National Immunisation Programme (PNI): Performance audit of Brazilian courts of accounts

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Abstract

This article presents findings from a coordinated performance audit conducted by the Brazilian Federal Court of Accounts (TCU) alongside twenty other autonomous subnational courts between January and November 2024. The audit assessed the management of Brazil's National Immunisation Program (PNI) across national, state and municipal levels during 2022 and 2023. The overarching objective was to evaluate stock management and vaccine provision, and storage infrastructure. The audit also monitored the implementation of TCU recommendations from a 2022 audit. The study involved document analysis, and on-site inspections of vaccination rooms and storage facilities. Surveys were completed by state and municipal immunisation coordinators, and interviews were conducted with various stakeholders. Data on vaccination and stock movements were analysed, and a multivariate statistical model was developed to explain the variation in vaccination coverage rates (VCRs) across the country. The audit revealed inconsistencies in stock management data and an estimated loss of at least thirty million vaccine doses due to expire in 2023. Vaccine shortages were identified, the main causes linked to procurement processes. Furthermore, deficiencies in storage infrastructure and temperature monitoring were observed, and weaknesses in the implementation of the VCR recovery microplanning were noted. Despite these challenges, a positive trend was the reduction in

unaccounted vaccine doses. Recommendations from the TCU and other courts aimed to enhance VCRs and reduce vaccine wastage. It is estimated that a 10% improvement in loss management efficiency could generate savings of at least USD 6.8 million a year for the programme.

Key words: vaccination coverage rates, vaccine shortage, vaccine waste, cold chain, coordinated audit

Introduction

The Brazilian Federal Court of Accounts (TCU) carried out a coordinated performance audit of the National Immunisation Programme (PNI) together with twenty other autonomous Brazilian courts of accounts from January to November 2024. The area of activity of the participating courts covered 74.8% of the Brazilian population. The audit assessed the programme management at the national, state and municipal levels of government in 2022 and 2023.

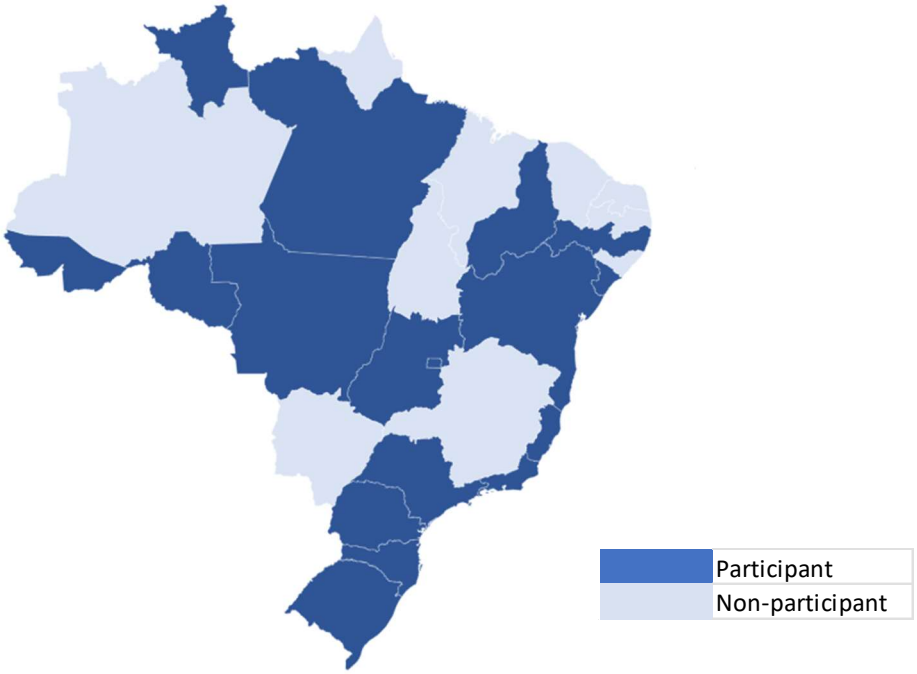


Figure 1 - Brazilian states that make up the geographical base of the courts of accounts participating in the coordinated audit in the PNI in 2024. Source: own elaboration.

