

**REVISÃO** REVIEW

# The Brazilian National Immunization Program: 46 years of achievements and challenges

46 anos do Programa Nacional de Imunizações: uma história repleta de conquistas e desafios a serem superados

46 años del Programa Nacional de Inmunizaciones de Brasil: una historia repleta de conquistas y desafíos que superar

Carla Magda Allan Santos Domingues <sup>1</sup> Ana Goretti K. Maranhão <sup>1</sup> Antonia Maria Teixeira <sup>1</sup> Francieli F. S. Fantinato <sup>1</sup> Raissa A. S. Domingues <sup>2</sup>

doi: 10.1590/0102-311X00222919

#### **Abstract**

The Brazilian National Immunization Program (PNI, in Portuguese) is coordinated by the Ministry of Health in cooperation with state and municipal health departments. Since the program's creation in 1973, it has become one of the country's most relevant public health interventions, having produced important results such as certification of Brazil as free of wild poliovirus circulation, the elimination rubella virus circulation, and an important reduction in cases and deaths from vaccine-preventable diseases. Brazil is one of the countries that offers the most vaccines free of cost to the population, with 15 vaccines for children, 9 for adolescents, and 5 for adults and the elderly. The program's expansion and the maintenance of high vaccination coverage rates led to a rapid decrease in vaccine-preventable diseases, completely changing the epidemiological scenario of these diseases in Brazil in the last four decades. The country is currently witnessing an increasing share of the population without adequate vaccination. To the extent that these diseases are no longer circulating, precisely because of the high vaccination coverage rates, especially since the early 2000s, many of them are now unknown to the population. As a result, many people have no notion of the danger these diseases represent. We thus need to understand the multiple factors contributing to this decrease in coverage, which has created the risk of resurgence of serious diseases that had already been controlled or eliminated in Brazil.

Immunization Programs; Vaccination Coverage; Vaccination Refusal; Anti-vaccination Movement

#### Correspondence

C. M. A. S. Domingues SMDB Conjunto 12B, lote 3, casa B, Brasília, DF 71680-122, Brasil.

cmasdomingues@gmail.com

1 Ministério da Saúde, Brasília, Brasil.

<sup>2</sup> Secretaria de Estado de Saúde do Distrito Federal, Brasília, Brasil.



# Introduction

The Brazilian National Immunization Program (PNI, in Portuguese), coordinated by the Ministry of Health in cooperation with the state and municipal health departments, has become one of the country's most relevant public health interventions <sup>1</sup>. The program was created in 1973 and has witnessed many achievements and challenges in its 46 years of history. It represents an efficient public policy with a growing impact on the Brazilian population's morbidity and mortality profile, having adapted to changes in the country's political, epidemiological, and social fields <sup>(1)</sup>.

At least part of this success can be attributed to the fact that the PNI adopts the same basic principles of the Brazilian Unified National Health System (SUS, in Portuguese), featuring universal and equitable care, as well as the organizational principle of decentralization under a single direction at each level of government, defined according to the regulation of the SUS by the *Organic Health Law n. 8,080* of 1990, as described next <sup>2</sup>.

In relation to adherence to the SUS principles, universal care has been ensured with the supply of immunobiological products to all target groups for vaccination in the more than 36,000 vaccination rooms in Brazil's 5,570 municipalities <sup>3</sup>.

Equity has been ensured by expansion of the supply of vaccines in routine vaccination and campaign strategies, beyond the territorial context, but especially the population context, reaching the target groups for vaccination and including all the life phases: 15 vaccines for children, 9 for adolescents, and 5 for adults and the elderly, protecting from more than 20 diseases. Vaccines are also supplied in Special Immunobiological Centers (CRIE, in Portuguese), serving groups with special clinical conditions in addition to the different vaccination schemes for pregnant women, indigenous peoples, and military personnel 4.

Finally, the PNI adheres to the principle of decentralization through an interconnected, hierarchical, and integrated network, requiring permanent discussion on standards, targets, and results, thus ensuring the program's operationalization at the three levels of administration of the SUS. This decentralization has contributed to the reduction of regional and social inequalities, allowing access to vaccination for all Brazilians throughout the country, as exemplified by the vaccination strategy "Operation Droplet", which conducts vaccination in hard-to-reach geographic areas and in indigenous groups in the North of Brazil <sup>3</sup>.

In order to ensure the sustainability of inputs supplied by the PNI, the target is to reach self-sufficient domestic production in the long term, based on strengthening the Health Industrial Complex, where the principal strategic inputs are produced by public laboratories. Two main mechanisms have been adopted to encourage domestic production: stimulus for the internal development of products and the pursuit of partnerships with private laboratories, aimed at technology transfers to Brazil's public laboratories. This approach has allowed public laboratories to produce the program's main strategic inputs 5,6.

In order to support the program's administration, since 1994 the PNI has conducted a partnership with the Brazilian Health Informatics Department (DATASUS, in Portuguese) to develop and expand the use of information systems, evolving from the consolidated recording of aggregate data to the individualized (nominal) recording of vaccination, including recording of adverse events, use and losses of immunobiological products, and acquisition and distribution of vaccines <sup>7</sup>.

Since 2019, the recording of vaccinated individuals in primary healthcare units has been implemented progressively based on the Primary Healthcare Information System (e-SUSAB, in Portuguese), with the objective of integrating data from all the health information systems now used in the SUS 7.

Given the growing complexity of the National Vaccination Calendar (CNV, in Portuguese) with the inclusion of new vaccines throughout its history, it has become extremely important to draw on the support and expertise of the scientific and professional societies belonging to the Technical Advisory Committee (CTAI, in Portuguese), created in 1991. The work by CTAI has ensured that the vaccination strategies defined by Ministry of Health enjoy the population's credibility and adherence <sup>6</sup>.

In this context, the epidemiological scenario of vaccine-preventable diseases changed radically in Brazil, making vaccination one of the most relevant public health interventions, with the eradication of poliomyelitis and the elimination of rubella, congenital rubella syndrome, and neonatal tetanus. There has also been a drastic reduction in the occurrence of other transmissible diseases such as diph-

theria, tetanus, and pertussis which had led to deaths or severe sequelae that jeopardized the quality of life and health of millions of Brazilians 4.

Paradoxically, the PNI has faced major challenges despite all the achievements listed above. Many diseases have become unknown to the general population, so that some people have no idea of the danger they represent, which results in the risk of reintroduction or recrudescence of diseases that had been controlled or eradicated in the country. A new phenomenon emerged, not only in Brazil, but in various countries that are falling short of the targets for vaccination coverage rates (VCR), especially since 2016 8,9,10.

The reduction in VCRs in recent years cannot be attributed to a single cause. It is necessary to understand the multiple factors contributing to this decrease, such as ignorance of the importance of vaccination, vaccine hesitancy, fake news especially via social networks on the purported harms of vaccines for health, partial shortages of some products, and operational problems with the execution of vaccination, ranging from inadequate data recording to difficult access to health units. Understanding these factors is extremely important for seeking new approaches aimed at reestablishing the VCRs reached just a few years ago 8,9.

Thus, an analysis of the program's successes throughout its history and the current challenges for maintaining these achievements in the near future can contribute to the identification of factors that are preventing the PNI from reaching ideal coverage rates, since vaccination is one of the most important forms of disease prevention and failure to use this preventive measure can expose the population to serious risks.

# Methodology

This is a descriptive case study on the history of the PNI, discussing facts ranging from the program's formulation in 1973 to its current status. We focused on the program's achievements and challenges, especially the fulfillment of its mission to protect the population from vaccine-preventable diseases. The data sources were publications on immunization in Brazilian and international journals, accessed via internet, or produced and furnished by the General Coordinating Division of the Immunization Program (CGPNI, in Portuguese), including: technical reports; rulings; guidelines, and national vaccination calendars; epidemiological bulletins, the Information System of the Immunization Program (SIPNI, in Portuguese), accessed on the websites of the SIPNI (http://sipni.datasus.gov.br) or the Brazilian Ministry of Health (http://www.saude.gov.br).

