

Bioethical Perspectives about Notion of Mandatory Vaccine for SARS-CoV-2

Perspectivas Bioéticas frente a la Noción de Obligatoriedad de la Vacuna para SARS-CoV-2

Recibido: 23/03/2021 | Aceptado: 13/07/2021

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RESUMEN

Introducción: En diciembre del 2019, el SARS-CoV-2 fue detectado en Wuhan (China), que se asoció principalmente a cuadros severos de dificultad respiratoria. La pandemia fue declarada en marzo del 2020, y hasta el momento ha cobrado más dos millones de vidas. Al inicio del 2021 se inició la vacunación en las principales ciudades del mundo, estrategia que generó grandes controversias frente a la posibilidad de aplicarla de manera obligatoria en la población. **Objetivo:** Abordar los aspectos éticos más relevantes de la noción de obligatoriedad de la vacuna contra la COVID-19 y aportar elementos para el análisis bioético sobre esta medida. **Metodología:** Búsqueda amplia de la literatura en las principales bases de datos y análisis hermenéutico. **Resultados:** Se encontraron seis documentos relacionados con aspectos éticos frente a la vacunación obligatoria. Análisis de diversas perspectivas bioéticas en favor y en contra de la inmunización. **Conclusión:** En favor de la noción optativa de la vacunación existen importantes razones bioéticas para considerar el respeto a los principios de autonomía, no maleficencia, de responsabilidad y agencia. Frente a la vacunación en pandemia, debe considerarse la información y la educación como una de las estrategias más importantes para la adherencia a esta medida de salud pública.

Palabras clave

ética; ético; vacuna; COVID-19; SARS-CoV-2.

ABSTRACT

Introduction: In December 2019, SARS-CoV-2 was detected in Wuhan (China), which was mainly associated with severe symptoms of respiratory distress. The pandemic was declared in March 2020, which so far has claimed more than two million lives. At the beginning of 2021, vaccination began in the main cities of the world, a strategy that generated great controversies regarding the possibility of applying it as a mandatory application to the population. **Objective:** To address the most relevant ethical aspects of the notion of obligatory nature of the vaccine against COVID-19, and to provide elements for the bioethical analysis on this measure. **Methodology:** Wide literature search in the main databases and hermeneutical analysis. **Results:** Six documents related to ethical aspects regarding compulsory vaccination were found. Analysis of various bioethical perspectives for and against immunization. **Conclusion:** In favor of the optional notion of vaccination, there are important

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How to cite: Pedraza Galvis MP. Bioethical perspectives about notion of mandatory vaccine for SARS-CoV-2. Univ. Med. 2021;62(4). <https://doi.org/10.11144/Javeriana.umed62-4.vacu>

bioethical reasons to consider respect for the principles of autonomy, non-maleficence, responsibility and agency. Faced with vaccination in a pandemic, information and education should be considered as one of the most important strategies for adherence to this public health measure.

Keywords

ethics; ethical; vaccine; COVID-19; SARS-CoV-2.

Introduction

In December 2019, a new coronavirus was detected in Wuhan (China). It was named SARS-CoV-2 and it was reported that this agent could present among those infected with a varied spectrum of manifestations ranging from an asymptomatic picture to the development of acute respiratory distress syndrome and death. Within months, this microorganism rapidly spread to all continents and the World Health Organization declared a global pandemic in March 2020 (1). By the first week of July 2021, more than 180 million people worldwide have been reported infected and nearly 3.9 million have died from the new COVID-19 (2).

The consequences of this pandemic have been devastating. The United Nations (UN) has reported that cities have reported approximately 90% of the cases of infection and have suffered the worst consequences of the crisis. In all latitudes of the world, the population has faced shortages of supplies, declining purchasing power, and overburdened health systems. The UN states that the pandemic has "exposed deep-seated inequalities" in today's society (3).

Major pharmaceutical companies quickly began research to develop drugs and technologies to reduce the number of infections and deaths caused by this disease. The development of vaccines against this etiological agent seemed to be a glimmer of hope in the last year.

