Diagnostic Tests, Vaccination and SUS: Analysis of Brazilian Measures to Address the COVID-19 Pandemic

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Mass testing and vaccination are essential for controlling the COVID-19 pandemic. This study aims to evaluate the initial strategies adopted by Brazil to combat the COVID-19 pandemic. Information collected from public and government databases on the approvals and acquisition of diagnostic tests and the immunization process in several countries was analyzed. It was observed that 73% of the tests approved by Anvisa were of the rapid type, of which 92.5% were for antibody detection. However, immunization against COVID-19 started late in Brazil, with 75% of the population vaccinated faster than in the United States, United Kingdom, and Russia. Negligence in the scope of public health policies, combined with reduced testing and the troubled start of vaccination, may have contributed to the high number of cases and deaths presented at the beginning of the pandemic.
Keywords: COVID-19. Vaccine. Diagnostic Kit. SUS.

Introduction

COVID-19 is an acute respiratory disease with an inflammatory profile caused by the coronavirus SARS-CoV-2, whose clinical characteristics vary from mild to fatal [1]. The disease was identified in late 2019 in the city of Wuhan, China, and only in March 2020 was it officially declared pandemic status by the World Health Organization (WHO). Due to the intrinsic characteristics of the new coronavirus, such as high virulence and speed of propagation, the virus soon spread throughout the world, leading to 761.07 million cases and 6.88 million confirmed deaths worldwide [2,3].

Primary health measures to combat COVID-19, recommended by the WHO, are limited to combating the spread of the virus - such as hand hygiene, social distancing, and epidemiological surveillance - as well as reducing the severity of the disease - such as vaccine administration. Consequently, the world has experienced an unprecedented scientific race to develop and approve vaccines against COVID-19, in addition to diagnostic tests. As a result, there was a rapid development and availability of several *in vitro* diagnostic products for COVID-19 worldwide, as well as the availability and approval of effective vaccines in 2020. Therefore, countries such as Russia, the United Kingdom, and the United States United States began mass vaccination of the population in the first year of the pandemic [4,5].

On the other hand, Brazilian strategies to contain the spread of the pandemic were composed of a mix of political and economic interests, logistical problems, and ideological disputes, causing the country to present regional inequalities in allocating resources for the health system. Such measures affect not only the process of acquiring vaccines and diagnostic kits but also the acquisition of strategic inputs, such as syringes and needles, and vital, such as compressed oxygen, used in hospitals to support patients affected by COVID-19 or other illnesses [6,7]. Consequently, the country ended 2020 presenting the worst indicators of the pandemic, such as a high number of confirmed cases and deaths and without starting vaccinating the population.

We analyzed the measures adopted by the Brazilian government in the first year of the pandemic to combat COVID-19, the approval of diagnostic kits for COVID-19, the acquisition of vaccines, and the importance of the Unified Health System (SUS) as a catalyst for the mass vaccination process. The analysis of the conduct adopted by Brazil at the beginning of the pandemic constitutes

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a vital learning tool, which makes it possible to evaluate the effectiveness of the actions adopted, setting precedents for implementing more effective measures to combat new health crises.

Materials and Methods

Database

A systematic search was carried out in the PubMed bibliographic database, on the Anvisa website, through the access "Complete List of *In vitro* Diagnostic Products for COVID-19"; on the Our World in Data website. Data on approval and testing were collected on the Anvisa and Ministry of Health (MS) website until December 5, 2020.

Software

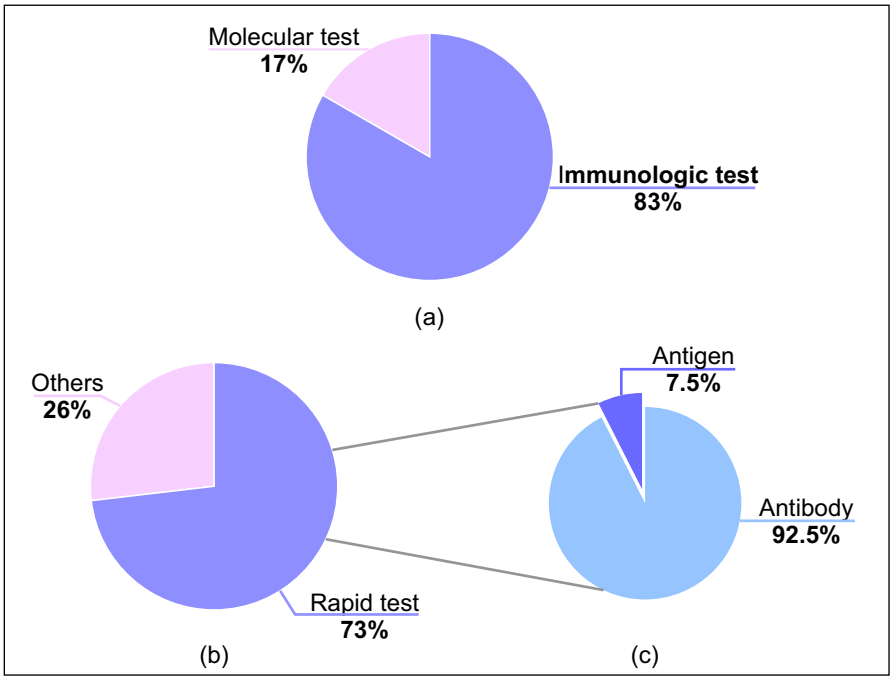
The data presented were prepared in GraphPad Prism v.9.00 for Windows (GraphPad Software, San Diego, California).

