COVID-19 Vaccinations: Medical, Ethical and Legal Aspects

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ABSTRACT

Background: Following the consideration of COVID-19 as a pandemic by the World Health Organization (WHO), developing new vaccinations against COVID-19 was the dream of humanity. Leading companies competed to achieve this task. Several vaccinations have been developed relatively quickly.

Objective: The aim of the present study was to review the literature regarding medical, ethical, and legal aspects of COVID-19 vaccination.

Methods: Literature was reviewed regarding various issues of COVID-19 vaccinations.

Results and Discussion: The main findings showed that a dilemma exists in literature regarding the ethics in general in keeping the rights of individuals to retain their rights to receive the vaccine and considering receiving the vaccination as compulsory.

Conclusion: As the disease has become pandemic with high mortality rates, keeping the safety of the community has received the priority on individual rights, and many countries considered compulsory vaccinations.

Keywords: COVID-19, vaccination, ethics, legal aspects, medical aspects.

1. THE NEED FOR COVID-19 VACCINATION

It has been determined that the most effective preventative measure that is currently available is the vaccination against COVID-19. This has led to fewer deaths and hospitalizations, which has made it possible to combat the pandemic by combining it with non-pharmacological interventions. Additionally, this has resulted in the pandemic being able to be contained. Even though most adverse reactions to vaccination present with mild symptoms and serious effects are extremely rare, individuals who have experienced them have the right to take legal action against the healthcare workers (HCWs) who administered the vaccination. This is the case even though most adverse reactions to vaccination present with mild symptoms. In order to find information on vaccine injury compensation programs, new laws or policies to protect HCWs administering vaccinations that were introduced during the COVID-19 pandemic, and policies on mandatory vaccinations, we conducted a search for the three most populous countries on each continent. This search was conducted in order to find information on the pandemic [1].

2. THE IMPACT OF COVID-19 ON HEALTH CARE WORKERS

Since the beginning of the first half of the year 2020, due to the global health emergency caused by COVID-19 patients, healthcare workers (HCWs) have been experiencing high levels of stress due to the increased amount of work they have to do [2]. Because of the gravity of the situation, every country on the planet is contributing to the care of COVID-19 patients. The network of health care workers who were a part of the emergency management system served as the foundation on which the response to the COVID-19 outbreak was built. As a consequence of this, it is of the utmost importance to preserve their physical and mental health to the fullest extent possible, in addition to making certain that they are protected legally and by regulatory authorities [3]. Indeed, health care workers were required to perform their jobs despite a high level of scientific uncertainty, particularly in the early stages of the pandemic and in the area of COVID-19 vaccinations. This was especially the case during the time when the pandemic was at its most severe. They were put in the position of having to choose, in some instances, between the protection of their own legal safety and the protection of the health of patients “at their own risk.” This choice was imposed upon them. Most countries continue to have a low vaccination coverage [4], even though the COVID-19
vaccination is one of the safest and most effective measures to prevent infection, hospitalization, and death. Indeed, the dissemination of misleading information and breakdowns in communication helped contribute to the growth of a distrust not only of vaccinations but also of the medical professionals who give them [5].

3. THE ADVERSE EFFECTS OF COVID-19 AND LEGAL FRAMEWORK

The COVID-19 vaccination can cause some unwelcome side effects in some people, just like any other medical treatment. This is true for both children and adults. Even though most of these reactions exhibit mild symptoms and severe effects are extremely uncommon, it is important to keep in mind that they can give rise to legal action against the healthcare operator who administered them [6]. Both national and international institutions have made efforts to increase vaccine coverage and confidence in the COVID-19 vaccination by promoting vaccine injury compensation programs, which are also known as VICPs. At the same time, specific laws have been enacted to protect physicians from the legal responsibility for injuries caused by the administration of vaccines. These laws have been enacted in several countries. In Europe, for instance, the countries of France and Italy have made use of these tools, with the former nation establishing a specific compensation system for COVID-19 vaccine-related injuries and the latter nation establishing a criminal shield [7]. In both countries, the compensation system for COVID-19 vaccine-related injuries was established by France, while the criminal shield was established by Italy. Both the World Health Organization (WHO) and the United Nations worked to increase awareness of the COVAX No-Fault Compensation Program on an international scale. This program is an example of a VICP, and its objective is to provide high-risk and vulnerable populations with vaccines that are both safe and effective against COVID-19 [8].