In January 2021, the Centers for Disease Control and Prevention, in the United States, published on its official website the benefits of vaccination against COVID-19 as a complementary measure to the already known health policies (such as the use of masks, hand washing, and social distancing), to stop the global advance of the pandemic (4).

In the press release of the second week of January 2021, the national government of Colombia, through the Minister of Health and Social Protection, highlighted the importance of vaccination against COVID-19 in approximately 34 million Colombians who were considered a priority population for the immunization plan for the first semester of 2021 (5). This country, through bilateral and multilateral mechanisms for the acquisition of the biologic, started the vaccination program in February 2021. Since then, immunization has been offered to health personnel, the elderly population, and individuals with comorbidities (6).

The rapid development of vaccines against COVID-19 and the reports of some isolated side effects (7) with media coverage have generated doubts among the population regarding their intention to receive the vaccine. Historically, the existence of anti-vaccine civil movements (estimated at around 58 million people worldwide) has been known, arguing fear of the immunological impact that the vaccine may cause in the organism, rejection of the imposition of public health measures on the individual agency, and even distrust of institutions and technology developers such as the pharmaceutical industry, to decline the option of receiving immunization against various pathologies (8-38).

In this context, despite the availability of several vaccines against COVID-19, which successfully completed the first phases of clinical trials and with apparent effectiveness and safety, some sectors have expressed their rejection of this alternative. Citing fear of possible side effects, political and religious beliefs, or simply a disbelief in the disease itself, a minority number of individuals have expressed their reluctance to receive the vaccine and are concerned about the potential negative impact of anti-vaccine movements on the control of this pandemic (9). Moreover, there are denialist tendencies about the potential benefit of the vaccine. For example, in Tanzania, President John Magufuli "said that Tanzanians should not be used as guinea pigs," referring to the application of the biologic, to discourage immunization in his territory (10).

On the other hand, in a recent publication, Emiliano Rodriguez Mega (11) reports on a survey conducted by Imperial College London, which assessed global attitudes towards the COVID-19 vaccine in fifteen countries. The results show that confidence in the vaccine among respondents suggests an encouraging trend, but the researchers warn that doubts about the vaccine could delay recovery from the pandemic. Ethical tensions over this preventive option have generated controversy and a host of questions, for example: should vaccination as a public health measure be mandatory for the most vulnerable people or those working in health systems? What are the legal and moral consequences for an individual if he/she chooses not to be vaccinated? Would the vaccination certificate have any implications for employment or continuation in public positions or the provision of essential services? Is it ethically correct to appeal to conscientious objection to refuse this preventive option?

The ethical dilemmas that confront the possible greater good of society with mass and compulsory vaccination versus the preferences of the individual who may choose not to receive immunization for different personal arguments will be the subject of this article. The main objective of this paper focuses on developing a non-systematic literature review to respond to the concerns raised. An analysis from the perspective of the 2005 Declaration on Bioethics and Human Rights (12) is proposed to contextualize the topic under discussion and leave on the table hypotheses that may guide future research on the subject.

Methodology

Hermeneutics was used as the main methodology, through a critical review of texts and documents that gave an account of the ethical perspectives on the topic under discussion. There was an extensive literature search in the main databases: Pubmed, Google Scholar, SciELO, and EBSCO. The keywords used were: *ethics*, *vaccine*, *COVID-19*, and *SARS-CoV-2*, without filters for

the year of publication, in Spanish and English. The main papers discussing ethical conflicts in pandemic vaccination were identified. Clinical trials related to vaccine production and development were excluded. Titles and electronic abstracts were reviewed, filtering those that offered a bioethical perspective for the analysis of the questions raised.

Results

A total of 256 electronic products were obtained, and after a detailed review of the titles and abstracts, most of them were discarded because they did not address the topic of interest. Six papers (7,8,9,18,26,36,37) published in scientific journals were reviewed. In addition, multiple documents from governmental and academic agencies were included in the analysis to enrich the dissertation. The most relevant aspects regarding the general context of vaccination against COVID-19, the ethical principles surrounding vaccination against this virus, and the ethical tensions between the notions of obligatory and voluntary immunization with this biologic will be discussed below.

