

# COVID-19 and mandatory vaccination: Ethical considerations

Policy brief

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## Introduction

Vaccines are one of the most effective tools for protecting people against COVID-19. Consequently, some governments and organizations have made COVID-19 vaccination ‘mandatory’ to increase vaccination rates, discharge what are perceived to be duties of care to at-risk populations and/or achieve public health goals. Others may be considering whether they ought to do the same, and, if so, under what conditions, for whom, and in what contexts.

Governments and institutions mandate many actions or types of behaviour to protect the well-being of the public. For instance, in many parts of the world, people are required to wear seatbelts, motorists with poor visual acuity are required to wear corrective lenses, restaurant owners are required to regularly submit to food service inspections and medical assessments are required for certain jobs. Governments and institutions also have a history of requiring vaccination as a condition for working in certain settings/roles or attending school. Such policies can be ethically justified, as they may be crucial to protect the health and well-being of the public. This value, however, may come into tension with others, such as individual liberty and autonomy (i.e., allowing individuals to make their own decisions about their health) (1). Although interfering with individual liberty or autonomy does not necessarily make a policy intervention unjustified, policies that constrain or eliminate individual choice can be controversial and raise a number of ethical considerations, and so they should be justified by advancing another valuable social goal, like protecting public health.

Vaccination mandates can be ethically justified; however, their ethical justification is contingent upon a number of conditions and considerations, including the contexts within which they are implemented. This document identifies and articulates important ethical considerations that should be explicitly evaluated and discussed through ethical analysis by governments and/or institutional policy makers who may be considering mandates for COVID-19 vaccination. The aim of the document is to identify and articulate salient ethical considerations so that policy makers may engage with them; it does not aim to fully explain or address these ethical considerations and issues. This document updates a policy brief initially published in April 2021 in response to changes in the COVID-19 vaccine landscape, including authorization of vaccines for children and additional information about, and experiences with, vaccination mandates for COVID-19.

## What does “mandatory vaccination” entail?

Contemporary forms of “mandatory vaccination” make vaccination a condition of, for example, working in particular jobs or settings such as health care, attending school or participating in certain activities (2). Typically, mandatory vaccination policies permit a limited number of exceptions, such as medical contraindications that are recognized by legitimate authorities (3). Despite its name, “mandatory vaccination” is rarely compulsory, i.e., people are not forced to be vaccinated. In other words, there is a difference between saying ‘you must be vaccinated’ and ‘you must be vaccinated in order to...’. Still, mandatory vaccination policies constrain individual choice in non-trivial ways, for example, by carrying consequences that make noncompliance challenging. Vaccination mandates are not uncommon (2), although it should be noted that the World Health Organization (WHO) does not presently support the direction of mandates for COVID-19 vaccination, having argued that it is better to work on information campaigns and making vaccines accessible (4). In addition, WHO has issued a position statement that national authorities and conveyance operators should not require COVID-19 vaccination as a condition of international travel (5).

Laws and the legal justifications for mandatory vaccination differ by jurisdiction (6). Yet, what is ethical or ethically obligatory cannot and should not necessarily be reduced to what the law entails because not all that is ethical is legal, and vice versa.

## Ethical considerations regarding mandatory COVID-19 vaccination

The following considerations should **all** be explicitly evaluated and discussed through an ethical analysis by governments and/or institutional policy makers who may be considering COVID-19 vaccination mandates. They should be considered alongside other relevant scientific, medical, legal and practical considerations not described in this document and should be reviewed in the light of evolving evidence.

### 1. Necessity and proportionality

Mandatory vaccination should be considered only if it is necessary for, and proportionate to, the achievement of one or more important societal or institutional objectives (typically but not exclusively public health objectives, which may also be in service of social and economic objectives). Among others, such objectives may include interrupting chains of viral transmission, preventing morbidity and mortality, protecting at-risk populations and preserving the capacity of acute health care systems or other critical infrastructure. If such objectives can be achieved with acceptable, less intrusive policy interventions (e.g. public information campaigns, community mobilization campaigns, non-pharmaceutical interventions) and within an acceptable time frame, the ethical justification for a mandate would be weaker because achieving those objectives with less restriction of individual liberty and autonomy tends to yield a more favourable balance between the values of protecting the health and well-being of the public and individual liberty and autonomy (*1*). It should be noted that the use of vaccination mandates and other policy interventions, such as public information campaigns, are not mutually exclusive.

