Instruments used to supervise vaccination rooms: scoping review protocol

Instrumentos utilizados para realizar a supervisão em salas de vacinas: protocolo de *scoping review*

Instrumentos utilizados para supervisar las salas de vacunación: protocolo de revisión del alcance

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RESUMO

Objetivo: Mapear todos os instrumentos, sendo eles informatizados ou não, que auxiliem no processo de supervisão das salas de vacinas. **Métodos:** Protocolo de *scoping review*, desenvolvido conforme as diretrizes da JBI, que será conduzida em três fases de busca: (1) busca nas fontes de dados Embase, MEDLINE/PubMed, *Web of Science*, Scopus, SciELO via *Web of Science*, LILACS e *ScienceDirect*; (2) busca pela literatura cinzenta no Portal de Teses e Dissertações da CAPES (Catálogo de Teses e Dissertações (CAPES), Biblioteca Digital Brasileira de Teses e Dissertações (BDTD) e *Scholar* Google; e (3) busca manual nas listas de referências dos estudos selecionados. **Resultados esperados:** Espera-se mapear uma amostra para sintetizar os instrumentos que auxiliam no processo de supervisão das salas de vacinas. Esses dados serão utilizados como aporte teórico para a segunda etapa de um estudo maior que visa construir e validar um instrumento de supervisão em sala de vacina no formato de *web* aplicativo. **Conclusão:** A análise dos dados identificará informações sobre os instrumentos de supervisão em salas de vacinas, o que pode facilitar o processo de trabalho de gestores de imunização, com incentivo a busca da qualidade das salas de vacinas e identificação de problemas no serviço de imunização.

Descritores: Imunização; Monitoramento em Saúde; Avaliação de Processos em Cuidados de Saúde.

ABSTRACT

Objective: To map all instruments, both computerized and non-computerized, that assist in the vaccination room supervision process. **Methods**: Scoping review protocol, developed according to JBI guidelines, which will be conducted in three search phases: (1) search in the data sources Embase, MEDLINE/PubMed, Web of Science, Scopus, SciELO via Web of Science, LILACS and ScienceDirect; (2) search for gray literature in the CAPES Theses and Dissertations Portal (Catalogue of Theses and Dissertations (CAPES), Brazilian Digital Library of Theses and Dissertations (BDTD) and Google Scholar; and (3) manual search in the reference lists of the selected studies. **Expected results**: The expected results are to map a sufficient sample to synthesize the instruments that assist in the process of supervising vaccination rooms. These data will be used as theoretical input for the second stage of a larger study that aims to develop and validate a vaccine room supervision tool in the form of a web application. **Conclusion**: Data analysis will identify information on the instruments used for supervising vaccination rooms. of vaccines, which can facilitate the work of immunization managers, encouraging them to improve the quality of vaccination rooms and identify problems in the immunization service. The results of the scoping review are disseminated to the scientific community through publication in scientific journals.

Descriptors: Immunization; Health Monitoring; Healthcare Process Assessment.

RESUMEN

Objetivo: Mapear todos los instrumentos, tanto informatizados como no informatizados, que facilitan el proceso de supervisión en salas de vacunación. **Métodos**: Protocolo de revisión de alcance, desarrollado según las directrices del JBI, que se realizará en tres fases de búsqueda: (1) búsqueda en las fuentes de datos Embase, MEDLINE/PubMed, Web of Science, Scopus, SciELO vía Web of Science, LILACS y ScienceDirect; (2) búsqueda de literatura gris en el Portal de Tesis y Disertaciones de CAPES (Catálogo de Tesis y Disertaciones (CAPES), Biblioteca Digital Brasileña de Tesis y Disertaciones (BDTD) y Google Scholar; y (3) búsqueda manual en las listas de referencias de los estudios seleccionados. **Resultados esperados**: Se espera mapear una muestra suficiente para sintetizar los instrumentos que asisten en el proceso de supervisión de las salas de vacunación. Estos datos se utilizarán como insumo teórico para la segunda etapa de un estudio más amplio que busca desarrollar y validar una herramienta de supervisión de salas de vacunación en forma de aplicación web. **Conclusión**: El análisis de datos identificará información sobre los instrumentos utilizados para la supervisión de las salas de vacunación. de vacunas, lo que puede facilitar el trabajo de los gestores de inmunización, alentándolos a mejorar la calidad de las salas de vacunación e identificar problemas en el servicio de inmunización. Los resultados de la revisión exploratoria se difunden a la comunidad científica mediante su publicación en revistas científicas.

