Vaccines against Covid-19: Two ethical dilemmas to consider

Las vacunas contra el Covid-19: dos dilemas éticos a considerar

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https://doi.org/10.36105/mye.2021v32n1.06

Abstract

The Covid-19 epidemic has altered and redefined the capacity of health systems around the globe, while being a challenge for bioethicists who must focus on issues such as the ethical process of vaccine development, and the strategies to be followed, to ensure fair and equitable distribution of these vaccines. Human challenge trials and their ethical implications are discussed, as a possible way to accelerate the availability of vaccines against Covid-19. Another ethical problem that is discussed is the global dilemma that will have to be faced to ensure a universal and accessible vaccine. Some viable strategies for the distribution of vaccines, both worldwide and at the local level are presented. Different philosophical viewpoints are presented regarding both problems, offering diverse arguments and answers to the ethical dilemmas exposed.

Keywords: SARS-CoV-2, vaccine development, human challenge trials, ethical distribution.

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Reception: September 20, 2020. Acceptance: October 15, 2020.

Introduction

The year 2020 brought with it the most extensive and deadly pandemic on record in human history. SARS-CoV-2, which was later associated with the name of coronavirus disease, Covid-19, as its clinical manifestation, came to alter and redefine the capacity of health systems worldwide. In addition, it gave a preponderant role to bioethics, given the dilemmas derived from the management of the pandemic. Among the many challenges to be faced are the allocation of scarce resources in the medical field, the ethical management of patients and, in the particular case of later stages, the development of drugs and vaccines capable of fighting the disease.

Ethics in research applied to vaccine development is a field that has been analyzed for many years, and in which the protocols to be followed by the pharmaceutical industry are well established. The discussion now focuses on some ethical issues that may arise during the research and development stage of vaccines, independent of those already regulated in research ethics, and on the dilemmas that will undoubtedly be faced when the vaccine distribution stage is reached.

First, the process for producing a vaccine from the initial stages of research to its approval for marketing is outlined. In the second part, it is analyzed the strategy of direct exposure tests to the virus as a possible way to accelerate the availability of the vaccines against Covid-19, and its ethical implications. Finally, it presents the global problems that will have to be faced to guarantee a universal and accessible vaccine to all, and some strategies of distribution of the vaccines at a local level, which ensure an ethical and fair process for all the members of society.

1. The development process of Covid-19 vaccines

Vaccines are the most «cost-effective» way to control the Covid-19 pandemic, and international efforts have focused on producing a

vaccine that can soon be distributed globally. At the time of writing, there are more than 165 SARS-CoV-2 vaccines in various stages of research and development. Thirty-one of them are already in the human testing phases (1). Recent estimates indicate that the first vaccines will be available in 12 to 18 months (2).

For the development of this type of vaccines, different techniques are being used, most of which are focused on the *spike* proteins, which cover the surface of the virus, and which are the key proteins that allow the entry into human cells. The different types of vaccines use the inactivated or attenuated complete coronavirus, the viral genetic material, either DNA or RNA, other viral vectors, such as adenovirus, or fragments of the virus' protein (3).

For the public to be confident that the Covid-19 vaccines under development will be truly safe and effective there must be a process of extreme vigilance that meets the highest global scientific and ethical standards (4). The protocols in this regard are very strict, and only those vaccines whose results can be verified by peer agencies, and that make their findings transparent, should be approved for application to the population.

The process of developing a vaccine goes through several phases. It begins with the preclinical stage, in which the vaccine's immune response is tested in animal models. It then moves on to the safety phase 1, in which the vaccine is applied to a small group of people to test the safety and dosage of the vaccine, and the stimulation of the immune system in the volunteers is tested. In phase 2, an expanded study is conducted, with hundreds of people testing the vaccine. Phase 3 corresponds to efficacy tests, where the vaccine is applied to thousands of people, evaluating how many individuals are infected compared to people in the control group receiving a placebo. In this stage, it is checked if the vaccine protects against the virus and it is revealed if it presents side effects that have not been detected before. Volunteers who are given the vaccine continue with their normal activities, and come into con-

tact with the virus in a random way during their daily lives. Phase 3 is the longest phase of the study, and takes the most time, because it must test the effectiveness and safety of the vaccine in a large group of volunteers, many of whom take precautions to avoid being infected.