As mandates represent a policy option that must be balanced with other values, such as individual liberty and autonomy, their ethical justification will tend to be stronger if they increase the prevention of significant risks of morbidity and mortality and/or promote significant and unequivocal societal or institutional benefits. If such benefits or objectives cannot be achieved without a mandate—for instance, if a substantial portion of individuals are able but unwilling to be vaccinated and this is likely to result in significant risks of COVID-19-related harms—their concerns should be addressed, proactively if possible. If addressing such concerns is ineffective, and those concerns remain a barrier to the achievement of important objectives, and/or if low vaccination rates in the absence of a mandate put others at significant risk of serious harm, a mandate may be considered necessary. In this case, those proposing the mandate should communicate the reasons for the mandate to the affected communities through effective channels and find ways to implement the mandate in such a way that it addresses the reasonable concerns of communities.

Individual liberties should not be restricted for longer than necessary in order to achieve the most favourable balance between the values of protecting the health and well-being of the public and individual liberty. This can be achieved, for example, by introducing ‘sunset’ clauses indicating the conditions that would warrant the removal of a mandate. Policy makers should therefore frequently re-evaluate the mandate to ensure it remains necessary and proportionate to achieve important objectives. In addition, the necessity of a mandate to achieve important objectives should be evaluated in the context of repeated vaccinations (boosters) and the durability of protection conferred by vaccination. Ultimately, mandates may be necessary and proportionate in some circumstances and not others, at one time and not another, and in some jurisdictions and not others.

It is important to acknowledge that there may be significant uncertainty about whether less intrusive policy interventions would be capable of achieving important societal or institutional objectives (which would thereby render vaccination mandates unnecessary). Where a threat of severe outcomes exists in the absence of effective countermeasures, waiting to implement vaccination mandates until all other options have been found to be ineffective may result in significant harms that might otherwise have been avoided, violating the duty to protect the public from harm. Consequently, while an obligation exists to ground decisions about vaccination mandates in the best available evidence, a lack of full certainty regarding the ineffectiveness of other measures should not necessarily preclude the use of vaccination mandates if there is reason to believe they would be effective at averting significant harm.

Finally, if alternatives to mandates exist that are capable of achieving desired objectives but are considered less acceptable (e.g. school closures, stay-at-home orders), a mandate could in this case also be considered necessary—that is, necessary to achieve stated objectives without using less acceptable interventions. Insofar as vaccination mandates are used to facilitate the removal or easing of other public health and social measures used in pandemic response—such as remote learning, business closures and border restrictions—*not* using vaccination mandates may in fact represent a less favourable balance between protecting the health and well-being of the public and individual liberty and autonomy.

## 2. Sufficient evidence of vaccine safety

Data should be available that demonstrate the vaccine being mandated has been found to be sufficiently safe in the populations for whom the vaccine is to be made mandatory. When safety data are lacking or when they suggest the risks associated with vaccination outweigh the risks of harm without the vaccine, the mandate would not be ethically justified, particularly without allowing for reasonable exceptions (e.g. medical contraindications). Policy makers should consider specifically whether vaccines authorized for emergency or conditional use (as opposed to receiving full market licensure from a national regulatory authority) meet an evidentiary threshold for safety sufficient for a mandate (7). In the absence of sufficient evidence, there would be no guarantee that mandating vaccination would achieve public health or other objectives. Furthermore, exposure of populations to a potentially harmful product via a mandate would violate the ethical obligation to protect the public from unnecessary harm if the harm the product might cause outweighs the degree of harm that might exist without the product. Evidence generated from clinical trials and real-world use has demonstrated that authorized COVID-19 vaccines meet this condition of safety (8).

Even when the vaccine is considered sufficiently safe, mandatory vaccination should be implemented with no-fault compensation schemes to address any vaccine-related harm that might occur. This is important because it would be unfair to require people to seek legal remedy from harm resulting from a mandatory intervention (9). Such compensation would depend on countries' health systems, including the extent of universal health coverage and how they address harm from vaccines that are not fully licensed (e.g. vaccines authorized for emergency or conditional use).