The overall audit objective was to assess stock management and vaccine supply, as well as the structure of the cold chain[i] (CC) and the implementation of the new vaccination coverage rates (VCRs) recovery strategy. The audit also monitored the implementation of TCU recommendations from a 2022 audit of the PNI.

The coordinated audit assessed important aspects of both the National Health Plan (NHP) and commitments to the Sustainable Development Goals (SDGs). The NHP 2024-2027 and SDG 3 include performance indicators for achieving VCR targets and guaranteeing the supply of vaccines to the population.

The total amount of the resources audited was USD 585.4 million, representing to federal spending on vaccination in 2023.

Method

The data collection and analysis methods comprised requesting and analysing the content of technical notes from State Departments, as well as documents related to microplanning[ii], stock management, and temperature control. Microplanning documents from thirteen states and 89 municipalities were examined, along with documentation from 205 cold chain units at state, municipal and local levels.

Between May and July 2024, auditors carried out inspections in 222 vaccination rooms, as well as 87 municipal immunobiological storage centres and 32 state-managed centres. During this period, all state coordinators and 2,304 municipal immunisation coordinators responded to surveys. Interviews were conducted with 15 state immunisation coordinators, 102 municipal coordinators, 22 professionals in state/regional storage centres, 87 in municipal centres and 225 in vaccination rooms.

Data on vaccination and stock movement were gathered from five different Department of Health (DoH) information systems.

A multivariate statistical model was developed to explain variation in VCRs across the country's health regions. The VCRs of the five vaccines prioritised by the audit were used as dependent variables, however only the results for the MMR vaccine are presented here, as this had the best fit.

Audit teams from the 21 courts of accounts shared information, work papers and audit reports through weekly coordination meetings, as well as via MS Teams and Google Forms. Some of the data collected was analysed in Excel spreadsheets and Power BI dashboards. Vaccine loss and other datasets were stored in .txt and .json files, then converted into tabular data and translated into maps, graphs, and tables.

A total of 67 audit reports were produced at national, state, regional or municipal levels. These reports were analysed and summarised in an executive summary prepared with the support of large-scale language models, primarily the Gemini 2.0 Pro tool.

The audit followed the procedures set out in the TCU's Performance Audit Manual[2], as well as the conceptual framework provided in the Reference for Assessing Multilevel Governance in Decentralised Public Policies[3]. In addition, the *Whole of Government* approach was adopted[2]. Common audit questions were examined by all participating courts, with flexibility to the context of each jurisdiction.

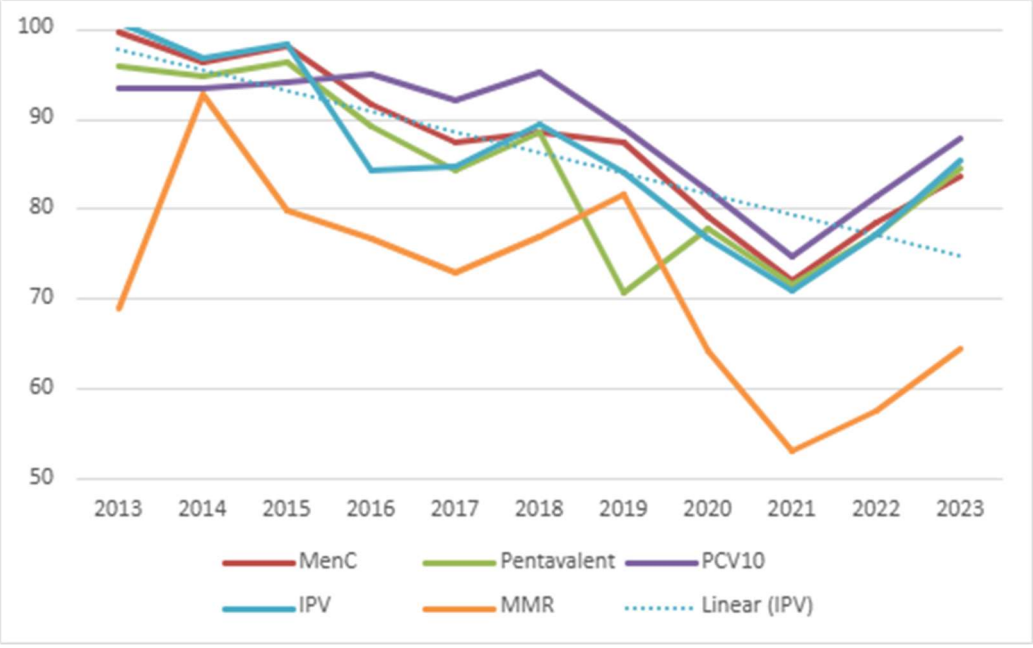
The audit was conducted in accordance with the Auditing Standards of the Federal Court of Accounts[4] and the applicable Brazilian Public Sector Auditing Standards[5], which align with the International Standards of Supreme Audit Institutions (ISSAI). No significant restrictions were imposed on the examinations.

