

# Child compulsory vaccination for COVID-19

## Compulsoriedade da vacinação infantil para COVID-19

## Vacunación infantil obligatoria para COVID-19

### RESUMO

A Lei n. 13.979/2020 previu a vacinação compulsória para fins de combate à pandemia do coronavírus, tendo sido decidido pelo Supremo Tribunal Federal que vacinação compulsória é distinto de vacinação forçada, devendo ser obtido o consentimento e permitida a sua recusa, podendo ser adotadas, contudo, medidas indiretas. O Plano Nacional de Operacionalização da vacinação contra a Covid-19 incluiu a vacinação de crianças a partir dos 12 anos, após aprovação da vacina da Pfizer pela Anvisa. Há, contudo, um embate: quais são os entraves ético-jurídicos colocados frente à compulsoriedade da vacinação infantil? O presente estudo discute dois desses entraves: o processo de consentimento informado versus a compulsoriedade da vacinação, e a ausência de uma política nacional de reparação por efeitos adversos. Conclui-se que o programa de vacinação infantil contra Covid-19 deve garantir segurança necessária à saúde individual, atendendo ao interesse público e da saúde coletiva sem desamparar direitos individuais fundamentais.

**DESCRIÇÕES:** Vacinação; Consentimento Livre e Esclarecido; Efeitos adversos

### ABSTRACT

Law n. 13.979/2020 provided for the possibility of compulsory vaccination for combating the coronavirus pandemic, and the Supreme Court decided that compulsory vaccination is distinct from forced vaccination, and the person's consent must be obtained and allowed its refusal, but indirect measures may be adopted. The National Plan for the Operationalization of Vaccination against Covid-19 included the vaccination of children from 12 years of age, after approval of the Pfizer vaccine by Anvisa. There is, however, an conflict: what are the ethical and legal obstacles placed before compulsory child vaccination? This study tackles two of these obstacles: informed consent process versus compulsory vaccination, and the absence of a national policy of reparation for adverse effects. It is concluded, then, that the child vaccination program against Covid-19 must guarantee the necessary safety for individual health, in order to conciliate public interest and collective health without abandoning fundamental individual rights.

**DESCRIPTORS:** Vaccination; Informed Consent; Side Effects.

### RESUMEN

A Ley n. 13.979/2020 preveía la posibilidad de vacunación obligatoria con fines de combate a la pandemia de coronavirus, habiendo sido resuelto por el Tribunal Supremo Federal que la vacunación obligatoria es distinta de la vacunación forzada, debiendo obtenerse el consentimiento y permitir su denegación, pero pueden adoptarse medidas indirectas. El Plan Nacional para la Operacionalización de la Vacunación contra Covid-19 incluyó la vacunación de niños de 12 y más años, luego de la aprobación de la vacuna Pfizer por Anvisa. Sin embargo, hay un conflicto: ¿Cuáles son los obstáculos éticos y legales que se encuentran frente a la vacunación infantil obligatoria? El presente estudio discute dos de estos obstáculos: el proceso de consentimiento libre e informado versus la vacunación obligatoria, y la ausencia de una política nacional de reparación de efectos adversos. Se concluye, entonces, que el programa de vacunación infantil contra Covid-19 debe garantizar la seguridad necesaria para la salud individual, atendiendo la demanda del interés público y la salud colectiva sin abandonar los derechos fundamentales individuales.

**DESCRIPTORES:** Vacunación; Consentimiento Informado; Efectos adversos.

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## INTRODUCTION

According to the Ministry of Health, in December 2021, Brazil reached 616 thousand deaths due to the coronavirus. Although in small numbers compared to adults, according to research data carried out by Fiocruz, based on the Information System on Infant Mortality (SIM), of the Ministry of Health, “almost half of Brazilian children and adolescents killed by Covid -19 in 2020 were up to 2 years old; a third of deaths up to 18 years of age occurred among children under 1 year of age and 9% among babies under 28 days of age”.<sup>1</sup>

Considering, therefore, in the context of combating the pandemic, that there is still no treatment available, duly proven and incorporated into health systems for the treatment of coronavirus, there is a worldwide consensus that mass vaccination of the population will play an essential role in combating and containing the advance of the coronavirus pandemic.<sup>2</sup>

The coronavirus pandemic has affected some established paradigms in terms of clinical trials with human beings: the need for an urgent response to a problem of global proportions meant that the protections for the human person enshrined in the last century, consolidated in the country through CNS Resolution 466/2012.<sup>3</sup>

The immunological response obtained after the vaccination process allows the need for hospital admissions to be reduced, thus facilitating the care of cases that require hospitalization, both in quantitative aspects - lesser number of people hospitalized - and in qualitative aspects - smaller number of people with severe conditions.