## 3. Sufficient evidence of vaccine efficacy and effectiveness

Data demonstrating that the vaccine is efficacious in the population for whom it is to be mandated and is an effective means of achieving the identified public health/societal/institutional objective should be available. For instance, if mandatory vaccination is considered necessary to interrupt transmission chains and/or prevent harm to others, there should be sufficient evidence that the vaccine is efficacious in preventing infection and/or transmission (as appraised by legitimate authorities such as WHO's Strategic Advisory Group of Experts on Immunization or national regulatory authorities). Alternatively, if a mandate is considered necessary to prevent hospitalization and protect the capacity of the acute health care system, there should be sufficient evidence that the vaccine is efficacious in reducing hospitalization. Policy makers should carefully consider whether vaccines authorized for emergency or conditional use (as opposed to receiving full market licensure from a national regulatory authority) meet evidentiary thresholds for efficacy and effectiveness sufficient for a mandate (7). Additionally, for vaccines consisting of multiple doses, policy makers should consider the number of doses necessary to effectively pursue stated objectives.

## 4. Justice in access and availability

As a condition for implementing a mandate, supply of the authorized vaccine should be sufficient and reliable, and the populations that would be affected by the mandate should be able to easily access the vaccine without cost to them. Those implementing a mandate should make it as easy as possible to be vaccinated. For instance, vaccination programmes should be delivered in community settings with a particular emphasis on targeting communities that face disadvantage for systemic reasons. The absence of a sufficient supply, free access and meaningful, barrier-free opportunities to be vaccinated would not only render a mandate ineffective but would create an unduly burdensome, unfair demand on those who are required to be vaccinated but are unable to access the vaccine. Such a mandate would threaten to exacerbate social inequity.

In many cases, there is a social gradient in vaccine uptake owing to multiple factors, including distrust resulting from histories of oppression, marginalization and discrimination. Consequently, insofar as mandates could lead to negative outcomes for those choosing not to meet the condition of being vaccinated, mandates could disadvantage populations already experiencing systemic disadvantage, which may create or exacerbate inequity. In addition to ensuring meaningful access and availability of vaccines and taking steps in good faith to respect human rights obligations, effort should therefore be made to work with communities to proactively address reasons for vaccine hesitancy. At the same time, it should be acknowledged that insofar as vaccination mandates can protect at-risk populations (such as people who are unable to be vaccinated or are immunocompromised), *not* using vaccination mandates could exacerbate inequity experienced by such groups because of increased vulnerability to exposure and/or illness.

## 5. Public trust

Policy makers have a duty to carefully consider the effect that mandating vaccination could have on public confidence and public trust, particularly on confidence in the scientific community and vaccination

generally (10). If such a policy threatens to undermine confidence and public trust, it might affect both vaccine uptake and adherence to other important public health measures, which can have an enduring effect (11). In particular, the coercive power that governments or institutions display in a programme that constrains or eliminates choice could have unintended negative consequences for at-risk or marginalized populations (12). High priority should therefore be given to threats to public trust and confidence among historically disadvantaged minority populations, ensuring that cultural considerations are taken into account. Vaccine hesitancy may be stronger in such populations and may not be restricted to concerns about safety and effectiveness (13) because mistrust in authorities may be rooted in histories of unethical medical, public health and other policies and practices as well as structural inequity (10). Such populations may regard mandatory vaccination as another form of inequity or oppression that makes it more difficult for them to access jobs and essential services (14).

At the same time, policy makers should consider the effect that *not* mandating vaccination could have on public confidence, public trust and inequity, as well as on various important freedoms. Public confidence and trust may be undermined, for example, if steps known to protect the public from harm are not taken as part of the pandemic response, particularly if they are not implemented in settings with populations that are in vulnerable situations (e.g. congregate settings in which care is provided to older adults and hospitals).

The extent to which mandatory vaccination policies accommodate conscientious objection may also affect public trust (15). There should, however, be strict scientific and prudential limits to appeals for accommodation or “conscientious objection”, especially when such accommodation might be used by individuals to ‘free ride’ the public health good of community protection (i.e., taking advantage of the benefit without contributing towards the cost of its production) or if they threaten public health and others’ right not to be infected with a virulent infectious disease (16, 17).

