Policy considerations for mandatory COVID-19 vaccination from the Collaboration on Social Science and Immunisation

The benefits gained by vaccination mandates must be greater than the harms they may cause

ublic attention has been intensely focused on how Australia can achieve the very high vaccination coverage needed for optimal control of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Governments and businesses have already mandated coronavirus disease 2019 (COVID-19) vaccination for workers in certain sectors, and vaccination is currently required for entry into many public venues in New South Wales and Victoria. International air travel without requiring an exemption is now possible for the fully vaccinated, as is the case in other countries. Outbreaks of COVID-19, with their restrictive public health measures, have meant there is widespread support to mandate COVID-19 vaccination in settings where people gather.

Mandatory vaccination policies impose individual consequences for non-vaccination. They vary in the population subject to the requirement, the scale and type of consequences for non-compliance, and accepted exemptions. Consequences for non-compliance include change or loss of employment; a requirement to use masks; reduced access to money, goods or services; and inability to travel to another country. In some countries, more severe consequences may include fines or convictions and potential imprisonment.

Vaccine mandates are legitimised through reducing the risk of one person passing an infection to others. Requirements in occupational settings are often used to reduce risk of health workers infecting others, including those who are at higher risk of the disease and its severe effects. In general community settings, mandates may be used as a strategy to increase vaccination coverage more broadly. Because they are more coercive than other interventions to increase vaccination coverage, mandates demand stronger ethical justification. Policy makers should balance rights of individuals and the promotion of public good while carefully considering the epidemiological, programmatic and legal issues.

This article outlines the range of issues that need to be considered before, and when, making vaccination mandatory in any setting. It is intended for government policy makers, managers and executives. State and private sector mandates may differ in design, reach, purpose and implications. However, we provide guidance that is relevant for both, including outlining areas that are governments' responsibility. We base our considerations on epidemiology, behavioural science and ethics, as well as policy and program issues learnt from other mandatory vaccination regimes.

The authors are members of the Collaboration on Social Science and Immunisation, Australia's leading network informing immunisation policy and practice with high quality evidence from the social sciences. We initially contributed to a working paper in February 2021, which was updated in May. We then met to consolidate the normative position and structure for this article, and collaboratively refined the arguments through three meetings. A webinar was also held on 26 July 2021.²

Prerequisites for mandatory COVID-19 vaccination

Mandates should only be implemented once a set of conditions relevant to the setting is satisfied. Below we set out these considerations.

The mandate should be legal

In most settings, mandatory vaccination must have legislative support.³ For occupational settings, the Fair Work Ombudsman provides general guidance (https:// coronavirus.fairwork.gov.au/coronavirus-and-australianworkplace-laws/covid-19-vaccinations-and-the-workp lace). Broadly, employers can only require their employees to be vaccinated when a specific law requires it, when it is permitted by an enterprise agreement or other registered agreement or employment contract, or when it is lawful and reasonable to do so. The Fair Work Ombudsman divides work into four tiers of risk to facilitate case-by-case assessment: Tier 1, where employees are at higher risk of being exposed to COVID-19; Tier 2, where employees work with people who are at higher risk of serious health impacts from COVID-19; Tier 3, where interaction with others is likely; and Tier 4, where there is limited face-to-face interaction.

Burden of disease should be high enough to justify a mandate

The heavier the disease burden, the more justifiable mandates may be to increase coverage. In a setting that poses a higher risk of transmission, particularly to people more likely to experience serious harm, imposition on liberties may be more justifiable, at least while the background disease rates are high and transmission is more likely.

The mandated vaccines should be safe

Vaccines are an invasive intervention with risks of rare but serious side effects. Each required vaccine should have an acceptable safety profile, and where possible, the safest vaccine option should be available.

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julie.leask@sydney. edu.au Governments need to operate a no-fault vaccine injury compensation scheme to compensate those required to vaccinate who experience a rare serious adverse event.⁴

The vaccines should reduce transmission

Ethically, it is difficult to justify requiring someone to do something for their own good alone. A mandate is, however, more justifiable when vaccinating one person helps protect others around them. COVID-19 vaccines will prevent some degree of transmission because the vaccinated are less likely to acquire infection to begin with. In transmission studies, early evidence estimated a 40–50% reduction in risk of household transmission of the Alpha variant after at least one vaccine dose in an index case. Early evidence suggests that the current vaccines are less effective in reducing transmission from the Delta variant among those with breakthrough infection, and that this protection also wanes over time.