Main results and analyses

The PNI and vaccination coverage rates in Brazil

From 2016 to 2019, the VCRs of the National Vaccination Calendar (NVC) vaccines for children under the age of two declined, and most of them were below the levels needed to achieve population immunity (see Graph 1). During the COVID-19 pandemic, from 2020 to 2021, VCRs continued to fall, and some measures to prevent and combat the virus were added to other causes to this decline. In 2022 and 2023, vaccination rates began to increase.

Despite this, in 2023, the VCRs for five priority vaccines remained below 2015 levels and well below the 95% target. For three of these vaccines, the rates were also lower than those recorded in the pre-pandemic year. Notably, data available for 2024 shows an increase in all VCRs, although they remain below their targets, except for the BCG vaccine, whose rate will be just above its 90% target.



Graph 1 - Vaccination coverage rates in Brazil for five selected vaccines from 2013 to 2023 and linear trend line for Poliomyelitis VCR. Source: https://infoms.saude.gov.br/extensions/SEIDIGI_DEMAS_VACINACAO_CALENDARIO_NACIONAL_

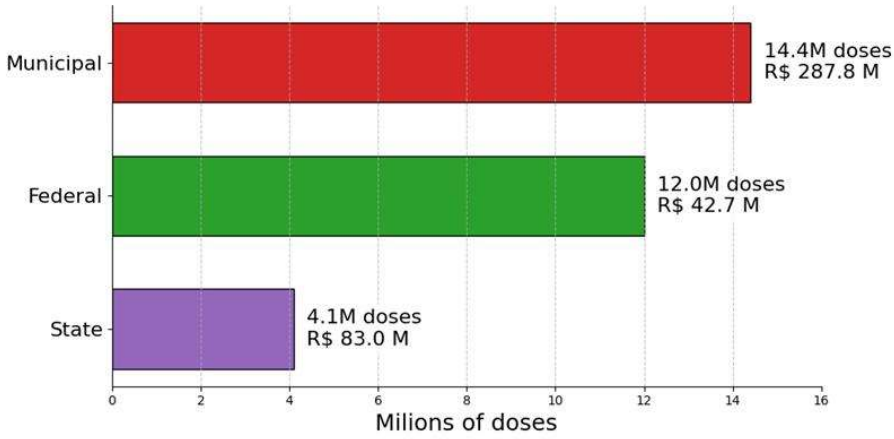
COBERTURA_RESIDENCIA/SEIDIGI_DEMAS_VACINACAO_CALENDARIO_NACIONAL_COBERTURA_RESIDENCIA.html# Access in 3 jul. 2024.