Descriptores: Inmunización; Vigilancia de la Salud; Evaluación del Proceso de Atención Sanitaria.

REVIEW PROTOCOL

Introduction

Vaccines are capable of preventing the reemergence of diseases that have already been eradicated or controlled, as well as significantly reducing premature mortality rates in the population. To maximize the objectives achieved through vaccination, it is essential that healthcare professionals ensure the correct storage, preparation, and administration of vaccines.[1–3]

In vaccination rooms, immunobiologicals must be maintained under appropriate conditions, without exposure to temperature fluctuations, and must preserve their original characteristics until the time of administration. Otherwise, their immunogenic potency may be compromised, resulting in reduced or absent vaccine efficacy.[4]

In the Brazilian context, vaccination services must comply with the criteria established by Collegiate Board Resolution No. 197, which aims to define the minimum requirements for the operation of services involved in human vaccination activities.[5]

Given the need to assess the operational conditions of vaccination rooms, the National Immunization Program (Programa Nacional de Imunizações – PNI) recommends that this evaluation be conducted using a semi-structured questionnaire — the Supervision Instrument Assessment Program for Vaccination Rooms (PAISSV). The PAISSV was designed to facilitate the tabulation of data obtained through the supervision instrument applied in vaccination rooms. Published in 2004, the instrument collected information related to identification; general aspects; technical procedures; cold chain; information systems; adverse events following immunization; special immunobiologicals; epidemiological surveillance; and health education in the supervised facility.[5-7]

Currently, Brazilian states employ supervision instruments for vaccination rooms adapted from the model developed by the Ministry of Health, typically in the form of printed *checklists* or paper forms. The state of Rio Grande do Norte follows this same approach, using an evaluation instrument based on the 2004 model. Despite technological advances over the years, this instrument continues to be applied manually, and there are no standardized criteria for qualifying the results obtained after its application.[7]

Moreover, the current paper-based format generates a large volume of written information, which hinders data preservation, aggregation, and report generation. From this perspective, the implementation of an automated system would facilitate data consolidation and improve the quality of information records.[5]

To address this issue in the state of Rio Grande do Norte—through its State Immunization Program—and to optimize the supervision activities of vaccination rooms while ensuring the quality of both immunobiologicals and the vaccination process, it is necessary to develop a supervision instrument that generates scores in a web-based application format, accessible via computers, smartphones, tablets, and laptops. Furthermore, this instrument must undergo validation by state immunization managers to ensure its quality and usability among future end-users in their routine activities. In this regard, it becomes essential to investigate the various types of instruments currently used for the supervision of vaccination rooms, allowing for the mapping of all existing scientific evidence in order to answer the following guiding question:

Which instruments are used to conduct supervision in vaccination rooms?

Therefore, this study aims to map, identify, and synthesize all instruments—digital or otherwise—that assist in the supervision process of vaccination rooms.

Method

This is a protocol for a *scoping review*. Developing a *scoping review* protocol is highly important, as it defines in advance the scope of the review, its objectives, methodology, and reporting procedures. This preparatory step ensures transparency and consistency throughout the entire review process.[8]

To ensure methodological rigor and reporting quality, this review will follow the guidelines established by the *Joanna Briggs Institute* (JBI) and the Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for *Scoping Reviews* (PRISMA-ScR). The development of this protocol was guided by the Best Practice Guidance and *Reporting Items for the Development of Scoping Review Protocols*.[8-10]

Initially, a detailed study protocol was developed and registered in the Open Science Framework (OSF), including all information required for conducting the study, namely: topic of interest, research question, objectives, search strategy with respective data sources, descriptors used, and eligibility criteria. This protocol can be accessed online at: https://osf.io/3r4ky/
(Appendix A).