Finally, it should be acknowledged that those opposed to the use of vaccination mandates may take advantage of social dissent even when the use of a mandate is ethically justified, which may impact social and community cohesion. Where mandates are used, careful and compassionate consideration must be given to the impact of the mandate on those who remain unvaccinated. Mandates should be used as a means of pursuing an important societal or institutional objective, not as a means of punishing disagreeable behaviour. Careful attention to the ethical considerations outlined in this document and about *how* mandates are introduced and managed may help to promote and/or preserve public trust, which may work to mitigate threats to social and community cohesion.

## 6. Ethical processes of decision-making

Policy makers have a duty to act in trustworthy ways, which can be promoted through ethical processes of decision-making and communicating decisions to the public. Transparency of decision-making is a fundamental element of ethical analysis and decision-making about mandatory vaccination. Policy makers have a duty to communicate the reasons justifying a mandate (or not), including how those decisions were reached and the consequences of noncompliance, in a manner that the general public can understand. Reasonable effort should be made to engage affected parties and relevant stakeholders, and particularly people who are marginalized or in a vulnerable situation, such as migrant workers, refugees and minorities, to elicit and understand their perspectives. Authorities contemplating mandatory vaccination policies should use transparent, deliberative procedures to consider the ethical issues outlined in this document in an explicit ethical analysis, including the threshold of evidence necessary for vaccine safety and effectiveness to justify a mandate. They should also demonstrate accountability for such decisions by explicitly and transparently communicating the rationale for decisions regarding the use of vaccination mandates to the public. As in other contexts, mechanisms should be in place to monitor evidence constantly and to revise such decisions periodically.

### Mandatory COVID-19 vaccination in context

No vaccine is perfect. However, authorized COVID-19 vaccines have been shown to be safe and highly effective in preventing severe disease, hospitalization and death, and there is some evidence that being vaccinated will make it less likely to become infected and pass the virus on to others (18). That said, the nature of the COVID-19 pandemic and evidence on vaccine safety, efficacy, and effectiveness continue to evolve (including with respect to variants of concern, boosters, durability of protection, and authorization of new vaccines). Consequently, the six considerations identified above are described generally so that they can be applied at any point in time and in any context. The following examples illustrate how ethical considerations can be applied in three settings for which mandatory vaccination might commonly be considered.



## The general public

Vaccination mandates for general adult populations are rare (7), though several countries have made, or plan to make, COVID-19 vaccination mandatory for the general public (19). In the absence of a sufficient, reliable vaccine supply that would permit every eligible member of the general public to be vaccinated, a mandate for the general public would fail to address ethical consideration 4 regarding meaningful access and availability. Even if there is meaningful access and availability, policy makers should consider whether mandatory vaccination of the general population is necessary and proportionate to achieve important societal objectives (ethical consideration 1). More evidence may be required about vaccine uptake to determine whether a mandate is necessary. This will depend on local contexts and on the goals of the health system (e.g. protecting at-risk populations, preserving health system capacity). Similarly, the extent to which a mandate for the general public is proportional will depend to some extent on the local context, given the variation in COVID-19 epidemiology in different jurisdictions. Even if there is sufficient access and availability, and a mandate for vaccination of the general public is considered necessary and proportionate, policy makers should still consider how to promote trust and prevent or mitigate inequity if using a mandate (ethical consideration 5).

## In schools

In some jurisdictions, vaccination against the viruses that cause a number of diseases (e.g. polio, measles, mumps, rubella) is a condition for attending school. The objectives are to directly protect children from disease, reduce the risk of disease outbreaks and more generally control vaccine-preventable diseases (2, 20, 21). The justifications for the vaccination mandates for the aforementioned infectious diseases might be considered as a justification for COVID-19 vaccination mandates in school contexts, since COVID-19 vaccines authorized for children and adolescents are safe and effective in reducing the disease burden in these age groups and can reduce intergenerational transmission and minimise school disruptions (22). It could be argued, however, that mandates for routine paediatric vaccines are distinct from COVID-19 vaccines given the rapidly evolving nature of the COVID-19 pandemic and evolving evidence for COVID-19 vaccines, including their effectiveness against novel variants of concern, the number of doses necessary to achieve important societal or institutional objectives and durability of protection.