The dumbbell that takes the lead in the race to produce the vaccine is that of the University of Oxford and the pharmaceutical company AstraZeneca, which proposes a non-replicative viral vector as a model for its vaccine (5). It is expected that this study will obtain the results of phase 3 by the end of 2020.

Given the urgency of the Covid-19 pandemic, many scientists and bioethicists have proposed that Phase 3 vaccine development be based on evidence of direct exposure to the virus, to shorten the time that vaccines may be available.

2. Tests for direct exposure to SARS-CoV-2

Human challenge trials are a type of clinical study, in which volunteers are directly exposed to the pathogen, to test the efficacy of a drug or vaccine under development. Conventional vaccine and drug development protocols are very long and usually take several years, especially in phase 3. This is because enough time has to pass for the volunteers to be exposed to the virus naturally, so that it can be determined if the vaccine worked, as it should, and if, among other things, it produced adverse effects.

With the direct exposure test, the time of the study is significantly shortened, since the volunteers are exposed directly to the virus in a deliberate way, and in very few weeks, the toxicity and immune response to the vaccine can be determined, when compared to a control group that receives a placebo. Other advantages of this method are that fewer participants are needed to obtain preliminary results of the vaccine's efficacy and safety, and that it allows

comparisons between different candidate vaccines to determine which is more effective (4). In this way, the response to conditions such as the current pandemic can be made more rapid and efficient.

In 2016, Leiden University Medical Center in the Netherlands organized an international, independent workshop to discuss the opportunities and challenges presented by direct exposure testing. Clinical researchers, scientists, regulators, and funders attended the workshop from 22 countries. During the workshop, the importance of this type of evidence for critical information about disease mechanisms and the efficacy of new vaccines was discussed. The safety of these studies was emphasized as it reduces the number of participants and the time needed to develop the vaccines (6).

Notwithstanding the above, direct exposure evidence presents a number of ethical dilemmas that must be addressed before implementation (7). A major criticism focuses on the potential exploitation of economically vulnerable populations to benefit from participation in such studies in exchange for monetary incentives. This criticism is not exclusive to direct exposure trials, but also applies to all clinical trials conducted with any new drug or vaccine.

The success of clinical research depends on the participation of volunteer subjects. According to the ethical guidelines of the Council for International Organizations of Medical Sciences (CIOMS), financial or material incentives are essential to induce individuals to participate in clinical research projects that are inherently beneficial (8). Monetary compensation appeals to those participants who are altruistic, confident in the goals of the study, and possess the physical characteristics needed for the particular research.

Some authors say that many participants seek ways to meet their financial needs through volunteering for these types of medical studies. By offering monetary incentives as a strategy to recruit volunteers, the most vulnerable and poor in society are exploited. They propose that, in order to ensure that people with low incomes participate in these types of studies; volunteers should be com-

pensated sufficiently to cover their daily expenses, without offering them additional payments that result in coercive decisions (9).

Adair Richards, from the University of Warwick, mentions some other ethical arguments against the use of direct exposure tests for the development of a vaccine against Covid-19: a) there is a significant risk of death or serious harm to health for study participants; this point is debated by other authors; b) the experiments may not result in a viable vaccine; c) it may be impossible for an individual to give truly informed and free consent; the participant may be subject to psychological pressure as a result of his or her own fear, the desire to make a social contribution, or to receive social pressure from friends or society to speed up vaccine development; d) conducting these experiments may damage the reputation of the research and of the researchers involved, which would be reflected in a decrease in public confidence in these studies; and e) these investigations could become a slippery slope, where potentially unethical experiments begin to be licensed (10).

