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Review article

The vaccine against COVID-19 and institutional trust☆

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ABSTRACT

Major public and private laboratories have entered into a race to find an effective Covid-19 vaccine. When that vaccine arrives, the governments will have to implement vaccination programs to achieve the necessary immunization levels to prevent the disease transmission. In this context, the ethical dilemma of compulsory vaccination vs. voluntary vaccination will be raised. Underlying this dilemma, lies the problem of the ethical models on which the political decisions of governments in matters of health are based. The article proposes and argues the need to base health policy decisions on an ethical "first person" model, based on responsibility, that allows us to move from a normative ethic to an ethic of responsible behavior. This change in the ethical model, together with certain proposals for political action, will help us to restore institutional trust so that the necessary levels of collective immunity against Covid-19 can be achieved through the voluntary vaccination of the citizens.

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La vacuna frente a la COVID-19 y la confianza institucional

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RESUMEN

Los principales laboratorios públicos y privados han entrado en una carrera para encontrar una vacuna eficaz contra el Covid-19. Cuando esa vacuna llegue, los gobiernos tendrán que implementar los programas de vacunación que permitan alcanzar los niveles de inmunización necesarios para evitar la transmisión de la enfermedad. En este contexto se planteará el dilema ético de la vacunación obligatoria vs. vacunación voluntaria. En el fondo de este dilema subyace el problema de los modelos éticos en los que se basan las decisiones políticas de los gobiernos en materias de salud. El artículo propone y argumenta la necesidad de fundamentar dichas políticas en un modelo ético de "primera persona", basado en la responsabilidad, que permita pasar de una ética normativa a una ética del comportamiento responsable. Este cambio de modelo ético, junto con determinadas propuestas de acción de tipo político, ayudará a recuperar la confianza institucional para que se puedan alcanzar los niveles necesarios de inmunidad colectiva frente al Covid-19 a través de la vacunación voluntaria de los ciudadanos.

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Introduction

In December 2019, the health authorities of Wuhan, capital of the province of Hubei in China, reported a serious disease that caused severe pneumonia and death.[1] The number of cases dramatically increased at an alarming rate, spreading throughout China and the rest of the world. The disease was caused by a coronavirus, now known as SARS-CoV-2, which is very similar to those caused by other zoonotic coronaviruses, such as SARS-CoV detected in 2002.[2] SARS-CoV-2 infection (hereinafter referred to as COVID-19) causes a wide range of symptoms, with an incubation period of around five days.[3] The period from the onset of COVID-19 symptoms to patient death ranges from six to 41 days.[4] The symptoms and their severity will depend both on the age of the patient as well as underlying conditions. The most common symptoms are fever, cough and fatigue. Other symptoms include increased sputum, headache, haemoptysis and diarrhoea.[5] In more severe cases, computed tomography

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scans reveal pneumonia with abnormal RNAaemia, acute respiratory distress syndrome, acute heart injury and increased ground glass opacities around the bronchioles, which may cause patient death.[6]

While still suffering the effects of the COVID-19 pandemic, the largest public and private pharmaceutical companies have entered into a race to develop an effective vaccine. A vaccine that can generate immunity is the only way to stop the virus from spreading. As of 8 April 2020, there were 115 candidate vaccine development projects worldwide.[7] Of these, six vaccines are already being tested in healthy volunteers. However, the development of these vaccines is raising serious ethical issues. Some groups are conducting animal and human trials simultaneously, despite standard protocol dictating animal testing first, followed by human trials only once safety and efficacy have been confirmed.[8,9] Other groups plan to directly inject the virus into healthy volunteers to test vaccine efficacy.[10] The most optimistic forecasts have lead some authors to believe that a vaccine will be available by the end of 2020, while others predict a period of 12–18 months, or mid-2021.[11] The landscape will change in the coming months depending on the progress of the ongoing clinical trials. At some point in the future, we are likely to be confronted by two successive scenarios: firstly, there will initially be two or three available vaccines, those whose safety and efficacy have been proven in clinical trials but with limited production that shall not suffice for the entire population; subsequently, once the safety and efficacy of the first vaccines have been proven in the vaccinated population, production of the safest and most effective vaccines will have increased, and we will be in a position to offer the vaccine to the majority of the population.[12] In the initial scenario, given the lack of available vaccine units, the ethical dilemma to be overcome will be, who should be vaccinated? When there is a shortage of health resources, their allocation must be decided based on the principle of distributive justice, and the inclusion criteria (prioritisation) of the groups of users given access to the vaccination will have to be determined. In the second scenario, once vaccine production has increased, mass vaccination of the population shall be planned. The implementation of a mass vaccination programme raises two basic ethical dilemmas: the first is "free vaccination" vs "paid vaccination"; and the second is "voluntary vaccination" vs "mandatory vaccination". For the COVID-19 vaccination, the focus will clearly be on mass vaccination and governments are likely to offer the vaccine free of charge to their citizens, thereby bypassing the first dilemma. This being the case, the only ethical dilemma to overcome will be mandatory vaccination vs voluntary vaccination.