A positive development identified by the audit was that, despite the persistence of registration problems in vaccination data, the number of doses that were unaccounted for in the VCRs decreased from 4.4 million in 2022 to 1.7 million in 2023, with an estimated reduction in 2024 to half the volume of the previous year.

Stock management and vaccine loss

The audit found that around 58.5% of vaccination rooms used the software provided by the DoH to manage vaccine stocks. Some vaccination rooms input data into their own systems, but due to the absence of integration with the DoH's platform, the PNI management was unaware of them. Moreover, significant inconsistencies and gaps in data entry within the Department's official IT systems resulted in inaccurate and inefficient stock management.

In 2023, despite data limitations, at least thirty million doses of NVC vaccine for children under two were lost due to expiration. These losses amounted to over USD 71.3 million across federal, state and municipal levels, representing 14.1% of the DoH's total vaccine procurement expenditure in 2023 (See Graph 2).



Graph 2 - NVC vaccines lost for children under two due to expiration date at the three management levels in 2023. Source: DoH stock management system Audit.

The estimated vaccine loss alone does not reflect the quality of local management, as it is necessary to consider factors such as the expiration date of received batches, storage capacity and the completeness and accuracy of the data entry into the system. It is possible that facilities with lower reported losses may have failed to enter complete data into the system.

Expiration-related losses stem from various causes, including the determination of purchase quantities, the procurement process, and distribution. Vaccines may be overstocked due to decreased vaccination demand—partly driven by vaccine hesitancy—or delays in distribution caused by the identification of quality issues in vaccine batches and the shipment of doses with short shelf lives.

The effects of these losses are multifold and directly affect public health. In addition to the significant financial cost, the loss of millions of doses of vaccines compromises vaccine supply, makes it difficult to reach VCR targets, and increases the risk of outbreaks and the resurgence of previously eliminated diseases.

To reduce losses due to expiration, vaccine procurement planning must be improved to consider actual population demand, not just target demographics. Additionally, delivery of replacement batches should consider existing stocks and incoming supplies. Finally, also to improve management, the DoH should also define parameters for acceptable vaccine losses, based on historical data.

Implementing the audit's recommendations could increase the efficiency of vaccine loss management by at least 10%, resulting in annual savings of at least USD 6.9 million for the programme.

Vaccine shortages

According to municipal immunisation coordinators surveyed, vaccine shortages are the third biggest obstacle to achieving VCR targets. They were mentioned in 22.8% of the responses, following parental refusal to vaccinate and staffing shortages in vaccination rooms. The audit found that episodes of shortages of specific vaccines occurred at varying intervals between 2022 and 2024.

The survey of municipal PNI coordinators found that at least 67% of the responding municipalities reported a shortage of one or more NVC vaccines for children under two in more than half of their vaccination rooms between January and April 2024 (see Figure 2).