3.1 Who may possibly be held accountable for the results of an adverse effect?

In Australia, the potential liability for an adverse event connected to a COVID-19 vaccination will depend on the circumstances of the adverse event; nonetheless, the potential liability could include the following:

In the context of clinical trials for vaccines, the sponsor of the clinical trial has a duty of care to the people who are participating in the trial to ensure that the experiment is carried out in accordance with the protocol and that the necessary consent is obtained from the people who are participating in the trial. In addition, the sponsor must ensure that the necessary consent is obtained from the people who are participating in the trial [9]. The duty to warn of contra-indications and risks – this duty is likely to be held by the health professionals who administer the vaccine to the patient (and their employer, which could be a hospital or clinic), in addition to the manufacturer, who publishes product information along with the packaging of the vaccine [9].

The responsibility of ensuring that the product is stored and shipped in accordance with the guidelines provided by the manufacturer, which may include specific temperatures and the use of multi-dose vials (where appropriate), it is highly probable that not only the hospital or clinic, but also the supplier chain, will be liable for fulfilling this requirement [9].

When adhered to, the Good Manufacturing Practice (GMP) guidelines ensure that therapeutic items are of high quality. These guidelines consist of a set of concepts and procedures. The legislation that governs therapeutic goods places the obligation, in the form of a regulatory requirement, on the producer to produce the medication in compliance with regulatory requirements, one of which is known as Good Manufacturing Practice (GMP). The acronym GMP stands for "good manufacturing practice," and it refers to a collection of guidelines and processes that are designed to ensure the quality of medicinal products. Since it is not possible to test quality after it has been introduced into a batch of product, quality must instead be integrated into each batch of product at each step of the production process. This is a fundamental principle that must be adhered to in order to maintain good manufacturing practice, also known as GMP [9]. Good Manufacturing Practice for Medicines and Good Manufacturing Practice for Human Blood and Tissues are both examples of GMP; however, these standards are distinct from one another due to the fact that they apply to different kinds of therapeutic goods. Good Manufacturing Practice for Blood and Tissues and Good Manufacturing Practice for Medicines are both examples of GMP [9].

The obligation that is placed on the sponsor of the therapeutic good to comply with laws pertaining to the administration of therapeutic goods (this includes laws pertaining to the supply, packaging, and promotion of the goods), as well as the obligation that is placed on the sponsor to provide accurate information concerning the safety and efficacy of the therapeutic good to the Australian Therapeutic Goods Administration as part of the process of applying for provisional registration.

The obligation to guarantee that the drug is free of faults (other than declared contraindications), which is likely to rest on the supplier; the duty to ensure that the drug does not pose a risk to users; and the duty to ensure that the drug is not harmful when taken as directed [9].

There is the potential for legal action to be taken against the government in the event that it engages in any of the activities outlined above, as well as in the event that it chooses to mandate vaccinations for all citizens. We have taken note of the fact that the government has been following the medical advice in line with the suggestions made by its medical professionals. This is something that we have taken into consideration. This is necessary in order for the government to live up to its responsibilities, as specified in the legislation governing civil liability in Australia [9].
4. COMPULSORY VACCINATION AGAINST COVID-19 AND BIOETHICAL-LEGAL DEBATES

Both the legal and bioethical communities have, for an interminable amount of time, been engaged in a contentious debate regarding the compulsion of individuals to undergo particular medical procedures. Both the right to individual self-determination and the duty to defend and maintain collective safety, both of which are protected in some way by international treaties and constitutional provisions, conflict with one another, and as a result of this conflict, both rights threaten to be put in jeopardy. Both rights are safeguarded in some way by international treaties and constitutional provisions.

The global health crisis brought on by the COVID-19 pandemic has pushed the question of the legitimacy of imposing compulsory vaccination into the center of the complex debate on the various aspects of pandemic health policies. This debate is complicated by the fact that there are many different aspects of pandemic health policies. At this time, there are only four countries in the world that mandate the administration of the COVID-19 vaccine to each and every one of their citizens. These nations are the Federated States of Micronesia, Tajikistan, and Turkmenistan. Indonesia is also included in this group. Because of the decree-law that was approved on the 5th of January 2022, which imposed vaccination compulsory for everyone over the age of 50, Italy was the first country in the European Union to introduce this obligation. On the eighth of January in 2022, it became a law that applied to everyone who was fifty years old or older. Greece and Austria have both made the decision to take a path that is comparable to this one, and the beginning of their respective obligations will take place on the 16th of January 2022 (for citizens over the age of 60) and the 1st of February 2022. (Applicable to citizens of any age). However, “selective” forms of compulsory vaccination, which are aimed at particular groups of people, most notably healthcare professionals, are already provided for in a large number of nations that consider themselves to be civilized. These “selective” forms of vaccination are aimed at preventing the spread of disease among those individuals who work in the medical field [10].