The purpose of this article is to show that behind these dilemmas lies a series of ethical models on which the health-related political decisions of governments are based. This article therefore proposes and puts the case for an ethical "first person" model based on responsibility, that will allow us to move from a normative ethical model to ethics of responsible moral behaviour. Together with certain proposals for political action, this will help to regain institutional trust so that the required levels of COVID-19 herd immunity can be reached through the voluntary mass vaccination of citizens.

Who should be vaccinated?

With a vast array of ongoing vaccine development research projects, there are three that are ahead of the competition.[13] As such, the initial scenario envisages the approval of two or three vaccines with relative safety and efficacy, enough to reduce mortality, the spread of infection and the need for hospitalisation. Once approved, unprecedented amounts of these vaccines will need to be produced on a worldwide scale. Some sites hope to produce 100 million vaccines per year, while an alliance between different international organisations proposes the figure of 2,000,000,000 doses every year. Despite these efforts to increase production, there will still not be enough vaccines for everyone initially and governments will have to decide who to prioritise.

In the event of a shortage of health resources, in this case vaccines, the *principle of equality* of access to vaccination cannot be applied. Instead, the principle of *equity* should be followed. Equity is synonymous with *distributive justice*, defined not as the equal distribution of resources, but as the fair distribution of resources based on needs, particularly in terms of the distribution of risks and benefits in society. Following this principle, the risk/benefit ratio reveals at least two groups that should be the recipients of the first set of available vaccines: healthcare professionals and users of the health system who are over 70 years of age.

During the COVID-19 epidemic, a large number of healthcare professionals have been infected. In Spain, the infection rate among healthcare professionals is as high as 20% in some areas. The infection of health workers has had repercussions on hospital management and patient care.[14]

The COVID-19 mortality rate is highest among the over-70s.[15] This population group accounts for 66% of deaths recorded in Spain. The specific case of care homes[16] was particularly shocking, as reported by the WHO[17]. As such, the over-70 s and elderly people living in care homes, as well as their carers, should be included in the group of priority vaccine recipients.

Mandatory vaccination?

The question of mandatory vs voluntary vaccination may be raised both in the initial priority vaccination phase for at-risk groups, as well as during the second mass vaccination phase once production issues have been overcome. Mandatory vaccination is a controversial proposal from an ethical standpoint because it affects individual rights, including an individual's right to self-determination over their own health. Imagine the case of a healthcare professional who refuses to get vaccinated when the government wishes to enforce mandatory vaccinations for all health workers.

Would the government be forced to assume liability for any possible side effects that this mandatory vaccination may cause? It is clear that if the government enforces mandatory vaccinations for all healthcare professionals, legal liability would lie with the government, which would be forced to pay any compensation should these vaccines cause serious side effects or affect the health of those vaccinated. Yet it has been shown that even in cases of severe infection, a simple recommendation has not yielded good immunisation outcomes.[18] Should people refuse to have a COVID-19 vaccination, can the government force them to get vaccinated?[19]

Ethical models in national health systems

Obscured by this question on mandatory vs voluntary vaccination is a much broader debate about the ethical model that is applied when making political decisions on public and community health issues. The first model is the normative ethical model (third person ethics), which defends the legality of mandatory vaccination. The second model is a virtue ethics model (first person ethics), which defends the individual's right to make decisions about their own health, based on the premise that the common good of society is achieved through the personal good. When making public health policy decisions in times of COVID-19, we propose a shift from a normative ethical model to a virtue ethics model via an ethic of responsibility.[20]

The aim of normative or third person ethics is to identify and establish a series of moral rules or standards that must be observed when performing certain individual actions. Under this premise,

human action is governed by regulations that dispense with the subject who acts and who projects their own existence. The purpose of this branch of ethics is not to investigate how "one should" live nor the most desirable lifestyle, but simply if a certain action is deemed lawful or unlawful by an exterior judge: the "third person".

