RESEARCH ARTICLE

COVID-19 Vaccine Passports: Derogating Non-Derogable Fundamental Human Rights

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Abstract

The global fervor to develop and deliver a vaccine to protect people against COVID-19, the disease caused by SARS-CoV-2, has been extraordinary. COVID-19 vaccine development has been pursued at an unprecedented speed and scale; following the Emergency Use Authorization (EUA) of COVID-19 vaccines, rapid mass vaccination deployment efforts commenced in all earnest. This fervor to get a needle into every arm has now led to the European Commission president calling on the EU's 27 member states to consider mandatory vaccination across Europe. With an intensification in COVID-19 vaccine hesitancy and many refusing to be vaccinated, an important question that arises is whether obligatory COVID-19 vaccination policies are ethical and legal in terms of international human rights norms and standards. Article 4(2) of the International Covenant on Civil and Political Rights which was ratified by 173 States Parties worldwide enumerates a specific list of human rights from which no derogation is allowed even in times of a public emergency. Included in this list of non-derogable rights is a sub-category of internationally recognized human rights known as "physical integrity rights" that includes the right to be free from medical or scientific experimentation. International human rights law is unambiguous that all people should be afforded their non-derogable fundamental human right to free and informed consent. Normative ethical perspectives and legal obligations erga omnes dictate that States Parties should not make COVID-19 vaccination mandatory in breach of International Human Rights Law relating to non-derogable rights that are regarded as core human rights, jus cogens. A bioethics perspective, rooted in fundamental human rights, should play a crucial role in the COVID-19 pandemic.

1. Introduction

The global fervor to develop and deliver a vaccine to protect people against COVID-19, the disease caused by SARS-CoV-2, has been extraordinary. COVID-19 vaccine development and production have been pursued at an unprecedented speed and scale. Following the Emergency Use Authorization (EUA) of a number of COVID-19 vaccines, rapid mass vaccination deployment efforts commenced in earnest. By July 20, 2021, a total of 3,568,861,733 vaccine doses had been administered globally, and as of December 28, 2021, a total of 8,687,201,202 vaccine doses have been administered. [1]

This fervor to get a needle into every arm has now led to discussions about making COVID-19 vaccines compulsory and the European Commission president calling on the EU's 27 member states to consider mandatory vaccination across Europe [2,3]. Many are calling for mandatory COVID-19 vaccinations of all adults and children to be implemented by state and non-state actors such as schools, colleges, private employers, airlines, cruise ships, sports stadiums, concert venues, shopping malls, and others [4]. Some argue that obligatory COVID-19 vaccination can be justified on ethical grounds and recommend penalties for noncompliance and the loss of freedoms and liberties. In contrast, others point out that such draconian actions are illegal and a gross violation of international human rights law.

With the intensification in COVID-19 vaccine hesitancy and many declining to be vaccinated, an important question is whether mandatory COVID-19 vaccination policies not requiring prior free and informed consent are ethical and legal in terms of international human rights norms and standards [5].

Numerous international treaties spell out the specific legal obligations of States Parties to

respect the fundamental human rights of their inhabitants. The important assumptions behind the universally recognized human rights in these treaties are that human rights are:

- a. immutable, not being able to be taken away by any state party
- b. universal, always applying to all persons; and
- c. interdependent and indissoluble, requiring respect for specific individual rights as mutual reinforcement for respect of all rights.

While these assumptions seem to imply that respect for fundamental human rights ought to be absolute, international human rights law provides States Parties an exception, whereby authorities may depart from the assumption of absolute respect for certain human rights during a declared state of emergency. In international human rights law, a state divergence from its legal obligations to respect the fundamental human rights of its people is known as "derogation".

However, the International Covenant on Civil and Political Rights ["ICCPR"] specifies a list of seven fundamental human rights from which no derogation is allowed, not even during a declared state of emergency [6]. Included in all lists of non-derogable rights is sub-category of globally recognized a fundamental rights known as "physical integrity rights". These rights are "the entitlements individuals have in international law to be free from arbitrary physical harm and coercion by their government" and include freedoms from torture and medical or scientific experimentation that obviously includes the right to be injected with an experimental vaccine with potentially fatal side effects. [7]

Since the beginning of the COVID-19 pandemic, public health policies have continued to raise valid questions regarding

the legitimacy, efficacy, necessity, and proportionality of public health guidelines and practices [8]. In pursuing public health policy, it is essential to strike an appropriate balance between the public interest and individual human rights guaranteed by numerous international human rights conventions.