On November 4, 2021, the World Health Organization (WHO) made the official announcement that the world had entered the fourth wave of the pandemic. This news was met with widespread alarm around the globe. They also determined that Europe is the primary location where the new phase of the epidemic is spreading. The percentage of the population that has been fully vaccinated against COVID-19 in industrialized countries is encouraging; 70% of the population in the United States and Canada, 67% of the population in South America, 64% of the population in Asia, and 62% of the population in Europe have received at least one dose of the vaccine. In addition, the percentage of the population that has been fully vaccinated against COVID-19 in industrialized countries is encouraging [11]. However, the impact of COVID-19 vaccination hesitancy could be a major barrier to overcome during this crucial phase of the fight against the pandemic. The global epidemiological trend has brought the issue of mandatory vaccination, which was momentarily neglected during the summer break due to the lack of school, back to the attention of national institutions. This is significant because the summer break is traditionally a time when children do not attend school. Vaccination against COVID-19 is already required in a number of countries for particular categories of workers, the majority of which are healthcare professionals. On the other hand, a mandatory vaccination program that is extended without discrimination to the entirety of the population is still largely unprecedented [10].

5. HISTORICAL PERSPECTIVES OF COMPULSORY IMMUNIZATION

In the latter half of the 18th century, when the United States was during its Revolutionary War, General George Washington gave the order for all of his soldiers to be immunized against disease. This event is regarded as the beginning of the very first compulsory vaccination policy in the history of the world [10]. In 1777, it was the marked year that the first person was inoculated with the virus that causes smallpox [Cantey, 2011]. Due to the extremely high mortality rate associated with the smallpox epidemic, it was one of the most terrifying diseases that the Continental Army had to contend with during this time. It varies from 10 to 60 percent in hosts that do not have an immune response. According to the projections made by historians, by the end of the seven-year conflict [12].

During the war, the effects of disease resulted in the deaths of nine times as many soldiers (63,000) as were lost as a direct result of the fighting that took place (7,000) [13]. It is to Washington’s credit that he swiftly recognized the seriousness of the disease and devised an effective immunization strategy for his army. This was a significant accomplishment on Washington’s part. As a direct consequence of this, Washington’s troops enjoyed a significant advantage over those of their opponents, both in terms of their physical capabilities and their mental fortitude. A few years later, in 1796, English physician and naturalist Edward Jenner officially tested the first vaccine against smallpox. He did this by injecting a child’s arm with a small amount of pus taken from the bumps of a cowpox-afflicted woman. This was the first time a vaccine had been successfully tested against a disease. Cows and, to a lesser extent, humans can be infected with a form of the smallpox virus known as cowpox. Jenner gave the child in his care an injection in the arm with the pus that had been removed from the cowpox patient’s bumps. As a result of the scientific community’s acknowledgement that the vaccine was both effective and safe, the administration of smallpox vaccinations became widespread throughout Europe, and several nations made the vaccinations mandatory for their citizens. Jenner concluded that inoculation
with the cowpox virus was a secure substitute for inoculation with the human smallpox virus and was similarly effective in terms of protection against the smallpox disease [Riedel, 2005].

As early as 1811, 1812, and 1816, respectively, countries such as Norway, Russia, and Sweden established vaccination mandates for their respective populations [15]. With the passage of the Vaccination Acts in 1840, 1853, and 1867, England became the first nation in the western hemisphere to implement a free, universal, and mandatory smallpox vaccination program. These acts were passed as part of the Vaccination Acts. The text that was written in 1840 stated that patients should be given the smallpox vaccine at no cost to them and that the procedure of variolation should not be allowed to take place [16].

The act of 1856 established penalties for those who did not comply with the rules regarding the vaccination of all children up to the age of five and three months, and it mandated vaccination for all children up to the age of five. The new version of the law that went into effect in 1867 mandated mandatory jail time for those who disobeyed the law and increased the penalties for parents who refused to vaccinate their children [17]. As a result of the outbreak of new smallpox epidemics that occurred in the decades that followed the Franco-Prussian war, several European states decided to make vaccination mandatory for their citizens. In 1905, the landmark decision that legitimized the authority of states to "reasonably" violate personal liberties during a public event was handed down by the Supreme Federal Court of the United States of America. This decision was issued in the United States of America. This judgement gave states the permission they needed to restrict the rights of their citizens [18].