The review will be conducted to answer the following research question:

"Which instruments are used to conduct supervision in vaccination rooms?". This question was structured using the PCC mnemonic, as follows: "P" refers to the Population (instruments), "C" refers to the Concept (supervision), and "C" refers to the Context (vaccination room), as shown in Table 1.

Table 1. Description of the PCC mnemonic used to structure the research question.

Population: Instruments	Standardized tools, computerized or not, used to monitor, evaluate, and ensure the quality of activities and processes.
Concept: Supervision	A systematic and continuous process of monitoring, evaluating, and guiding activities and processes.
Context: Vaccination Room	Physical environment intended for the handling, storage, preparation, administration, recording, and disposal of waste resulting from vaccination activities.

The inclusion criteria will consist of studies addressing the topic of supervision in vaccination rooms and available in full text. No time frame or language restrictions will be applied, in order to broaden the number of studies retrieved. The exclusion criteria will include protocols, letters to the editor, editorials, commentaries, and abstracts.

As mentioned, this study will follow the Joanna Briggs Institute (JBI) guidelines, with the search strategy conducted in three distinct phases. In the first phase, the search will be carried out in the following data sources:

MEDLINE/PubMed, Embase, *Web of Science*, Scopus, SciELO via *Web of Science*, LILACS, and *ScienceDirect*. The second phase, focused on the grey literature, will be conducted in the following sources: the CAPES Theses and Dissertations Portal (Catálogo de Teses e Dissertações – CAPES), the Brazilian Digital Library of Theses and Dissertations (BDTD), and *Google Scholar*. The third phase will consist of manual searching of the reference lists of the selected studies.

The search strategies were developed by a professional librarian, as librarians are the most qualified professionals to construct search strategies in electronic databases, given their training and expertise.[11]

For the identification of descriptors, the following controlled vocabularies were used: Health Sciences Descriptors (DeCS), *Medical Subject Headings* (MeSH), and Emtree (Embase). In addition, free terms relevant to the topic were included. The final strategy was peer-reviewed to ensure accuracy and comprehensiveness, as shown in Table 2.

Table 2. Search strategies to be used across data sources Natal, RN, Brazil, 2024.

Data Source	Search Strategy
MEDLINE/PubMed	("vaccination centre"[tiab] OR "immunization clinic*"[tiab] OR "immunisation clinic*"[tiab] OR "vaccine room*"[tiab] OR "vaccination unit*"[tiab] OR "vaccination room*"[tiab] OR "immunization room*"[tiab] OR "immunisation room*"[tiab] OR "vaccination site"[tiab] OR "immunization site"[tiab] OR "immunisation site"[tiab]) AND ("nursing, supervisory"[mh] OR Supervisory[tiab] OR administr*[tiab] OR management[tiab] OR organization[tiab] OR cordinat*[tiab] OR logistic*[tiab] OR Supervision[tiab] OR Monitoring[tiab] OR "organization and administration"[sh])
Embase	('vaccination centre':ti,ab OR 'immunization clinic':ti,ab OR 'immunization clinics':ti,ab OR 'immunisation clinic':ti,ab OR 'immunisation clinics':ti,ab OR 'vaccine room*':ti,ab OR 'vaccination unit*':ti,ab OR 'vaccination rooms':ti,ab OR 'immunization room':ti,ab OR 'immunization rooms':ti,ab OR 'immunisation room':ti,ab OR 'immunisation rooms':ti,ab 'vaccination site':ti,ab OR 'immunization site':ti,ab OR 'immunisation site':ti,ab) AND ('nursing'/exp OR supervisory:ti,ab OR administr*:ti,ab OR management:ti,ab OR organization:ti,ab OR cordinat*:ti,ab OR logistic*:ti,ab OR supervision:ti,ab OR monitoring:ti,ab OR 'organization and administration':lnk)
Web of Science	("vaccination centre" OR "immunization clinic*" OR "immunisation clinic*" OR "vaccine room*" OR "vaccination unit*" OR "vaccination room*" OR "immunization room*" OR "immunisation room*" OR "vaccination site" OR "immunization site" OR "immunisation site") AND