Vaccine supply should be sufficient and easily accessible

Before a vaccine mandate, governments must ensure a stable vaccine supply, effective distribution, equity of access, and convenient services. Australia's vaccine supply was limited for many months, and access remains a challenge for some, particularly those living in regional areas. People with disabilities have reported ongoing vaccine access challenges. Early inequities in access have affected certain groups disproportionately, such as Aboriginal and Torres Strait Islander communities and culturally and linguistically diverse groups. A penalty for not vaccinating when the government has not met its service delivery obligations is unjust and may be ineffective without addressing the access barriers limiting uptake.

Less restrictive, trust-promoting measures should come first

Before a mandate is introduced, there should be sufficient time for voluntary acceptance. Non-coercive measures targeting known causes of low vaccination should be exhausted (eg, on-site vaccination, reminders and incentives), in concert with efforts made to understand and address other context specific barriers using available tools.

Establishing community trust and confidence is essential. People need opportunities to have their questions and concerns addressed. Since mandates can undermine trust in voluntary vaccination programs, those imposing them should invest in tailored communications well in advance. ¹⁰

Procedural recommendations if a mandate is planned

The type of mandate chosen should not penalise the poor

Mandates should not compound disadvantage. Those involving loss of money, goods or services can disproportionately affect lower income earners. Crude financial penalties such as No Jab, No Pay impose a greater leverage on the poor and there is insufficient evidence that monetary sanctions improve uptake. ^{11,12}

Those mandating need to plan and support implementation

Reliable systems for documenting and retrieving evidence of vaccination are essential. Legislation now requires immunisation providers to record an individual's vaccination status for "certain relevant vaccinations" on the Australian Immunisation Register. Governments must make it easy to correct recording errors, and retrieval systems should take into account privacy considerations.

Implementing mandates is logistically complex and time consuming for governments. In health care settings, managers have reported difficulties with identifying which staff are covered by the mandate and confusion as to why others are not included. Mandating mask use for unvaccinated people also creates challenges, as staff are then required to police subordinates or colleagues.

Those who implement and enforce requirements in any setting must be supported. For example, there can be conflict when a health professional determines a person is ineligible for a medical exemption, occasionally leading to verbal or physical threats. There need to be clear consequences for such actions.

Affected populations should be considered in planning

If mandates are considered necessary, those imposing them should develop and implement them transparently and in consultation with targeted groups. This will help ensure the most acceptable programs and communication strategies, maintain trust in agencies and vaccination programs, and guard against some groups being left worse off than others.

Mandatory vaccination should not result in the continuation of trauma or disadvantage for Aboriginal and Torres Strait Islander peoples arising from past state and territory health policies. Specific exemptions may be appropriate if governments develop them in consultation with communities.

Individuals who remain unvaccinated should be considered in planning. All mandates must include exemptions for those with a valid medical reason. Governments should design medical exemptions to enable suitably qualified practitioners to make clinical decisions, based on individual patient risk and inherent uncertainties with the new COVID-19 vaccines. Clear clinical advice is needed for people who have previously had an adverse event following immunisation.

A proportion of the population will persistently reject vaccination on the basis of personal belief, even in the face of negative social or economic impacts. ¹⁴ In October 2021, 7% of respondents to a national survey were not willing to be vaccinated against COVID-19, even in the face of restrictions for the unvaccinated in some states. ¹⁵ These populations should be accounted

Prerequisites for mandatory COVID-19 vaccination

Is the mandate legal?

State and territory public health orders can require certain employees to be vaccinated. Where a public health order is not in place, the Fair Work Ombudsman (https://coronavirus.fairwork.gov.au/coron avirus-and-australian-workplace-laws/covid-19-vaccinations-and-the-workplace/covid-19-vaccinations-workplace-rights-and-obligations) states that individual employers' mandates are more likely to be considered reasonable where affected staff are Tier 1 or Tier 2 workers (eg, health care workers), due to the increased risk of contracting and transmitting coronavirus to at-risk populations.

Is the burden of disease high enough?

Areas with outbreaks of COVID-19 present a high burden of disease, which pose a threat to both the worker and those that they interact with or care for, particularly when many patients are likely to be unvaccinated.

Is the vaccine safe?

Workers should be able to access the safest vaccine. Currently, the AstraZeneca (Vaxzevria), Pfizer (Comirnaty) and Moderna (Spikevax) vaccines currently approved in Australia are generally very safe. However, in view of the low risk of thrombosis with thrombocytopenia syndrome associated with Vaxzevria, it is preferable that workers under a mandate can access their vaccine of choice. On 28 August 2021, the federal Minister for Health announced that government had finalised details for a COVID-19 Vaccine Claims Scheme to compensate those who suffer injury and loss of income due to their COVID-19 vaccine (https://www.health.gov.au/ministers/the-hon-greg-hunt-mp/media/no-fault-covid-19-indem nity-scheme).