An initiative to develop a strategic plan for the complete and total elimination of the smallpox virus was launched by the World Health Assembly (WHA) in the late 1960s. This initiative ultimately led to the adoption of Resolution 11.54 by the Eleventh World Health Assembly in the year 1958. Smallpox was declared eradicated in 1980 [19]. On January 1, 1967, the World Health Organization (WHO) launched a program to rid the world of the disease known as smallpox. The virus was finally eradicated in the year 1980 as a direct result of the successful implementation of this program. The worldwide campaign against the disease made it possible to eradicate a virus that was responsible for the deaths of 500 million people between the 19th and 20th centuries [20], primarily through the implementation of mandatory vaccinations. This was made possible by the global effort to fight the disease.

6. CONTROVERSIAL REASONS ASSOCIATED WITH COVID-19 VACCINATION

Citizens in most civilized nations are required, beginning when they are still children, to go through a series of vaccinations that are carried out by the government. These vaccinations are spread out over the course of their lives. For instance, in Italy, all children under the age of sixteen as well as children from other countries who are living there by themselves are required to receive ten different vaccinations [10].

Children who are not up to date with their vaccinations are not allowed to participate in the activities that are offered by their schools [21]. The imposition of obligatory health treatments such as childhood vaccinations was always accompanied by a lively debate on bioethics. On the other hand, this debate on bioethics never reached even remotely the proportions of the dispute regarding the obligatory vaccine against COVID-19. This is because COVID-19 vaccines possess characteristics that make their mandatory imposition particularly controversial. The reason for this can be found in the previous sentence. The failure of regulators in a significant number of countries to give their final approval is the most notable of these characteristics. Any pharmaceutical company that is interested in selling their product within the borders of the European Union is required to first submit an application to the European Medicines Agency in order to receive marketing authorization for their product. This is the case irrespective of whether the pharmaceutical company in question is based inside or outside of Europe (EMA). The European Commission has the authority to grant one of three distinct kinds of authorization: an emergency use authorization (EUA), a conditional marketing authorization (CMA), or a standard marketing authorization (SMA). Each of these types of authorization has a specific purpose. These authorizations are granted on the basis of recommendations that are given by the EMA, which carefully evaluates the efficacy and safety profiles of the drug in question [22, 23]. The European Medicines Agency (EMA) gave a positive assessment of the vaccines' safety and efficacy, and as a result, the European Commission has so far granted four conditional marketing authorizations for vaccines developed by BioNTech and Pfizer, Moderna, AstraZeneca, and Janssen Pharmaceutica NV. These vaccines were approved for sale in the EU on the condition that they are used in conjunction with other vaccines. The European Union has given its blessing for the commercial distribution of each of these vaccines. The other vaccines are currently going through a number of different stages of testing right now. When not all of the clinical data for a drug that are required for standard authorization are available, but it is determined that the benefits of placing the drug on the market immediately outweigh the risks related to the temporary incompleteness of the data, a conditional marketing authorization may be granted. This type of authorization allows for the drug to be sold despite the lack of all of the required clinical data for standard authorization. A favorable benefit-risk ratio for the drug is required; all conditions must be present to believe that the pharmaceutical company will be able to provide complete data after authorization; the medicine must fulfill an unmet medical need; and the benefits of the drug's immediate availability to patients must outweigh the risks that are inherent in the fact that additional data are still required.
When these four requirements are simultaneously satisfied, a conditional marketing authorization will be issued. The conditional marketing authorization has a duration of one year, with the possibility of being extended for additional years in the event that it is required. The person who holds the conditional marketing authorization is responsible for several obligations, all of which must be completed within certain time limits that have been established in advance. One of these responsibilities is the gathering of additional evidence to demonstrate that the medication is not only effective but also safe. The marketing authorization can be converted into a standard marketing authorization once the holder of the marketing authorization has fulfilled the imposed obligations and full data confirm that the benefits of the drug continue to outweigh the risks. At this point, the marketing authorization is eligible to be converted. The process for authorizing the marketing of a drug in accordance with the regulatory authority in the United States, the Food and Drug Administration (FDA), has similar characteristics, but it is carried out more quickly due to the implementation of streamlined procedures such as “fast track,” “priority review,” and “accelerated approval.” These procedures are similar in that they have similar characteristics, but they also have similar characteristics.