Brazilian legislation, through Law n. 13.979/2020<sup>4</sup>, provides, in art. 3, the possibility of determining compulsory vaccination, to be adopted by the authorities, within the scope of their competence, to face the pandemic. Thus, the National Plan for the Operationalization of Vaccination against Covid-19 was developed by the Ministry of Health, whose 11th edition dates from October 2021, and which includes the vaccination of children and adolescents

from 12 years old.

The mandatory vaccination was discussed by the Federal Supreme Court, through the Direct Action of Unconstitutionality (ADI) 6586, which established the thesis that the concept of compulsory vaccination is distinct from forced vaccination, and the consent of the person must be obtained and their refusal is permitted, and may be adopted, however, indirect measures that restrict rights, such as the case of restriction on the exercise of certain activities or the frequency of certain places, provided that they are provided by law, or resulting from it.<sup>6</sup>

There is, however, an ethical clash to be considered: what are the ethical-legal obstacles placed in the face of the possibility of compulsory childhood vaccination? From the research problem pointed out, the present study aims to discuss two of the main ethical-legal obstacles placed in the face of compulsory vaccination, taking into account the current legislation and the recent position of the Federal Supreme Court.

## METHOD

This is a reflective study based on scientific articles and academic works in the legal and bioethics area, with the purpose of discussing the main ethical and legal obstacles placed in the face of the compulsory nature of childhood vaccination for Covid-19. The position of the Federal Supreme Court in the judgment of the Direct Action of Unconstitutionality (DAU) 6586 was analyzed, and related to the current position of the legislation.

## DISCUSSION

The practice of vaccination is one of the most economical ways of containing diseases, and according to the World Health Organization (WHO) it is currently responsible for preventing about 2-4 million deaths per year. With the exception of access to clean water, no other method is comparable in terms of population growth and mortality reduction, not even antibiotics.<sup>7</sup> From another perspective, the practice of

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mass vaccination also has a socioeconomic appeal, acting in a preventive way due to the precariousness of health infrastructures. 8

Compulsory childhood vaccination is not new in world history, nor in Brazil, where Law No. 6,259/1975 is in force, which in its art. 3 provides that the Ministry of Health is responsible for the elaboration of the National Immunization Program, created in 1973, which defines mandatory vaccines and plays an active role in combating regional and social inequalities.

In November 2019, the World Health Organization issued the Thirteenth General Program of Work 9, a five-year strategic plan (2019-2023) with measures to address emerging issues affecting health worldwide. In this report, the Organization included the anti-vaccine movement among the top ten threats to global health.

In modern history, vaccine safety controversies gained worldwide notoriety after the publication of Wakefield's article in the *Lancet*, associating measles, mumps and rubella (MMR) vaccination with autism, due to the temporal association between vaccination and the presentation of the first signs of the disorder. Wakefield's article involved scientific fraud, being discredited and removed from the list of published articles. 10

However, such measures were not satisfactory, and the reflexes of the anti-vaccination movement can also be observed in Brazil, over the last few years, with the drop in vaccination rates, whose causes, although there is no consensus, can be listed as resulting from the phenomenon of "vaccination hesitation", alongside supply problems, access barriers and underfunding of the program. 11

An example is the measles outbreaks faced in the states of Amazonas and Roraima in 2018, despite the measles eradication certificate issued by the Pan American Health Organization (PAHO) in 2016. 12 In addition to living with the return of "old diseases", Bioethics is now also concerned with new dilemmas, this time related to access and equal distribution of immunizers and the possible private purchase of vaccines during the coronavirus pandemic

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situation.