Do the vaccines reduce transmission?

A vaccinated health care worker is less likely to acquire a SARS-CoV-2 infection and, if infected, is less likely to pass on the virus, according to current evidence.⁵

Is vaccine supply sufficient and accessible?

All affected staff should have had prior opportunity to access vaccination without facing any barriers. The Fair Work Ombudsman advises that employers should cover employee travel costs for vaccination and time off to receive the vaccine during work hours.

Have other less restrictive measures been tried first?

In certain health care settings, it may be sufficient to require documentation of protection.

Procedural recommendations

Does the mandate penalise the poor unfairly?

Where access remains difficult, some workers will need more help to be vaccinated. Employers have a duty of care to ensure all possible barriers are removed for all staff, irrespective of employment status or role, before imposing requirements. On-site vaccination should be considered for optimal convenience, or workplaces should provide paid time off for employees to receive a vaccine, particularly those on lower incomes. Certain health care workers may need additional time and resources to address vaccine questions and concerns. This group may include those with lower levels of health literacy and those who come from cultural backgrounds where English is not the first language.

Is there a plan to support those mandating vaccination? Employers should train and resource staff implementing the mandate. This could include training to support conversations with hesitant staff and advice for those who plan to decline vaccination. Medical exemptions, including consideration of special medical exemptions if applicable, must be available with clear pathways and support. Such staff may need temporary relocation. Workers who lose their jobs as a result of non-compliance are owed a duty of care from employers to support transition and provide assistance.

Are affected populations considered in planning?

Employers should consider the items above and develop policies in consultation with affected groups, including peak bodies and unions, across all the health care worker groups affected.

Conclusion

A vaccine mandate may be justified for health care workers in situations where they are at high risk of infection and of infecting others who are at greater risk of the severe effects of COVID-19. This should only occur once sufficient vaccine supply is available and employees have had ample opportunity to access the vaccine. Worker representatives should be consulted on the policy details and implementation.

for in planning. In occupational settings with a mandate, the potential loss of workers should also be considered.

One option to offset such issues is to consider stepdown requirements such as mandatory documentation of a recent negative test result as an alternative for the unvaccinated. This maintains an avenue for trenchant refusers and the medically exempt to access privileges afforded to the vaccinated while still protecting the community. However, in situations of heightened occupational risk, such as health and aged care settings, it may not be appropriate to extend exemptions beyond medical ones, as organisations have responsibilities to ensure the safety of their staff and patients. In some contexts, a personal belief exemption may be reasonable, and childhood vaccination mandates with personal belief exemptions can be as effective as requirements without them. 16 Exemptions that are procedurally complex to acquire reduce the rate at which people seek them, compared with easily acquired exemptions.¹⁷ Provision of these exemptions can also maintain trust and engagement with medical services, public health officials and governments, reducing alienation and disenfranchisement. Regardless of the type of exemption, all should be organised and administered at a state or Commonwealth level (or both) and made accessible to private or public organisations considering or intending to introduce mandates.

2 Domestic and international travellers: governments and travel industry stakeholders are considering requirements for vaccination and/or test-negative documentation, citing protection of citizens, and commercial duty of care to employees and travellers

Prerequisites for mandatory COVID-19 vaccination

Is the mandate legal?

There is precedent for requiring proof of vaccination (eg, yellow fever) for international travel to selected destinations under the International Health Regulations (https://www.who.int/ith/annex7-ihr. pdf). Some countries have announced COVID-19 vaccine mandates for domestic air travel (eg, Canada, Pakistan), and international travellers are increasingly required to show proof by airlines or countries (https://www.abc.net.au/news/2021-10-08/covid-vaccine-travel-overseas-from-australia-tga-appro ved/100520008). There will be complexity depending on which COVID-19 vaccines are accepted by different countries.

Is the burden of disease high enough?

The risk posed by international travel will vary across place and time, and responding to rapid change is not feasible. This means that a general mandate to protect Australian citizens and residents is more likely. Jurisdiction-level mandates could be based on COVID-19 burden in the state or territory of origin at different time points.

Is the vaccine safe?

As per Box 1: safety applies to any vaccine a traveller is required to have.

Do the vaccines reduce transmission?

As per Box 1.

Is vaccine supply sufficient and accessible?