We assessed the simultaneity of vaccination estimated by the VCRs with each dose for vaccines with equivalent vaccination schemes in relation to months of life, by the variation in the percentage of coverage, comparing the data from 2015 and 2018. Indirectly, we measured the loss of vaccination opportunity (not vaccinated simultaneously) by the difference in the number of doses applied, based on the highest coverage identified for the vaccines that were analyzed.

Routine vaccination coverage rates were also analyzed by age bracket for vaccines with components against measles (measles; measles and rubella - double viral; and measles, rubella, and mumps - triple viral), based on records of first doses, accumulated from 1994 to July 2019, with data provided by the CGPNI in Excel (https://products.office.com/) file.

The VCR is estimated using as the numerator the total number of doses applied according to each vaccine's complete vaccination schedule and as the denominator the vaccination's target population, multiplied by 100 for each year analyzed. The denominator used to calculate the vaccination coverage rates for children was obtained from the Information System on Live Births (SINASC, in Portuguese), the latest database available at the national level for each year assessed, and population estimates from the Brazilian Institute of Geography and Statistics (IBGE) for other age brackets.

Trends in vaccine-preventable diseases were assessed from 1982 to 2018, with available data in already published files updated with data from the Information System on Diseases of Notification (SINAN; http://portalsinan.saude.gov.br/).

The starting point for the study's description was the year 1973, when the PNI was created, and the final year was 2019, according to the availability of data.

#### Results and discussion

#### **Achievements**

The achievements of the PNI are irrefutable and are even more relevant considering Brazil's continental dimensions and huge socioeconomic diversity <sup>4</sup>.

Following the program's creation and structuring, the first CNV was published in 1977, standardized by Brazilian Ministry of Health *Ruling n. 452/1977*, consisting of mandatory vaccines available for the first year of life. This was consolidated as a major achievement, since the vaccination activities had been deployed by the specific disease control programs under the Brazilian Ministry of Health, such as yellow fever and smallpox, or conducted by vaccination programs developed by some states that had the resources to purchase vaccines, including the programs for the control of polio, measles, or diphtheria, tetanus, and pertussis with the DTP vaccine, which did not guarantee access to vaccination for all children <sup>11</sup>. This Ruling's publication launched the first public policy for universal vaccination throughout Brazil's territory.

Importantly, despite the introduction of new vaccines on the list of products available in the PNI since the publication of the first national calendar, *Ruling GM n. 597/2004* was not published until 2004, innovating with the scope of the vaccination calendar by including not only children, but also adolescents, adults, and elderly <sup>12</sup>. From the publication of this Ruling until 2016, seven more Rulings were published, in addition to Informative Notes regulating the expansion of the use of vaccines already on the CNV to include other target groups and the introduction of new vaccines in the PNI.

The 2000s, especially since 2006, also saw the growing incorporation of new vaccines by the PNI (Figure 1).

Brazil is one of the countries that supplies the most vaccines free of cost. With this growing expansion, in 22 years the program's expenditures on immunobiological products have increased by 44 times, from BRL 94.5 million in 1995 to BRL 4.7 billion 2019. Since 2014, the annual allocation of budget resources has been guaranteed by *Law n. 13,707* of August 14, 2018, enforced by law, with no possibility of conditioning these expenditures <sup>13</sup>.

The PNI began to conduct studies to assess the cost-effectiveness of the introduction of new vaccines in the national calendar. Since 2006, with the introduction of the rotavirus vaccine, all the vaccines included in the PNI have been preceded by this type of study: 10-valent pneumococcal, meningococcal C, varicella, hepatitis A, DTaP for pregnant women, and HPV <sup>14</sup>.

Epidemiological studies have been conducted to assess vaccines' impact on the morbidity and mortality profile of vaccine-preventable diseases since their introduction in the PNI, a methodology that has served to measure whether the vaccination strategies are adequate or if it is necessary to revise the vaccination schedule following their introduction.

In addition to these studies, vaccination's impact is also evaluated by monitoring the VCRs over time. In the 1980s, the VCRs remained around 60%. The strengthening and prioritization of vaccination activities in the 1990s, with the expansion of vaccination rooms nationwide and the guaranteed supply of vaccines led to an increase in VCRs, but this increase was still uneven. From 2000 to 2015, the targets set by the Brazilian Ministry of Health were met 4.

The maintenance of high VCRs contributed to a significant reduction in the number of cases of vaccine-preventable diseases, which were still endemic in Brazil in the 1980s. Every year in that decade there were approximately 100,000 cases of measles, 80,000 cases of whooping cough, and 10,000 cases of polio and diphtheria <sup>3</sup>.

The certification of smallpox eradication in the Americas was announced in 1973, followed by other achievements. The 1990s saw an important drop in the incidence of vaccine-preventable diseases for which the vaccines were available in Brazil's public health system. One outstanding achievement was the certification of territory free of wild poliovirus circulation in 1994 <sup>3</sup>.

There was an important drop in the annual incidence of diseases prevented with the DTP vaccine (diphtheria, tetanus, and pertussis). Diphtheria decreased from 0.45 cases/100,000 inhabitants in 1990 as the VCRs increased, reaching zero cases in 2012, although 1 case was reported in 2018. There was also an important reduction in the incidence of pertussis, from 10.6 cases/100,000 inhabitants in 1990 to 0.9 cases/100,000 inhabitants in 2000. Starting in 2011, there was an increase in incidence,

Figure 1

Principal strategies and updates to the National Vaccination Calendar in the 46 years of the National Immunization Program. Brazil, 1973 to 2019.

1973-1989	1990-1999	2000-2005	2006-2013	2014-2019
1973: Launch of the National Immunization Program (PNI)  1977: Publication of the 1st National Vaccination Calendar with four mandatory vaccines in the 1st year of life: BCG, measles, oral polio, and triple bacterial (DTP) 1980: Implementation of National Vaccination Days, with the 1st polio vaccination campaign for children under 5 years of age  1989: Introduction of recombinant DNA hepatitis B vaccine in the Legal Amazonia	1991: Creation of the Technical Advisory Committee on Immunizations (CTAI)  1992: National Measles Vaccination Campaign for children up to 14 years of age, a milestone in the Plan for the Control and Elimination of Measles 1993: Implementation of Reference Centers for Special Immunobiological Products (CRIE)  1994: Initial implementation of the Computerized Information System for Assessment of the Immunization Program (SIAPI)  1998: Expansion of hepatitis B vaccine to under 1 year of age Replacement of the tetanus toxoid vaccine with the diphtheria- tetanus (dT) vaccine starting at 7 years of age. Conclusion of the implementation of the SIAPI in the states.  1999: Introduction of seasonal influenza vaccine in the population 65 years and older Introduction of the Haemophilus influenzae b (Hib) vaccine	2000: Expansion of the influenza vaccine to the population 60 years and older Incorporation of the yellow fever vaccine Vaccination campaigns for implementation of the triple viral vaccine (measles, mumps, rubella) for the population 1 to 11 years of age  2001: Expansion of yellow fever vaccine to airport and port workers Start of vaccination of childbearing-age women against measles and rubella as part of the plan to accelerate rubella control  2002: Conclusion of vaccination of childbearing-age women against measles and rubella  2003: Replacement of monovalent measles vaccine with triple viral vaccine Replacement of DTP vaccine with DTP/Hib vaccine with DTP/Hib vaccine to adolescents under 20 years of age  2004: Publication of the National Vaccination Calendar by life cycle (children, adolescents, adults, and elderly) Introduction of 2nd dose of triple viral vaccine at 4 years of age	2006: Introduction of oral human rotavirus vaccine  2008: National Vaccination Campaign in the population of adolescents and young adults for the elimination of rubella  2010: Introduction of conjugate meningococcal C vaccine Introduction of 10-valent pneumococcal vaccine. Publication of indigenous peoples' vaccination calendar. National Vaccination Campaign Against Pandemic H1N1/09 Influenza A  2011: Expansion of hepatitis B vaccine to the population up to 24 years of age Expansion of the influenza vaccine to children from 6 months to 2 years of age, indigenous people, pregnant women, and health workers.  2012: Replacement of the DTP/Hib/Hep B (pentavalent) Introduction of inactivated polio vaccine (IPV) in the sequential IPV/OPV (inactivated/oral) schedule Expansion of the hepatitis B vaccine to the population up to 29 years of age.  2013: Expansion of influenza vaccine to postpartum women and groups with comorbidities Expansion of hepatitis B vaccine to the population up to 29 years of age Introduction of quadrivalent viral vaccine (measles, mumps, rubella, varicella) at 15 months, replacing 2nd dose of triple viral at 4 years of age	2014: Introduction of hepatitis A vaccine Introduction of DTaP vaccine for pregnant women and health workers Introduction of HPV vaccine for girls 11 to 13 years of age Expansion of influenza vaccine to include prison inmates and prison staff  2015: Expansion of 2nd dose of triple viral vaccine to the population up to 29 years of age  2016: Expansion of HPV vaccine to girls 9 to 14 years; population 15 to 26 years living with HIV-AIDS, cancer patients, and transplant patients; Universal access to hepatitis B vaccine  2017: Adoption of single dose for yellow fever vaccine Expansion of meningococcal C and HPV vaccines to adolescents 11 to 14 years  2018: Introduction of 2nd dose of varicella vaccine for children 4 to 6 years  2019: Expansion of influenza vaccine to first responders and security personnel Introduction of 13-valent pneumococcal vaccine in the CRIE