However, any conscious choice by an individual, such as deciding whether or not to get vaccinated against COVID-19, should be based on so-called "first person ethics", defined as the search for the good of human life in its globality and in its complexity. According to this model, ethics would be conceptualised as a kind of "discussion" about different lifestyles and ways of living, with only secondary emphasis on individual actions, with the aim of establishing what is the best life to lead and strive for.

The "responsibility" alternative

An effective way to move from third person ethics to first person ethics is by re-reading Hans Jonas' "ethic of responsibility".[21] Jonas highlights the responsibility and duty that we have towards our own children, who would perish without the care they require, as the clearest example in everyday morality of a non-reciprocal elementary responsibility and duty, which is recognised and practiced spontaneously. Jonas conceptualises the origin of the idea of responsibility not in relation to other autonomous adults, but in relation to offspring in need of protection. For Jonas, a parent's care for their children is the archetype of responsible action. An archetype that is not guided by principles, but is naturally engrained in all of us.

Together with parental responsibility, Jonas proposes politics as another fundamental form of responsibility. Although different, political responsibility and parental responsibility have much in common. Jonas proposed five elements that these two forms of responsibility have in common: *totality, purpose, feeling, continuity* and *future*. This last mutual element, the future, shows that both parental and governmental responsibility include concern about tomorrow, today. In the context of total responsibility, every individual act that concerns the present also encompasses the future existence of that child or community as its purpose. As such, responsibility cannot be determining, but rather *enabling*; it should lay the foundations and keep as many options open as possible. It is about keeping open the future of the subject for whom one is responsible, whether that be the future of one's child or of an individual who is part of the social community.

The concept of prevention

To facilitate this, governments and health authorities need to change the concept of prevention that is normally applied. In normative ethics, which would support mandatory COVID-19 vaccination, the concept of prevention is defined as *risk reduction*. This means that a health system would achieve better prevention when the risk of contracting the disease decreases. For the COVID-19 vaccination, this will occur when the highest possible number of individuals have been vaccinated. This is the argument which, from a normative ethics standpoint, would justify mandatory COVID-19 vaccination for the greatest possible number of people.

However, from this normative ethics perspective, all preventive medicine measures, including COVID-19 vaccination, are in danger of becoming a set of *obligations and prohibitions* that citizens are forced to abide by. These obligations and prohibitions could be interpreted as an attack on individual autonomy or increase people's individual frustration, being perceived only as an instrument for the good of society. Worse still, they could also demotivate the population in all matters concerning their own health.

We propose a different concept of preventive medicine. For us, prevention involves the *adoption of ethical behaviours by individuals*, which is where we deviate from Hans Jonas' thinking. This would enable people to progress towards "first person ethics" in the general pursuit of their own good, and specifically in pursuit of their own health which, as Descartes observed, is the "highest" good that one possesses.

If we citizens act from this perspective of responsibility in pursuit of our health, making the COVID-19 vaccination mandatory would become unnecessary: if the efficacy and medical and social value of the new COVID-19 vaccines are guaranteed and citizens are correctly informed, getting vaccinated would become a "moral responsibility" or a moral duty,[22] and vaccination would be seen as one more action that leads the individual towards achieving personal and community health. We believe that through first person ethics, an alternative can be created based on personal responsibility. Together with a series of legal actions of a political nature that are detailed below, this would ensure the effective protection of the entire community while also guaranteeing the expression of personal autonomy. For example, to enforce lockdown measures, a sanctions regime was established by the government (normative ethics). Yet the concept that ensured the high success rate of lockdown was prevention driven by personal responsibility, exercised by citizens thanks to their own volition to responsibly abide by the prevention measures (first person ethics).