2. Are COVID-19 Vaccines Experimental or Not?

It is vital to differentiate between vaccines with long-term safety and efficacy data—such as the mumps, measles, and rubella vaccine; the polio vaccine; and others—and COVID-19 vaccines for which there is not yet medium- to long-term safety and efficacy data. To determine the legality of vaccine passports, a critical question to be answered is whether the COVID-19 vaccines are still experimental or not.

The ascertainment and classification of a medical procedure as experimental or not is of paramount importance, given that international human rights law states that experimental medical interventions always necessitate prior informed consent.

2.1 COVID-19 Vaccine Development versus Standard Vaccine Development

Based on a typical vaccine development timeline, it takes ten to fifteen years to assess whether a vaccine is safe and effective in clinical trials, complete the regulatory authorization processes, and produce an adequate quantity of vaccine doses for common distribution. [9]

On January 10, 2020, the SARS-CoV-2 genetic sequence data were shared through GISAID, and by March 19, 2020, the global pharmaceutical industry had announced a major commitment to developing a vaccine to prevent COVID-19 [10]. The clinical development, including safety and efficacy evaluations of COVID-19 vaccines, was completed in less than one year—about 10 to 15 times faster than a standard clinical vaccine development program [10,11,12].

Table 1: Comparative table of a Standard Vaccine Development Timeline and the COVID-19

 Development Timeline

Years	Standard Vaccine Development Timeline	Years	COVID-19 Vaccine Development Timeline
2–5	Discovery Research	0–1	Discovery Research, Preclinical Trials, Phases 1–3 Clinical Trials, EUA**
2	Preclinical Trials	1-?	Post-EUA Vaccine Safety Monitoring
1–2	Phase 1 Clinical Trials: Are they safe?		
2–3	Phase 2 Clinical Trials: Do they activate an immune response?		
2–4	Phase 3 Clinical Trials: Do they protect against the disease?		
1–2	Regulatory Review and BLA Licensure		
1–?	Post-Licensure Vaccine Safety Monitoring		

* Biologics License Application (BLA)

** Emergency Use Authorization (EUA)

From the above table, it is apparent there are no medium- or long-term safety and efficacy data available for the COVID-19 vaccines. These vaccines were created and authorized in less than one year, with the mass rollout of the COVID-19 vaccines only commencing in January 2020, thereby providing a further 11 months of real-world data as of November 2021.

The very definition of an experiment is a scientific procedure undertaken to discover or test a hypothesis. The current hypothesis being tested with the rapid real-world mass vaccination effort is that the Pfizer-BioNTech, Moderna, Oxford-AstraZeneca, and Johnson & Johnson's Janssen COVID-19 vaccines, most of which make use of advanced messenger RNA technology never used before, will not cause any serious medium- to long-term health problems.

2.2 Emergency Use Authorization versus Biologics License Application

The traditional pathway to vaccine licensing in the United States is the Food and Drug Administration's (FDA) Biologics License Application (BLA) procedure. This is a thorough process that requires extensive data on a vaccine's safety and efficiency and various levels of evaluation by federal advisory committees. The BLA process has an excellent track record of promoting confidence and public trust in vaccines that are ultimately approved [11].

All the main COVID-19 vaccines received Emergency Use Authorization (EUA) only and not the time-tested BLA. A EUA does not require safety and efficiency data that are as thorough and comprehensive as the standard BLA procedure. For instance, EUA regulations for a COVID-19 vaccine required a median of two months of follow-up safety data, as opposed to two years under normal circumstances. The use of a EUA to make a vaccine available is almost unique, having been utilized only in 2005 to make the anthrax vaccine available [12].

US Federal law 21 USC § 360bbb-3(e)(1)(A)(ii)(III) requires that the person to whom a EUA vaccine is administered be advised: "of the option to accept or refuse administration of the product."

