COVID-19 and mandatory vaccination: Ethical considerations and caveats

Policy brief

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Background

Vaccines are one of the most effective tools for protecting people against COVID-19. Consequently, with COVID-19 vaccination under way or on the horizon in many countries, some may be considering whether to make COVID-19 vaccination mandatory in order to increase vaccination rates and achieve public health goals and, if so, under what conditions, for whom and in what contexts.

It is not uncommon for governments and institutions to mandate certain actions or types of behaviour in order to protect the well-being of individuals or communities. Such policies can be ethically justified, as they may be crucial to protect the health and well-being of the public. Nevertheless, because policies that mandate an action or behaviour interfere with individual liberty and autonomy, they should seek to balance communal well-being with individual liberties (1). While interfering with individual liberty does not in itself make a policy intervention unjustified, such policies raise a number of ethical considerations and concerns and should be justified by advancing another valuable social goal, like protecting public health.

This document does not provide a position that endorses or opposes mandatory COVID-19 vaccination. Rather, it identifies important ethical considerations and caveats 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.

What does "mandatory vaccination" entail?

Sub-heading

Contemporary forms of "mandatory vaccination" compel vaccination by direct or indirect threats of imposing restrictions in cases of non-compliance (2). Typically, mandatory vaccination policies permit a limited number of exceptions recognized by legitimate authorities (e.g., medical contraindications) (3). Despite its name, 'mandatory vaccination" is not truly compulsory, i.e., force or threat of criminal sanction are not used in cases of non-compliance. It is therefore the kind of mandatory vaccination described at the beginning of this paragraph to which we refer in this document. Still, "mandatory vaccination" policies limit individual choice in non-trivial ways by making vaccination a condition of, for example, attending school or working in particular industries or settings, like health care. Such policies 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 recently 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). A legal obligation to be vaccinated is distinct from an ethical obligation insofar as the latter is not enforced by threats of restrictions in the case of non-compliance. The focus of this document is ethical considerations and caveats for mandatory COVID-19 vaccination policies.

Ethical considerations and caveats regarding mandatory COVID-19 vaccination

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

1. Necessity and proportionality

Mandatory vaccination should be considered only if it is necessary for, and proportionate to, the achievement of an important public health goal (including socioeconomic goals) identified by a legitimate public health authority. If such a public health goal (e.g., herd immunity, protecting the most vulnerable, protecting the capacity of the acute health care system) can be achieved with less coercive

or intrusive policy interventions (e.g., public education), a mandate would not be ethically justified, as achieving public health goals with less restriction of individual liberty and autonomy yields a more favourable risk-benefit ratio (1).

As mandates represent a policy option that interferes with individual liberty and autonomy, they should be considered only if they would increase the prevention of significant risks of morbidity and mortality and/or promote significant and unequivocal public health benefits. If important public health 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 harm – their concerns should be addressed, proactively if possible. If addressing such concerns is ineffective and those concerns remain a barrier to achievement of public health 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" to achieve public health objectives. 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 such that it accommodates the reasonable concerns of communities. Individual liberties should not be challenged for longer than necessary. Policy-makers should therefore frequently re-evaluate the mandate to ensure it remains necessary and proportionate to achieve public health goals. In addition, the necessity of a mandate to achieve public health goals should be evaluated in the context of the possibility that repeated vaccinations may be required as the virus evolves, as this may challenge the possibility of a mandate to realistically achieve intended public health objectives.

2. Sufficient evidence of vaccine safety

Data should be available that demonstrate the vaccine being mandated has been found to be 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 meet an evidentiary threshold for safety sufficient for a mandate (7). In the absence of sufficient evidence of safety, there would be no guarantee that mandating vaccination would achieve the goal of protecting public health. Furthermore, coercive exposure of populations to a potentially harmful product would violate the ethical obligation to protect the public from unnecessary harm when the harm the product might cause outweighs the degree of harm that might exist without the product.

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, as it would be unfair to require people who experience vaccine-related harm to seek legal remedy from harm resulting from a mandatory intervention (8). 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 on efficacy and effectiveness should be available that show the vaccine is efficacious in the population for whom vaccination is to be mandated and that the vaccine is an effective means of achieving an important public health goal. For instance, if mandatory vaccination is considered necessary to interrupt transmission chains and prevent harm to others, there should be sufficient evidence that the vaccine is efficacious in preventing serious infection and/or transmission. 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 meet evidentiary thresholds for efficacy and effectiveness sufficient for a mandate (7).

4. Sufficient supply

In order for a mandate to be considered, supply of the authorized vaccine should be sufficient and reliable, with reasonable, free access for those for whom it is to be made mandatory (i.e., there should be few barriers that make it difficult for populations affected by the mandate to access the vaccine). The absence of a sufficient supply and reasonable, free access would not only render a mandate ineffective in achieving vaccine uptake, 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 access to health care.

