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Research Article

The Mandatory COVID-19 Vaccination of School Children: A Bioethical and Human Rights Assessment

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ABSTRACT

The COVID-19 infection fatality rate for children under the age of 17 is less than 0,003%. Children are at extremely low risk of severe illness from COVID-19, and children do not spread the illness in any significant way. Once a vaccine becomes widely available for schoolchildren, will lawmakers leave it up to parents and guardians to choose whether to vaccinate their children or will they mandate schoolchildren to get a COVID-19 vaccine to attend school? This article assesses both arguments for and against mandatory COVID-19 vaccination for school children. The article further analyzes applicable international bioethical and human rights norms and standards with regard to informed consent as contained in the various international treaties to hold states legally accountable for their actions under international law. To determine whether states may impose vaccine mandates for school children in terms of international human rights law, a proportionality test is applied. The critical focus of this article is explicating the rudiments of the bioethical and human rights standards relating to the mandatory COVID-19 vaccination of schoolchildren that must be confronted to ensure that children, that is, humanity's most valuable asset for the future, are afforded their fundamental human rights. Ultimately, it highlights the importance that these international bioethical norms are built into decision-making by public authorities when measures to prevent the spread of infectious disease with a case fatality rate of less than 0,003% in children are instituted.

Keywords: COVID-19; Vaccine; Infectious disease; International human rights law; Fundamental human rights; Proportionality

INTRODUCTION

Both Moderna and Pfizer announced in March that their companies began testing their vaccines in children as young as six months. Despite the fact that COVID-19 affected relatively few children through severe morbidity and although infection fatality rates among children are less than 0.003% [1], Pfizer and Moderna requested the U.S. Food and Drug Administration (FDA) and the European Medicines Agency to extend the use of its COVID-19 vaccines to cover adolescents aged 12 to 15, marking a significant step in expanding access to COVID-19 vaccines to children.

Onyema Ogbuagu, MBBCh, associate professor of medicine, that led Yale's component of the 12-to-15 trial, as he had done in 2020 for the Pfizer BioNTech adult trial said "returning to school is just one of several important considerations. If kids make up nearly 30 percent of the population and we can vaccinate them with a low margin of error that puts us on an easier path toward herd immunity". According to the Yale School of Medicine, the effort to evaluate COVID-19 vaccines in even younger children is now moving forward with Moderna's clinical trial of a vaccine for children 6 months to 12 years of age called Kid COVE, with the phase 2/3 trial being conducted at approximately 90 sites across the U.S. and Canada and will include 6,750 children [2].

To date, at least one major school system, the Los Angeles Unified School District, has said it will require students to get immunized against COVID-19. Superintendent Austin Beutner said in a recorded briefing that students will have to get the vaccine once it is available to attend school in person. According to a new Axios/Ipsos survey conducted during April 2021, only half of Americans intend to get their children immunized against COVID-19 as soon as vaccines become available.

With the FDA's recent emergency use authorization of Pfizer's COVID-19 vaccine for children aged 12 to 15, there are some important questions that arise from a bioethical and international human rights law perspective:

- Is it ethical to vaccinate children who are not at risk, while millions of vulnerable elderly at-risk patients in developing countries do not have access to vaccines?
- Is it ethical to vaccinate children with an experimental vaccine without obtaining prior informed consent?
- Is it ethical to vaccinate children with a vaccine that they do not need?

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• Can state parties mandate the vaccination of children in terms of the International Human Rights Law?

The critical focus of this article is explicating the rudiments of the bioethical and human rights standards relating to the mandatory COVID-19 vaccination of schoolchildren that must be confronted to ensure that children, that is, humanity's most valuable asset for the future, are afforded their fundamental human rights.

ARGUMENTS FOR AND AGAINST COVID-19 VACCINATION FOR SCHOOL CHILDREN

Once a vaccine becomes widely available for schoolchildren, will lawmakers leave it up to parents and guardians to choose whether to inoculate their children or will they require schoolchildren to get a COVID-19 vaccine to attend school?

The protagonists of the perspective that supports mandatory vaccination for school children inter alia argue that

Children are the next vaccination frontier: In regard to vaccinating children, the same urgency and large-scale coordination efforts driving adult vaccination must continue if we want to eradicate COVID-19 cases and ultimately end the pandemic [3].

Schoolchildren make up approximately 20% of the population and should be vaccinated to achieve herd immunity: Vaccinating children are seen as crucial to ending the pandemic. Governments are unlikely to achieve herd immunity until children can get vaccinated. Between 70% and 80% of the U.S. population needs to be vaccinated against COVID-19 to achieve herd immunity [4].