The World Health Organization currently recommends against requirements for COVID-19 vaccination for international travel as a condition of departure or entry (https://www.who.int/news-room/artic les-detail/interim-position-paper-considerations-regarding-proof-of-covid-19-vaccination-for-inter national-travellers). This is partly on the basis of limited vaccine supply globally. For domestic travel within Australia, there may be populations where vaccine supply remains challenging. Thus other less restrictive measures should be considered, as below.

Have other less restrictive measures been tried first?

The impact on those who cannot, or will not, vaccinate would be significant if travel is indefinitely restricted for them, such as for those separated from family overseas. At the same time, it is desirable to limit transmission of SARS-CoV-2 resulting from travel. A step-down requirement may be a reasonable compromise. For example, the European Union Digital COVID Certificate will provide proof that a person has been vaccinated against COVID-19, received a negative test result, or recovered from COVID-19. Medical exemptions must also be accessible and recognised. Type of quarantine should be adjusted according to individual and country risk level.

Procedural recommendations if a mandate is planned

Does the mandate penalise the poor unfairly?

Mandatory vaccination for global travellers will penalise those unable to access vaccination due to supply and slow country procurement. Many low and middle income countries that are dependent on vaccine supply through COVAX (https://www.who.int/initiatives/act-accelerator/covax) need to be given consideration and their citizens not penalised unfairly, especially by countries that may have not contributed to COVAX supply. These ethical issues need to be considered and other means made available to travellers from these countries; ie, vaccination and quarantine on arrival.

Is there a plan to support those mandating vaccination?

A range of actors need to be involved with informing travellers about the mandates, including those working in the travel industry. There may be implications for those travelling away from Australia, as well as those wishing to travel into Australia for holidays, work or study. It is critical that easily navigable information is made available and translated so that there is sufficient time for travellers to understand the requirements. Communication about COVID-19 vaccine requirements could also include recommendations for other relevant travel related vaccines.

Are affected populations considered in planning?

Restricting freedom of movement requires transparency and fairness, as well as raising operational considerations for incoming visitors. These include demonstration of proof of vaccination; how to regard receipt of vaccines that have not been approved under WHO Emergency Use Listing or licensed by the national regulator; and how to account for those who seek to travel from a country without adequate vaccine supply.

Conclusion

While mandatory vaccination is not justified for travel, evidence of vaccination, a negative test result or previous infection is reasonable to protect travellers and reduce transmission. The implementation of these requirements must consider inputs from all stakeholders, including those in the travel industry and travellers.

Vaccine mandates, particularly without exemptions, can bring backfire effects among those more resistant to vaccination. Mandates have also intensified antivaccination activism, as was seen in the 19th century with the smallpox vaccine. Political polarisation about mandates may increase organised political opposition, especially among minor party voters. 19

In Box 1 and Box 2, we outline two worked examples of how the above considerations apply to specific situations where mandates have already been proposed or enacted.

Conclusion

Mandatory vaccination requires strong justification. If there are ways of achieving the same outcomes using measures that are less restrictive, they should be attempted. The benefits gained by mandates must be greater than the harms they may cause. These harms and benefits may be difficult to meaningfully compare.

A justifiable mandate must take into account the context and the goal of vaccination. Requiring vaccination for one group, or within one organisation,

does not automatically make mandates acceptable for another.

A goal of vaccine mandates is to achieve a certain level of uptake in a population (eg, > 80%). However, all other avenues to increase uptake must first be exhausted and then certain ethical criteria satisfied. A general population mandate could cause resentment and mistrust in government and public health agencies, and undermine trust in vaccination more broadly and in other public health programs. Mandates cannot be ethically justifiable if they further entrench existing disadvantage, or if penalties will be experienced very differently by different populations (including between the rich and the poor). Different background risk levels — levels of COVID-19 transmission, willingness to receive the vaccine — will mean the calculus around justifications for vaccine mandates could change quickly.

We have presented two worked examples using prerequisite criteria and procedural recommendations (Box 1 and Box 2). However, an overall guidance on thresholds for justifying mandates is beyond the scope of this article. Thresholds are value judgments that require stakeholders to consider what matters. Questions include: how high is "high enough" for the burden of disease? What levels of effectiveness are sufficient to justify the negative consequences of a mandate? How should we prepare for the inevitable backlash that will come from a policy of mandatory vaccination in any setting? The answers to these questions will differ over time and place and with the goal of the mandate. Addressing these considerations in ways that are procedurally just can ensure that outcomes are fairer and more trusted.²⁰ Mandate decisions that are careful and responsive to context are more likely to avoid social harms while, ideally, helping to achieve a public good.

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