The United States Food and Drug Administration (FDA) was able to grant final approval of the mRNA vaccine developed by BioNTech and Pfizer on August 23, 2021 for anyone over the age of 16. This was made possible due to the simplification of the process. Prior to that point, a date of 11 December 2020 had been affixed to an authorization for the emergency use of the vaccine, which had made it possible for the vaccine to be sold commercially in the United States [24]. The vaccines that were developed by Moderna and Janssen Pharmaceuticals NV are still being marketed in the United States thanks to an emergency authorization that was granted by the FDA on 18 December 2020 and 27 February 2021, respectively. This authorization allows the vaccines to be sold in the country.

The fact that the etiological agent that causes the COVID-19 disease is relatively unknown and that vaccines had to be developed in an extremely condensed amount of time led to the described criticalities that occurred on the way to the final approval of vaccines. Vaccines had to be developed in an extremely condensed amount of time. Nonetheless, these predicaments were not unnatural in any way. In any case, it is essential to note that the COVID-19 vaccine is the first medication in the annals of world history to have benefited from a "real-life" test of exceptional proportions. This is true despite the fact that the process for marketing approval may vary from country to country. The vaccine has been administered to over 5.5 billion people, and results have shown that both its efficacy and safety profiles are completely satisfactory. This accomplishment took place before the process of obtaining marketing approval. According to information obtained from the EMA, as of the 28th of October 2021, there have been the following numbers of reports of adverse effects following the administration of vaccines: 412,571 reports of adverse effects following the administration of 428,000,000 doses of the Comirnaty vaccine to citizens of Europe (0.09%); 214,528 reports of adverse effects following the administration of 68,800,000 doses of the Vaxzevria vaccine (0.31%); 94,636 reports of adverse effects. The vast majority of adverse effects that were recorded were either mild or moderate in severity [25]. Concerning effectiveness, although COVID-19 vaccines show relatively modest effectiveness in preventing the contraction of viral infection [26, 27], their overall ability to control the onset of serious illness requiring hospitalization and intensive care has been proven by the world’s most authoritative clinical studies. This ability to control the onset of serious illness has been shown to reduce the number of patients who require hospitalization and intensive care. Vaccines against COVID-19 have this ability, which enables them to protect against severe illnesses that require hospitalization and intensive care [28]. On January 27, 2021, the Council of Europe signed Resolution no. 2361, which was titled "Covid-19 vaccines: ethical, legal, and practical considerations." The Council of Europe is the primary international organization dedicated to the protection of human rights, and it is distinct from and independent of the European Union. Resolution no. 2361 was titled "Covid-19 vaccines: ethical, legal, and practical considerations." Within the European institutions, significant decisions have been made regarding the implementation of mandatory vaccination against COVID-19. The document makes it abundantly clear that the possibility of individual states making vaccination against COVID-19 mandatory is eliminated because it expressly forbids the use of the COVID-19 vaccine as a means of discrimination, which makes it abundantly clear that the use of the vaccine as a means of discrimination is expressly forbidden. As it is stated in points 7.3.1 and 7.3.2, the Resolution requires all member states to carry out the following obligations: "... ensure that citizens are informed that the vaccination is not mandatory and that no one is under political, social, or other pressure to be vaccinated if they do not wish to; ensure that no one is discriminated against for not having been vaccinated, due to possible health risks or not wanting to be vaccinated" "... ensure that citizens are informed that the vaccination is not mandatory and that no one is under political, social, or other pressure to be vaccinated if they do not wish to so; (36). On the other hand, this Resolution, which is being issued by the Parliamentary Assembly of the Council of Europe, is not a source of law and is therefore neither binding nor mandatory for the various member states individually [19].

7. CONCLUSION

Emerging health problems, such as COVID-19, are accompanied by a dilemma among the general community. This dilemma is caused by the existence of contradicting information regarding the disease, as well as the fact that people developed negative attitudes towards the disease and vaccine. There have been disputes between
laws and bioethics. Protecting the lives of the citizens should be the first priority for those who make decisions in the government, and this should be given the utmost importance. In the same vein, the rights of individuals to make choices regarding their own health that are best for them are put in a precarious position under these conditions. Through this research, we were able to show that the interests of individuals ought to take a secondary place to the interests of the general population.

**REFERENCES**


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