General Considerations for COVID-19 Vaccination

COVID-19 vaccines

Vaccination is a public health strategy that has shown benefits for the world population, as seen with the eradication of smallpox and the control of infections such as poliomyelitis and measles (9,13). It cannot be overlooked that, compared to other vaccines available for different infectious diseases, the vaccine against COVID-19 has some particularities.

Vaccines against COVID-19 have different mechanisms of action (through messenger RNA, protein subunits, and vectors), whose main purpose is the development of immunity in the organism without contracting the disease, stimulating defense cells such as memory T

lymphocytes and B lymphocytes (14). Pioneer pharmaceutical companies in the development of vaccines such as Pfizer, at the end of November 2020, reported that the vaccine had an efficacy of up to 95% in preventing complications of the disease. For its part, the Moderna laboratory reported a vaccine efficacy of 94.5%; while Russian manufacturers confirmed efficacy of more than 90% for the Sputnik vaccine. This could be interpreted theoretically as meaning that out of every 100 people vaccinated with these biologics, between 90 and 95 will be protected against presenting severe symptoms of the disease (15). A study published in the *New England Journal of Medicine* reported that the efficacy of the Pfizer vaccine, between the first and second dose, was 52% (with a 95% confidence interval between 29.5% and 68.4%). After the seventh day following the second dose, efficacy increased to 95% (16).

For their part, Doroftei et al. (17) published in March 2021 a general review of the efficacy of the vaccines available up to that time against COVID-19. After reviewing 19 relevant published articles, the authors concluded that Pfizer-BioNTech, Moderna, and Sputnik V had greater than 90% efficacy. In addition, they reported that the Moderna, Sputnik V, and Oxford-AstraZeneca vaccines have also shown fewer serious adverse reactions. Convidicea, Johnson & Johnson, Sinopharm, Covaxin, and Sinovac vaccines were analyzed for their immunogenicity. The authors concluded that the aforementioned vaccines are efficient and safe regardless of age and sex, apart from being well tolerated by the recipients.

It is important to wait cautiously for the follow-up of vaccinated subjects to better observe both the efficacy of the vaccine and the safety measured against the main adverse effects in the medium and long term. In this context, it is understandable that there is reluctance among the population to be immunized with these biologics, which some still call "experimental" vaccines. Would it be valid to raise the question of whether the application of a vaccine in a pandemic or a state of functional emergency, in this case, SARS-CoV-2, should be mandatory?

Some regulatory background on vaccination

In the United States, the 14th Amendment to the Constitution states that no state may enact laws that restrain or deprive any person of life, liberty, or property without due process of law. The Supreme Court recognizes that this amendment protects U.S. citizens from arbitrary legislative action, but that does not mean that laws with a legitimate government purpose cannot be enacted to be declared constitutional. In addition, the Supreme Court has recognized the "police power" in each state, which grants authority to the state to enact health ordinances, including quarantine and vaccination to protect public health and safety (18).

On the other hand, in Spain vaccination is considered voluntary. However, the Vaccine Advisory Committee reported on the website of the Spanish Academy of Pediatrics that some situations allow the competent public authorities to impose forced vaccination, and one of these exceptional cases is the occurrence of epidemics, following Organic Law 4 of June 1, 1981, which allows action in states of alarm, exception, and siege (19).

In Colombia, the general vaccination schedule is aimed at all children under five years of age. Adults are vaccinated against specific diseases, such as yellow fever or tetanus. In addition, vaccination for seasonal influenza (20) and pneumococcus (21) is offered free of charge to at-risk groups (especially the elderly), since these agents are responsible for prevalent respiratory diseases in the population and are associated with significant morbidity and mortality in this age group. However, except for the immunizations included in the Expanded Plan of Immunization (22), vaccination in this territory is neither free nor mandatory.

It seems only logical that for the employment of health care workers, immunological antecedents should be verified (either through a vaccination card or by measuring antibody concentrations for specific diseases such as chickenpox or hepatitis B); however, it is likely that if these immunizations are not accredited

(for various reasons, including refusal to receive a vaccine), this would constitute a reason for discrimination in the job selection process.