In addition to evaluating the impacts of a mandate (or lack of a mandate) on the health of children, teachers, school staff and the broader community, mandates in schools should be evaluated for their potential impact on children's education and related social and mental well-being. In particular, mandates should not result in denial of education to unvaccinated children in order to respect every child's right to an education (23). Reasonable steps should therefore be taken to accommodate unvaccinated children so as to interfere as little as possible with their education while not jeopardizing the well-being or education of other children. Similarly, policy makers should evaluate the impacts that *not* having a mandate in schools might have for children's health, education, and related social and mental well-being. The ethical justification for mandates in schools might therefore be strongest where it could be expected that the absence of a mandate would result in school disruptions that would affect the education and well-being of all students. In any case, policy makers will have to consider whether mandating vaccination as a condition of attending school is necessary and proportional to the achievement of an important societal or institutional objective (ethical consideration 1) and whether this could undermine public trust (ethical consideration 5).

## Health workers

Mandatory vaccination is perhaps most often discussed in the context of health and social care, particularly where health workers have direct contact with populations at high risk of SARS-CoV-2 infection or severe illness or death resulting from COVID-19 and given their ethical obligation not to harm their patients. Mandatory COVID-19 vaccination might appear to be particularly plausible for health workers given that vaccination of this population might be seen as necessary to protect health system capacity (ethical consideration 1) and because health workers are generally identified as a priority group for vaccination, meaning there is more likely to be a sufficient supply to meet the needs of this population (ethical consideration 4). Whether a mandate for health workers is necessary and proportionate (ethical consideration 1) and would not undermine trust (ethical consideration 5) might depend on the local context and, if possible, should be investigated empirically before a mandate is considered for this population.

Mandatory vaccination against specific diseases is not uncommon in health care settings (24), including requirements that unvaccinated health workers stay at home during outbreaks, policies in which vaccination is required as a condition of employment, requirements that unvaccinated health workers be transferred to settings where the risk is lower and so-called "vaccinate-or-test" policies.

Given current rates (and concerns) of health worker “burn-out” as a result of the pandemic and the potential consequence of an inadequately resourced health workforce (25), mandatory vaccination policies that require unvaccinated health workers to stay at home or require vaccination as a condition of employment or hospital privileges might have significant negative consequences for already overburdened health systems. Policies that require unvaccinated health workers to be transferred to settings where the risk is lower might have similar consequences, as they might remove critical health workers from settings that badly need personnel, such as congregate living settings where care is provided to older adults. Additionally, it may be difficult to distinguish high- and low-risk settings where there is widespread community transmission of SARS-CoV-2. At the same time, the absence of a policy that all but guarantees a high rate of vaccination coverage in health care settings may result in more infections, illness and hospitalizations among health workers, which could similarly negatively impact already overburdened health systems. It could also undermine public trust in the health system’s commitment to take steps to protect the health of its patients.

Finally, some might consider whether vaccination mandates should be accompanied by an alternative to vaccination consisting of frequent testing as a means of demonstrating that one is not infected or infectious. So-called ‘vaccinate-or-test’ policies could plausibly be justified if they are just as capable of achieving important societal or institutional objectives as a vaccination requirement (and if barriers do not exist to frequent, reliable testing). In this case, such a policy would benefit from a more favourable balance between the values of protecting the health and well-being of the public and individual liberty and autonomy. Yet, it is hitherto unclear whether vaccinate-or-test policies would be as effective as vaccination mandates that do not have a testing option, because unlike vaccination, testing on its own does not reduce risk of infection and may fail to identify infections because of false negatives or inadequate testing frequency. In this case, vaccinate-or-test policies risk placing too much emphasis on the protective effect of frequent testing.

## Conclusions

Ideally, policy makers should use less intrusive means or methods to encourage voluntary vaccination against COVID-19 before contemplating mandatory vaccination. In other words, mandates should be considered only after people have been given the opportunity to get vaccinated voluntarily and/or once there is sufficient reason to believe this alone will not be enough to achieve important societal or institutional objectives. Efforts should be made to demonstrate the health risks of not being vaccinated and the benefit and safety of vaccines for the greatest possible acceptance of vaccination. A number of ethical considerations should be explicitly discussed and addressed through ethical analysis when evaluating whether mandatory COVID-19 vaccination is an ethically justifiable policy option. Just as it is the case for other public health policies, decisions about mandatory vaccination should be supported by the best available evidence and should be made by legitimate decision-makers in a manner that is transparent, just, fair and non-discriminatory and involves the input of affected parties.

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