Do people retain the right not to be vaccinated?

The principle of respect for autonomy of the individual, enshrined in the Spanish law on patient autonomy,[23] bestows upon individuals the right to refuse treatment and, therefore, to also refuse to be vaccinated.[24] It is therefore clear that an individual has the right to choose not to be vaccinated. Yet it is also a fact that some democratic countries have legislated for the possibility of introducing mandatory vaccination in exceptional circumstances. For example, Spanish Organic Law 3/1986, of 14 April, on *Special public health measures*, authorises the approval of exceptional measures, such as mandatory vaccination, in the face of a specific risk to public health such as an epidemic outbreak.[25] Notwithstanding the above, it should not be forgotten that vaccination is a treatment given to healthy individuals who do not have the disease. Moreover, in the specific case of COVID-19, the rate of severe complications is very low in a significant proportion of the population (the under-20 s age group without prior complications). It therefore follows that in many cases, medical justification would not be based on protection of the individual, but rather on protection of the community (herd immunity).[26]

Before implementing mandatory COVID-19 vaccination protocols, it is important to ask ourselves why the voluntary vaccination rate during other pandemics, such as the H1N1 virus, was so low. Or, in other words, why would someone refuse a vaccine that could save their life?

In August 2017, France's Ministry of Health announced its decision to introduce mandatory vaccination for children against 11 diseases from 2018. The measure was taken due to the alarmingly low vaccination rates among the population for diseases such as measles.[27] In Spain, where vaccination is not mandatory, childhood vaccination rates are the highest in Europe (95–98% for childhood vaccines), but taper off slightly in adolescence (particularly boosters). The lowest vaccination uptake is for the seasonal flu vaccine (54% in 2018).[28]

The situation in France is not unique to that country. Other European countries have seen their vaccination rates decreasing year on year.[29] There are a number of factors that explain why some people's perception of vaccination has changed[30]: there is

a sense that vaccination programmes are driven by the financial and business interests of large pharmaceutical companies, which put pressure on public institutions and governments[31]; user deaths are related directly to the vaccines rather than being perceived to be simple coincidences[32]; the at times alarmist reporting by the media of the risks and side effects[33]; healthy individuals are generally more afraid of the risks associated with the vaccines themselves than with the use of medicines to treat the disease, because the decline of the diseases targeted by the vaccine has distorted the perception of their severity due to ignorance, as was the case with the measles outbreak in many European countries last summer[34]; there is a certain degree of distrust of scientific knowledge, which is perceived to be ever-changing and outdated with each new discovery.[35] In the specific case of COVID-19, these two scenarios will give rise to different situations of trust. On the one hand, the first vaccines to be approved will not necessarily be the safest or most effective. This may cause many people to question whether or not to have the vaccine. On the other hand, during the second mass vaccination phase, the efficacy data of the initial vaccines will be available and the ones with the best safety and efficacy data will be able to be administered, increasing people's trust in them. The above scenarios include the possibility of different vaccines being available in different countries, or even in different regions of the same country. Trust in the vaccines is also going to depend on how the promotion and perpetuation of conspiracy theories surrounding COVID-19 and its vaccines by *fake news* spreads and develops. All these factors are going to have an impact on the population's level of trust/distrust of institutions and the COVID-19 vaccines.

The issue of institutional trust

The population's trust in public health systems is a critical aspect that affects the development and maintenance of health and individual, community and social well-being. That is why healthcare professionals and politicians in particular have to take the concept of "institutional trust" seriously[36] if they are to improve both the general population's and their public health systems' commitment to health.

Both the theoretical and empirical literature show that today's societies are built on very low levels of trust.[37,38] There are two types of trust in our societies: interpersonal and institutional. Interpersonal trust is determined by past interactions that people may draw from to make decisions about future interactions. In other words, a person will learn whether or not to trust someone in the future based on their past experiences. Institutional trust is defined as the trust that people place in a system or institution such as a government, political party, non-governmental organisation or a particular public or private organisation. Institutional trust is based on personal experience, particularly any negative experiences that a person may have had in their life, not so much with the institution, but with the people representing the institution.[39] Research shows that in times of crisis, interpersonal trust tends to increase as institutional trust decreases.[40]