reaching 4.2 cases/100,000 inhabitants in 2014, with a new decrease from that year on, coinciding with a new achievement by the PNI with the deployment of the triple acellular vaccine (diphtheria, tetanus, and acellular pertussis) for pregnant women. This strategy aimed to induce the production of high antibody titers to pertussis in pregnant woman, allowing transplacental transfer to the fetus 15.

Following the introduction of vaccines containing the *Haemophilus influenzae* b component in 1999 and the 10-valent pneumococcal and conjugate meningococcal C vaccines in 2010, Brazil saw a rapid and important reduction in the incidence of *Haemophilus influenza* b meningitis, pneumococcal meningitis, and meningococcal disease (Table 1).

In 2015, the International Expert Committee of the Pan-American Health Organization (PAHO) awarded Brazil with the Certificate of Elimination of Rubella and Congenital Rubella Syndrome, followed in 2016 by the Certificate of Elimination of Measles. Neonatal tetanus was eliminated as a public health problem in 2017. There was a significant reduction in cases of accidental tetanus (Table 1), while the group affected now is rural workers, following an important reduction in cases of accidental tetanus in urban areas.

This important public policy for vaccination has also been essential for the reduction of underfive mortality and thus the improvement in the Brazilian population's life expectancy. In 1996, the Mortality Information System (SIM, in Portuguese) recorded 168 deaths in children under five years of age from vaccine-preventable diseases. In 2017 there were 28 such deaths, representing a decrease of 83% comparing the years 1996 and 2017 (DATASUS. http://datasus.saude.gov.br/mortalidade-1996-a-2017-pela-cid-10-2/, accessed on 02/Feb/2020).

Vaccination and improvements in the population's living conditions, with better sanitation and access to running water and health services, directly impacted the infant mortality rate, which decreased from 96.6 per thousand live births in 1970 to 12.4 in 2018. During the same period, life expectancy at birth in Brazil increased from 57.6 to 76.3 years (IBGE. https://www.ibge.gov.br/apps/populacao/projecao/, accessed on 12/Mar/2020).

# Challenges

Paradoxically, despite all these strides and perhaps due partly to them, major challenges have emerged in various areas of the PNI because of the program's growing complexity throughout its history. One key need involves rapid and timely capillarity of information to serve the country's extensive vaccination network.

Concerning the program's main target, the population protected from vaccine-preventable diseases, an important challenge is to establish a strong partnership with states and municipalities, scientific societies, public and private bodies, government agencies, and nongovernmental organizations to ensure the population's adherence and reach and maintain high VCRs.

There was a drop in VCRs starting in 2016, with levels below the vaccination targets for vaccines on the national calendar (95% coverage for the majority of vaccines for children, except for BCG and rotavirus, where the target is 90%) (Table 2).

From 2016 to 2018, BCG was the only vaccine to reach the target (Table 2).

The low VCRs for childhood vaccination with the triple viral vaccine (measles, mumps, and rubella) in recent years, especially in 2018, reaching a VCR of 92.6% for the first dose and 76.9% for the second dose, contributed to the accumulation of susceptible individuals and the resurgence of measles, the same year in which more than 10,000 cases were reported (Table 2). As a result, Brazil lost its certification as territory free of autochthonous measles virus circulation, which the country had been awarded in 2016.

In order to maintain the World Health Organization (WHO) target of eliminating measles, it is necessary to reach high coverage with the triple viral vaccine for children, adolescents, and young adults. Over the years, the VCRs with accumulated doses from 1994 to July 2019, containing the measles component in the routine vaccination strategy, are still below 70% of the population 20 years and older. This explains the high measles incidence in the 15-19 and 20-29-year age brackets, with the highest incidence rates, 28.9 and 32.0 cases per 100,000 inhabitants, respectively (Table 3).

Measles incidence in children under one year of age has increased, since they have still not had the opportunity to be vaccinated, and the passive immunity received from the mother is insufficient to

Table 1 Incidence rates per 100,000 inhabitants of vaccine-preventable diseases by disease and year. Brazil, 1982-2018.

Year	Polio	Measles	Rubella	Diph- theria	Pertussis	Neonatal tetanus *	Accidental tetanus	Haemophilus influenzae b meningitis	Pneumococcal meningitis	Meningo coccal disease
1982	0.1	31.0	-	-	-	-	-	-	-	-
1983	0.0	46.0	-	-	-	-	-	-	-	-
1984	0.1	63.0	-	-	-	-	-	-	-	-
1985	0.3	58.0	-	-	-	-	-	-	-	-
1986	0.5	97.0	-	-	-	-	-	-	-	-
1987	0.2	48.0	-	-	-	-	-	-	-	-
1988	0.1	19.0	-	-	-	-	-	-	-	-
1989	0.0	16.0	-	-	-	-	-	-	-	-
1990	0.0	42.7	-	0.5	10.7	0.2	1.1	-	1.1	3.5
1991	0.0	31.1	-	0.3	4.9	0.2	1.0	-	1.1	3.3
1992	0.0	5.2	-	0.2	3.5	0.1	0.9	-	1.0	3.3
1993	0.0	1.6	-	0.2	3.6	0.1	0.8	-	1.2	3.9
1994	0.0	0.8	-	0.2	2.7	0.1	0.7	-	1.1	4.1
1995	0.0	0.6	-	0.1	2.4	0.1	0.6	-	1.1	4.6
1996	0.0	2.1	-	0.1	0.8	0.1	0.7	-	1.0	4.7
1997	0.0	33.6	20.6	0.1	1.9	0.1	0.6	-	1.0	4.0
1998	0.0	1.7	4.2	0.1	2.5	0.0	0.4	-	0.8	3.7
1999	0.0	0.6	8.8	0.0	1.0	0.0	0.5	0.2	0.9	3.2
2000	0.0	0.0	9.3	0.0	0.9	0.0	0.3	0.1	0.6	2.5
2001	0.0	0.0	3.4	0.0	0.5	0.0	0.3	0.1	0.7	2.4
2002	0.0	0.0	0.8	0.0	0.4	0.0	0.3	0.1	0.7	2.1
2003	0.0	0.0	0.3	0.0	0.6	0.0	0.3	0.1	0.8	1.9
2004	0.0	0.0	0.2	0.0	0.7	0.0	0.3	0.1	0.8	2.0
2005	0.0	0.0	0.1	0.0	0.7	0.0	0.2	0.1	0.7	1.8
2006	0.0	0.0	0.0	0.0	0.4	0.0	0.2	0.1	0.7	1.6
2007	0.0	0.0	0.0	0.0	0.5	0.0	0.2	0.1	0.6	1.3
2008	0.0	0.0	0.0	0.0	0.8	0.0	0.2	0.1	0.6	1.4
2009	0.0	0.0	0.0	0.0	0.5	0.0	0.2	0.1	0.6	1.5
2010	0.0	0.0	0.0	0.0	0.3	0.0	0.2	0.1	0.6	1.6
2011	0.0	0.0	0.0	0.0	1.2	0.0	0.2	0.1	0.6	1.5
2012	0.0	0.0	0.0	0.0	2.8	0.0	0.2	0.1	0.6	1.3
2013	0.0	0,1	0.0	0.0	3.2	0.0	0.1	0.1	0.5	1.1
2014	0.0	0,4	0.0	0.0	4.2	0.0	0.1	0.1	0.5	0.8
2015	0.0	0,1	0.0	0.0	1.5	0.0	0.1	0.1	0.5	0.7
2016	0.0	0.0	0.0	0.0	0.6	0.0	0.1	0.1	0.4	0.5
2017	0.0	0.0	0.0	0.0	0.9	0.0	0.1	0.1	0.5	0.5
2017	0.0	5,3	0.0	0.0	0.5	0.0	0.1	0.1	0.5	0.5