In this new scenario, the National Plan for the Operationalization of Vaccination against COVID-19 was prepared by the Ministry of Health, which provides for the vaccination of children aged 12 years and over. According to the Plan, Anvisa authorized the use of the Comirnaty vaccine, from Pfizer, for children aged 12 and over, being the only vaccine authorized for this population. Law no. 14.124/2021 still provides in the fifth paragraph of art. 13 that children and adolescents with permanent disabilities, with comorbidity or deprived of their liberty will be included as a priority group in the National Plan for the Operationalization of Vaccination against COVID-19.

At this juncture, based on the assumption that childhood vaccination is mandatory in Brazil - and there is, for that purpose, a legal, jurisprudential and legislative apparatus in this sense, for the purposes of the discussion proposed here, two ethical-legal obstacles will be analyzed, namely: (1) conflict between the requirement of free and informed consent for the purposes of vaccination and the legislative provision that allows compulsory vaccination and (2) absence, in Brazil, of a well-defined compensation policy for vaccine side effects.

The first ethical-legal dilemma consists of the conflict between the requirement of the free and informed consent at the time of vaccination, on the one hand, and the legislative provision that allows compulsory vaccination, on the other.

In the immunization process, it would be appropriate to provide detailed information that explains the benefits (and possible risks), helping those responsible for the patient and valuing the health professional's duty to inform. However, although the ideal is to obtain free and informed consent, the scenario really changes when there is a legislative imposition, 13 as provided for in art. 3 of Law no. 13,979/2020, whose exercise limits were determined through the judgment of the Federal Supreme Court at the time of the judgment of ADI 6586, in December 2020.

It is also worth noting that the National

Immunization Program, which provides for a mandatory childhood vaccination schedule, reflects the constant tension between the autonomy of parents, the collective rights of children and the collective rights of society,

making it mandatory to be adopted in Brazil, implemented through indirect measures and sanctions. The Federal Supreme Court has also positioned itself in this regard, through the judgment of ARE 1267879 14, of the rapporteurship of Minister Roberto Barroso, understanding that the mandatory immunization through vaccines is constitutional.

This compulsory situation is superimposed by the fact that the groups that were defined by the legislation as priorities for the purposes of vaccination in children and adolescents aged 12 to 17 years are considered vulnerable groups - children and adolescents with permanent disabilities, with comorbidity or deprived of liberty -, which represents an additional obstacle for the purpose of obtaining free and informed consent.

The principle of Autonomy, consolidated from a bioethical thought, arises from the premise that the patient has the right to protect their physical and psychic inviolability, deciding on what can or cannot be done with their own body, and it is carried out through an informed consent process.

An example is the US method of obtaining informed consent in the case of vaccination. First, the general framework of informed consent is used, but with an important change: at the heart of informed consent are the requirements of the federal law, Vaccine Information Statement, and the other state requirements can be added to the document. Second, state requirements related to mandatory vaccines for school enrollment are considered, with a view to an informed refusal procedure. Thirdly, the responsibilities of the parties limit the assessment of a judicial review in the area. 15

The discussion about mandatory vaccination revolves around the limits of autonomy and individual freedoms. The benefits of immunization go beyond the sphere

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of the individual, also affecting the rights of others - especially those who still do not have the capacity to consent to the act of vaccination, or those who for medical reasons cannot undergo the procedure. This is the classic legal dilemma that contrasts individual rights and collective rights.

In this sense, one of the main public health challenges has been to maintain high rates of vaccination coverage for the control and prevention of epidemics, or to avoid the resurgence of diseases that have already been controlled; thus expanding the individual's responsibility for the maintenance and protection of their health and collective health. 16

Another aspect is that consent presupposes the person's free conscience and will to undergo a certain procedure. Parents, after obtaining the necessary information, must express voluntary consent, which, given the compulsory nature, is compromised, as refusals can compromise or restrict the exercise of other fundamental rights, such as the right to education.

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There are those who defend, therefore, the transfer of responsibility from parents to entities involved in the mandatory policy, such as the government or vaccination manufacturers, for any collateral event - from the very mild to the rarest and most extreme. 17 Informed consent along these lines should be replaced by a simple signature on an appropriate document proving immunization, which would avoid any burden on the parents.