Results and Discussion

Approval and Acquisition of Diagnostic Kits

Carrying out diagnostic tests is crucial for controlling infectious diseases, as it allows the identification and correct management of contaminated people and their contacts [8,9]. In this context, regulatory agencies in several countries have adopted measures to speed up the processes of analysis and registration of diagnostic kits [10-12]. In Brazil, the regulatory flexibilities imposed by ANVISA, through RDC n. 348/2020, culminated in the approval of 441 *in vitro* diagnostic kits for COVID-19 in 2020, of which 83% (n = 364) were immunological tests and 17% (n = 73) were molecular tests (Figure 1a) [13]. Furthermore, it was observed that 73% (323) of the approved tests were rapid tests, of which 92.5% were for antibody detection (Figure 1b and 1c). MS data show that Brazil prioritized acquiring rapid diagnostic tests for detecting antibodies about others, since until

Figure 1. Characteristics of diagnostic tests for COVID-19 registered with ANVISA between May 18 and December 9, 2020.



(a) percentage of serological and molecular tests; (b) percentage of rapid tests and (c) percentage of rapid tests for antigen detection and antibody detection.

December 2020, the SUS carried out around 19,507,974 tests, of which 11,409,144 were of this type.

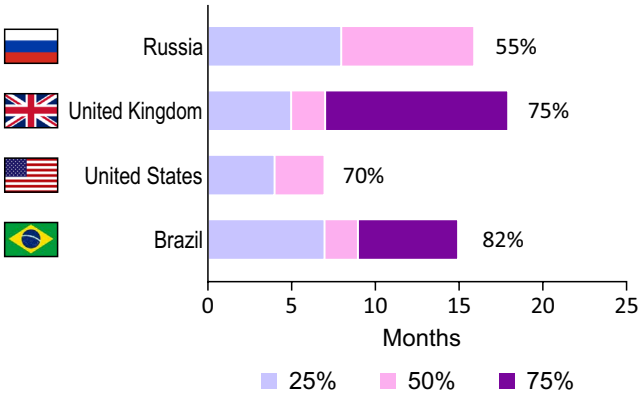
This measure is in line with WHO recommendations, which guide the use of molecular tests and rapid antigen detection tests for diagnosis and epidemiological surveillance of COVID-19 due to the better analytical performance of these tests.

Mass Vaccination and the Role of SUS

Unlike countries like the United States and the United Kingdom, which prioritized and ensured the rapid acquisition of large quantities of vaccines, even those still under development, Brazil initially delayed and restricted the purchase of immunizations to a few suppliers. In this sense, despite negotiations for the purchase of 1.5 million doses from Pfizer/BioNtech dating back to August 2020, the Brazilian government only signed a contract with the pharmaceutical company in March 2021, even with authorization from Anvisa for a clinical trial in Brazil dating back to July 2020 [14,15]. Thus, the vaccination of the Brazilian population began late, on January 17, 2021, and was characterized by slowness, staggering of doses and heterogeneity in the acquisition and application of immunizations between Brazilian states [16].

On the other hand, the SUS and the National Immunization Program (PNI) once again showed their potential in immunizing large masses of the population, revealing that the country already had essential tools to combat COVID-19. In this sense, despite Brazil starting the immunization process late compared to the United States, United Kingdom, and Russia, the country reached 75% of the population vaccinated with the initial immunization protocol more quickly than other countries in 15 months. Currently, the country has around 82% of the population fully vaccinated, surpassing the other countries evaluated (Figure 2). Part of the scientific community defends the need to obtain coverage vaccination rate between 60-70% to achieve "herd immunity", defined as acquired mass immunity capable of protecting

Figure 2. Percentage of people fully vaccinated with the initial vaccination protocol against COVID-19 by country and time.



susceptible people and preventing infectious agent transmission. In this sense, the WHO advises countries to increase efforts to reach the goal of 70% vaccination coverage, prioritizing the vaccination of 100% of health professionals and 100% of the most vulnerable groups [17].

Final Considerations

Although Brazil has the most famous free healthcare system in the world, the SUS, as well as one of the most extensive mass immunization programs, the PNI, these resources were not used to their full potential at the beginning of the pandemic, mainly due to delays in vaccine purchase contracts by the Brazilian government, as well as planning and logistics problems in the acquisition and distribution of immunizations, diagnostic tests, and medical supplies. This fact may have contributed to the high number of cases and deaths at the beginning of the pandemic.

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