COVID-19 vaccines for children will be safe and effective: Adverse events are extremely rare [5]. Clinical trials to prove that vaccines are safe for use in children are underway. Parents can rest assured that once the vaccine trials for children are complete and emergency use authorization has been granted by the FDA the European Medicines Agency and other health regulators, it will be considered safe to begin vaccinating children.

Even though children have an extremely low risk of dying or getting sick from COVID-19, children can still contract the virus, be asymptomatic carriers and spread the virus to other people who may become severely ill or die: The more people of all ages who get the vaccine, the safer everyone will be. Mandatory vaccination for school children can therefore be justified based on the "Harm Principle". The harm principle determines that the human rights of individuals can be limited to prevent harm to other individuals. John Stuart Mill articulated this principle in On Liberty, where he argued that "The only purpose for which power can be rightfully exercised over any member of a civilized community, against his will, is to prevent harm to others" [6].

Even a small number of critical COVID-19 cases among children are worth vaccinating against: The burden of long-term effects from COVID-19 in children-including rare but serious cases of inflammatory syndrome-remains unclear, especially since many have asymptomatic infections that go undiagnosed.

Irrespective of whether school children have already been infected with COVID-19 and already have antibodies in their system, they need to be vaccinated: COVID–19 vaccines generate both antibody and T cell responses that are possibly stronger and more consistent than immunity from natural infection [7]. One study found that four months after receiving their first dose of the Moderna vaccine, 100% of people tested had antibodies against SARS-CoV-2 [8].

Allowing unvaccinated children to circulate freely may be associated with the development and spread of mutations of the virus, some of which might become vaccine-resistant and more dangerous variants, including ones that could harm both children and adults: The coronavirus genome is highly prone to mutations that lead to genetic drift and escape from immune recognition [9]. Variants "of concern" first identified in Britain, South Africa, Brazil and California are being closely followed by epidemiologists. Some of these appear more contagious than earlier versions. The COVID-19 variant that seems to have emerged in south eastern England is up to 70% more transmissible. There is a further concern that this variant spreads more easily among children [10]. Variants that cause more severe illness in children are likely to emerge from children themselves.

The proponents of the perspective that opposes mandatory COVID-19 vaccinations for school children, on the contrary, argue that

There is no basis for vaccinating children against COVID-19: In the USA, the infection fatality rate for children under the age of 17 is less than 0,003% [11]. Children are at extremely low risk of severe illness from COVID-19, and children do not spread the illness in any significant way [12]. The most updated data by the American Academy of Paediatrics showed that "Children were 0.00%-0.19% of all COVID-19 deaths, and 10 (US) states reported zero child deaths. In states reporting, 0.00%-0.003% of all child COVID-19 cases resulted in death" [13].

The contention that governments can only get to herd immunity by vaccinating children is absurd, patently false and denying scientific reality: Children can become naturally infected as they do with other pathogens that have a case fatality rate of 0.003% [11]. If children are needed from a 'numbers' point of view for driving population level 'herd' immunity, they should be allowed to get infected naturally and harmlessly as part of day-to-day living and we do it by opening schools and allowing them to live normal lives.

COVID-19 vaccine safety science for school children is in its initial stages, not scrupulously tested and inadequate: All COVID-19 vaccines received the "Emergency Use Authorization" (EUA) and not the time-tested "Biologic License Application" (BLA), where rigorous and thorough testing and analysis preceded the issuance of such a license. Emergency Use Authorized vaccines do not meet the criteria for a fully biologically licensed vaccine that takes 10-15 years of efficacy and safety data [14]. It is premature to even guess what the medium- and long-term side effects of the COVID-19 vaccines could be. US Federal law 21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(III) requires that the person to whom an EUA vaccine is administered be advised, "of the option to accept or refuse administration of the product". Emergency Use Authorization is not appropriate for children. Under this provision, the FDA and other regulators can allow products to be used based on lower levels of evidence than traditional approvals in times of emergency [15].