2.3 FDA-Issued EUA COVID-19 Vaccine Fact Sheets

For each COVID-19 vaccine authorized under a EUA, the FDA requires that vaccine recipients or their caregivers be provided with a EUA Fact Sheet for Recipients and Caregivers. This fact sheet is similar in purpose and content to vaccine information statements (VISs) for licensed vaccines but differs in that it is "specific to each authorized COVID-19 vaccine, is developed by the manufacturer of the vaccine, and is authorized by the FDA" [8-12]. There is no VIS for COVID-19 vaccines authorized under a EUA. Instead, the FDA-approved EUA Fact Sheet for Recipients and Caregivers for each COVID-19 vaccine must be used [13-17].

As of December 3, 2021, after 4.29 billion people worldwide have received a dose of a Covid-19 vaccine, equal to about 55.9 percent of the world population, the EUA's fact sheets for Pfizer-BioNTech, Moderna, and Johnson & Johnson's Janssen still state the following [8-10]:

- "[T]he... COVID-19 vaccine is an unapproved vaccine that may prevent COVID-19. There is no FDA-approved vaccine to prevent COVID-19."
- "[T]he... COVID-19 vaccine is still being studied in clinical trials."
- "[T]he... COVID-19 vaccine is an unapproved vaccine in an ongoing clinical trial."

• "[T]he... COVID-19 vaccine has not undergone the same type of review as an FDA approved or cleared product."

According to the official communications of the US Centers for Disease Control and Prevention (CDC) dated December 3, 2021, "the CDC continues to closely monitor the safety of COVID-19 vaccines" [16] and on June 2, 2021, the CDC confirmed it is "still in the process of learning: how well vaccines prevent you from spreading the virus that causes COVID-19 to others, how long COVID-19 vaccines protect people, how many people need to be vaccinated against COVID-19 before the population can be considered protected (population immunity), and how effective the vaccines are against new variants of the virus that causes COVID-19." [17]

As is abundantly clear from the above, the FDA, the CDC, and vaccine manufacturers are transparent and open that the COVID-19 vaccines are still in clinical trials and the experimental stage.

3. Free Consent to Medical or Scientific Experimentation Is a Non-Derogable Human Right

Article 4 of the legally binding International Covenant on Civil and Political Rights (ICCPR), which was ratified by 173 governments worldwide including the United States, is of paramount importance for the system of safeguarding human rights [18]. On the one hand, it allows for States Parties unilaterally to derogate temporarily from a part of their commitments under the Covenant. On the other hand, article 4 subjects both this specific measure of derogation and its significant consequences to a definite regime of legal precautions [19]. Article 4(1) of the ICCPR provides that, in a time of public emergency that threatens the life of the nation, States Parties may take actions derogating from their duties under the Covenant to the degree strictly required by the pressures of the situation. Article 4(2), however, explicitly determines that "no derogation from article 7 may be made under this provision" [6].

Article 7 of the ICCPR clearly dictates that "no one shall be subjected without his free consent to medical or scientific experimentation" [6]. On April 30, 2020, the United Nations Human Rights Committee again reiterated that:

> "States Parties cannot resort to emergency powers or implement derogating measures that violate obligations under international human rights treaties from which no derogation is allowed. States Parties cannot deviate from the non-derogable provisions of the Covenant such as article 7 or from other rights that are essential for upholding the nonderogable rights, even in times of public emergency." [20]

Therefore, a person's right to free consent to medical or scientific experimentation is a nonderogable fundamental human right that cannot be violated, even in times of a public health emergency.

The Siracusa Principles on the Limitation and Derogation Provisions in the International Covenant on Civil and Political Rights specifically determine that no State Party shall, even in a time of emergency threatening the life of the nation, derogate from the covenant's guarantees of the right to life and the right to freedom from torture; from cruel, inhumane, or degrading treatment or

punishment, and from medical or scientific experimentation without free consent. These derogable rights are not under anv circumstances, even for the stated purpose of safeguarding the life of the nation [21]. The Siracusa Principles further establish that no government, including those that are not parties to the covenant, may suspend or infract, even in times of a public health emergency, the fundamental human right to from freedom medical or scientific experimentation without free consent [21].