	("nursing, supervisory" OR Supervisory OR administr* OR management OR organization OR cordinat* OR logistic* OR Supervision OR Monitoring OR "organization and administration")
Scopus	("vaccination centre" OR "immunization clinic*" OR "immunisation clinic*" OR "vaccine room*" OR "vaccination unit*" OR "vaccination room*" OR "immunization room*" OR "immunisation room*" OR "vaccination site" OR "immunization site" OR "immunisation site") AND ("nursing, supervisory" OR Supervisory OR administr* OR management OR organization OR cordinat* OR logistic* OR Supervision OR Monitoring OR "organization and administration")
SciELO via *Web of Science*	("vaccination centre" OR "immunization clinic*" OR "immunisation clinic*" OR "vaccine room*" OR "vaccination unit*" OR "vaccination room*" OR "immunization room*" OR "immunisation room*" OR "vaccination site" OR "immunization site" OR "immunisation site") AND ("nursing, supervisory" OR Supervisory OR administr* OR management OR organization OR cordinat* OR logistic* OR Supervision OR Monitoring OR "organization and administration")
LILACS via BVS	("centro de vacinação" OR "vaccination centre" OR "Clínica de vacinação" OR "Clínica de vacina" OR "Clínica de imunização" OR "immunization clinic*" OR "immunisation clinic*" OR "Sala de vacina" OR "Sala de vacinação" OR "vaccine room*" OR "unidade de vacinação" OR "vaccination unit*" OR "vaccination room*" OR "immunization room*" OR "sala de imunização" OR "immunisation room*" OR "vaccination site" OR "immunization site" OR "Local de vacinação" OR "immunisation site") AND (mh:"Supervisão de Enfermagem" OR mh:"nursing, supervisory" OR Supervisão OR Supervisory OR administr* OR management OR organization OR cordinat* OR logistic* OR Supervision OR Monitoring OR Acompanhamento OR sh:"organization and administration")
ScienceDirect	("vaccination centre" OR "immunization clinic" OR "vaccine room" OR "vaccination unit") AND (Supervisory OR management OR organization)
Portal de Teses e Dissertações da CAPES	vaccine room AND (supervision OR instrument)
BDTD	vaccine room AND (supervision OR instrument)
Scholar Google	("vaccination centre" OR "immunization clinic") AND (Supervisory OR Instrument)

The results obtained from the database searches will be exported to the Rayyan *software*. From this point, two researchers will independently and blindly perform the initial selection of relevant studies by screening the titles and

abstracts. The selected studies will then be read in full, and those meeting the eligibility criteria will be included in the sample. In cases of disagreement between the researchers, a third reviewer will be invited to resolve the discrepancies. The entire process will be documented to allow detailed monitoring of the study selection process, in accordance with the PRISMA-ScR flowchart.

After data collection from the first and second phases, the researchers will analyze the reference lists of the studies selected in the initial stages. The manual search of these references allows the inclusion of additional relevant studies that may not have been identified in the electronic databases. The mapped results will be presented through tables and charts, according to the study's variables of interest.

Data collection for this study will be carried out using a data extraction tool adapted from the model proposed by the Joanna Briggs Institute (JBI) for *scoping reviews*. The data will be stored in an electronic instrument using Microsoft Excel, according to the following variables: identification number, data source, title, authors, year of publication, country of publication, language, study design, supervision instrument used in the vaccination room, level of evidence, and main conclusions.

A pilot test for data extraction will be conducted using a random sample of 25 studies, as recommended by JBI guidelines, to ensure that the selected variables meet the review's objective. All researchers involved in the review process will examine the extraction tool according to the eligibility criteria and study variables. In case of discrepancies regarding the tool's items, the necessary adjustments will be made based on the team's discussion.

The studies included in the sample will be assessed for their level of evidence, according to the JBI classification: Level 1 – Experimental studies; Level 2 – Quasi-experimental studies; Level 3 – Analytical observational studies; Level 4 – Descriptive observational studies; Level 5 – Expert opinion and bench research. This analysis enables a fairer discussion of the results based on the level of evidence presented, helping readers better understand the strength of the evidence that supports clinical practice.[12]

This stage of the research does not involve human participants; therefore, submission to a Research Ethics Committee was not required.

