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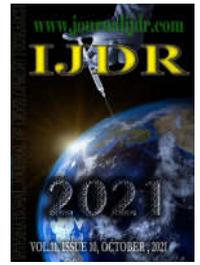
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POTENTIALS AND CHALLENGES FOR THE OPERATIONALIZATION OF THE VACCINATION CAMPAIGN AGAINST COVID-19 IN BRAZIL

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ABSTRACT

The Unified Health System (SUS) has the National Immunization Program (NIP), coordinated by the Ministry of Health, which has been consolidating itself as one of the most relevant public health interventions in the world. Created in 1973, in its 46-year trajectory, the NIP is characterized as an efficient public policy, increasingly impacting the profile of morbidity and mortality of the Brazilian population, adapting to changes in the political, epidemiological, and social fields. Indeed, the NIP has extensive experience in organizing mass vaccination campaigns, achieving high vaccine coverage and its objective, which is to protect the health of the population defined in these strategies. However, the lack of central coordination on the part of the federal government has led some states to seek their own initiatives decentralizing the vaccination against COVID-19. In 2020, the Ministry of Health of Brazil rejected the aforementioned proposal to sell the 70 million doses of the Pfizer/BioNTech vaccine. In Brazil, vaccination began at the end of January. On June 4, 2021, we had 74.8 million doses of vaccines administered to the Brazilian population, 23.3 million of which were fully vaccinated (with both doses), which corresponds to 11.1% of the Brazilian population. Brazil has a structure to succeed in the vaccination campaign against Covid-19 and has a universal health system - SUS, what is missing is to depoliticize the issue of the vaccine against Covid-19 and focus on what should be the focus since the beginning of the epidemic in Brazil: saving lives!

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INTRODUCTION

The Unified Health System (SUS), which must be understood as a state policy capable of guaranteeing the right and universal access to health¹⁻³ was the result of struggles in defense of democracy from the Brazilian Sanitary Reform movement, which culminated in 1988 with the promulgation of the Federal Constitution that brought the philosophical foundations to the largest public health system in the world.¹⁻³ Regardless of the knowledge one has about the history of SUS, its conceptual, philosophical, legal and political bases, or about its structure, organization and functioning, it is possible to state that any and all Brazilian citizens, at some point in their life, have already had contact with SUS, whose principles are universality, integrality and equity.⁴ In addition, the entire Brazilian population has benefited from several programs developed by SUS, mainly those focused on health promotion, prevention and protection against certain risks and aggravations resulting from the changes that have occurred due to the accelerated demographic, epidemiological and nutritional transition in Brazil that affect the health of the population.³

Among the programs developed to face these problems, including, e.g., the National Immunization Program, National HIV/AIDS Policy, National Health Promotion Policy, National Comprehensive Care Policy for users of alcohol and other drugs among countless others.⁴ From vaccine to transplantation, the numbers related to the production of health actions and services by SUS are in terms of thousands, millions and billions, which explains in part why several authors worldwide affirm SUS as the largest system of universal and public health in the world, with intense capillarity throughout the national territory through its extensive network of services with coverage in all states and in the 5,570 municipalities of the federation.²⁴ The analysis of the current situation of SUS is a task that demands, firstly, the recognition of the complexity of the political process, the organizational development and the reorientation of the work processes at the various levels of management of the system.²⁻⁵ In a special issue of *The Lancet* dedicated to SUS, researchers reaffirmed that the main problem with SUS is political.⁴ Hence, several other problems arise, with an emphasis on underfunding, insofar as a low public expenditure is maintained due to the priority

given to fiscal adjustment policies and economic growth and competitiveness.¹⁴ However, even after 32 years of its creation, although its advances are recognized, the main obstacles and threats to SUS stand out, i.e.: limited social and political bases; economic and financial interests linked to healthcare companies; political-ideological proposal for Universal Health Coverage; divestment; insufficient public infrastructure; and the reproduction of the hegemonic medical model.¹⁶