The Paris Minimum Standards of Human Rights Norms in a State of Emergency are directed to help guarantee that, even in circumstances where a bona fide declaration of a state of emergency has been announced, the government concerned will refrain from suspending those basic human rights that are regarded as non-derogable under article 4 of the ICCPR, article 15 of the European Convention on Human Rights, and article 27 of the American Convention on Human Rights [22,23,24]. The Paris Minimum Standards specifically determine that during the period of the existence of a public emergency, the government may not derogate from internationally prescribed rights that are by their own terms "non-suspendable" and not subject to derogation, and they confirm that the basic rights and freedoms guaranteed by international law, such as the right to free and informed consent for any medical experiment, shall remain non-derogable even during emergencies [22].

In terms of International Human Rights Law, certain fundamental rights can never be derogated under any circumstances, even in times of a declared public emergency. Because of their normative specificity and status, nonderogable rights are core human rights *jus cogens* and obligations *erga omnes*. [25] Jus Cogens or embodies the community interest and are reinforced by its link with public morality existing in modern international law as a matter of necessity. [26] The rationale for treating non-derogable rights as "higher law" is both functional and deductive: nonderogable rights should be seen as primary because all other rights are dependent on them. As recent events again demonstrated, a governmental order in which the rights to life, physical security, freedom from medical experimentation, and due process are frequently violated generates an intense and pervasive fear which annuls the will to exercise other fundamental rights. [27]

4. Vaccine Passports and Proof of Vaccination Demanded by Non-State Actors

In terms of the Doctrine of State Responsibility for Human Rights Abuses Committed by Non-state Actors, governments cannot sideline their international legal obligations not to derogate the non-derogable right to be free from medical experimentation without free consent [28]. Governments cannot coerce or allow private institutions such as colleges, schools, private employers, airlines, and others to mandate COVID-19 vaccination for citizens to be able to work and earn a living, to travel, to study at a college, to attend school, to attend sporting events, to attend concerts, or to get access to shopping malls. The choice between being vaccinated against COVID-19 or not being employed and losing one's livelihood, or the choice between being vaccinated or not attending school or college, is, in fact, no choice at all-but rather the same as mandating a vaccine-and thus a blatant and abrasive form of force, duress, overreach, and coercion, directly contravening the Nuremberg Code and all other relevant jus gentium in relation to the derogation of nonderogable fundamental human rights.

Article 2 of ICCPR, article 1 of the EU Convention, and article 1 of the American Convention all determine that each State Party undertakes to respect and to ensure (secure) to all individuals within its territory and subject to its jurisdiction the rights recognized in the covenant, without distinction of any kind [6,23,24].

In terms of this obligation, the state party to the covenant must prevent, investigate, and punish any violation of the fundamental human rights recognized and protected by the convention, whether committed by state or non-state actors [28]. Significantly, the duty to ensure protected human rights and freedoms places a positive legal duty on states parties to the convention to protect individuals from the harmful acts and omissions of not only the state or its representatives but also private institutions [28]. The general obligation to ensure protected human rights consists of four principle state obligations:

- A duty to prevent
- A duty to investigate
- A duty to punish
- A duty to remedy [28]

Jus inter gentes governments have an international legal obligation "to take reasonable steps to prevent human rights violations" by public and private actors [28]. The duty to prevent includes all those means of an administrative, legal and political nature that promote the protection of human rights and guarantee that any violations are considered and treated as illegal acts, which must lead to the punishment of those responsible and the legal duty to indemnify the victims for damages [28,29].

On April 27, 2021, the Office of the United Nations High Commissioner for Human Rights affirmed that states should take measures to prevent human rights violations and abuses perpetrated by state and non-state actors and associated with the state of emergency and that claims of such violations and abuses should be investigated with a view to putting an end to the violation, bringing offenders to justice, and providing victims with protection and effective remedies [8].

In terms of prevailing public national, and international law, it is illegal for any government to make COVID-19 vaccines mandatory or to allow non-state actors to make COVID-19 vaccines mandatory and to derogate the non-derogable fundamental human right to freedom from medical or scientific experimentation without free consent.

5. International Bioethical Normative Standards

Although ethics, the study of morally acceptable standards of behavior and ethical judgment, should be a branch of science, ethical laws are distinct from scientific laws. Ethical laws are dogmatic and prescriptive, and they dictate what ought to be. Ethical laws are normative, asserting standards and principles that need to be followed [30]. Bioethics, a branch of ethics, is the interdisciplinary study of ethical issues emerging from medical advancements and their impact on society, public health policy, and medical practice [30]. Bioethical normative standards should inform both public health policy and guidelines during times of crisis management and all experimental interventions [30].