Although, in the first instance, evidence of direct exposure would appear unethical, there is a consensus among the philosophical community that intentionally infecting study participants would be ethically acceptable in certain circumstances, such as those prevailing in the design of current studies, and in the context of the severity of the SARS-CoV-2 pandemic we are experiencing (6, 11, 12).

One of the arguments behind the ethical approval of direct exposure studies for the Covid-19 vaccine is that if a volunteer were correctly and fully informed about the risks and benefits of participating in such a study, it would be permissible for him or her to be enrolled in the study. Even if the project were potentially dangerous, even if it were minimal, the results would reduce the time required to develop an effective vaccine for all those exposed to the virus. If we do not accelerate the time that a safe and effective vaccine is available, the virus will continue to be a threat to the population and especially to health care workers, the elderly, and those with comorbidities that increase their risk of not surviving

infection (11). When balancing the risks and benefits of direct exposure testing, both for volunteers and the general population, it appears that the benefits far outweigh the risks.

For the philosopher Peter Singer, we must be consistent with our attitude to the concept of risk. He points out that, in other circumstances such as, for example, in the donation of a kidney, the action is considered laudable, even though it represents a risk of one in 3,300 of dying because of the intervention. Nevertheless, kidney donation is not prohibited. The probability that a young, healthy volunteer will die because of a direct exposure test is less than one in 10,000 (11, 13). Therefore, volunteers in these studies should be recognized for putting their health at risk to save others.

These volunteers should also be considered to have made the decision to risk their health on their own. As stated by Eyal in his article: *Adults can legitimize many interventions in their bodies and health, which are normally prohibited, by simply saying 'Yes' with full understanding and willingness* (14).

The process of giving informed consent is outlined below, to be considered rigorous and to conform to all established ethical standards.

Another argument in favor of direct exposure testing is based on the number of lives that can be saved with a vaccine that is available in a short time (12, 14). Even with the mitigation measures that have been implemented globally, it is estimated that deaths from Covid-19 will reach several million in one year (15). If the time to produce an effective vaccine is accelerated, the number of victims of the pandemic could be significantly reduced, in addition to mitigating the social and economic effects that have arisen because of government distancing measures.

The World Health Organization proposes eight ethical criteria for direct exposure studies to be accepted,[1] including the following:

1. *Scientific justification:* there must be a solid scientific justification for carrying out studies with the SARS-CoV-2 virus. This is summarized in that the results obtained could not be obtained so

efficiently or expeditiously with studies based on other designs that involve less risk for participants (14), and therefore influence a greater and earlier benefit to public health.

2. *Evaluation of risks and possible benefits*: The possible benefits expected should be much greater than the risks. Quantifiable risks and benefits should be assessed in three main groups: a) the participants, b) society at large, and c) those in contact with the participants (16).

3. *Site selection*: Studies should be located where the research can conform to the highest scientific, clinical, and ethical standards; they should ensure that they could provide high-quality medical care, including intensive care services, long-term follow-up of participants, and full compensation for any trial-related harm.

4. *Participant Selection*: Researchers should ensure that participant selection criteria limit and minimize risks. Initial studies should be limited to groups of young, healthy adults between 18 and 30 years of age (13), and exclude those who are at increased risk of infection from their background, resulting in social injustice and exploitation, or who are vulnerable in any way.

5. *Informed consent*: studies should include a rigorous informed consent, ensuring that participants fully understand all relevant information. Consent should be reaffirmed periodically, when important new information emerges, to confirm good understanding by participants and their voluntary adherence to the study. Some authors, such as Richards, propose that participants have a sufficient period to reflect on the decision to join the study, after being informed of the risks and benefits; in addition, they should have the possibility of withdrawing from the study at any time, and still benefit from the best available medical care (10).

