

NEED OF THE HOUR-MANDATING COVID-19 VACCINATION: ETHICAL OR NON-ETHICAL?

Abstract

The world has been battling with COVID-19 pandemic for almost two years now. Despite intensive research in treatment, none of the currently licensed therapeutic options are completely effective in all patients. This leaves vaccines as the one of the most effective tools for protection against COVID-19.

Since the deadliest modern-day pandemic the world has seen has multifactorial impact on the healthcare, economy and welfare of society, Government authorities have been pushed to consider mandatory vaccination. Contemporary forms of “mandatory vaccination” compel vaccination by direct or indirect threats of imposing restrictions in cases of non-compliance. It is a matter of public debate whether such policies can be ethically justified. On one hand they may be crucial to protect the health and well-being of the public while on the other, the policies that mandate vaccination restrict individual liberty and autonomy.

The nature of the COVID-19 pandemic and evidence on vaccine safety and effectiveness continue to evolve. Given the lacunae of data on the long term safety and efficacy of COVID-19 vaccines, the future consequences of vaccination and who will take the onus for them remains questionable.

Indirect “mandatory vaccination” policies limit individual choice by constraining the options for education, work and travel. The absence of a free and sufficient supply to vaccination creates an unfair demand on those who are required to be vaccinated but are unable to access the vaccine.

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This chapter discusses significant ethical considerations and stipulations that should be explicitly evaluated while implementing mandatory COVID vaccination without taking a stand that endorses or opposes mandatory COVID-19 vaccination.

Keywords: COVID-19, Mandatory, Vaccination, Policies, Ethical.

I. INTRODUCTION

COVID-19 has changed the world's socioeconomic fabric with significant repercussions for the future-perhaps forever. The repeated waves of COVID-19 in multiple countries have greatly influenced people's lives with exacerbated social inequalities. Healthcare, travel and education sectors have borne the brunt to the greatest extent. Despite the massive lockdown measures and multiple treatment modalities, no definitive cure for COVID-19 spread has been achieved in the past two years.

This has led to the emphasis on social behavior and preventive measures for minimizing the spread of COVID-19. As social behavior cannot be effectively policed in populous countries, vaccination is turning out to be a crucial tool to put a stop to the pandemic. Conventionally, vaccination has been the most potent way to avert viral infections, impede dissemination, and expand herd immunity. The development and the distribution of safe and efficient COVID-19 vaccines have been critical to fight this pandemic. COVID-19 vaccines are highly effective in reducing severe disease and hospitalization, even though their effectiveness in minimizing spread is undermined by newer variants. Considering the evidence from randomized controlled trials and observational data from countries with high vaccination rates, corroborates the fact that vaccines have demonstrably shown a reduction in cases, hospitalizations and deaths.

Globally, as of December 2021, 279,114,972 confirmed COVID cases and 5,397,580 COVID-related deaths, have been reported by WHO with a total of 8,649,057,088 vaccine doses administered.¹ Currently with the advent of Omicron, the latest variant, global COVID-19 cases has attained the highest ever peak of 1.44 million new cases in a single day.² This has pushed multiple governments for making Covid-19 vaccination mandatory.

II. WHAT DOES “MANDATORY VACCINATION” INVOLVE?

Current forms of “mandatory vaccination” for COVID induce public to opt for vaccination by direct or indirect threats of imposing restrictions in cases of non-compliance.³ Mandatory vaccination policies, however, permit special cases to be excused which are recognized by authorities such as medical contraindications (e.g. pregnancy, allergies). ‘Mandatory vaccination’ has existed previously in over a hundred countries in some version to enhance uptake of vaccines primarily for pediatric vaccinations against infectious diseases such as measles, mumps, rubella, tetanus, and polio.^{4,5} Mandates can be ‘hard’ (ie, vaccines required to work or attend school or travel) or ‘soft’ (nudging people into the easiest choice or incorporating in universal immunization schedules).⁵ These mandates are usually not truly obligatory, i.e., threat of monetary sanctions or use of force is not used in cases of refusal, compared to implementation of lockdowns in a few countries.^{4,5}

However, “mandatory vaccination” policies limit individual choice in non-trivial ways by making vaccination a condition of attending school or working in particular industries or settings, like health care or for social gatherings or travel.