Source: data extracted from Information System on Diseases of Notification (http://portalsinan.saude.gov.br/dados-epidemiologicos-sinan, accessed on 12/Mar/2020).

protect these infants. This highlights the importance of maintaining high VCRs in the target groups for measles vaccination, aimed at creating herd immunity, thereby protecting individuals that cannot be vaccinated or that are not included in the vaccination strategy (Table 3).

Due to the decrease in the circulation of various vaccine-preventable diseases, some people actually believe that prevention is secondary or even unnecessary. Since 2012, the WHO has reaffirmed

<sup>\*</sup> Neonatal tetanus incidence per 100,000 infants under 1 year of age.

Table 2

Vaccination coverage for vaccines in vaccination schedule recommended simultaneously by type of vaccine in infants under 1 year of age and 1 year of age and percentage variation in 2018, compared to 2015. Brazil, 2010 to 2018.

commended age vaccination	Type of vaccines	2010	2011	2012	2013	2014	2015	2016	2017	2018	Variation, 2015 and 2018
											2016
birth	BCG	106.7	107.9	105.7	107.4	107.3	105.1	95.6	97.1	99.8	-5.30
birth ≤ 30 days	Hepatitis B	NA	NA	NA	NA	88.5	90.9	81.8	85.2	86.3	-4.60
d-4th month	Human rotavirus	83.0	87.1	86.4	93.5	93.4	95.4	89.0	84.7	89.4	-6.00
d-4th month	Pneumococcal	n.a.	81.7	88.4	93.6	93.5	94.2	95.0	91.6	93.1	-1.10
d-4th-6th month	Inactivated polio (IPV)	99.4	101.3	96.6	100.7	96.80	98.3	84.4	84.3	87.9	-10.40
d-4th-6th month	Penta (DTP/HB/Hib)	NA	NA	24.9	96.0	94.8	96.0	89.2	84.0	86.8	-9.20
d-5th month	Meningococcal C	NA	105.7	96.2	99.7	96.4	98.2	91.7	87.0	87.2	-11.00
n month	Yellow fever (AWRV)	NA	NA	NA	NA	NA	51.6	52.8	55.3	66.3	14.70
months	Triple viral, 1st dose	99.9	102.4	99.5	107.5	112.8	96.1	95.4	90.9	91.7	-4.40
months	Pneumococcal (1st booster)	NA	NA	NA	93.1	88.0	88.4	84.1	79.7	79.9	-8.50
months	Meningococcal C (1st booster)	NA	NA	NA	92.4	88.6	87.9	93.9	82.1	79.6	-8.30
months	Hepatitis A	NA	NA	NA	n.a.	60.1	97.1	71.6	83.1	82.0	-15.10
months	DTP (1st booster)	NA	NA	NA	91.0	86.4	85.8	64.3	74.3	67.4	-18.40
months	Polio (1st booster)	NA	NA	NA	92.9	86.3	84.5	74.4	78.1	71.8	-12.70
months	Triple viral (2nd dose)	NA	NA	NA	68.9	92.9	79.9	76.7	76.5	76.4	-3.50
months months months months	Meningococcal C (1st booster)  Hepatitis A  DTP (1st booster)  Polio (1st booster)	NA NA NA	NA NA NA NA	NA NA NA	92.4 n.a. 91.0 92.9	88.6 60.1 86.4 86.3	87.9 97.1 85.8 84.5	93.9 71.6 64.3 74.4	82.1 83.1 74.3 78.1	79 82 67 71	9.6 2.0 7.4 .8

NA: data with calculation of vaccination coverage not available in the information or vaccine not available on the child's calendar in the year or period. Source: data extracted from Information System on Diseases of Notification (http://portalsinan.saude.gov.br/dados-epidemiologicos-sinan, accessed on 12/Mar/2020).

Table 3

Number of cases, incidence rates \* for measles by age bracket and vaccination coverage with accumulated first doses of vaccines with components against measles. Population referring to places with registered confirmed cases. Brazil, 2019.

Age bracket (years)	Population (millions)	Number of cases	Incidence rate	Vaccination coverage (%)
< 1	1.4	3,194	222.1	-
1-4	5.2	2,529	48.3	84.6
5-9	6.8	447	6.5	108.0
10-14	7.9	337	4.3	97.6
15-19	7.9	2,310	28.9	129.0
20-29	17.6	5,651	32.1	58.2
30-39	15.6	2,351	15.1	68.7
40-49	13	1,115	8.6	63.2
≥ 50	20	89	0.4	20.1
Total	96	18,203	18.3	69.0

Source: data extracted from Information System on Diseases of Notification (http://portalsinan.saude.gov.br/dados-epidemiologicos-sinan, accessed on 12/Mar/2020).

<sup>\*</sup> Preliminary data extracted from Information System of the Immunization Program (http://sipni.datasus.gov.br, accessed on 12/Mar/2020).

this issue's importance and its implications, attempting to understand this phenomenon and gathering evidence to develop public health interventions to reverse this trend. Vaccine hesitancy is defined as the delay in the vaccination schedule or refusal to receive the recommended vaccines, despite their availability in health services <sup>16</sup>.

This is a complex issue involving cultural, social, and economic aspects that vary over time, across geographic territories, and according to the types of vaccines used in the various vaccination programs. The phenomenon should be understood as a continuous process ranging from hesitant individuals that only accept some vaccines to others who intentionally delay or refuse the recommended vaccination schedule, and even those who purposely refuse to vaccinate, regardless of the immunobiological product being offered <sup>17</sup>. In 2019, the WHO classified "vaccine hesitancy" as one of the ten most daunting global health threats <sup>18</sup>.

Vaccine safety is crucial to the success of vaccination programs. Vaccines produce extensive public health benefits, but like any drug, their use can result in some unintended events. Since there are no more cases of many of these diseases, what prevails are reports of adverse events related to vaccination. This leads to fear that vaccines cause harmful physical reactions. This argument has been used by many parents to not be vaccinated themselves or to not vaccinate their children. The overwhelming majority of such events are mild, with pain and redness at the injection site or malaise, fatigue, or fever 8.