3. Ethical distribution of vaccines

There is great expectation from the global community as to when an effective vaccine against Covid-19 will be available. Once the

clinical, technical and ethical difficulties of the research for its development are overcome, a second stage will come in which there will be conflicts with distribution and administration, and fair access to the whole population.

The inherent differences between developing and developed countries present a basic inequality for the whole process of fair access to the vaccine for everyone. Nationalistic, geographic, and commercial factors will make it difficult to achieve equitable access to all populations, both in terms of time and volume of vaccines (17). Governments are likely to give priority to their own populations, given the high investments they have made in the production processes of both vaccines and anti-Covid-19 drugs.

On April 24, 2020, the World Health Organization (WHO), in conjunction with humanitarian and private sector organizations, reaffirmed its commitment to ensure fair and global access to *safe, good quality*, *effective and accessible vaccines against Covid-19 and, therefore, to ensure that in the battle against Covid-19, no one is left behind* (18).

The development and mass distribution of an effective vaccine is of global interest. Without access to it, SARS-CoV-2 will continue to circulate freely around the planet, worsening the serious health, social and economic consequences that have already permeated the world. Governments have the greatest incentive to collaborate on multinational plans when research is conducted in one country and vaccine manufacture takes place in another. Thus, global cooperation is necessary and imperative. Distribution must be guided by accurate information about the size and risk profile of affected populations; by each country's capacity to implement immunization campaigns; and by epidemiological monitoring data, as success depends on countries collecting and sharing relevant data (19).

As an example of the above, there is the recent news of Russia's invitation to Mexico to be part of phase 3 of the Sputnik vaccine against Covid-19. Mexico's participation will be through the inoculation of between 500 and 1,000 volunteers. This collaboration

is part of the international collaboration strategy, through which Mexico will be guaranteed timely access to vaccines that prove to be effective and safe (20).

Some authors propose four principles, under which vaccine distribution is currently carried out: a) *ability to develop and purchase*: those countries that produce the vaccines, or have the purchasing power to buy them, are the ones that receive them; b) *reciprocity*: in many cases, developing countries participate in the vaccine production process, but do not benefit from them; c) *ability to implement mass vaccination programs*: because the process of mass vaccination of the population involves technical considerations such as specialized transportation, sufficient trained personnel, and a strong health infrastructure, vaccines are distributed in those countries where benefits can be maximized and waste of this scarce resource is reduced; and d) *distributional justice for developing countries*: although this principle requires the equitable distribution of scarce resources, the conditions of the current pandemic make such distribution sub-optimal or even impossible because of the principles mentioned above (21).

If the principles outlined above were examined, one would expect an unethical and uneven process in the accessibility of a potential SARS-CoV-2 vaccine to poor and emerging countries. Therefore, a governance framework that promotes equitable access to a vaccine for Covid-19 must be in place and trusted by the international community. Within this framework, political and commercial influences should be avoided. The establishment of this framework requires the coordination of various institutions, investors, governments and pharmaceutical companies. In addition, the WHO must have a central role in implementing the agreements, based on its experience and credibility in promoting equitable access to medical technologies. Pharmaceutical companies and those entities that support the distribution of this type of technology in developing countries, such as Gavi,[2] CEPI[3] and the Global Fund, should

also be involved (19). Both Gavi and the Global Fund have a similar policy for country eligibility, based on income classification and disease burden. As an example, on August 7, 2020, collaboration was announced between SII –the world's largest vaccine manufacturer–, Gavi, and the Bill & Melinda Gates Foundation to accelerate production and distribution of up to 100 million doses of Covid-19 vaccine in low- and middle-income countries (24).

It is important to ensure a good financing mechanism for vaccine production and distribution in developing countries. One of the mechanisms that can be used is advance purchase commitments (APCs), supervised by WHO. This mechanism ensures a viable market for the vaccine in question, once it is developed. Funds could come from both governments and philanthropic contributions, as is the case in Mexico with the agreement between the Carlos Slim Foundation and the pharmaceutical company AstraZeneca. In this case, the agreement guarantees the production and distribution, without economic benefit in Latin America, of the vaccine developed by the pharmaceutical company, with an initial availability of 150 million doses (25).