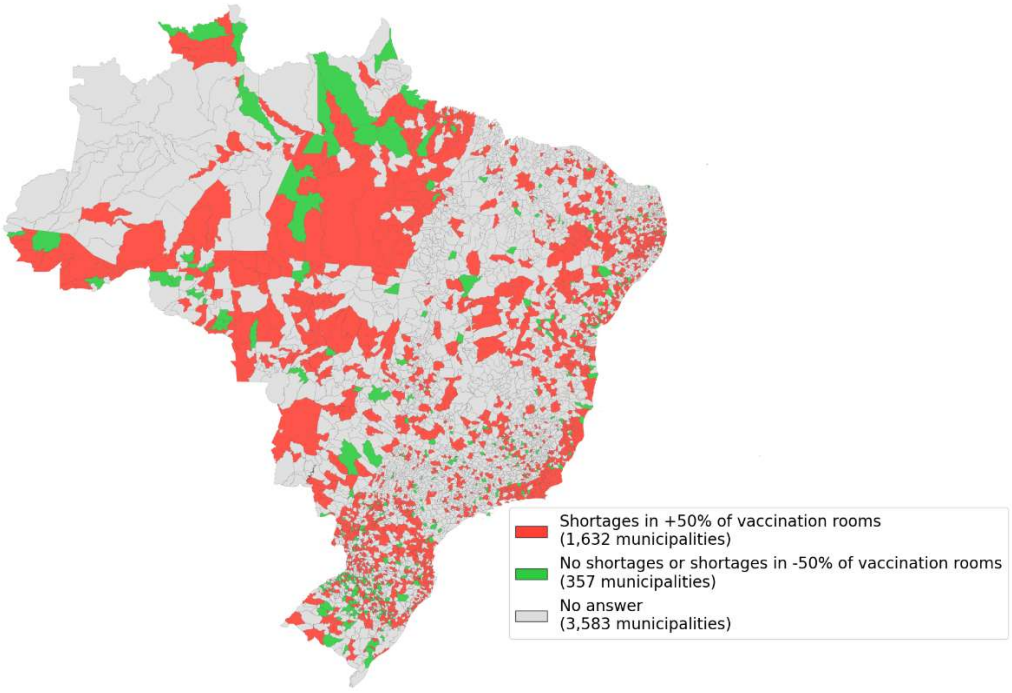
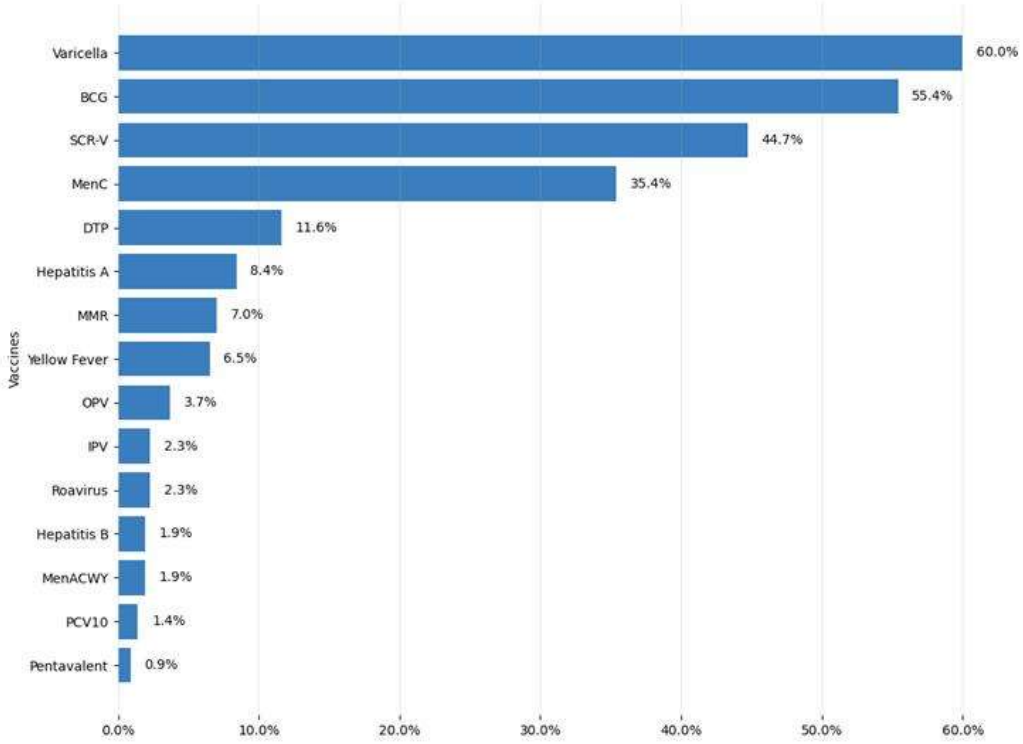


Figure 2 - Municipalities surveyed that reported unavailability of NVC vaccines for children under two in more than half of the vaccination rooms between January and April 2024. Source: survey of municipal immunisation coordinators, Q37.

Reports of shortages were frequent and covered a wide range of vaccines in different time periods. Five NVC vaccines for children under two were found to be unavailable

in over 10% of the 220 vaccination rooms inspected by the audit between May and July 2024, as shown in Graph 3.