In addition to the fear of adverse events, the expansion of the vaccination calendar, especially for children, began to trigger a fear that the high number of vaccines applied simultaneously might overload the immune system. Studies show that both the simultaneous application or the use of combined vaccines does not interfere in the vaccines' efficacy or compromise the immune system <sup>19,20,21</sup>. The simultaneity of schedules allows a child to be vaccinated on the same occasion with the largest number of vaccines, thus protecting against more diseases.

The assessment of VCRs indicates that in recent years Brazil has been missing the opportunity to guarantee children's complete and timely vaccination calendar. That is, children are coming to the health posts, but they are not being vaccinated simultaneously according to the program's recommended vaccinations schedules, since the vaccines are not applied in the same period and they present different coverage rates.

In order to determine whether the simultaneity of vaccination has been conducted according to the guidelines under the Children's Calendar, the VCR for 2018 was assessed according to the child's age (Table 4) and not only at the completion of the vaccination schedule, as is usually monitored by the VCR. According to the SINASC, there were 2,854,295 births in 2016, the basis for calculating vaccination coverage by age (DATASUS. http://datasus.saude.gov.br/nascidos-vivos-1994-a-2017/, accessed on 02/Feb/2020). Comparing the doses applied for the BCG and hepatitis B vaccines, recommended at birth, only 8,280 children failed to receive the BCG vaccine. Meanwhile, 331 thousand children failed to receive the hepatitis B vaccine. Comparing the total doses of BCG vaccine that were applied, 323 thousand doses of hepatitis B failed to be applied simultaneously, representing an important loss of opportunity for vaccination, suggesting that BCG vaccine is being applied late, when the application of hepatitis B vaccine is no longer recommended, since this dose should only be received up to 30 days after birth. Similar losses of opportunity for vaccination were identified in all the periods analyzed and for the majority of vaccines (Table 4).

In addition to vaccine hesitancy, the non-concurrent application of vaccines may also be related to insufficient training of the health professionals working in vaccination services <sup>8,9</sup>. Brazil's vaccination calendar became more complex, requiring extensive knowledge by health workers on the vaccination schedules and their updates, especially for children appearing late at the vaccination services. In order to upgrade the vaccination teams, the PNI has invested in online training to increase the network's capillarity, with various courses provided on this platform, addressing different topics via diverse approaches.

However, it is necessary to further expand the training of health workers in the vaccination rooms. This should be a priority not only for the Ministry of Health, but also for the states and municipalities, which are responsible for keeping their networks prepared to serve the population.

Table 4

Number of doses applied, vaccination coverage rates by type of doses of vaccination schedule, estimate of unvaccinated individuals in relation to the largest number of doses of simultaneous schedule for each vaccine on the childhood calendar. Brazil, 2018 \*.

Recommended age for vaccination	Type of vaccines	Number of doses applied	Vaccination coverage (%) **	Number not vaccinated simultaneously ***
At birth	BCG (single dose)	2,846,012	99.7	-
At birth ≤ 30 days	Hepatitis B (dose)	2,522,856	88.4	323,156
2nd month	Polio (1st dose)	2,795,958	97.9	-
2nd month	Pneumococcal (1st dose)	2,789,938	97.7	6,020
2nd month	Penta (DTP/Hib/HB) (1st dose)	2,787,762	97.6	8,196
2nd month	Human rotavirus (1st dose)	2,741,217	96.0	54,741
4th month	Pneumococcal (2nd dose)	2,718,779	95.2	-
4th month	Polio (2nd dose)	2,681,139	93.9	37,640
4th month	Penta (DTP/Hib/HB) (2nd dose)	2,659,241	90.4	59,358
4th month	Human rotavirus (2nd dose)	2,606,784	91.3	111,995
6th month	Polio (3rd dose)	2,601,329	91.1	-
6th month	Penta (DTP/Hib/HB) (3rd dose)	2,531,580	88.7	69,749
12 months	Triple viral (1st dose)	2,643,322	92.6	-
12 months	Pneumococcal (booster)	2,312,229	81.0	331,093
12 months	Meningococcal (1st booster)	2,289,582	80.2	353,740
15 months	Hepatitis A	2,359,644	82.7	-
15 months	Triple viral (2nd dose)	2,209,212	77.4	150,432
15 months	Polio (1st booster)	2,116,395	74.1	243,249
15 months	DTP (1st booster)	2,103,283	73.7	256,361

Source: data extracted from Information System on Diseases of Notification (http://portalsinan.saude.gov.br/dados-epidemiologicos-sinan, accessed on 12/Mar/2020).

Studies show that recommendation by health professionals is a determinant factor for the vaccine's acceptance. The physician's role has been identified as one of the main facilitators for adherence to vaccination, especially for vaccines to which the population has displayed some resistance, like HPV. Qualified professionals that know how to recommend the vaccines and answer the population's questions are thus an important strategy for increasing vaccination coverage 22.

Another issue that may be related to the difficulty in vaccination is irregular supply of immunobiological products resulting from production problems in both the public and private laboratories, identified in recent years. When shortage of a vaccine occurs, even if temporary, the child's parents may not have time to return to the health service in time for the vaccination. The child may be vaccinated later, with a delay, but depending on the child's age, he or she may not be included in the calculation of the VCR, which can compromise monitoring of the rate. Besides, if a child outside of the recommended age bracket comes to the vaccination service, the health worker may not know which vaccines should be applied simultaneously at this visit. This may result in some delay in the vaccination, as shown in the failure to reach the target for hepatitis A vaccine or the inactivated polio and live oral polio vaccines (IPV/OPV) in the last three years, when there were shortages of these vaccines (Table 2).

<sup>\*</sup> Preliminary data extracted from Information System of the Immunization Program (http://sipni.datasus.gov.br, accessed on 12/Mar/2020);

<sup>\*\*</sup> Vaccination coverage rates estimated for each dose of the vaccination schedule. Denominator: obtained from the Information System on Live Births, 2,854,295 births, in 2016 (DATASUS. http://tabnet.datasus.gov.br/cgi/deftohtm.exe?sinasc/cnv/nvuf.def, accessed on 12/Mar/2020);

<sup>\*\*\*</sup> Estimate of individuals not vaccinated simultaneously, with the highest vaccination coverage (in bold) as the reference.

A computerized logistics network is also needed for distribution and storage to optimize the use of inputs, especially decreasing the losses of vaccines. Brazil's large territory and the expansion of vaccination rooms in recent years involve huge complexity to keep these services supplied, so it is crucial to minimize such losses, especially during times of short supply.

The increase in the propagation of fake news on the social networks has also contributed to vaccine hesitancy. Catch phrases with an emotional and gripping appeal, with no scientific evidence, widely shared on the social networks and message apps, end up confusing the population and spreading panic on possible side effects. The Brazilian Ministry of Health has identified fake news as one of the reasons for the reduction in immunization rates in Brazil. According to a Brazilian Ministry of Health survey of social media in 2018, 89% of the fake new related to health specifically attacked the credibility of vaccines  $^{23}$ .

To fight the fake news, the Brazilian Ministry of Health took an innovative approach by providing a WhatsApp number to receive messages from the population. The channel is not a Customer Service Hotline, nor does it answer users' questions; rather, it serves as an exclusive space to receive viral information that is then fact-checked for its veracity by the respective technical divisions. The number is +55 (61) 99289-4640.

Although the phenomenon of vaccine hesitancy has grown in recent decades, it has been present throughout the history of vaccination. There were already cartoons ridiculing smallpox vaccine in the United Kingdom in the 1800s. Beginning in the 20th century, mandatory vaccination caused resistance in individuals that considered it an invasion of their freedom over their own bodies, sparking the first legal battles against mandatory vaccination. In the United States, beginning in 1980, resistance emerged to vaccinating children with DTP, a vaccine that contained the whole cell pertussis component and is more reactogenic, leading the pharmaceutical industry to pursue the development of the acellular vaccine <sup>17</sup>.