The justifications for enforcing “mandatory vaccination” policies are multiple. Vaccination reduces spread by offering individual protection without the massive lockdown measures required to achieve physical distancing. Recent reports indicate that single dose of

either the Oxford-AstraZeneca or the Pfizer-BioNTech vaccines reduce severe COVID-19 in older population by providing a high level of protection. ⁶ Vaccines have reduced the risk of serious illness and inpatient hospitalization as well as deaths due to COVID-19. This has eased the acute burden on healthcare facilities which was seen in the initial wave of COVID in 2020.

A continued reduction in new cases and viral transmission will aid to minimize the case load and thereby avoid evolution of mutant strains. Herd immunity is achieved when a significant proportion of a community becomes immune to a disease, reducing the spread of disease from person to person. This results in protection for the whole community including those who are not previously exposed to the disease. Over the long term, natural immunization of global populations with the COVID virus might lead to higher mortality in the world even before herd immunity is attained. ⁷ Safe, effective and mass vaccination is necessary to build widespread SARS-CoV-2 immunity and for transition to endemic stage as predicted by recent modeling trends. Eventually it opens the gates for business, freedom to travel and safe opening of schools.

With a proven track record of many years, vaccination is effective for protecting people from infectious diseases. However, the following ethical considerations and caveats should be explicitly discussed and addressed before mandating COVID-19 vaccination as an ethically permissible policy option.

III. ETHICAL CONSIDERATIONS REGARDING MANDATORY COVID-19 VACCINATION

1. Respecting Civil Rights and Freedoms: Vaccine hesitancy is the disinclination to receive vaccines even though vaccination services are offered. Vaccine hesitancy is not a new phenomenon as it has been noted earlier with routine vaccination policies as well. Research in high income countries suggests that the five key individual-level determinants for vaccine hesitancy are confidence, complacency, convenience (or constraints), risk calculation, and collective responsibility. This is called 'the 5C model of the drivers of vaccine hesitancy'.⁹

During the COVID-19 vaccination drive, skepticism about vaccine safety and efficacy has marred the uptake of vaccination. Contemporary research suggests that the decisive factors of vaccine hesitancy are largely dependent on personal experiences and community belief systems. The most common reasons to refuse or delay vaccinations include concerns about safety as the vaccine were produced in a short period of time with shorter clinical trials, concerns about side effects, considering the vaccine to be useless because of the inability of the vaccine to prevent infection post vaccination, belief that the person is already immunized due to prior (undocumented) exposure and being against vaccines in general.¹⁰

While there is enough scientific verification for the safety and effectiveness of vaccines, this uncertainty against vaccination may sound unfounded. Nevertheless the mandatory COVID vaccination policies interfere with the basic rights of individual liberty and autonomy. As there may be a significant section of society that mistrusts

vaccine trials and efficacy, mandatory vaccination may cause legal issues and obstacles for vaccination drives.¹¹

A better approach to promote vaccine uptake is to understand the reasons for opting out of vaccination and to address the same. Public perception highlights that health workers are the most credible sources of advice about vaccines against COVID-19. This fact must be leveraged topinpoint and mitigate the concerns regarding vaccines and avoid spread of vaccine misinformation. Authorities and the healthcare sector need to build confidence in vaccines and act in response to the requirements and apprehensions of citizens

- 2. Avoiding Discrimination and Societal Divides: Social Equity:** The widespread nature of the COVID-19 pandemic commenced a period of unparalleled international funding and cooperation for rapid vaccine research, development, and production. In order for mandatory vaccine policy to be implemented, supply of authorized vaccines should be sufficient and reliable with reasonable access for the targeted populations. The vaccine availability globally has been skewed with only a limited number of countries producing the approved vaccines. The number of vaccine doses estimated to vaccinate the entire global population is approximately 12-16 billion which far surpasses the capability of any solitary manufacturer or country. As the demand outstrips the supply, mandates for vaccination will not only be rendered ineffective but would create an unfair burden for those willing to be vaccinated, but unable to access the vaccine.^{3,12}

The short supply of vaccines has resulted in governments emphasizing on high risk groups in the first roll out of vaccines. These include both people at high risk of severe disease or death if infected and people at high risk of infection such as individuals aged 65 and older, healthcare workers and essential personnel.¹³

The inequitable supply also highlights the fact that across the world, high-income countries can vaccinate low risk populations but low-income countries are struggling to offer vaccination even to the high risk groups. Given the widespread reach of the infection, it becomes extremely crucial to contain the spread of the disease across all populations within a stipulated time else newer stains could continue to surface thereby prolonging the epidemic.¹⁴

The unequal treatment of people based on the vaccination status can cause stigmatization and societal divides, particularly if vaccination certificates are required to get access to specific activities (school, work) or public spaces (travel, hospitals). This may result in exclusion of those who cannot get vaccinated because of medical reasons or a shortage of vaccines.