5. Public trust

Policy-makers have a duty to carefully consider the effect that mandating vaccination could have on public confidence and public trust, and particularly on confidence in the scientific community and public trust in vaccination generally (9). 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 (10). In particular, the coercive power that governments or institutions display in a programme that undermines voluntariness could have unintended negative consequences for vulnerable or marginalized populations (11). High priority should therefore be given to threats to public trust and confidence amongst 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 of safety and efficacy (12), as mistrust in authorities may be rooted in histories of unethical medical and public health policies and practices as well as structural inequity (9). Such populations may regard mandatory vaccination as another form of inequity or oppression, making it more difficult for them to access jobs and essential services (13).

The extent to which mandatory vaccination policies accommodate conscientious objection may also affect public trust (14). 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 herd immunity or if they threaten public health and others' right not to be infected with a virulent infectious disease (15, 16).

6. Ethical processes of decision-making

Transparency and stepwise decision-making by legitimate public health authorities should be fundamental elements of ethical analysis and decision-making about mandatory vaccination. Reasonable effort should be made to engage affected parties and relevant stakeholders, and particularly those who are vulnerable or marginalized, to elicit and understand their perspectives. Steps should be taken in good faith to respect human rights obligations not to discriminate or disproportionately disadvantage vulnerable populations. Legitimate public health authorities that are 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 efficacy to justify a mandate. 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

Authorized COVID-19 vaccines have been shown to be safe and efficacious in preventing severe disease and death, and it is clear that vaccine supply will continue to increase globally, albeit inequitably. That being 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). Consequently, the six considerations identified above are described generally so that they can be applied at any point in time and in any context. For illustrative purposes, we now turn our attention to the application of these ethical considerations in three settings for which mandatory vaccination is commonly discussed: for the general public, in schools, and for health workers.

The general public

Vaccination mandates for general adult populations are rare (7). 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 sufficient supply. Even if there is a sufficient, reliable vaccine supply, policy-makers should consider whether mandatory vaccination of the general population is necessary and proportionate to achieve intended public health goals (ethical consideration 1). More evidence may be required about vaccine uptake to determine whether a mandate is necessary, which will depend on local contexts and on the goals of the health system (e.g., achievement of herd immunity, protecting the most vulnerable). 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 a sufficient supply and a mandate for vaccination of the general public is considered necessary and proportionate, policy-makers should still consider whether a mandate for the general public would threaten public trust or exacerbate inequity for the most vulnerable or marginalized (ethical consideration 5).

In schools

Given the lack of data on the safety and efficacy of COVID-19 vaccines for children (ethical considerations 2 and 3), COVID-19 vaccines have not yet been authorized for this population. Consequently, vaccination is not currently ethically justified as a condition for attending school. Once such data are available and show favourable safety and efficacy in this population, policy-makers will have to consider whether mandating vaccination as a condition of attending school is necessary and proportional to achieve the public health objectives (ethical consideration 1) and whether this could undermine public trust (ethical consideration 5). 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 or receiving state-sponsored entitlements (2); however, mandates for routine paediatric vaccines are distinct from vaccines authorized for emergency use in many respects, including the relatively limited and evolving evidence for COVID-19 vaccines in addition to uncertainty regarding herd immunity and new SARS-CoV-2 variants in the context of COVID-19.

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 (e.g., congregate settings in which care is provided to older adults), because of the unique settings in which health workers work and their ethical obligation not to harm their patients. Moreover, 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 commonly 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 should be investigated empirically before a mandate is considered for this population.

Forms of mandatory vaccination are not uncommon in health care settings (17), 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-mask" 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 (18), 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 health human resources, 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.

Finally, some health institutions might wonder whether vaccinate-or-mask policies, which have not been proposed for COVID-19 but are sometimes used as a type of vaccine mandate for seasonal influenza (19, 20), should be similarly used to mandate COVID-19 vaccinations among health workers. As masks are likely to be a requirement in health care settings for the foreseeable future, the incentive for health workers to be vaccinated under vaccinate-or-mask policies – namely, that they will not have to wear a mask in all patient care settings while the virus is circulating if they are vaccinated – will simply lack the same force. Vaccinate-or-mask policies would retain this force if vaccination against COVID-19 meant that vaccinated health workers could refrain from wearing masks, but this is not scientifically or ethically justified given the importance of personal protective equipment for institutional infection prevention and control (21), particularly where there is uncertainty surrounding a vaccine's capacity for sterilizing immunity. In this case, vaccinate-or-mask policies risk placing too much emphasis on the protective effect of masks. Because 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.