Graph 3 - Percentage of audited vaccination rooms with unavailable stock to meet the population's demand for vaccines, 2024. Source: Inspections of 220 vaccination rooms in 99 municipalities between May and July 2024, Q 33.

The causes of vaccine shortages are complex and span all levels of PNI management. At the federal level, problems in vaccine procurement by the DoH stand out, such as delays from suppliers (national and international), shortages of raw materials for manufacturing, limited availability of domestic suppliers, regulatory challenges related to manufacturing processes.

The audit highlights the need for the DoH to implement a risk assessment model for vaccine procurement across all contracting methods. Additionally, it emphasizes the importance of training municipal personnel to accurately estimate vaccine

requirements, using appropriate data, methodologies, and criteria to ensure confidence in their calculations.

Cold chain and vaccine storage

The PNI's cold chain refers to the infrastructure used to store immunobiological products at the national, state, municipal and local levels. It consists of the DoH's Central Warehouse, state and regional vaccine storage centres, municipal and regional vaccine storage centres, and vaccination rooms.

An analysis of the maturity of the PNI's cold chain revealed that most state and regional centres visited were classified as being at the “improved” level (21 out of 32). In contrast, most municipal centres and vaccination rooms were categorized as “intermediate” (66.7% and 68.5%, respectively), highlighting disparities in cold chain performance across different levels.

The coordinated audit developed a maturity scale to assess how effectively cold chain facilities comply with regulations. This scale categorizes them into four levels: basic, intermediate, improved, and advanced. The assessment consisted of four dimensions: storage infrastructure, stock and loss management, storage equipment, and monitoring and control of temperature excursions—i.e. deviations from required temperature conditions during storage or transport.

Among the issues identified in the equipment and temperature monitoring processes for vaccine storage in the Cold Chain, the audit found that over 70% of the 310 municipal centres and vaccination rooms inspected failed to meet essential requirements. These include the exclusive use of authorized equipment for vaccine storage—which prohibits the use of domestic refrigerators—and the implementation of preventive maintenance (See Figure 3). These shortcomings increase the risk of

temperature fluctuations during storage, potentially compromising vaccine quality or leading to dose losses.