In the 1990s, these groups came to be called "antivaccination movements", bolstering their efforts with a fraudulent publication claiming that the triple viral vaccine caused autism. Even after other scientists demonstrated that there was no association between the vaccine and autism, to this day many of these group cite this study to claim that this association with autism exists <sup>24</sup>.

This movement currently consists of individuals motivated primarily by ideological, religious, or cultural issues, with intense activity in the United States and Europe. Until recently it was made up of groups with abundant financial resources, but it has now reached lower-income segments of society via intensive use of social networks, penetrating an audience that could not previously be reached by this propagation of erroneous information <sup>17</sup>.

In Brazil, this phenomenon was seen for the first time in a popular uprising in Rio de Janeiro in 1904 against a law determining mandatory smallpox vaccination, a movement that went down in history as the "Vaccine Revolt" <sup>25</sup>. Although the law's intentions were valid, it was enforced by authoritarian and violent means. In some cases, the health agents invaded people's homes and vaccinated them by force, sparking revolt in the populace due to their ignorance of what the vaccine was and fear of its effects. However, due to the severity of the disease plaguing the country, causing thousands of deaths, the population eventually gave in to being vaccinated <sup>26</sup>.

The activity by these groups is still limited in Brazil, although more aggressive action has already been seen in comes cases, especially in places that have recorded adverse events following immunization related to the HPV vaccine <sup>27</sup>.

The fall in VCRs may also be related to the change in the system for recording vaccination data in Brazil, launched in 2010 and stepped up since 2016. A recent study on the evolution of the Information System of the PNI showed that the digitization of vaccination data by the Brazilian Ministry of Health, launched in 1994, used the Information System for the Assessment of the Immunization Program (SIAPI) until 2009, developed in a partnership between the PNI and DATASUS. This system aimed to record aggregate data on vaccine doses applied by a vaccination service in a given time frame and target group <sup>7</sup>.

The authors report that due to the huge mass of data generated by the PNI in its complex activities, the initial subsystems displayed some limitations, especially with data transfer, storage, security, and integrity. Another major limitation was the recording of vaccine doses aggregated by municipality

(county) in which the vaccination occurred, hindering the identification of vaccinated individuals and their place of residence and thus the analysis of the real vaccination situation 7.

The SIPNI was developed to reduce the shortcomings in the information subsystems. The PNI thus began to recommend that the municipalities shift the recording of vaccination to the SIPNI, earmarking funds for purchases of computer equipment in order to accelerate the system's implementation 28. This strategy aimed to decrease the data quality problems, so that for example the data entry became individual, including the vaccinated person's place of residence, allowing to monitor individuals' vaccination status and the scheduling of their vaccines according to the CNV.

Another incentive for use of the SIPNI was the inclusion of the indicator "proportion of vaccination rooms reporting monthly to the SIPNI" on the list of 14 indicators in the Program for Upgrading Health Surveillance Activities (PQAVS, in Portuguese), with bonus transfer of up to 20% over the annual value of the Fixed Minimum for Health Surveillance (PFVS, in Portuguese) for municipalities that reached the targets set by the PNI 29. Even with the financial incentive for implementing the SIPNI, there was no massive adherence to its use, and 20% of the vaccination rooms were still not using this system in 2019 6.

Despite the strides in upgrading the country's immunization data with the SIPNI, there are still serious problems that may be affecting the quality of the recorded data. The main obstacles reported by states and municipalities involve lack of transmission of locally recorded data to the national database and the delay in transmitted data processing by DATASUS, due partly to the incompatibility between the SIPNI version and the systems used by some municipalities 7.

The greater complexity involved in recording vaccination data in the SIPNI has led to irregular, inadequate, or late feeding of data. That is, the applied doses are either not recorded at all, or they are recorded with delays. There are also constant keying-in errors identified in the database, which compromises the information's quality. These problems can lead to differences between the local data and the consolidated numbers at the national level 7.

In order to minimize these problems and guarantee that the data recorded in the vaccination rooms faithfully represent the entire country's true vaccination coverage, the Brazilian Ministry of Health is reformulating the SIPNI, which will have a single repository of vaccination data to be fed by various apps originating in the SUS itself or from third parties 7.

The vaccination coverage rate is highly useful for assessing the degree to which the vaccination targets set by the PNI are being met. Still, the rate can be influenced by the population's mobility if the recording is done from aggregate data, without identifying the vaccinated individual or by overestimation or underestimation of the numerator or denominator. Impact studies and vaccination coverage surveys are thus essential for estimating the population's real benefits from vaccination activities in the country.

Finally, women's growing participation in the work market deserves attention. Data from the IBGE population census showed that in 1950 only 13.6% of Brazilian women were in the work force, compared to 80% of men (IBGE. https://www.ibge.gov.br/apps/populacao/projecao/, accessed on 12/Mar/2020) 30. Workforce participation is defined as the proportion of the population over 15 years of age who are economically active. By 2017, based on World Bank data, Brazilian women's workforce participation was 71.19% that of men 31.

Lack of time to take children to vaccination services poses a problem for ensuring that children's vaccination booklets are maintained on schedule. Access to vaccination's rooms can be difficult, especially because of the office hours at health units, inconsistent with the population's new work routines, especially for mothers, who are usually responsible for taking their children. In this current context, it is essential to rethink the functioning of primary healthcare units (UBS, in Portuguese) in order to keep the VCRs high.

Seeking to strengthen primary care and expand vaccination coverage, the Brazilian Ministry of Health launched the "Health on Time Program", which increases the office hours in UBS in municipalities that join the program. In order to facilitate the population's access to primary health care services, the program provides that units joining the program expand their hours to function from 60 to 75 hours a week 32.

#### **Conclusions**

Looking to the future of the PNI, we glimpse the need to consolidate the existing achievements and to tackle the challenges raised by the growing complexity of the epidemiological profile of communicable diseases in a world in which health risks are shares almost immediately.

Overcoming the challenges requires growing integration of the PNI at all administrative levels of the SUS, as well as in other areas of the health sector and the social and educational sectors, and especially the full participation of health workers that make vaccination available to the entire population. The vaccinators have been the true protagonists in this success story and need to reengage in mobilizing the population, but with sufficient conditions to do their work.

With the flow of tourists and commerce between countries, the interruption of vaccination could lead to increasing mortality, especially in children, with serious social and financial costs, further overloading health services in hospitals and rehabilitation services. This would also prevent reaching the target of eliminating measles transmission in the world by 2020, set by the 64th World Health Assembly of the WHO with the support of 195 countries, besides opening the way for the resurgence of other diseases that had already been controlled in Brazil.

Strengthening the Health Industrial Complex is also essential at this moment of crisis in the global production of immunobiological products. The expansion of vaccine production with good manufacturing practices is the only way to fill this gap in the supply of products offered by the PNI, since budget resources alone have not been capable of keeping the vaccination rooms supplied.

The conclusion of implementation of the information system with nominal recording of vaccinated individuals is crucial for guaranteeing adequate monitoring of VCRs, thus identifying the real pockets of susceptible individuals in time and developing strategies to guarantee maintenance of high VCRs. The Brazilian Ministry of Health must therefore maintain its systems to avoid both loss of data and discrepant information between the various levels of the SUS. It is also highly relevant for vaccination services to have properly training healthcare personnel in sufficient numbers to meet the current demand of the CNV and vaccination records using nominal systems.

Adequate and timely maintenance of the SIPNI is also necessary for integration/interoperability of the respective health databases.

The online channel of the SUS ("e-SUS") has not met all the needs of the PNI satisfactorily to back its administration, since the program requires more information besides records of vaccinated individuals. For example, one of the reasons the SIPNI was developed was to integrate the systems' databases on the use and losses of immunobiological products in the network; vaccination of special groups in the CRIE; and adverse events following immunization. Currently, in the area of immunizations, the e-SUS channel only applies to recording of vaccinated individuals in UBS. Even within the same UBS, two information systems are being used to guarantee the above-mentioned data for the program. The scope does not include maternity hospitals, mixed health units, private vaccination services, and CRIE that should use the SIPNI.