The second ethical-legal dilemma corresponds to the absence, in Brazil, of a well-defined compensation policy for side effects, which generates certain complications in the scope of the judicialization of health and in terms of biopolitics.

As with any existing medical procedure, vaccines are not completely safe, and sometimes unpredictable and unknown adverse reactions can occur.<sup>18</sup> Thus, the incidence of such effects usually causes widespread panic, and one of the factors for this is precisely the failure to discuss post-vaccination effects. This can also make it more difficult to implement programs to control pandemics and accept new vaccines, a phenomenon observed during the COVID-19 pandemic. Added to this scenario is the difficulty of carrying out clinical trials with children, due to the stricter requirements provided for by CNS Resolution n. 466/2012.

However, it is still necessary to talk about the safety of vaccines, since this factor is intrinsically related to the success of a vaccination policy. For this reason, the state apparatus needs to be ready for these events, following the principles of precaution and prevention, as in any other medical procedure. That is, care for the vulnerable needs to be comprehensive.

An example is the model adopted by the United States, through the National Vaccine Injury Compensation Program, which since 1986 has been regulated by the National Childhood Vaccine Injury Act, providing a special resource fund, maintained through taxes levied on doses of vaccines applied in the country.<sup>19</sup>

This model seems somewhat functional, since in the country families need to turn to the private sector for vaccination. In Brazil, on the other hand, although it is possible to acquire most vaccines in the private sector, most families depend on the Public Health System.

Lessa and Schramm emphasize that it is morally undesirable to cause preventable harm to people, either because of the possible adverse effects after vaccination or because of exposure to diseases resulting from non-vaccination, as much as it is necessary in epidemic scenarios that there is a mass vaccination.<sup>20</sup>

Therefore, there seems to be a discrepancy between the norms of special protection of the vulnerable and the state's failure to offer compensation for those who were

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victimized by the erroneous application of an immunizing agent, and a distance from civil liability described in the Brazilian legal system.

It is noteworthy here that even though the occurrence of adverse effects is really rare, this is not why a minority should face these ills in abandonment and marginalization, because such an attitude makes the situation even more serious. Such omission contradicts fundamental precepts, after all, the Constitution grants equality to all, but special protection to certain groups, such as children and adolescents.

Indeed, just as it is important to increase vaccination coverage rates, it is also essential to dialogue directly with society, creating prevention and precautionary mechanisms in relation to vaccines.

In this way, as Brazil does not have a compensation fund, the demands related to Adverse Effects Post Vaccination (AEPV's) end up turning into judicial demands. On the attempt to create the aforementioned program nationwide, Campos 21 highlights that Brazil even started negotiations to create its system to compensate for the adverse effects of vaccination. However, due to the high technical, administrative and budgetary complexity, it has not yet been put into practice.

Therefore, the creation of a program in this sense would probably be very beneficial, mainly because it allows the reporting of adverse effects, encouraging new studies to increase the safety of existing vaccines.

## CONCLUSION

Compulsory vaccination to combat the advance of the coronavirus pandemic is allowed in Brazil through current legislation, as the topic has already been discussed by the Federal Supreme Court. In the case of childhood vaccination, its compulsory nature is already provided for by the legal system in relation to the mandatory vaccination schedule, being required, for example, for the purposes of children's school enrollment.

In the case of the vaccine against COVID-19, until now, only the use of the

Pfizer vaccine for this population has been authorized by Anvisa. The key point of the matter is that, because the disease was discovered recently, and clinical studies for vaccine development have not yet obtained results in relation to its long-term effects, mandatory vaccination encounters some legal ethical obstacles.

Taking into account that the process of free and informed consent can only be

considered valid outside a context of compulsion, basing vaccination on the freedom of choice of individuals, especially children and adolescents, when the exercise of the right to formal education is in conflict, does not represent a valid justification, both from an ethical and a legal point of view.

Therefore, the need to establish a national program to repair the damage caused by vaccination is reinforced. It

is concluded then that the childhood vaccination program against COVID-19 must guarantee the security necessary for individual health, as well as the provision of reparation for effective adverse effects, in order to meet the demand of the public interest and collective health without abandoning fundamental individual rights. ■

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