Children do not readily transmit the COVID-19 virus, and the theory of symptomless spread has been severely queried, especially for children: There are numerous studies and data that clearly show that school children, if infected, do not spread COVID-19 to other children or adults easily [16,17]. This was demonstrated elegantly in a study performed in the French Alps that examined the spread of the virus via a cluster. The researchers followed one

infected child who visited three different schools and interacted with other children, teachers, and various adults. They reported no instance of secondary transmission despite close interactions [18]. It is further well noted that symptomless COVID-19 cases are not the drivers of the pandemic, something particularly important in relation to children. As they're mostly symptomless [18]. A determinative study calling into question 'asymptomatic' spread in COVID-19, which was published in Nature, showed that in a sample of ten million, when all positive 'asymptomatic' cases were followed and all close contacts were traced (n=1,174), there were zero (0) instances of asymptomatic spread [19]. The WHO also confirmed that "From the data we have, it still seems to be rare that an asymptomatic person actually transmits onward to a secondary individual."

You do not vaccinate people who aren't at risk from a disease: COVID-19's Case Fatality and Crude Mortality Rate for children range between 0, 003% and 0, 0003%, respectively [1,20]. A total of 99.997% of all school children under the age of 18 who contract COVID-19 will have mild to no symptoms and survive. No mass vaccinations of school children are reasonably required to combat a disease with a population-level crude mortality rate and of 0.0001% - 0,5% [1,20,21].

There is no need to vaccinate people who recover from COVID-19 and already have antibodies: It is extremely important to understand the mechanisms of protective immunity elicited by infection [22,23]. Significantly fewer people need to be vaccinated to achieve herd immunity. Only 25% to 45% of Americans need to vaccinate to achieve herd immunity, and not the 70% to 90% claimed by the CDC. As of May 7, 2021, 43,6% of the total population in the USA had received at least one dose, and 33.4% had been fully vaccinated [21]. In terms of recent estimates, 55% of Americans have already had COVID-19 and already have antibodies in their system. There is no need to vaccinate those who already had COVID-19. A pivotal study found that "the ratio of serum virus neutralization GMT to recombinant RBD-binding IgG GMC is lower after immunization with BNT162b1 than after infection with SARS-CoV-2 [24]. Researchers have also shown that the components of immune memory (memory B cells, CD8+ T cells, and CD4+ T cells) in persons who had been exposed to SARS-CoV-2 persist for some time post-infection [25-27]. Importantly, the issue of reinfections in patients who had COVID-19 seems to be rare, underscoring the idea that natural immunity is very real and adequate [28]. Cross protection immunity from prior coronaviruses and common colds are also totally disregarded by those calling for vaccination of schoolchildren. Effective immune memory can persist for decades and typically results in enhanced responses and accelerated pathogen control [22,23]. Natural immunity provides the type of comprehensive protection needed and is even more effective than immunity induced by vaccination [29].

There is no scientific evidence that the COVID-19 variants may drive infection in children and harm them nor are there any data to support the notion that a lethal strain may emerge among the variants: It is simply rampant speculation fraught with 'potentially', 'may', 'could' and 'might'! From the pediatric academic literature, it is settled science that children do not readily spread the virus [30,31]. Not only is there a want of evidence supporting the notion that children spread the COVID-19 virus in any meaningful way, but there is direct evidence showing that they do not spread COVID-19 in any meaningful way [32]. This has been shown in school settings and published in numerous authoritative academic research papers [33].

There are potentially real adverse side effects from the COVID-19 vaccines: Canada and numerous European countries have now suspended the AstraZeneca-Oxford vaccine for those under 55 because of safety concerns relating to blood clotting and thrombocytopenia. Deaths, harms, and adverse events such as blood clots and anaphylaxis are being reported in the CDC's VAERS system as well as globally [34]. There need to be comprehensive long-term studies of the sequential connection between reported adverse events following the administration of COVID-19 vaccines [35]. There were 3362 COVID-19 vaccine-related deaths reported to VAERS between late December 2020 and April 23, 2021 [35]. There were more COVID-19 vaccine-related deaths in less than five months than deaths from all other safe and tested vaccines over a period of 15 years [35].

ASSESSING THE BIOETHICAL NORMS AND INTERNATIONAL HUMAN RIGHTS STANDARDS

In the last number of years, there have been enormous advances in the development of human rights law, bioethical normative standards, and the instruments to implement it. States are no longer "free" to do as they will in the domestic sphere; instead, they are bound by provisions in international law that are aimed at protecting individuals from government acts and omissions [36].

Now more than ever, the international community should insist on a universally accepted set of legal and bioethical norms that must be adhered to by all states. The constitutive relation between human rights law and politics in the international sphere is complex and dynamic and makes use of a prodigious body of customary human rights norms and the legal norms contained in the various international treaties to hold states legally accountable for their actions and omissions under international law [36]. All the major international human rights treaties and conventions also contain language creating positive legal duties on states to protect individuals against human rights abuses committed by non-state actors such as schools and commercial corporations [36].