Results and Discussion

The results will be presented to characterize the studies included in the sample, using tables and charts for better visualization of the data, along with a narrative synthesis of the findings.

It is expected to map a sufficient number of studies to synthesize the instruments that support the supervision process of vaccination rooms. These data will serve as a theoretical foundation for the second phase of a broader study aimed at developing and validating a supervision instrument for vaccination rooms in the format of a *web*-based application.

This review will provide comprehensive information on the instruments used in the supervision of vaccination rooms. The main objective is to support research focused on the development and validation of a *web* application-based supervision instrument for vaccination rooms. However, the findings may also support vaccination room supervision practices conducted by health managers in

other regions of Brazil. Furthermore, they may help identify knowledge gaps in the scientific literature and suggest new or more robust studies and reviews.

As limitations that may affect this *scoping review*, the data sources used may lead to the omission of relevant studies. In addition, *scoping reviews* do not include an internal quality assessment of the studies. Therefore, it is recommended that future research conduct systematic reviews and meta-analyses to compare the methodologies and interventions adopted in studies addressing this topic.

Conclusion

The data analysis will identify information on supervision instruments used in vaccination rooms, which may facilitate the workflow of immunization managers by encouraging quality improvement in vaccination rooms and identifying issues within immunization services. The results obtained from this *scoping review* will be disseminated to the scientific community through publication in peer-reviewed journals.

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Appendix A – Study Planning Protocol Registered on the *Open Science Framework Platform*

Planning Protocol for Scoping Review
Topic: Instruments that support supervision in vaccination rooms.
Objective: To map scientific evidence regarding instruments that support supervision in vaccination rooms.
1) Research question: What instruments are used to conduct supervision in vaccination rooms?
2) Literature search **Example of the search strategy in MEDLINE/PubMed:** ("vaccination centre"[tiab] OR "immunization clinic*"[tiab] OR "immunisation clinic*"[tiab] OR "vaccine room*"[tiab] OR "vaccination unit*"[tiab] OR "vaccination room*"[tiab] OR "immunization room*"[tiab] OR "immunisation

room*"[tiab] OR "vaccination site"[tiab] OR "immunization site"[tiab] OR "immunisation site"[tiab]) AND ("nursing, supervisory"[mh] OR Supervisory[tiab] OR administr*[tiab] OR management[tiab] OR organization[tiab] OR cordinat*[tiab] OR logistic*[tiab] OR Supervision[tiab] OR Monitoring[tiab] OR "organization and administration"[sh])

2.1) Phase 1: Search in databases

MEDLINE/PubMed, Embase, *Web of Science*, Scopus, SciELO via *Web of Science*, LILACS e *ScienceDirect*

2.2) Phase 2: Search in gray literature

CAPES Theses and Dissertations Portal (CAPES Catalog of Theses and Dissertations), Brazilian Digital Library of Theses and Dissertations (BDTD), and *Google Scholar*

2.3) Phase 3: Manual search

Search in the reference lists of selected studies.

Eligibility criteria

Inclusion criteria: Studies addressing the topic, available in full text, with no time restriction or language limit.

Exclusion criteria: Protocols, letters to the editor, editorials, commentaries, and abstracts.

3) Study selection

Studies will be exported to Rayyan software, where screening will be conducted through title and abstract reading by two independent reviewers. After this process, the selected studies will be read in full. Disagreements will be resolved by a third reviewer. Studies that do not meet the eligibility criteria will be excluded, and duplicates will be counted only once.

4) Data mapping and analysis

For data mapping, a *Microsoft Excel* tool will be developed, including the following variables of interest: identification number, data source, title, authors, year of publication, country of publication, language, study design, supervision instrument used in vaccination rooms, level of evidence, and main conclusions.

5) Synthesis of results

The synthesis of results will be presented through figures, tables, and charts to facilitate visualization of the data..

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