It is important to remember that Colombia is considered a social state governed by the Political Constitution of 1991, article 16 of which states that "All persons have the right to the free development of their personality with no limitations other than those imposed by the rights of others and the legal order." This is coupled with Article 18, according to which "freedom of conscience is guaranteed. No one shall be reprimanded on account of his convictions or beliefs, nor compelled to reveal them, nor forced to act against his conscience" (23).

From these perspectives, concerns arise as to whether in the case of the COVID-19 vaccine in this country: should vaccination be a mandatory requirement? Could the immunological and vaccination status generate some type of discrimination among those who are already employed or who aspire to be employed? Would residents in Colombian territory be obliged to receive the immunization or could they object to freedom of conscience?

Ethical considerations in vaccination

Vaccination is a preventive intervention to which all users of a health system should have access to maintain their state of well-being, as long as they have a confirmed medical indication and if the condition of not having access to this option could endanger their integrity. The following is an analysis of some categories that support the discussion of the ethical dilemma in the light of some of the principles suggested in the 2005 Universal Declaration on Bioethics and Human Rights (UDBHR) (12).

Autonomy

Siurana (24) states that "The word autonomy comes from Greek and means self-government." Article five of the 2005 UDBHR emphasizes respect due to the individual's decision-making capacity and the need to protect the rights

and interests of those who cannot exercise their autonomy (12).

For Serge (25), in the chapter "Individual autonomy" of the Latin American Dictionary of Bioethics, autonomy is an ethical principle that is part of the theory of principlism, proposed by Beauchamp and Childress. The latter author indicates that the principles within bioethical theories are intended to support the norms that guide ethical judgments, but they must also be consistent with the "feeling," i.e., Serge states that the "ethical position emerges from the perception of a phenomenon that happens within each of us" (25); however, the autonomy construct, says Serge, is a recent conquest that began during the European Enlightenment. This principle, which denotes the importance of respect and recognition that individuals may think and feel differently, could even become an ideal for modern society, in which respect for identity and free will have become fundamental notions of bioethics.

Although some have felt that their autonomy has been violated during this pandemic by some restrictions such as the limitation of free movement, Chia and Oyeniran (26) indicate that the draconian isolation and quarantine measures that were initiated in the first half of 2020 were necessary as a consequence of the rapid spread of the virus. They recall that in 2003, in the SARS outbreak, these same measures were useful to curb the disease. The authors argue that in this context autonomy plays an important role in the face of the "autonomous reflection" of self-government and the limits that individual autonomy must signal in the face of the benefit of others.

Should individuals who claim their legitimate right to autonomy to refuse vaccination be subject to moral criticism? Has the country historically discriminated against individuals who do not accept public health measures such as immunization?

It is important to bring up a scenario of mandatory vaccination in Colombia. For example, unemancipated individuals under five years of age must receive the immunizations scheduled for their age with the authorization of

their caregivers. The Constitutional Court (27) indicated that the non-vaccination of minors is considered a violation of the right to health of children and adolescents. Consequently, the competent authority (family defender, family commissioner, or police inspector) may initiate a process of re-establishment of rights. On the other hand, at present, adults, in general, do not have any obligation to be vaccinated in Colombian territory.

In favor of autonomy, public and private institutions should optimize the processes of comprehensive care for candidates to be immunized against COVID-19. The UDBHR (12), in its sixth and eleventh articles, refers to the importance of carrying out the "free, express and informed" consent of any person who is going to receive a medical intervention such as immunization and, in turn, invites to "avoid discrimination or stigmatization" of the individual to ensure respect for human dignity.

Justice

The UDBHR (12) mentions the importance of "fair and equitable treatment of human beings" in the tenth article of the 2005 declaration. This principle of justice is, in turn, complemented by the fifteenth principle, which cites the "Sharing of benefits" so that all individuals can have access to scientific and technological knowledge and progress.