The primary principle in the Nuremberg Code is that "the voluntary consent of the human subject is absolutely essential." Under the Nuremberg Code, no one may be coerced to participate in a medical experiment. While this right to choice in international law sprang from the Nuremberg Code, the international right to informed consent now encompasses the right to free and informed consent for all medical decision making [37].

The International Covenant on Civil and Political Rights (ICCPR), which was ratified by 193 governments worldwide, including the USA, clearly dictates that "no one shall be subjected without his free consent to medical or scientific experimentation" [38]. The ICCPR is a legally binding international convention to all 193 state parties that ratified the convention.

The United Nation's Education, Scientific, and Cultural Organization (UNESCO), with 193 members and 11 associated members, Universal Declaration on Bioethics and Human Rights (UDBHR) determines that "human dignity, human rights and fundamental freedoms are to be fully respected and the interests and welfare of the individual should have priority over the sole interest of science or society" and that "any preventive, diagnostic and therapeutic medical intervention is only to be carried out with the prior, free and informed consent of the person concerned,

based on adequate information" [39]. Whilst the UNESCO Declaration on Bioethics does not establish enforceable human rights, it is convincing regarding what the global requirement for informed consent must be.

The Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine 1997 (OVIEDO Convention) further specifically determines that "An intervention in the health field may only be carried out after the person concerned has given free and informed consent to it. This person shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks. The person concerned may freely withdraw consent at any time" [40,41]. Even though the Oviedo Convention is only legally binding on the 29 European Union member states that signed the convention, it obviously sets an authoritative moral normative standard with regards to the safeguarding of fundamental human rights and freedoms in the biomedical field.

The World Medical Association (WMA), an international and independent confederation of free professional medical associations representing more than ten million physicians worldwide, adopted the Declaration of Helsinki Ethical Principles for Medical Research Involving Human Subjects that confirms that "Participation by individuals capable of giving informed consent as subjects in medical research must be voluntary [42].

According to the WHO's "Guidance for Managing Ethical Issues in Infectious Disease Outbreaks 2016 WHO", the bioethical basis for the justification of emergency use medical interventions "is the ethical principle of respect for patient autonomy — i.e. the right of individuals to make their own risk–benefit assessments in light of their personal values, goals and health conditions" [43]. The WHO Guidance is also explicit that "The ultimate choice of whether to receive the unproven intervention must rest with the patient, if the patient is in a condition to make the choice. If the patient is unconscious, cognitively impaired, or too sick to understand the information, proxy consent should be obtained from a family member or other authorized decision-maker" [43]. The WHO's Guidance for Managing Ethical Issues is a further authoritative indication of the global ethical standard and requirements regarding the use of emergency medical interventions.

International bioethical norms and human rights standards with regard to informed consent for all medical interventions logically apply to the vaccination school children with COVID-19 vaccines, an invasive medical procedure that carries both known and unknown risks and benefits.

COVID-19 vaccines are experimental, and parents have the right to refuse such a vaccine for their children [37,44]. The right of refusal therefore stems from the fact that EUA products are, by definition, experimental and under the Nuremberg Code and other relevant international human rights conventions prior informed parental consent is an essential prerequisite [37-42].

RESTRICTION OF FUNDAMENTAL HUMAN RIGHTS DURING TIMES OF NATIONAL EMERGENCY

Mandatory vaccination of school children represents a limitation on fundamental human rights [38,45,46]. The Siracusa Principles, which contain criteria for limiting civil and political rights to advance various public purposes, have offered goverments standards for acceptable limitation on rights to reduce the spread of infectious disease [47]. They inter alia require that restrictions should respond to a pressing public or social need, pursue a legitimate aim, be necessary, be the least restrictive and proportionate [47]. Importantly, Siracusa specifically determines that "No state, including those that are not parties to the Covenant, may suspend or violate, even in times of public emergency freedom from torture or cruel, inhuman or degrading treatment or punishment and from medical or scientific experimentation" [47].

To determine whether the government may impose vaccines, a proportionality analysis which is the typical legal test for resolving human rights disputes, should be applied [48,49]. The proportionality analysis examines the following set of sequential questions once a prima facie infringement of a fundamental human right has been found [50]. First, does the infringing public policy pursue a legitimate aim? (Legitimacy); second, is the public policy suitable and rationally connected to the fulfilment of policy goals? (Adequacy or efficacy); third, is the infringing policy necessary and the least restrictive option? (Necessity); and forth, do the benefits of the policy measures outweigh the cost? (Proportionality "strictu sensu") [51-53].