Conclusions

Vaccines are effective for protecting people from COVID-19. Governments and/or institutional policy-makers should use arguments to encourage voluntary vaccination against COVID-19 before contemplating mandatory vaccination. Efforts should be made to demonstrate the benefit and safety of vaccines for the greatest possible acceptance of vaccination. Stricter regulatory measures should be considered only if these means are not successful. A number of ethical considerations and caveats should be explicitly discussed and addressed through ethical analysis when considering whether mandatory COVID-19 vaccination is an ethically justifiable policy option. Similar to other public health policies, decisions about mandatory vaccination should be supported by the best available evidence and should be made by legitimate public health authorities in a manner that is transparent, fair, non-discriminatory, and involves the input of affected parties.

References

1. Nuffield Council on Bioethics. Public health: Ethical issues. London: Nuffield Council on Bioethics; 2007 (https://www.nuffieldbioethics.org/assets/pdfs/Public-health-ethical-issues.pdf).
2. Gravagna K, Becker A, Valeris-Chacin R, Mohammed I, Tambe S, Awan FA et al. Global assessment of national mandatory vaccination policies and consequences of non-compliance. Vaccine. 2020;38:7865–73.
3. Colgrove J, Bayer R. Manifold restraints: Liberty, public health, and the legacy of Jacobson v Massachusetts. Am J Public Health. 2005;95:571–6.
4. World Health Organization. COVID-19 virtual press conference 7 December 2020 (https://www.who.int/publications/m/item/covid-19-virtual-press-conference-transcript---7-december-2020).
5. World Health Organization. Interim position paper: Considerations regarding proof of COVID-19 vaccination for international travellers. Geneva: World Health Organization; 2021 (https://www.who.int/news-room/articles-detail/interim-position-paper-considerations-regarding-proof-of-covid-19-vaccination-for-international-travellers).
6. Walkinshaw E. Mandatory vaccinations: The international landscape. Can Med Assoc J. 2011;183:e1167–8.
7. Gostin LO, Salmon DA, Larson HJ. Mandating COVID-19 vaccines. JAMA. 2020;325:532–3.
8. Halabi S, Heinrich A, Omer S. No-fault compensation for vaccine injury – The other side of equitable access to Covid-19 vaccines. N Engl J Med. 2020;383:e125.
9. Schwartz JL. Evaluating and deploying Covid-19 vaccines – The importance of transparency, scientific integrity, and public trust. N Engl J Med. 2020;383:1703–5.
10. Shetty P. Experts concerned about vaccination backlash. Lancet. 2020;375:970–1.
11. Giubilini A. Chapter 3, Vaccination policies and the principle of least restrictive alternative: An intervention ladder. In Giubilini A, The ethics of vaccination. Cham (CH): Palgrave Pivot; 2019.
12. Goldenberg M. Vaccine hesitancy: Public trust, expertise, and the war on science. Pittsburgh, PA: University of Pittsburgh Press. 2021.
13. Opel DJ, Lo B, Peek ME. Addressing mistrust about COVID-19 vaccines among patients of color. Ann Intern Med. 2021;M21-0055. doi: 10.7326/M21-0055.
14. Colgrove J. Immunization and ethics: Beneficence, coercion, public health, and the state. In: Mastroianni AC, Kahn JP, Kass NE, editors. The Oxford handbook of public health ethics, New York City (NY): Oxford University Press; 2020:435–44.
15. Sutton EJ, Upshur REG. Are there different spheres of conscience? J Eval Clin Pract. 2010;16:338–43.

16. Harris J, Holm S. Is there a moral obligation not to infect others? BMJ. 1995;311:1215–7.
17. Gruben V, Siemieniuk RA, McGeer A. Health care workers, mandatory influenza vaccination policies and the law. Can Med Assoc J. 2014;186:1076–80.
18. Krystal JH. Responding to the hidden pandemic for healthcare workers: Stress. Nat Med. 2020;26:639.
19. Van Buynder PG, Konrad S, Kersteins F, Preston E, Brown PD, Keen D, et al. Healthcare worker influenza immunization vaccinate or mask policy: Strategies for cost effective implementation and subsequent reductions in staff absenteeism due to illness. Vaccine. 2015;33:625–8.
20. Caplan A, Shah NR. Managing the human toll caused by seasonal influenza: New York State's mandate to vaccinate or mask. JAMA. 2013;310:1797–8.
21. World Health Organization. Mask use in the context of COVID-19 – Interim guidance. Geneva: World Health Organization; 2020. (https://www.who.int/publications/i/item/advice-on-the-use-of-masks-in-the-community-during-home-care-and-in-healthcare-settings-in-the-context-of-the-novel-coronavirus-(2019-ncov)-outbreak).

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