Siurana (24) quotes Beauchamp and Childress to clarify that justice does not mean that everyone should receive the same; rather, he states that this principle appeals to "equitable and appropriate treatment in light of what is due to a person". Therefore, in the face of the ethical dilemma posed by the notion of obligatory COVID-19 vaccination, one can appeal to Beauchamp and Childress' concept of distributive justice, which refers to "the impartial, equitable and appropriate distribution in society, determined by justified norms that structure the terms of social cooperation" (24).

Since immunization is a strategy that favors community health, and from the principle of

justice, the national government must guarantee vaccination to all inhabitants of the national territory without discrimination of any kind. On the official page of the Colombian Ministry of Health and Social Protection, the Government informed that it has purchased "enough vaccines to immunize, with the complete scheme, 40.5 million people. This is approximately 70 million doses of vaccines, of which 51.5 million will be received through direct agreements with producers and the rest through the COVAX mechanism" (6).

For Pinto Bustamante et al. (8), the "cardinal principle" that should guide the allocation of immunization prioritization is "the intrinsic value of people, their dignity." The distribution and availability of COVID-19 vaccines have become one of the major global determinants of infection control and pandemic-associated mortality. This measure also represents a fundamental reason for economic and social reactivation; therefore, when public and private sectors are expected to join efforts so that vaccination can be administered in Colombia with celerity and equity, it is when the principle of justice becomes more valid.

Responsibility

The UDBHR (12), in its fourteenth article, mentions the importance of health promotion by the government and all sectors of society concerning "Social responsibility and health," which, together with article 13, called "Solidarity and cooperation," puts on the table the importance of cooperative work and solidarity among human beings. This, together with Article 13, entitled "Solidarity and cooperation", brings to the table the importance of cooperative work and solidarity among human beings. Could it be understood that all members of society have an inescapable responsibility for the welfare of other individuals? What responsibility should be attributed to official institutions in the vaccination process in a pandemic?

According to Battin et al. (29), in the context of infectious diseases, such as COVID-19, the

patient should be understood as a "victim and vector" who has a potential risk of becoming ill, but also of participating in the chain of contagion so that others like him become ill, and given the risk of lethality that this disease represents, the principle of responsibility is fundamental when facing the crisis caused by the pandemic. For Battin et al. (29), the individual agency from the feminist perspective demonstrates that human beings need to establish social, cultural, and biological ties for the free development of their personality, but this situation also represents a responsibility for the "social location" of each citizen and the repercussions of their actions concerning others.

It is striking that scenes of social disobedience to the health measures proposed by governments to control COVID-19 infection rates are observed daily in the world's media. The simple use of a mask or social distancing has become a challenge for public health and authorities in this pandemic.

Siqueira (30) proposes the principle of responsibility, according to Hans Jonas, through a categorical imperative: "Act in such a way that the effects of your action are compatible with the permanence of an authentically human life on Earth," with a preventive rather than punitive perspective on the consequences of the agent's decisions. Siqueira (30) quotes again Jonas to recall his thesis: "The responsibility of the human being with himself is inseparable from that which he must have with all others. It is a solidarity that connects him to all men and to nature that surrounds him."

However, responsibility does not only have to do with the individual agency or the private sphere. Consuegra-Fernández (7) questions the responsibility of governmental entities concerning the growing strength of anti-vaccine movements. This author suggests that the multifactorial origin of distrust among citizens regarding public policies (such as vaccination) in times of crisis should be studied in-depth and claims the importance of the participation of the scientific community in the transparent and neutral dissemination of knowledge. Perceptions of inequity in

the distribution of health resources or even logistical difficulties in the timely administration of vaccines in the national territory may become other factors favoring reluctance towards immunization against COVID-19 in Colombia.

From this perspective, responsibility would require compliance with all available strategies currently available to halt the advance of COVID-19, including vaccination, risk management, transparency, and fairness in informing the population. Could this be a sufficient argument to support the mandatory application of the biologic in Colombia?

The common good

The UDBHR (12) suggests some mechanisms to apply the principles mentioned in the declaration. It proposes that "decision making and treatment of bioethical issues" be discussed in spaces of dialogue and discussion not only in public debate, but also in instances such as ethics committees, and urges governments to assess and manage the risks related to medical practices and related technologies for the common good of society.

