Never | Almost never | Almost always | Always |
| **Evaluative** | | | | |
| Availability of batteries or generators in case of power grid failure | 206 (74.9) | 1 (0.4) | 1 (0.4) | 67 (24.3) |
| Presence of other temperature measurement instruments in addition to a maximum and minimum thermometer (instantaneous temperature reading) | 185 (67.3) | - (0.0) | - (0.0) | 90 (32.7) |
| Vaccination room equipped with refrigerated chambers for immunobiological agent storage | 182 (66.2) | - (0.0) | - (0.0) | 93 (33.8) |
| Transportation from municipal facilities (immunobiological agent center) to all vaccination rooms, in a refrigerated vehicle | 235 (85.5) | - (0.0) | - (0.0) | 40 (14.5) |
| Air-conditioned vaccination room (between +18 ºC and +20 ºC) | 199 (72.3) | 4 (1.5) | 31 (11.3) | 41 (14.9) |
| **Descriptive** | | | | |
| Use of polyurethane cooler boxes | - (0.0) | - (0.0) | - (0.0) | 275 (100.0) |
| The exclusivity of vaccination rooms for vaccination-related activities | 82 (29.8) | 15 (5.5) | 11 (4.0) | 167 (60.7) |
| Qualified health care professional who received immunization training | 23 (8.4) | 125 (45.5) | 40 (14.5) | 87 (31.6) |
| The occurrence of direct sunlight/heat close to refrigeration equipment | 211 (76.7) | 10 (3.6) | 7 (2.6) | 47 (17.1) |
| Replacement of reusable ice coils after the expiration date | 134 (48.7) | 1 (0.4) | 19 (6.9) | 121 (44.0) |
| Preventive maintenance for refrigeration equipment | 214 (77.8) | 11 (4.0) | 18 (6.6) | 32 (11.6) |
| Keeping the professional working in the room informed on immunization update available | - (0.0) | - (0.0) | 1 (0.4) | 274 (99.6) |

**Table 3 – Adequacy of immunobiological agent conservation (n=275) by micro-regions of the Western health macro-region, Minas Gerais State, Brazil, 2017**

| Micro-regions | Vaccination rooms (n) | Score[a] | Average score[b] |
|---|---|---|---|
| **1** | 27 | 173 | 6 |
| **2** | 28 | 101 | 4 |

a) Total scores of the municipalities belonging to each health micro-region of the Western macro-region of Minas Gerais State; b) The Immunobiological Conservation Assessment Scale (EACI) was used to measure the mean score for the micro-regions of the Western health macro-region of Minas Gerais State, all classified as 'inadequate'.

To be continued

Continuation

**Table 3 – Adequacy of immunobiological agent conservation (n=275) by micro-regions of the Western health macro-region, Minas Gerais State, Brazil, 2017**

| Micro-regions | Vaccination rooms (n) | Score[a] | Average score[b] |
|---|---|---|---|
| **3** | 37 | 169 | 5 |
| **4** | 33 | 153 | 5 |
| **5** | 30 | 222 | 7 |
| **6** | 31 | 95 | 3 |
| **7** | 31 | 65 | 2 |
| **8** | 58 | 84 | 1 |
| **Western Health Macro-region** | **275** | **1,062** | **4** |

a) Total scores of the municipalities belonging to each health micro-region of the Western macro-region of Minas Gerais State; b) The Immunobiological Conservation Assessment Scale (EACI) was used to measure the mean score for the micro-regions of the Western health macro-region of Minas Gerais State, all classified as 'inadequate'.

**Table 4 – Adequacy of immunobiological agent conservation (n=275) according to population size and the Family Health Strategy coverage, Western health macro-region, Minas Gerais State, Brazil, 2017**

| Variables | Total (n) | Adequate (n) | p-value[a] |
|---|---|---|---|
| **Population size (inhabitants)** | | | |
| ≤10,000 | 24 | 10 | 0.011 |
| >10,001 | 29 | 3 | |
| **Family Health Strategy coverage** | | | |
| ≤80% | 7 | 1 | 0.667 |
| >80% | 46 | 12 | |

a) Pearson chi-square test.

## Discussion

The vaccination rooms in the Western health macro region of Minas Gerais State presented failures that may compromise the immunobiological agent conservation. In most municipalities, it could be seen that some activities and parameters, standardized by the PNI, were not adequate for these standards. The EACI is based on the current WHO and the Brazilian PNI guidelines for the characterization of an ideal vaccination room, which justifies the failures pointed out in this study.

Caution is required with the generalization of the analyses and conclusions presented. The conditions for immunobiological agent conservation identified in vaccination rooms in the Western health macro-region of Minas Gerais, may not reflect the situation of other macro-regions of the state, other locations in Brazil or in the world. However, the results presented can support the implementation of actions aimed at improving the cold chain evaluated, by showing the real conditions of vaccination rooms in the Western health macro-region of Minas Gerais. The research provides support for managers and health professionals in order for them to improve work processes and structural conditions necessary for immunobiological agent conservation in their municipalities.

