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Comment

The unjustified and politicized battle against vaccination of children and adolescents in Brazil

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Facing the dynamic and complex scenario of the COVID-19 outbreak, countries worldwide are expanding COVID-19 vaccination programs to include young children. Despite hospitalizations and deaths associated with COVID-19 in pediatric populations being less common, the disease has emerged as a novel cause of mortality for children and adolescents in poor communities.^I In Brazil, the Pfizer-BioNTech COVID-19 vaccine (ComiRNAty) was authorized by the federal health regulator (ANVISA) for adolescents aged 12-17 years on June 11, 2021, six months after the beginning of the national vaccination campaign. Still, Health Minister Marcelo Queiroga announced on September 16 the intent to halt COVID-19 vaccination for adolescents with no underlying conditions due to a death under investigation and concerns regarding adverse events in this age group, even though more than 3.5 million teens had already been immunized. Despite the doubts raised by President Bolsonaro and Health Minister Marcelo Queiroga, multiple randomised, controlled clinical studies and surveillance programs have supported vaccine safety for children and adolescents. Fortunately, the immunization of this age group was only temporarily halted and has progressed since then, and at least 25% have already received two doses.

Recently, a new battle against COVID-19 in Brazil has been raging between ANVISA, scientists, antivaxxers, and federal authorities: the vaccination of children aged 5–11 years. Soon after the authorization of the ComiRNAty vaccine by the regulatory authorities, Brazilian President Jair Bolsonaro affirmed, "*children have not been dying in a way that justifies a vaccine for children*."² This position was further supported by the Ministry of Health which held an unprecedented public hearing on the vaccination of children against COVID-19, including questions about whether the vaccine

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should be administered only with the consent of parents (or guardians) and medical prescription. Regrettably, this recommendation would exclude the poorest and most marginalized children with reduced access to healthcare services from the chance of vaccination.

In his ongoing conflict with the federal health regulator, Bolsonaro has threatened to reveal the names of ANVISA officials responsible for approving the vaccine for children and has consistently cast doubts on the effectiveness and safety of COVID-19 vaccines. Despite the downplaying of the severity of SARS-CoV-2 infection in Brazilian children by the President, the unsupported allegations that vaccines can be dangerous for children and the delay in vaccine procurement by the Ministry of Health following the approval by the ANVISA for the use of ComiRNAty in children aged 5 -11 years on December 16, 2021, vaccination of this population began in Brazil on January 15, 2022. However, logistic changes in delivering pediatric doses to states have made it difficult to transport ComiRNAty doses to storage locations, increasing the risk of loss of vaccine batches. On January 20th, Brazilian regulators also granted emergency use authorization for children age 6 and older with CoronaVac. The inactivated-virus vaccine, produced by the Butantan Institute in partnership with the Beijing-based company Sinovac, has also been criticized by the President through speeches and social media networks. Even though the scientific evidence available³ and the lives lost to COVID-19, a technical note (N° 2/2022 - SCTIE/MS) published by the Ministry of Health on January 22 classifies hydroxychloroquine as effective and safe for the treatment against COVID-19 and stresses that the efficacy and safety of vaccines are not yet demonstrated. Concurrently, presidential allies continue to call for halting the vaccine rollout by spreading fake news on the Internet and social messaging apps.

In this context, five points need to be listed that support vaccination in children and adolescents in the country: (I) the ComiRNAty vaccine approved by ANVISA is safe, immunogenic, and efficacious against COVID-19 in children 5–11 years⁴ and adolescents 12–15 years.⁵ In addition, there is evidence that Corona-Vac is well tolerated and safe and induced humoral responses in children and adolescents aged 3-17 years;⁶



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Regions	Estimated population (0-19 years) ^(a)	Suspected or confirmed cases registered in notaries ^(b)	Deaths recorded inofficial bulletins ^(c)	Mortality rate per 100.000 children and adolescents
Northeast	17,292,563	1377	826	4.8
North	6,590,279	446	314	4.8
Central-West	4,832,898	243	197	4.1
Southeast	23,070,675	1498	919	4.0
South	7,782,811	521	274	3.5
Brazil	59,590,279	4076	2530	4.3

Table 1: Deaths and mortality rates from COVID-19 among children and adolescents aged 0-19 years in Brazil.

Sources: (a) Brazilian Institute of Geography and Statistics – IBGE (Estimated population for 2021); (b) National Civil Registry Information Center; (c) Official bulletins of the State Secretariats of Health.

(2) recent reviews from the Centers for Disease Control and Prevention (CDC) in the U.S. including more than 17.5 million doses of ComiRNAty vaccine administered in children⁷ and adolescents⁸ reported a total of 13,495 (~0.08%) adverse events with exceptionally rare (~0.005%) serious reports including 408 cases of nonfatal myocarditis (~I case per I million doses for children and \sim 45 cases per 1 million doses for adolescents); (3) in Brazil, there are about 20 million unvaccinated children aged 5-11 years who can become virus shelters as adults achieve immune protection and many states can not attain high vaccination coverage without comprehensive coverage of this group. Children can carry high SARS-CoV-2 viral loads,⁹ which may contribute to the human-to-human transmission in the community and the risks posed by the return to on-site activities in schools and daycare centers in February 2022; (4) despite the proportion of COVID-19-confirmed cases among children and adolescents is relatively small and deaths are uncommon, there is evidence that the disease has disproportionately affected this age group in Brazil, especially in the poorest regions¹; and, (5) in Brazil, deaths from COVID-19 among children and adolescents have exceeded the annual average of deaths from neoplasia, nervous system diseases, cardiac causes, and other vaccine-preventable diseases (http://tabnet.data sus.gov.br/cgi/deftohtm.exe?sim/cnv/obt1ouf.def).

Accumulated data until the second week of January 2022 showed that at least 2530 children and adolescents aged 0-19 died from COVID-19 in Brazil, of which \sim 53% were under 9 years old. The overall mortality rate for this age group was estimated at \sim_4 deaths per 100,000 children and adolescents, with higher rates registered in the North and Northeast (~5 deaths per 100,000 children and adolescents), considered the poorest regions in the country. In addition, the number of deaths from COVID-19 in this age group may be 1.5 times higher than that reported in the official bulletins of the Brazilian states (Table 1). Unfortunately, these figures suggest that our nation represents about 20% of the total deaths from COVID-19 worldwide and specifically for this age group, the mortality rates are 4 times higher than those observed in the U.S.¹⁰ Now,

the community spread of the Omicron variant has led to a sharp increase in the number of COVID-19 cases and hospitalizations in some Brazilian states since early January this year, especially among unvaccinated individuals. This catastrophic scenario has already been observed in the U.S. pediatric population and, more recently, in São Paulo and Salvador.

No matter how low the mortality rate associated with COVID-19 in children and adolescents may be, mothers have lost their children during these politically motivated delays and disruptions in the vaccination campaign. More than a moral obligation, the vaccination of children and adolescents in Brazil is a sanitary necessity to control the pandemic and prevent families from seeing their children die due to denialism of a vaccine-preventable disease.

Declaration of interests

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