From the perspective of Mill's utilitarianism (31), the actions of each human being, individual or collective, should be focused on the benefit of the greatest number of individuals involved, to maximize the utility of this action. In the case of a Latin American country, it seems that the notion of mandatory vaccination is a real option for the control of the COVID-19 pandemic. According to a well-known news media, the Brazilian Supreme Court "almost unanimously endorsed mandatory vaccination" (32). Although it seems that no one will be forced to receive this intervention, national authorities could sanction citizens who choose not to be immunized. This situation already has some historical antecedents, since in past decades Brazil, as well as other countries of the European Community, have tried to mitigate the impact of the tuberculosis epidemic with compulsory immunization with BCG vaccine in the child population.

Moreover, the immigration policy of many countries requires vaccination (e.g. yellow fever) for foreigners to enter their territory. On March 9, 2021, China announced to the world the official launch of a "digital passport" that allows verification of the health status of travelers, as to whether they have had the SARS-CoV-2 disease or have already been vaccinated for this microorganism (33). In the same sense, the European Commission approved the project to request the Digital Green Pass (also known as COVID-19 vaccination passport) to travelers wishing to enter the 27 member countries of the European Union as of July 1, to "allow movements within the continental bloc, without the need to submit to restrictions, to anyone who has been vaccinated against COVID-19, has a negative test for the virus, or has recently recovered from the disease" (34).

Against this backdrop, it is only fair to question whether, in the face of a possible greater good of society, vaccination against COVID-19 could come to be considered mandatory, at least in some populations that offer social care services and are not only more at risk of acquiring the disease, but also of transmitting it. Is it possible, from Engelhardt's perspective (35), that an agreement could be reached between "moral strangers" so that through widespread vaccination the devastating impact of this disease on health, the economy, and the very development of society could also be mitigated?

Should the application of the COVID-19 vaccine be mandatory or voluntary?

The ethical analysis of the mandatory application of vaccination on a global basis is fundamental, due to the potentially favorable effect of this public health measure to halt the advance of SARS-Cov-2. Although the start of vaccination in Colombia has generated an atmosphere of optimism, various sectors of society are concerned not only about how the vaccine administration is prioritized but also about the possibility that it could be mandatory. Based on the above background and categories, the

discussion will attempt to group the general arguments in favor and against compulsory vaccination to respond to the stated objective.

The notion of obligatory vaccination

The arguments that can support the notion of mandatory immunization against COVID-19 are diverse and relevant. From the point of view of distributive justice, individuals will receive what they need and deserve, i.e., mandatory vaccination could articulate the governmental duty to offer strategies in favor of the health of citizens with the duty of the social rule of law to guarantee the general welfare of the community, since the control of the pandemic allows for the economic and social recovery of the population. Moreover, from a utilitarian perspective, the mandatory administration of the vaccine would prioritize the common good or the good of the majority.

Chia and Oyeniran (26) expose the ethical debate on the supremacy between the concept of human health and the notion of individual rights, arguing that public health ethics differs from clinical ethics in that it promotes the prioritization of the "common good" over the protection of individual autonomy. For their part, Reiss and Caplan (36) raise an example to denote the greater good when referring to the vaccination of health personnel and the armed forces, who by accepting their mission in society cede some of their individual autonomy in favor of their profession. The authors strongly consider that vaccination in this group of people should be mandatory, for their own and society's safety.

Colombian authorities have reported on several occasions on civil disobedience concerning biosecurity measures, such as the use of masks and social distancing. Moros (37) indicates that from the "self-determination theory" it is usual for citizens to be reluctant to control external interventions (even governmental) and it has been observed that, in particular, young people show defiant behaviors in the face of mobility restrictions and generate risks to their integrity and that of other citizens.