Health Surveillance in the SUS and the COVID-19 vaccination strategies in Brazil: Despite the existence of so many challenges, SUS proves to be efficient.⁶ A point to highlight is the action of Health Surveillance, which was essential in detecting cases of microcephaly and in the causal association with the congenital Zika Virus syndrome, as well as, currently, facing the pandemic of the new coronavirus, acting in the identification, control, adequate management, and prevention of COVID-19 cases. It is through Health Surveillance that SUS was organized to receive the identified cases, seeking to guarantee the integrality and longitudinally of care as well as the flows and counterflows between the services in the Health Care Network.⁷ One aspect that should be highlighted is that among the recommendations of the national and international regulatory health agencies in the face of the COVID-19 pandemic, the accelerated vaccine development, therapeutic measures and diagnoses were proposed.⁸ Seeking to guarantee more doses for the Brazilian population, initially, three technology transfer agreements were signed in the country: one from the Institute of Technology in Immunobiologicals of the Oswaldo Cruz Foundation (Bio-Manguinhos/Fiocruz/Ministry of Health) with the AstraZeneca laboratory⁹ who is working in partnership with University of Oxford, which established the initial supply of 100 million doses; another from the Butantan Institute of the State of São Paulo with the company Sinovac, China (Coronavac),¹⁰ ensuring the supply of 46 million doses; and the last from the Paraná Institute of Technology of the State of Paraná with the Gamaleya Institute, Russia (Sputnik V).¹¹

The results of the AstraZeneca primary efficacy analysis point to an efficacy of 62.1% for participants who received two standard doses and 90% for those who received a first half dose and a full dose after one month. The vaccine from the Butantan Institute of the State of São Paulo achieved 50.38% of global efficacy in the study developed in Brazil.¹⁰ These results are promising since in this moment of global health urgency, WHO has defined that a vaccine with protection above 50% will be acceptable.¹² The Collegiate Board of The Brazilian Health Regulatory Agency (Anvisa) unanimously approved on January 17, 2021, the temporary authorization for emergency use of the CoronaVac vaccine, developed by the pharmaceutical company Sinovac in partnership with the Butantan Institute, and of the Covishield vaccine, produced by the pharmaceutical company Serum Institute of India, in partnership with AstraZeneca/ University of Oxford/Fiocruz.¹³ However, both Fiocruz and Instituto Butantan must continue their studies and generate data to allow health registration at Anvisa. Likewise, both need to maintain monitoring of vaccine safety, which is critical to ensuring that the benefits continue to outweigh the risks for people receiving Covid-19 vaccines. The Anvisa can even review and adjust the conditions for emergency use in the face of results that are considered relevant, including data and information from international regulatory authorities.^{13,14} On January 18, 2021, the country had already started receiving the first doses to be used in the national territory and is preparing for the start of the Vaccination Campaign against the new coronavirus with these two immunobiologicals. And this will be another major challenge for Health Surveillance in SUS, since, despite all the acceleration of development seen so far, there are still many gaps and challenges for the operationalization of the vaccination plan. The first major challenge concerns logistics for obtaining immunobiologicals. The fear of the Butantan Institute, responsible to produce the Chinese vaccine in partnership with the Chinese laboratory Sinovac, and of members of the government of São Paulo, is that the diplomatic stalemate will prevent the arrival of the Active Pharmaceutical Ingredients (API), the active ingredient from Coronavac.^{15,16}

This is also the fear of members of the Ministries of Health and Economy, who are following the Fiocruz negotiations with the Chinese to purchase the API for the production of the University of Oxford/Astrazeneca vaccine in Brazil.^{15,16} High-ranking members of the Jair Bolsonaro government admit that the country's troubled relationship with China has hampered the import of inputs for the production of vaccines against Covid-19 in Brazil.¹⁵ It is worth mentioning that in the May 2020 editorial of The Lancet "COVID-19 in Brazil: "So what?"", It was stated that "Yet, perhaps the biggest threat to Brazil's COVID-19 response is its president, Jair Bolsonaro".¹⁷ Despite the alarming data already known in Brazil about the numbers of confirmed cases and deaths by COVID-19 that already exceed 480 thousand deaths in June 10, 2021, the President, Jair Bolsonaro has still minimized the pandemic by discrediting public health authorities in Brazil and abroad regarding measures to mitigate the virus spread, turning him into a target for criticism from the media and political opponents worldwide. The position by the president calls into question all the mitigation measures that has been endorsed by the WHO and by scientists and experts in the areas of virology and epidemiology, creating confusion among Brazilians regarding what actions to take.^{17,18} Additionally, such disarray at the heart of the administration is a deadly distraction in the middle of a public health emergency and is also a stark sign that Brazil's leadership has lost its moral compass.¹⁷