Finally, it is necessary to restore the value of vaccination in the population's eyes, which was the original basis for this success story, maintaining all the previous achievements. This will require seeking a balance between coercive measures and persuasive approaches.

Coercion is the oldest tradition in public health. In the 19th century, many state and local authorities passed mandatory smallpox vaccination laws for both children and adults. These laws were a basic component in the expansion of public health regulations on such practices as quarantine, sanitation, and housing construction. The vaccination laws imposed various sanctions, including the exclusion of unvaccinated children from school enrollment and fines or quarantining of adults that refused to be vaccinated. However, over the years the use of coercion began to raise concerns about the restriction of individual freedom and the scope of parental control over raising their children, to the detriment of government interference in people's lives <sup>33</sup>.

In Brazil, besides the law on mandatory smallpox vaccination in 1904, vaccination measures established with the institutionalization of the PNI by Law n. 6,259 and regulated by Decree 78,231/1976 determined mandatory vaccination with all the vaccines on the National Vaccination Calendar. This legal framework which formally established the National Immunization Program is still in force today. However, rather than confronting the population, health professionals began to rely on

advertising techniques to identify attitudes, beliefs, and social contexts that predict vaccine-related behaviors in order to develop approaches to increase adherence to vaccination.

In this context, civil society's participation such as via the Rotary Club, Lions, and Children's Pastoral Commission and involvement by community leaders was essential to help develop more persuasive and less restrictive approaches.

Currently, when the phenomenon of vaccine hesitancy has reflected a diversity and complexity of attitudes and beliefs, including distrust towards medical and scientific issues, resistance to government authority and adherence to "natural" health or religious beliefs, persuasive approaches are apparently becoming less effective, plus they are time-consuming and labor-intensive.

Many countries are pursuing adherence to vaccination by strengthening compulsory vaccination laws, aimed at limiting the circumstances in which parents can refuse to vaccinate their children and making exemptions on religious or philosophical grounds more difficult. Given the reductions in vaccination coverage rates, Brazilian states such as Bahia, Distrito Federal, Espírito Santo, Mato Grosso, Paraná, Pernambuco, and Roraima have passed state laws conditioning school enrollment on the child's complete vaccination schedule.

The Brazilian Ministry of Health's strategy of conducting vaccination in schools with the implementation of the HPV vaccine in 2014 demonstrated that more than the mandatory application, the linkage between the three levels of government administration (municipal, state, and federal) in both health and education was crucial for the positive response by the Brazilian population and decisive for achieving the target. In the first year with the HPV vaccine, the 80% vaccination coverage target for the first dose was surpassed, having reached 100% in a short space of time, in girls 11 to 13 years of age 29.

Still, a broad debate is needed in Brazilian society concerning the best path for continuing to achieve high vaccination coverage rates and thus avoid the resurgence of diseases, some of which had even been eliminated or eradicated from Brazil, or the increase in the morbidity and mortality from many other diseases that can be prevented as long as the vaccination calendar for children, adolescents, adults, and the elderly is maintained on schedule. This will avoid wasting past achievements and an inadmissible setback for public health in Brazil.

## **Contributors**

C. M. A. S. Domingues wrote the article. A. G. K. Maranhão, A. M. Teixeira, Francieli F. S. Fantinato and Raissa A. S. Domingues revised the article.

## **Additional informations**

ORCID: Carla Magda Allan Santos Domingues (0000-0003-1463-4939); Ana Goretti K. Maranhão (0000-0003-1417-2009); Antônia Maria Teixeira (0000-0002-9196-6331); Francieli F. S. Fantinato (0000-0002-0110-2266); Raissa A. S. Domingues (0000-0002-0827-7165).

# Acknowledgments

The authors wish to thank the vaccinators and municipal and state immunization coordinators, who have always been and always will be the soul of the National Immunization Program (PNI), and the entire staff of the General Coordinating Division of the PNI under the Brazilian Ministry of Health for conducting their activities with calm, skill, and determination in order to guarantee the program's leading role in social inclusion in Brazil.

# References

- Domingues CMAS, Teixeira AMS. Coberturas vacinais e doenças imunopreveníveis no Brasil no período 1982-2012: avanços e desafios do Programa Nacional de Imunizações. Epidemiol Serv Saúde 2013: 22:9-27.
- 2. Brasil. Lei nº 8080, de 19 de setembro de 1990. Dispõe sobre as condições para a promoção, proteção e recuperação da saúde, a organização e o funcionamento dos serviços correspondentes e dá outras providências Diário Oficial da União 1990; 20 sep.
- Departamento de Vigilância Epidemiológica, Secretaria de Vigilância em Saúde, Ministério da Saúde. Programa Nacional de Imunizações (PNI): 40 anos. Braspilia: Ministério da Saúde; 2013.
- 4. Departamento de Análise em Saúde e Vigilância de Doenças não TransmissíveisSecretaria de Vigilância em Saúde, Ministério da Saúde. Avaliação dos indicadores de desempenho da vacinação do Programa Nacional de Imunizações e os desafios para elevar as coberturas vacinais no Brasil. In: Departamento de Análise em Saúde e Vigilância de Doenças não Transmissíveis, Secretaria de Vigilância em Saúde, Ministério da Saúde, organizador. Saúde Brasil 2019: uma análise da situação de saúde com enfoque nas doenças imunopreveníveis e na imunização. Brasília: Ministério da Saúde; 2019. p. 369-404.
- Risi Júnior JB. A produção de vacinas é estratégica para o Brasil. Hist Ciênc Saúde-Manguinhos 2003; 10 Suppl 2:771-83.
- Domingues CMAS, Woycicki JR, Rezende KS, Henriques CMP. Programa Nacional de Imunização: a política de introdução de novas vacinas. Revista Eletronica Gestão & Saúde 2015; 6:3250-74.
- 7. Departamento de Análise em Saúde e Vigilância de Doenças não TransmissíveisSecretaria de Vigilância em Saúde, Ministério da Saúde. Evolução dos sistemas de informação utilizados pelo Programa Nacional de Imunizações brasileiro. In: Departamento de Análise em Saúde e Vigilância de Doenças não Transmissíveis, Secretaria de Vigilância em Saúde, Ministério da Saúde, organizador. Saúde Brasil 2019: uma análise da situação de saúde com enfoque nas doenças imunopreveníveis e na imunização. Brasília: Ministério da Saúde; 2019. p. 445–84.
- 8. Zorzetto R. As razões da queda na vacinação. Pesqui Fapesp 2018; (270):19-24.
- Cruz A. A queda da imunização no Brasil. Revista CONSENSUS 2017; VII:20-9.
- Barata RB, Ribeiro MCSA, Moraes JC, Flannery B. Socioeconomic inequalities and vaccination coverage: results of an immunisation coverage survey in 27 Brazilian capitals, 2007-2008. J Epidemiol Community Health 2012; 66:934-41.