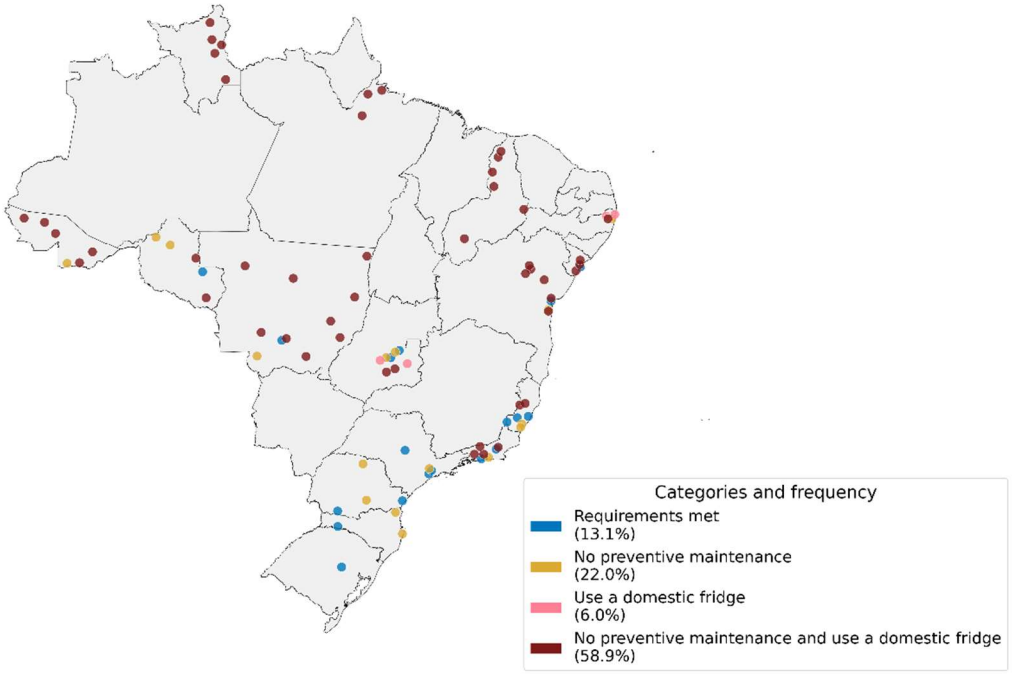


Figure 3- Use of a domestic fridge and lack of preventive maintenance of equipment in storage centres and vaccination rooms, in the municipalities visited, between May and July 2024. Source: inspections in municipal cold chain centres and vaccination rooms.

The TCU recommended the Department of Health advise states and municipalities to establish equipment maintenance contracts (including preventive maintenance) and acquire vaccine storage equipment that meets regulated technical specifications. It also recommended conditioning equipment donations on the existence of maintenance contracts. Implementing these measures is vital to ensure vaccine quality and safety, protecting public health.

Microplanning

The Department of Health's main strategy for recovering VCRs is microplanning, implemented in July 2023. However, audit teams found that, in a high percentage of cases, several important elements across all stages of this strategy were either not elaborated or unavailable for analysis. These include methods for strengthening key components of PNI governance, such as planning, monitoring, addressing territorial inequalities, evaluation, and accountability. These gaps weaken microplanning and increase the risk of not achieving its intended results.

One of the causes of implementing microplanning is the short time since its launch. The municipal coordinators surveyed who reported having adhered to microplanning (90.6% of respondents) said they were at the following stages of implementation of the strategy's first cycle in May and June 2024: 11.8% were in stage 1; 22.5% in stage 2; 21.7% in stage 3; 16.7% in stage 4; and 27.1% reported having completed the cycle (see Figure 4).

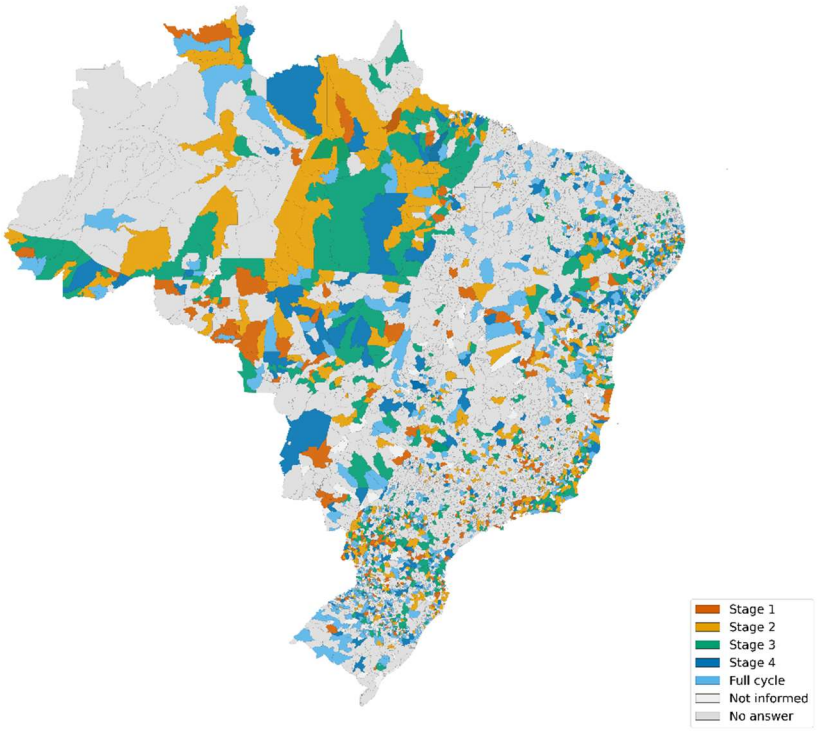


Figure 4 - Municipalities that joined Microplanning in 2023, by stage of implementation, between May and July 2024. Source: survey of municipal immunisation coordinators, Q53.