The Foreign Minister, although he was also in charge of several attacks on China, he would have changed his stance in the name of the vaccine negotiations. In addition, there has been contact with the Indian government to try to unlock the coming of 2 million doses of the Oxford vaccine.¹⁵ In addition to the diplomatic issue, members of the federal government say the impasse with China and India also involves financial negotiation.¹⁵ It is worth mentioning that SUS has the National Immunization Program (NIP), coordinated by the Ministry of Health, in a shared way with the State and Municipal Health Secretariats, which has been consolidating itself as one of the most relevant public health interventions in the world.¹⁹ Created in 1973, in its 46-year trajectory, the PNI is characterized as an efficient public policy, increasingly impacting the profile of morbidity and mortality of the Brazilian population, adapting to changes in the political, epidemiological and social fields.¹⁹ Indeed, the NIP has extensive experience in organizing mass vaccination campaigns, achieving high vaccine coverage and its objective, which is to protect the health of the population defined in these strategies. Its success made it possible for a unified vaccination calendar to gain popular acceptance and, consequently, for the country to gradually achieve high vaccination coverage rates.¹⁹ When high vaccination coverage is achieved, in addition to reducing cases of disease in the target population established for vaccination, it contributes to reducing the circulation of infectious agents in communities, positively impacting the health of those who will not be vaccinated, once they become indirectly protected (collective or herd immunity).^{14, 19} However, it is known that the relationship with vaccines has not always been peaceful: contestation and resistance are part of its own history, reflected, for example, in anti-vaccination movements around the world.^{20,21} Hesitation comprises a wide spectrum of postures, from fear to total refusal, having different gradations. It is a complex social phenomenon, insofar as it concerns a collective ideal, of a group of people who manifest in their question's dimensions such as individual freedom, for example.²²

Given that the epidemic crisis is accompanied and exacerbates economic crises and inequality scenarios on a global scale, the role of States and their governments is central, not only in coordinating actions to fight the epidemic and mitigate its social consequences at the national level, as well as providing guidance for the behavior of individuals, promoting the necessary social cohesion.^{23,24} A recent study investigated how current President Bolsonaro's speeches and actions affect citizen behavior during the epidemic. The results emphasize the deleterious impacts of their speeches and actions that publicly and emphatically discard the risks associated with the new coronavirus and go against the measures of physical distance, demonstrating that this decreases in pro-government locations in

relation to those places where support for part of the population is lower.²⁵ Indeed, the weakness of governments and the inability of their leaders to face the epidemic, recognizing that its confrontation is linked to the inseparability of the preservation of life and social protection, has clear examples in history, with perverse consequences when societies and citizens avoid facing it. the health risks they face.²⁶

The Vaccination Campaign against COVID-19 in Brazil moving slowly and without federal coordination: Until February 28, 2021, vaccination against COVID-19 in Brazil was being carried out with CoronaVac and Oxford-AstraZeneca vaccines. However, another vaccine was available to the Brazilian Government for acquisition, the one produced by Pfizer/BioNTech, whose testing phase included Brazilian volunteers from Bahia and São Paulo. It is a public fact and confirmed by the parties involved that the Ministry of Health of Brazil received a proposal from the pharmaceutical company Pfizer, dated August 2020, which offered the sale of 70 million doses of the Pfizer/BioNTech vaccine.²⁷ In 2020, the Ministry of Health of Brazil rejected the aforementioned proposal to sell the 70 million doses of the Pfizer/BioNTech vaccine. The promising potential of the vaccine, reported by the president of Pfizer in that proposal, was confirmed. About three months later, on December 8, 2020, in the UK, the first British citizen was vaccinated with the Pfizer/BioNTech vaccine. And, in the United States, on December 14, 2020, the first American was vaccinated in New York City, also with the Pfizer/BioNTech vaccine.²⁷ The lack of central coordination on the part of the federal government has led some states to seek their own initiatives decentralizing the vaccination process. The country has great expertise, 47 years of the PNI, and it is a shame that we are watching all this now. However, what should be considered from the beginning is that the problem of this pandemic cannot be solved if only one place, one state, vaccinates an entire population and the others do not have access. It does not solve it because Brazil is made up of several states, it is a very large country, with a lot of circulation, and solving the problem in one territory is not enough to guarantee the control of the pandemic in the country as a whole. On the contrary, it will separate a population that will be immunized at the same time that many other population segments will not be immunized. In addition, it will be promoting a break, as it will cause national policies, which are centralized policies and which in the case of vaccination is a correctly centralized policy, to be broken.²⁸