The Nuremberg Code adopted in 1947, following the medical experimentation atrocities committed by Nazi Germany, deals with permissible medical experiments and determines specifically that:

"The voluntary consent of the human subject is absolutely

essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision." [31]

Additionally, World Health the Organization's (WHO) Guidance for Managing Ethical Issues in Infectious Disease Outbreaks [32], the Universal Declaration on Bioethics and Human Rights [33], and the European Union Convention on Human Rights and Biomedicine determine that any preventive, diagnostic, or therapeutic medical intervention is "to be carried out only with the prior, free, and informed consent of the person concerned, based on adequate information [32,33,34]".

With respect to ensuring high vaccine uptake, the Council of Europe adopted Resolution 2361 (2021), entitled "COVID-19 Vaccines: Ethical, Legal and Practical Considerations," which urges member states and the EU to ensure:

> "that citizens are informed that the vaccination is NOT mandatory and that no one is politically, socially, or otherwise pressured to get themselves vaccinated, if they do not wish to do SO themselves; that no one is discriminated against for not

having been vaccinated, due to possible health risks or not wanting to be vaccinated" [35].

The public health response to the COVID-19 pandemic again highlights the need for States Parties to abide by universal ethical guidelines and normative standards in the field of bioethics and the need to promote shared values in relation to the formulation and implementation of public health policies.

6. Conclusion

The topic of mandatory vaccinations is a highly charged one. The COVID-19 contagion has presented many scientific, medical, legal, ethical, and policy challenges, and mandatory vaccination programs may well introduce more [36]. The UNESCO International Bioethics Committee (IBC) and the UNESCO World Commission on the Ethics of Scientific Knowledge and Technology (COMEST) recently declared the following:

> The many ethical issues that arise call for putting aside differences and collectively reflecting on ethically acceptable solutions. А bioethics and ethics of science and technology perspective, rooted in human rights, should play a key role in the context of this challenging pandemic. [37]

Hesitancy regarding the COVID-19 vaccines is rooted mostly in the fact that these vaccines are still undergoing ongoing clinical trials and have an unknown medium- and long-term safety and efficacy profile. To build further public support and confidence, there must be proof that the COVID-19 vaccines are safe and efficacious over the medium and long terms with an acceptable risk profile [40,41].

From even the most conservative viewpoint of law and justice, the right not to be subjected to medical or scientific experimentation without free consent can safely be considered as having attained the jus cogens status to be respected by all states at all times, no exceptions. The denial of certain rights fundamental to human dignity, such as the right to free and informed consent to medical experimentation, must never be derogated in any conceivable emergency. Even apart from contravening international public law, making COVID-19 vaccines mandatory without medium- and long-term data would be a mistake. Vaccine safety is fundamental to maintaining the public's trust in vaccines; mandating a vaccine with no medium- and long-term safety and efficacy data could have far-reaching ramifications [38]. Although less stringent safety standards may be used to justify emergency use authorization or voluntary use of COVID-19 vaccines, any public health policy mandating the use of COVID-19 vaccines must follow the standard long-term assessment of their safety and efficacy [40,41].

International human rights and bioethical norms and standards are unambiguous that all people should be afforded their non-derogable fundamental human right to free and informed consent and right of refusal in relation to any experimental medical procedure [6,32,33,34,35,39,40,41]. Respect for this fundamental right is essential to ensure the enjoyment of non-derogable rights and to provide an effective remedy against their violation.

Vaccine mandates are illegal and a gross violation of international human rights law Jus Cogens that is a Latin phrase that literally means "compelling law" designating norms from which no derogation is permitted. It stems from Roman law legal principles that certain legal rules cannot be contracted out, given the fundamental values they uphold [42].

Normative legal and ethical perspectives dictate that States Parties should not make COVID-19 vaccination mandatory, nor allow citizens to be coerced into taking the COVID-19 vaccine by non-state actors, in breach of international legal obligations that would derogate the non-derogable right to free and informed consent to any medical or scientific experimentation.

Considering that fact that major G 20 nations are derogating non-derogable rights through vaccination passports and mandatory vaccinations the safeguards from the unique legal status of non-derogable rights appears to be anemic, at best, during the COVID-19 pandemic.

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