Institutional trust is one of the most critical elements when implementing mass vaccination programmes,[41] not so much because users distrust the public health system, but rather because they distrust government recommendations.[42] Maintaining institutional trust is key to the success of mass COVID-19 immunisation programmes. A clear example of this can be seen in the low vaccination uptake during the H1N1 pandemic. Increased scepticism of the vaccination was caused by a lack of trust in the institutions involved in the vaccination during the H1N1 pandemic. This, combined with conspiracy theories and speculation that governments' response to the pandemic was driven by the commercial interests of large pharmaceutical companies, resulted in the resounding failure of immunisation programmes in most countries.[31]

There can be no doubt that both interpersonal trust as well as institutional trust have changed as a result of the COVID-19 pandemic. Studies suggest that interpersonal trust has increased and institutional trust has fallen[43] during the COVID-19 pandemic. Levels of institutional trust must increase when introducing both the initial vaccination programme for high-risk groups, as well as the subsequent mass vaccination programme. Restoring institutional trust will be key to achieving herd immunity vaccination levels.

Proposals for political action

From the perspective of first person ethics based on personal responsibility, at least two changes are required before competent governments can consider introducing mandatory COVID-19 mass vaccination programmes.

The first is for each citizen to rediscover their leading role in prevention policies and, more specifically, in health-related decision making. It is not the role of the government to decide for the individual. Rather, each individual must assess whether their decision not to get vaccinated is driven by a desire to preserve both their own "health" as well as the health of the community. From this first person ethics perspective, individuals will understand that it is "their moral responsibility" to get vaccinated against COVID-19 because it is a valid way to try to ensure both individual and community health.

The second change concerns the role of governments. Responsible governments must promote prevention policies based on the ethics of individual responsibility in order to increase institutional trust and thereby reduce any possible mistrust of the COVID-19 vaccine. When a person decides not to have the vaccine, their intention is clearly not to spread the disease, but is instead based on a fear and mistrust that the vaccine may not be good for their health. In this light, responsible governments must implement a series of initiatives aimed at strengthening institutional trust:

- Guarantee a policy of correct scientific information concerning the efficacy and safety of COVID-19 vaccines. John M. Barry wrote, "In the next... pandemic, be it now or in the future, be the virus mild or virulent, the single most important weapon against the disease will be a vaccine. The second most important will be communication."[44]
- Plan for well-trained healthcare professionals, particularly general practitioners and paediatricians, to offer the vaccination to health system users.
- Remove all socioeconomic barriers in order to grant all citizens access to the COVID-19 vaccination programme.
- Prepare an appropriate regional and national disease control system.
- And appoint a body to be politically and scientifically responsible for the introduction, distribution and monitoring in the public health system of new COVID-19 vaccine(s), both during the initial vaccination programme for high-risk groups, as well as the subsequent mass vaccination programme.

All of the above are appropriate actions that we propose to increase institutional trust among the general population once a COVID-19 vaccine (or vaccines) becomes available. These measures will help each individual to assume their personal responsibility, both during the priority vaccination phase (healthcare professionals + at-risk groups) as well as during the subsequent mass vaccination phase. These measures will ensure that sufficiently high COVID-19 immunisation levels are reached through voluntary vaccination.

Conclusion

Before responsible national and regional governments can implement COVID-19 vaccination campaigns in the various future scenarios envisaged, levels of institutional trust must increase among the general population to guarantee the success of any vaccination programme(s) introduced. This will be the only way to achieve the herd immunity levels required to combat this pandemic. This will only be possible if, together with the specific measures that we propose governments should implement, a concept of prevention is promoted that encourages individual ethical behaviour aimed at securing the health 'good' both for the individual and for their community. This concept of prevention, based on individual responsibility, should include all measures to prevent the spread of COVID-19, as well as vaccination measures. The success of future COVID-19 vaccination programmes will depend on the uptake of this ethic of responsibility, both by individuals and by the various governments involved.

Author contributions

The two authors were involved in the conception and design of the project, as well as its critical review. The first author, Fermín Jesús González-Melado, was responsible for the final drafting of the text in Spanish. The two authors approved the final version for publication and are responsible for all aspects of the manuscript.

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Conflicts of interest

The authors declare that they have no conflicts of interest.

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