Therefore if a vaccine mandate is to be enforced, vaccines should be freely available with simplified registration processes and special arrangements for patients who are unable to mobilize, use digital technologies or face transportation issues.

- 3. Accounting for Scientific Uncertainty:** The global competition to develop an anti-COVID-19 vaccine had a short targeted time frame for initial vaccine deployment resulting in rush-to-market. It is incredibly difficult to evaluate the potential adverse

vaccine effects not only in the short-term, but also in the mid- and long-term in accelerated vaccine development. An important factor in a vaccination decision is the perceived safety of the vaccination. Data should be available that clearly demonstrates the safety of the vaccine being mandated for the targeted population. Reasonable exceptions to the mandate need to be included in the mandate policy for special groups such as medical contraindications: allergies, pregnancies. When the safety data is inadequate, the mandate cannot be ethically justified as the exposure of large sections of populations to a potentially harmful product will far outweigh the degree of harm from the disease itself.^{15,16}

The long-term post-marketing surveillance data has been a challenge to analyze due to the varied nature of vaccine distribution strategies. Recent studies however indicate that the majority of COVID vaccines are safe with no serious adverse events, maximum side effects are of mild to moderate intensity and resolving in a few days. For people that experience vaccine related harm sue to mandatory vaccination, a compensation scheme could be explored as a more palatable alternative.^{17,18}

Therefore it is essential to be transparent regarding the known and unknown facts of vaccination so that the public confidence on government and scientific community is not undermined which may further decrease vaccine uptake.^{19,20}

- 4. Sufficient Evidence of Vaccine Efficacy:** Within the onset of the Omicron variant in November 2021, the trajectory of the pandemic has altered. Current data indicates the Omicron variant is considerably more transmissible than the Delta Variant and is capable of significant immune evasion. The spread of Omicron has further underlined the fact that vaccines are not effective in minimizing the spread of COVID, with so-called breakthrough infections being increasingly being diagnosed among individuals who have been vaccinated. In this scenario, the definition of fully vaccinated has changed with booster doses being rolled out in many countries.^{21,22}

There is still no consensus on how many COVID-19 vaccines are supposed to accomplish fully vaccinated status in the short or long term. Making COVID vaccination mandatory becomes a tricky question as certain populations require three doses to be “fully vaccinated” while other require only two doses as of now. In addition, forcing the entire population for mandatory vaccinations for an undefined number of boosters is unethical as the endpoint of the number of boosters stays undetermined.²³

- 5. Addressing Privacy Concerns:** Vaccine administration records are crucial to understand the distribution, compliance and side effects of vaccination. But they constitute a part of medical records of individual patients along with contact details. Furthermore the mobile apps which enable registration, contact tracing and vaccination proofs utilize the system of mobile sensors (e.g., location, proximity) and social networks to aid the process of recognition of individual patients. This may constitute a large scale surveillance infrastructure which may be misused to invade the privacy of patients. In order to protect the privacy of patients, it is essential that the health information systems maintain confidentiality at all stages if mandatory COVID-19 vaccination is enforced.²⁴