In such a scenario of civil disobedience, the notion of mandatory immunization could lessen the effect of the pandemic. Giubilini and Jain (38), senior researchers at the Uehiro Centre for Practical Ethics at Oxford University, argue that leaving everything to the conscience of individuals is insufficient and suggest that vaccination should be mandatory. They argue that "Being vaccinated drastically reduces the risk of seriously harming or killing others." Likewise, these researchers assert that mandatory immunization against COVID-19 fairly distributes the responsibility for achieving herd immunity because it "ensures that the risks and burdens of vaccination are evenly distributed among the population." They also support other less restrictive measures, highlighting the importance of information campaigns to promote the benefits of this public health measure to the public. Vaccination will not be the only measure to curb the infection rate, but it could be an additional strategy to biosecurity measures with the potential to mitigate new epidemiological peaks of infections and deaths associated with this disease.

The optional notion of vaccination

Against the optional notion of vaccination for SARS-CoV-2, it is possible to argue from a principled perspective the need to respect the autonomy of citizens. It is reasonable to consider that individuals in full use of their mental capacities can make the decision to be vaccinated or not, based on their preferences and deepest beliefs, but also the reflective exercise of the consequences of their decision. Citizens who reject the obligatory nature of vaccination could appeal to articles 16 and 18 of the Political Constitution of Colombia (14), already mentioned, to establish rights of tutelage to protect their right of free will.

In the case of children, adolescents, and persons incapable of giving their consent, it would be more complex to face this optional condition of the vaccine, due to the paternalistic tendency of medicine and legislation, since the

decision will depend on third parties. In the Colombian State, the legal framework favors the making of this type of decision by the guardians or legal representatives, who must receive all the corresponding medical information, evaluating the context of each individual against the potential risks and benefits to record their approval according to their best interest (39).

The right to non-maleficence cannot be disregarded. Although the vaccine does not imply voluntary harm to the individual, since it is an experimental vaccine, some may consider that the current options do not have the ideal guarantees compared to the safety and efficacy evaluated in others previously developed for other pathologies. The decision of some citizens not to receive the vaccine, at least for now, until they see better performance in phase IV (commercialization and mass administration) could be reasonable. It would be valid for other individuals to state their preference not to receive the vaccine in the face of potential side effects ranging from pain in place of administration to the risk of anaphylaxis (6).

For González-Melado and Di Prieto (40), the compulsory vaccination option that some governments may opt for reflects the problems of the ethical models on which health policies and their implementation are based. The authors propose building health policies on a "first-person" ethical model, based on responsibility, to favor the transformation from normative ethics to the ethics of responsible behavior.

Reiss and Caplan (36), for their part, indicate that the debate on the application of mandatory vaccines should be approached neutrally, trying to evaluate the commonalities between citizens' *values* and the pros and cons of the social benefit in each particular circumstance.

Pinto Bustamante et al. (8) quote Diego Gracia when they refer that the key to balanced decision making, which respects "individual freedoms and the common interest," is the weighing of conflicts between ethical values and extreme courses of action. Consequently, risk communication strategies, comprehensive counseling, and the quality of the informed consent process emerge as a fundamental point

to accompany the optional choice for vaccination against COVID-19. These authors state that autonomous decision-making regarding the process of accepting immunization should be based, as in any informed consent process, on clear and truthful information communicated assertively to citizens considered candidates to receive this public health measure.

Discussion

The SARS-CoV-2 pandemic has had devastating consequences in the last year. By the end of the first half of 2021, more than 100,000 deaths from COVID-19 had been reported in Colombia (41). Although the Ministry of Health and Social Protection has reported that more than 19 million doses of the vaccine have been administered in the national territory (6), the third epidemic peak has caused the highest daily mortality figures recorded so far in the pandemic (41).

The UN has said that the COVID-19 pandemic goes beyond a health emergency and "is also an economic, humanitarian, security and human rights crisis. It has revealed very serious fragilities and inequalities between and within countries," and can only be overcome through a comprehensive approach based on solidarity and compassion that includes all factors in society and governments (42). For his part, Horton (43) states that the current situation constitutes a true syndemic, in which two categories of diseases interacting within specific populations (SARS-CoV-2 infection and a series of additional non-communicable diseases) are experienced and accentuate deeply rooted patterns of inequality in the population. Antonio Guterres, UN Secretary-General, referring to this crisis, stated that "in a context where there are already high levels of informal labor and fragmented health services, the most vulnerable populations and individuals are once again the most affected" (44).