- 11. Ministério da Saúde. Portaria do Ministro da Saúde nº 452/NR, de 6 de dezembro de 1976. Institui, em todo o território nacional, os calendários de vacinação. Diário Oficial da União 1977; 2 feb.
- 12. Ministério da Saúde. Portaria nº 597, de 8 de abril de 2004. Institui, em todo o território nacional, os calendários de vacinação. Diário Oficial da União 2004; 9 apr.
- 13. Brasil. Lei nº 13.707, de 14 de agosto de 2018. Dispõe sobre as diretrizes para a elaboração e execução da Lei Orçamentária de 2019 e dá outras providências. Diário Oficial da União 2018; 15 aug.
- 14. Sartori AMC. Avaliação econômica da introdução de novas vacinas no Programa Nacional de Imunizações brasileiro [Tese de Doutorado]. São Paulo: Faculdade de Medicina, Universidade de São Paulo; 2017.
- 15. Secretaria de Vigilância em Saúde, Ministério da Saúde. Vigilância em saúde no Brasil 2003 2019: da criação da Secretaria de Vigilância em Saúde aos dias atuais. Boletim Epidemiol 2019; 50(n. esp.):1-154.
- 16. MacDonald NE, Eskola J, Liang X, Chaudhuri M, Dube E, Gellin B, et al. Vaccine hesitancy: definition, scope and determinants. Vaccine 2015; 33:4161-4.
- 17. Sato APS. Qual a importância da hesitação vacinal na queda das coberturas vacinais no Brasil? Rev Saúde Pública 2018; 52:96.
- 18. World Health Organization. Ten threats to global health in 2019. Geneva: World Health Organization; 2019.
- 19. U.S. National Institutes of Health. Glossary of clinical trials terms. Washingtion DC: U.S. National Institutes of Health; 2014.
- 20. Enkin M, Jadad A. Randomized controlled trials: questions, answers, and musings. 2nd Ed. Malden: Blackwell Publishing; 2007.
- 21. Weinberg GA, Szilagyi PG. Vaccine epidemiology: efficacy, effectiveness, and the translational research roadmap. J Infect Dis 2010; 201:1607-10.
- 22. Loke AY, Kwan ML, Wong YT, Wong AKY. The uptake of human papillomavirus vaccination and its associated factors among adolescents: a systematic review. J Prim Care Community Health 2017; 8:349-62.
- 23. 12 mil dúvidas em um ano de combate às fake news. Agência Saúde 2019; 27 ago. https://www.saude.gov.br/noticias/agencia-sau de/45719-12-mil-duvidas-em-um-ano-decombate-as-fake-news.
- 24. Seppa N. Journal retracts flawed study linking MMR vaccine and autism. ScienceNews 2010; 3 fev. https://www.sciencenews.org/blog/ deleted-scenes/journal-retracts-flawed-studylinking-mmr-vaccine-and-autism.

- 25. Brasil. Lei nº 1.261, de 31 de outubro de 1904. Torna obrigatórias, em toda a República, a vacinação e a revacinação contra a varíola. Diário Oficial da União 1904: 2 nov.
- Buss PM. Vacinas, soros e imunizações no Brasil. Rio de Janeiro: Editora Fiocruz; 2005.
- 27. Departamento de Análise em Saúde e Vigilância de Doenças não Transmissíveis, Secretaria de Vigilância em Saúde, Ministério da Saúde. A vacina contra o HPV no Brasil: monitoramento da cobertura vacinal. In: Departamento de Análise em Saúde e Vigilância de Doenças não Transmissíveis, Secretaria de Vigilância em Saúde, Ministério da Saúde, organizador. Saúde Brasil 2019: uma análise da situação de saúde com enfoque nas doenças imunopreveníveis e na imunização. Brasília: Ministério da Saúde; 2019. p. 331-46.
- 28. Ministério da Saúde. Portaria nº 2.363, de 18 de outubro de 2012. Institui repasse financeiro do Fundo Nacional de Saúde aos Fundos de Saúde dos Estados, Distrito Federal e Municípios, por meio do Piso Variável de Vigilância e Promoção da Saúde, para fomento na implantação do Sistema de Informação do Programa Nacional de Imunizações (SI-PNI). Diário Oficial da União 2012: 19 oct.
- 29. Ministério da Saúde. Portaria nº 1.708, de 16 de agosto de 2013. Regulamenta o Programa de Qualificação das Ações de Vigilância em Saúde (PQAVS), com a definição de suas diretrizes, financiamento, metodologia de adesão e critérios de avaliação dos Estados, Distrito Federal e Municípios. Diário Oficial da União 2013; 17 aug.
- 30. Andrade T. Mulheres no mercado de trabalho: onde nasce a desigualdade? Brasília: Câmara dos Deputados; 2016. (Estudo Técnico).
- 31. Ortiz-Ospina E, Tzvetkova S. Working women: key facts and trends in female labor force participation. Our World in Data 2017; 16 out. https://ourworldindata.org/female-laborforce-participation-key-facts.
- 32. Ministério da Saúde. Portaria nº 930, de 15 de maio de 2019. Institui o Programa "Saúde na Hora", que dispõe sobre o horário estendido de funcionamento das Unidades de Saúde da Família, altera a Portaria nº 2.436/GM/MS, de 2017, a Portaria de Consolidação nº 2/GM/ MS, de 2017 a 2019. Diário Oficial da União 2019; 16 may.
- 33. Colgrove J. Vaccine refusal revisited: the limits of public health persuasion and coercion. N Engl J Med 2016; 375:1316-7.

## Resumo

O Programa Nacional de Imunizações (PNI), coordenado pelo Ministério da Saúde, de forma compartilhada com as secretarias estaduais e municipais de saúde, vem se consolidando como uma das principais e mais relevantes intervenções em saúde pública, com a conquista de resultados importantes, como a certificação de área livre da circulação do poliovírus selvagem, a eliminação da circulação do vírus da rubéola e pelo importante impacto na redução dos casos e mortes pelas doenças imunopreveníveis, a partir da sua criação em 1973. O Brasil é um dos países que oferece o maior número de vacinas, de forma gratuita, com 15 vacinas para crianças, 9 para os adolescentes, cinco para os adultos e idosos. A partir dessa expansão do programa e da manutenção de elevadas coberturas vacinais, foi possível observar o rápido impacto na diminuição das doenças imunopreveníveis, mudando completamente o cenário epidemiológico dessas doenças no país, ao longo destas últimas quatro décadas. Atualmente, o país vive um contexto em que aumenta a parcela da população sem vacinação adequada. Na medida em que as doenças passam a não circular mais, justamente porque se mantiveram elevadas coberturas vacinais principalmente a partir dos anos 2000, muitas doenças tornaram-se desconhecidas, fazendo com que algumas pessoas não tenham noção do perigo representado por elas. É necessário, portanto, entender os múltiplos fatores que estão contribuindo para essa diminuição, criando, dessa forma, o risco de ressurgimento de doenças graves já controladas ou eliminadas na população.

Programas de Imunização; Cobertura Vacinal; Recusa de Vacinação; Movimento contra Vacinação

#### Resumen

El Programa Nacional de Inmunizaciones de Brasil (PNI), coordinado por el Ministerio de la Salud, de forma compartida con Las secretarías estatales y municipales de salud, se ha consolidando como una de las principales y más relevantes intervenciones en salud pública, con la conquista de resultados importantes, como la certificación de área libre de la circulación del poliovirus salvaje, la eliminación de la circulación del virus de la rubeola, además de por el importante impacto en la reducción de los casos y muertes por enfermedades inmunoprevenibles, a partir de su creación en 1973. Brasil es uno de los países que ofrece el mayor número de vacunas, de forma gratuita, con 15 vacunas, 9 para adolescentes, 5 para adultos y ancianos. A partir de esta expansión del programa y del mantenimiento de elevadas coberturas de vacunación fue posible observar el rápido impacto en la disminución de las enfermedades inmunoprevenibles, cambiando completamente el escenario epidemiológico de esas enfermedades en el país, a lo largo de estas últimas cuatro décadas. Actualmente, el país vive un contexto en que aumenta la proporción de la población sin vacunación adecuada. A medida que las enfermedades pasan a no circular más, justamente porque se mantuvieron elevadas, principalmente a partir de la década del 2000, muchas enfermedades se convirtieron en desconocidas, provocando que algunas personas no tengan noción del peligro representado por ellas. Es necesario, por tanto, entender los múltiples factores que están contribuyendo a esta disminución, creando, de esta forma, el riesgo de resurgimiento de enfermedades graves ya controladas o eliminadas de la población.

Programas de Imunización; Cobertura de Vacinación; Negativa de la Vacunación; Movimiento Anti-vacunación

Submitted on 23/Nov/2019
Final version resubmitted on 03/Apr/2020
Approved on 10/Apr/2020