IV. MANDATORY COVID-19 VACCINATION IN CONTEXT OF

1. **The General Public:** As the vaccine supply is still insufficient to allow each member of the populace to be vaccinated, a mandate for the all citizens cannot be implemented. At this point in time, with newer variants of concern coming up every few months, vaccination of the general public may not achieve public health goals. The authorities should consider if vaccination of the general population is indispensable and commensurate to the threat of disease before mandating the vaccination. Prioritizing targeted high risk groups for mandated vaccination such aged 65 and older may be more suitable for the purpose of avoiding severe cases and deaths. Mandatory vaccination in the general population may lead to discrimination against unvaccinated people in availing education, health services and employment opportunities.^{3,21}
2. **Health Workers:** Mandatory vaccination is frequently justified in health care workers (HCWs) as HCW have direct and frequent contact with COVID patients, and are thereby at high risk of contracting the infection themselves. Work-from-home is not feasible as a means of operation for hospitals, leading to risks to the non COVID patients from infected asymptomatic HCWs. This directly goes against the ethical principle of “First do no harm” embodied in the Hippocratic Oath. As HCWs are the back bone of the health care system, multiple HCWs being affected with COVID at the same time can lead to collapse of the health system capacity. If HCWs stay unvaccinated by choice, the hospital cannot bear the responsibility of them being infected with COVID.²⁵ Mandatory vaccines for other diseases such as Hepatitis B vaccination are widespread in health care settings. These include requirements such as home quarantine for health workers if infected with Varicella/ colonized with MRSA till cured, vaccination as arequisite for employment and policies that necessitate unvaccinated HCWs to be shifted to low risk settings.

With the current third wave, health worker “burn-out” and the possible ramifications of an insufficiently resourced health workforce will have a devastating effect on the already overburdened health systems. In this scenario, mandatory vaccination policies for HCWs may be justified as being for the greater good as they ensure safety for HCWs, Patients and society at large. However as no vaccine is 100% effective, standard infection prevention and control precautions, which includes masks but also a number of other standard precautions, should be used to minimize risk.^{3,25}

3. **In Children:** Children (under 18 yrs) are not the primary age group affected by severe COVID-19 disease. However, due to prolonged pandemic lockdowns, schooling has shifted primarily to an online mode. This has impacted the education as well as social development of children and may lead to lasting repercussions on the mental health of children.

The most common rationale against universal COVID-19 immunization in children is the justification of the use of emergency use authorized (EUA) vaccines to prevent mild COVID-19 disease in pediatric age groups. However, the recent vaccine trials of the Pfizer BNT162b2 vaccine as well as the Moderna vaccine have shown a very high efficacy and favorable safety profile in the age group from 6 months onwards. The risk of myocarditis in young adult males post vaccination has been shown to be lesser than that seen in post COVID cases. Even if the COVID-19 disease in children is

considered mild, the mortality attributed to COVID infections is higher than to either pandemic influenza or Varicella. Mandatory childhood immunization has been implemented in many countries against multiple infectious diseases and has been key to protecting communities from polio, measles, mumps, rubella, etc. as with the advent of the Omicron variant, vaccinations are crucial to initiating safe in-person schooling, without risk to the child or the extended community at large as children are often asymptomatic carriers, thereby increase dissemination in the community. The SARS-CoV-2-induced complication of *Multisystem Inflammatory Syndrome of Childhood (MIS-C)*, is still not clearly understood but has caused severe inflammatory response to infection that leads to multi-system organ damage. This requires prolonged steroid usage and intensive care hospitalization for treatment and yet causes high mortality. Preventing COVID infection through wide-spread pediatric vaccination should therefore decrease MIS-C. An additional benefit to children is the prevention of the residual, long-term central nervous system sequelae of infection called “Long COVID”. “Long COVID” is characterized by fatigue, alterations in taste and smell, and cognitive residua and is being observed increasingly in pediatric COVID infections.^{3,25}

Vaccination for children therefore has multiple benefits such as prevention of COVID-associated hospitalizations, reduction of mortality in children, protection against MIS-C and “long COVID” syndrome and allows for social reintegration with schools and outdoor activities starting in full swing. The choice of offering optional COVID or to make it mandatory to achieve the public health objectives rests with the authorities.

V. CONCLUSION: ARE MANDATES NEEDED?

As the third year of third year of the COVID-19 pandemic, the primary focus has changed from trying to eliminate COVID cases to containing the spread so that newer variants do not surface. COVID-19 has become a part of routine life and vaccination will help avoid the severe cases and deaths. With debates hovering around, concerning variants, vaccination efficacy, and opening businesses, it is implausible to believe the world is absolutely out of the danger. Despite clear benefits of vaccination in the short term, long term side effects still remain to be evaluated. Vaccination must be made universally available to confer enhanced protection against COVID-19. However, vaccination should be a collective decision-making process. Public education and building people’s trust in vaccination may be a preferred choice at the current situation instead of being an unconditional obligation, despite its importance for ending the pandemic.

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