According to Bollyky, Gostin and Hamburg, the benefits of obtaining a vaccine carry certain obligations. Among these obligations are: a) a commitment to participate in scientific collaboration; b) transparency; c) sharing of data and biological samples; d) sharing of data about vaccine safety and efficacy; e) governments must commit to eliminating vaccine export restrictions; and f) a commitment to ensure equitable distribution of the vaccine. This ensures an accessible product for the most vulnerable and marginalized groups, distributed based on each country's public health needs rather than its purchasing power.

Another issue in bioethics is the fair distribution of vaccines within a population, once they are available on the market. What criteria should be used to supply them? Which people should receive them first within a population? Who has priority, and why?

Vaccines, unlike medicines, are unique in that they not only protect the recipient, but also protect those around them. Most bioethicists agree that health workers on the front lines of the battle against Covid-19, and other essential workers, such as orderlies, cleaning personnel in hospitals, etcetera, should be the first to have access to the vaccine. Healthcare workers and other workers who provide essential services are constantly exposed to the virus, and by having the right to work in the safest possible conditions, they also have the right to priority access to the vaccine. In addition, they can be a source of infection for others; by vaccinating them, the health of the patients they come in contact with is also ensured (26).

The criteria most frequently used for the distribution of scarce resources in the health field are the maximization of expected utility, and the principle of distributive justice, giving priority to those with the greatest needs (27, 28). Under these principles, the elderly and populations that are vulnerable due to other associated morbidities would be the second beneficiaries of the vaccine.

In general, the above position regarding the order of vaccine distribution is the one that reaches the greatest consensus. However, some express the opposite position, explaining that those who should receive the vaccine are children, in order to maximize the benefits of indirect immunity for the elderly and for other vulnerable groups and those with comorbidities; it is a matter of vaccinating the young to protect the old and the sick (29). They are based on the premise that the end of the emergency will be achieved when there is an adequate vaccination policy that reaches people in the most effective way, and not when a vaccine is available. The number of deaths that can be prevented measures the effectiveness of the program. This approach depends on the type of vaccine developed, and the adverse effects and effectiveness it demonstrates, in both children and older adults.

Conclusion

The emergence of new diseases leads us to consider unconventional approaches to solving the problems that arise. The Covid-19 pandemic has been no exception.

Regardless of the science, which has been challenged to find drugs and vaccines to deal with SARS-CoV-2 disease, bioethics has taken a leading role during the pandemic. It is no longer just a question of what kind of molecule is developed, but what are the right ways to do it, in order to do the best good for everyone. This applies both to the processes of developing potential vaccines and to the fair and equitable distribution of that resource globally. The hope then is to find the best vaccine, developed in the best way and with the best accessibility for all.

Bibliographic notes

[1] To review the eight ethical criteria for direct exposure studies proposed by the World Health Organization, as well as the potential risks and benefits to society, to participants and to third parties in contact with them, see (4).

[2] *Gavi, the Vaccine Alliance*, is a joint project between the World Health Organization, UNICEF, the World Bank and the Bill & Melinda Gates Foundation. Its mission is to save lives, reduce poverty and protect the world from the threat of epidemics. It has also helped vaccinate more than 760 million children in the world's poorest countries, preventing more than 13 million deaths (22).

[3] CEPI (*Coalition for Epidemic Preparedness Innovations*) is a global partnership launched in 2017 to develop vaccines to combat future epidemics. Together with Gavi and WHO, they launched COVAX, to ensure equitable access to Covid-19 vaccines and thus end the acute phase of the pandemic by the end of 2021. It currently has the largest portfolio of potential vaccines, with the participation of 172 economies worldwide, to provide equitable and safe access to vaccines once they are approved (23).

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