In this context, the initiation of the vaccination process against COVID-19 in the main capitals of the world at the end of 2020 was

interpreted as a glimmer of hope to slow down the spread of infection with this disease, but it also generated an ethical debate on the notion of mandatory vaccination.

In Colombia, some sectors have expressed fear that part of the population may be subject to implicit or explicit discrimination if they refuse to receive this immunization. In the European Community and China, migration regulation according to the immunological condition associated with COVID-19 is already a fact, and although this is debatable from the point of view of the right to freedom of movement, transnational regulations have been justified considering that they can slow down the spread of the most contagious variants of the virus. In addition, there are reservations about the extent of the effectiveness and safety of vaccines that have so far entered Phase IV of development. The report of new mutations of the virus (45) generates uncertainty regarding the performance of vaccines in preventing COVID-19 infections.

The main arguments in favor of the optional nature of this public health measure appeal to respect for autonomy, non-maleficence, and individual responsibility. It is possible that the reluctance of some citizens to receive immunization is related to misinformation that can be addressed with better scientific and governmental educational channels. However, other individuals, being clear about the benefits and risks of the COVID-19 vaccine, resort to the already exposed historical reasons of the anti-vaccine movements to reject this intervention (38).

Giubilini and Jain (38) state that the notion of mandatory vaccination does not automatically increase the uptake of the biologic, and cite a European-funded project on epidemics conducted some years before the COVID-19 pandemic, the results of which did not support the hypothesis that vaccine regulation increased the number of immunized individuals. These authors clarify that the severity of COVID-19 infection is directly related to age and history of chronic pathologies, so it would be ethically debatable to force immunization of a population group such as adolescents who have a very low

risk of unfavorable or fatal outcomes, with a vaccine that is under evaluation and may not be harmless.

On the other hand, some authors suggest that mandatory vaccination could be a fundamental measure to control not only the impact of the pandemic but also to mitigate its devastating consequences, as it would accelerate the possibility of recovery on all fronts of societal development. It is uncertain whether, if a country were to make vaccination mandatory, the authorities would have the resources to ensure vaccination of all residents in the national territory and the logistics to verify adherence to the measure. In addition, there is greater uncertainty as to whether the health and legislative systems would be able to attend to the claims of individuals presenting side effects from immunization (mandatory or not). In this regard, Halabi et al. (46) recall that in 2006 the International Federation of Pharmaceutical Manufacturers and Associations "publicly demanded that manufacturers be granted protection against claims associated with vaccine-related adverse events if they were to participate in pandemic responses," thus exonerating vaccine developers from liability.

Therefore, before considering immunization from the regulatory level, it could be that the best strategy to strengthen the intention of immunization against COVID-19 among citizens is risk communication and comprehensive counseling to the population through pedagogical strategies that guide the potential individual, family, and social benefit. The compulsory nature of this public health measure may undermine respect for individual freedom, the principle of responsibility and agency, and leave an unfavorable ethical and legal precedent in a democratic state. Special groups that have a social service vocation should have access to vaccination as a priority, and in case of any objection to this public health measure, each case and its context should be analyzed individually.

Conclusions

The SARS-CoV-2 pandemic has generated a crisis never seen before in the recent history of the planet, which has affected social, political, and economic dynamics. There are ethical arguments in favor of the notion of voluntary vaccination against COVID-19 which, together with other individual and collective care measures, will reduce the increase in the number of infections and lethality caused by this virus. This pandemic should also leave a bioethical reflection on the challenges and opportunities in terms of planning, management, and communication of public policies such as vaccination, capable of offering the population better health and education conditions that favor citizen awareness as an engine of development and prevention of future crises.

Conflict of interest

No conflicts of interest are declared. The document has ethical implications that are precisely discussed to generate a reflection in the reader that will allow him/her to generate his/her own conclusions.

Agradecimientos

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