The TCU recommended that the Department of Health establish standardized, computerized systems to report on the fulfilment of microplanning commitments, results achieved, and identify opportunities for improvement. Considering the novelty of some of the procedures and tools associated with microplanning—and the lack of regulatory details—it also recommended that the DoH encourage states and municipalities to use institutional channels to clarify questions and disseminate implementation guidelines.

The implementation of these measures will enhance coordination and alignment across management levels in the execution of vaccination strategies, increasing the likelihood that these initiatives will efficiently address local needs to achieve the recovery of VCRs.

Explanatory model for VCRs

Most municipal PNI managers recognise the role that other public interventions can play in achieving the programme's objectives. The audit found quantitative evidence that the MMR VCR increases with greater numbers of basic health units (BHUs) per 10,000 inhabitants, higher expenditure on primary health care, increased population density, and expanded coverage of the Health at School Programme[iii].

In general, MMR VCRs decline as average nominal monthly income (Log_median_income) rises, and increases with population density (Log_dens_k2). In both cases, the effect of these variables on VCR is diminished in regions where population density is already high.

Counterintuitively, the quantitative model indicates that MMR VCRs decrease as coverage of the Bolsa Família Programme[iv] increases. A possible explanation for this unexpected finding is that the model captures reduced enforcement of the vaccination requirement for receiving financial benefits during the pandemic, along with declining data quality in the programme's beneficiary registry following its expansion to include single-person households.

Increased investment in analysing the causes of VCR declines, as well as the effects of other public policies and demographic and socioeconomic factors on vaccination, could contribute to the formulation of evidence-based strategies to improve VCRs.

Recommendations from courts of accounts

Monitoring of a 2022 audit shows that 80% of the TCU's recommendations are either being implemented or complied with—and they could reach full implementation in the short term, given the Department of Health's active engagement. The remaining 20% have been only partially implemented and, without any planned measures from the Department, are unlikely to advance.

TCU recommendations to the DoH include: making equipment donations contingent on preventive maintenance contracts; establishing mechanisms for information exchange and feedback across government levels concerning microplanning outcomes; adopting risk assessment methodologies for all vaccine procurement processes, regardless of contracting method; and developing historical data series on vaccine losses, alongside criteria for acceptable losses.

Subnational courts of accounts have recommended measures to improve cold chain infrastructure and logistics, enhance stock management to reduce vaccine losses,

train cold chain personnel, and strengthen the implementation of microplanning, intersectoral coordination, and communication.

The implementation of these recommendations is expected to reduce vaccine shortages and increase confidence in vaccine safety and efficacy, leading to positive effects on VCR recovery. Moreover, even a modest 10% improvement in managing losses due to expiration dates could yield annual savings of over USD 6.9.

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[i] The PNI´s cold chain consists of the infrastructure and processes used for storing and transporting immunobiological products at the national, state and municipal levels.

[ii] Microplanning is the PNI's new planning strategy, adopted in July 2023, which involves carrying out a diagnosis and situational analysis at the smallest coverage areas within municipalities, establishing priorities, and carrying out actions to reverse the drop in VCRs[1]. The concept of microplanning was formulated by the Department of Health (DoH), based on a proposal by the Pan American Health Organisation (PAHO), which has been applied and developed by that organisation for two decades.

[iii] Established in 2007, the Health at School Programme is jointly managed by the Departments of Health and Education. It is implemented through the voluntary participation of states and municipalities. The programme emphasizes health education by engaging the school community and involving both family health and primary education teams. One of its initiatives is verifying students' immunisation status.

[iv] The Bolsa Família Programme was established in 2003 and provides income transfers to families contingent upon meeting specific requirements in education and health, including ensuring that children follow the recommended vaccination schedule.