Do vaccine mandates for children pursue a legitimate goal? (legitimacy)

It is a legitimate goal of state parties to take action to safeguard the public against an infectious disease that represents a serious threat to the health of the population or individual members of the population [47].

Would vaccine mandates for children be adequate to achieve the purpose? (adequacy)

In other words would herd immunity be reached and would society be able to return to normal once children have been vaccinated? According to the WHO and CDC, fully vaccinated people still need to adhere to most COVID-19 restrictive measures given significant uncertainty around whether the COVID-19 vaccines:

- Provide long-term immunity (Vaccine efficacies are based on short-term data only) [54].
- Prevent the spread of the virus[54].
- Would be effective against other variants [53].

Mass mandatory vaccinations of children would not achieve the desired end result of achieving herd immunity and returning society to normality and therefore fails the adequacy requirement.

Are vaccine mandates for children the least intrusive and least restrictive measure available that will accomplish the public health goal?

Given that the Infection Fatality Rate (IFR) is close to 0 (zero) for children and young adults, an obvious alternative and less intrusive measure to mass mandatory vaccinations would be for children to naturally acquire immunity if and when exposed to COVID-19. Children below 18 have a 99.997% probability of recovering from COVID-19 and will have no to only mild symptoms while at the same time developing naturally acquired immunity that is superior to that which might be caused by a vaccine [29]. This approach would also accelerate the development of the much-needed herd immunity.

Dealing with concerns of the public at large, the ethical methodology would be to only vaccinate those in vulnerable groups after they

have given their informed consent and all other people who choose to be vaccinated. School children are not at risk and do not need to be vaccinated to achieve the required public health goal.

Are vaccine mandates for children a proportionate response? (proportionality stricto sensu)

The restriction of a human right is proportional stricto sensu if it is 'pondered or balanced because more benefits or advantages for the general interest are derived from it than damages against other goods or values in conflict [52].' Vaccine mandates for children would effectively discriminate against and deny approximately 20% of the world's population their most basic fundamental human rights to life, liberty, and free consent in order to combat a disease with a crude mortality rate of 0.0001% - 0.5% [1].

From a cost benefit perspective, a schoolchild has a close to zero risk of severe malady or death and thus no benefit from the vaccine but could be exposed to potentially significant adverse side effects from the COVID-19 vaccines (as reported in adults who have received the vaccines). In the presence of such potential risks, why would any loving parent or guardian allow their child to be vaccinated with experimental vaccines?

Taking even a "moderate" risk of serious side effects from a barely tested vaccine to combat a disease with a near zero case fatality rate in school children cannot be viewed as proportionate stricto sensu. The cost-benefit argument against using an essentially untested vaccine is heavily in favor of risk and virtually no benefit.

CONCLUSION

There has been convergence between Siracusa and approaches to limitations on fundamental human rights emerging from the field of bioethics [43]. The ethical and human rights standards that governments need to adhere to are unambiguous with regard to how restrictions on fundamental human rights during pandemics should be treated. As with many requirements of human rights and bioethics, these standards are sadly often honored in the breach [55-57].

While it is common to require children to be vaccinated before attending public school and important for ensuring a safe learning environment, the calculus for mandating a COVID-19 vaccine is different. Vaccines such as the Mumps, Measles and Rubella vaccine, the Polio vaccine and others have an important role in protecting human lives, but these protections have been the result of a thorough tradition of testing combined with long-term assessment over periods of 5-10-15 years to establish both safety and efficacy. The current COVID-19 vaccines do not have such a detailed record of either safety or efficacy to warrant the large-scale vaccination of children in a bio ethically responsible manner.

Vaccine mandates for school children without any data or evidence on long-term safety, especially when their risks of either suffering acute illness or dying from COVID-19 are almost zero, would be unethical and unlawful in terms of prevailing bioethical and international human rights norms. Depriving some of society's most vulnerable citizens—young children—and their guardians of informed consent would be particularly egregious under the international human rights norms providing for free and informed consent for all experimental medical interventions [46].

In response to COVID-19, governments should honor their international covenant obligations and ensure that public health responses by both state and non-state actors within their territories are legitimate, adequate, necessary and proportionate, consistent with Siracusa and fundamental bioethical principles. International human rights and bioethical moral and legal obligations, properly construed, demand these approaches.

What is of crucial importance is that these international bioethical norms are built into decision-making by public authorities when measures to prevent the spread of infectious disease with a case fatality rate of less than 0,003% in children are instituted.

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