Electrical grid stability, added to energy reserve for critical situations, is of fundamental importance for immunobiological agent conservation.[7,9,21] The refrigerated chamber is a battery-powered device. These batteries provide an autonomy for a period between 6 and 72 hours. Therefore, the Centers for Disease Control and Prevention of the United States (CDC/USA) and the Brazilian PNI have recommended that the household refrigerators should be replaced with refrigerated chambers.[4,11] The cold chain is badly affected by household refrigerators, despite their lower cost. They are not able to control the temperature efficiently, thus, the immunobiological agents may be exposed to temperature changes, resulting in a

significant loss of their immunogenic potency.[1] In the scenario of research, the majority of the vaccination rooms evaluated, were equipped with household refrigerators, which, unlike the refrigerated chambers, are not battery-powered devices.

National and international studies also report the predominance of the use of household refrigerators for immunobiological agent conservation.[12.16.21]

To meet the recommendations of the CDC/USA and Brazilian PNI, the Ministry of Health published the Ordinance GM/MS No. 2,855, of November 5, 2019, freeing up resources to municipalities with up to 100,000 inhabitants for the acquisition of refrigerated chambers, in order to expand and ensure better storage structure for immunobiological agents.[22] During a meeting with health managers from the Western health macro-region, to discuss the results of this study, some comments were made on the acquisition of refrigerated chambers with the support of these resources.

Although no other temperature measurement instruments are used in the immunization rooms in the Western health macro-region of Minas Gerais, as recommended by the WHO,[23] it is worth mentioning: good practices for monitoring refrigeration equipment were observed in most rooms. Such practices are essential for the control of immunobiological agent temperatures.[4.11.24]

Factors such as air conditioning and keeping the reusable ice coils at room temperature are also essential for the maintenance of temperatures.[12] In the rooms evaluated, temperatures outside the recommended range; and reports of air conditioners that had been turned off on cold days or during the vaccination in newborns and the elderly were observed. Studies conducted in the states of Bahia and Minas Gerais in 2015, identified irregular temperatures, even in vaccination rooms equipped with air conditioning.[15.25]

In the majority of the municipalities, the vehicles used in the transportation of immunobiological agents were not refrigerated, putting at risk the maintenance of temperatures during transportation, which is an indispensable measure according to the Brazilian PNI.[4] A study conducted in the Philippines in 2017 reported that 95.5% of the respondents 'did not believe' that inadequate storage of immunobiological agents during transportation would increase the risk of exposure to conditions that would compromise the immunogenicity of these products.[26] Thus, the importance of constant monitoring during transportation is emphasized in order to ensure the maintenance of temperatures and other immunobiological requirements,[11.21] especially when the available vehicles do not meet the requirements for adequate transportation.[27.28]

The association between small-sized municipalities and a better conservation of immunobiological agents may be due to the fact that these municipalities have a better fiscal management, both internally and in society, given a greater link and proximity among the population, professionals and managers.[29] A study conducted in the state of Rio Grande do Sul, in 2017, showed that smaller municipalities have optimized financial control, effectiveness of personnel management, better definition and implementation of investments, based on health and education improvement, and better quality of life index.[18]

If adequate immunobiological agent conservation prevents immunobiological agent losses,[2.21.24] management practices and frequent cold chain evaluations are equally essential for achieving the effectiveness, sustainability and good performance of immunization programs, thus qualified professionals and managers are required in this service.[3.30] Both measures, immunobiological agent conservation and work process improvement, can certainly impact on the reduction of the costs of immunization programs.[1.4.7-9]

All vaccination rooms evaluated showed similarities in management, i.e., vaccination activities performed by the nursing team and supervised by a nurse. The role of a professional nurse who is the technical responsible for vaccination activities, is fundamental to the management and monitoring of the maintenance of the cold chain, in addition to promoting improvement of the nursing team through systematic training, which, consequently, impacts on the quality of care provided in vaccination rooms.[3.20] Therefore, the use and dissemination of tools for the evaluation of activities in vaccination rooms, such as EACI, can support this management process.

Taking these results, it can be concluded that immunobiological agent conservation in vaccination rooms in the Western health macro-region of the state of Minas Gerais was inadequate. Significant improvement should be made in these rooms, until they reach adequate parameters for a vaccination room and, consequently, contribute significantly to the success of the activities of the Brazilian PNI.

## Authors' contributions

Amaral GG, Guimarães EAA, Tavares LOM, Silva BS, Cortez DN and Oliveira VC collaborated with the study concept, data analysis and interpretation, elaboration of preliminary versions and approved the final version of the manuscript. All authors have declared themselves to be responsible for all aspects of the study, including ensuring its accuracy and integrity.

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