In Brazil, vaccination began at the end of January. Until May 19, there were 24 doses per 100 inhabitants (counting first and second doses in some cases). In Israel, the country with the highest vaccination rate in the world, 121 doses per 100 inhabitants. In Chile, the Latin American country that has vaccinated its population the fastest, this rate is 86.7. In absolute numbers, the United States is the country that administered the most doses of vaccines against covid-19, about 273.5 million doses as of May 19, 2021.²⁹ On June 4, 2021, we had 74.8 million doses of vaccines administered to the Brazilian population, 23.3 million of which were fully vaccinated (with both doses), which corresponds to 11.1% of the Brazilian population.²⁹ Specialists warn that, in the midst of the worst moment of the pandemic, with the circulation of new variants of the virus in Brazilian territory, especially P.1 and Variante Delta (B.1 617.2) the only solution for Brazil is the adoption of stricter confinement and acceleration of vaccination. But without a strategy at the federal level, they add, that goal is unlikely to be met. In addition to the political issue, most vaccines that reached phase III of clinical trials have had a vaccine schedule with two doses and should be applied between 14 to 29 days after the first dose is applied,⁸ which required a huge effort and organization of health services to guarantee the adherence of the high population contingent to be vaccinated in a short term, for both doses. Also, it was required the identification of the person vaccinated in the vaccination posts, with the need to create a nominal system that is simplified and that managed to insert the data in a timely manner, monitored the evolution of the vaccination and that is integrated into the Information System of the National Immunization Program (SIPNI) of the Ministry of Health. At the same time, it was necessary to implement the surveillance of adverse events after active

vaccination in a timely manner, aiming to ensure the safety of vaccination throughout the process.¹⁴ Furthermore, was necessary to define and prioritize the groups to be vaccinated, listed based on the risk of becoming ill, having complications and death such as, those with chronic diseases, diabetes, hypertension, cancer, kidney disease, respiratory disease, hematological diseases, obesity and the elderly. Health professionals, being at the forefront of care for patients with COVID-19, were the first to be vaccinated.^{14,30,31} Simultaneously, an efficient communication should seek strategies to confront anti-vaccine groups and fake news that are already circulating on social networks, preventing the population from hesitating to be vaccinated and guarantee adherence to vaccination.^{14,30}

Conclusion and Implications: In conclusion, the COVID-19 pandemic has had repercussions not only of a biomedical and epidemiological nature on a global scale, but also of social, economic, political, cultural, and historical impacts unprecedented in the recent history of epidemics.³² Thus, it will be important to have a national vaccination plan to organize all the logistics for carrying out the campaign, aiming at making it successful regardless of which instruments or sources of funds are used to purchase all types of vaccines that will be available in the national territory. We already have a structure for this and also a universal health system - SUS, what is missing is to depoliticize the issue of the vaccine against Covid-19 and focus on what should be the focus since the beginning of the epidemic in Brazil: saving lives!

Authorship & Contributorship

- Substantial contributions to the conception or design of the work: LCLJ
- Acquisition, analysis, or interpretation of data for the work: LCLJ
- Drafting the work or revising it critically for important intellectual content: LCLJ
- Final approval of the version to be published: LCLJ
- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved: LCLJ.

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