

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

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Julie Leask sits on the Expert Advisory Group for the Victorian Department of Health and Human Services and was a temporary unpaid advisor to the Vaxzevria (previously COVID-19 Vaccine AstraZeneca) Advisory Board.

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## Background

Public attention is increasingly turning towards how Australia can achieve the very high vaccination coverage needed for optimal control of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) virus. Governments and businesses have already mandated coronavirus disease 2019 (COVID-19) vaccination for workers in certain sectors, and vaccination is now required for domestic air travel to Western Australia. International air travel is likely to involve vaccination requirements in future, as is already the case in other countries. Each new outbreak, with its restrictive public health measures, will see public pressure to mandate COVID-19 vaccination in other 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.<sup>1</sup> Consequences for non-compliance include change or loss of employment; a requirement to use masks; reduced access to money, goods, or services; or 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 whilst carefully considering the epidemiological, programmatic, and legal issues.

This paper outlines the range of issues that need to be considered prior to, 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. Authors initially contributed to a working paper in February, which was updated in May. They then met to consolidate the normative position and structure for this paper, and collaboratively refined the arguments through three meetings. A webinar was also held on 26 July 2021.<sup>2</sup>

## Prerequisites for mandatory COVID-19 vaccination

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

### The mandate should be legal

In most settings mandatory vaccination must have legislative support.<sup>3</sup> For occupational settings, Fair Work Australia provides general guidance. 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. Fair Work Australia divides work into four tiers of risk to facilitate case-by-case assessment.

### 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 thus 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. Governments need to operate a no-fault vaccine injury compensation scheme to compensate those required to vaccinate in the rare occurrence of a serious adverse event.<sup>4</sup>

### The vaccines should reduce transmission

Ethically it's 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.<sup>5</sup> Early evidence suggests the current vaccines may be less effective in reducing transmission from the Delta variant,<sup>6</sup> however published real world transmission studies are needed

### Vaccine supply should be sufficient and access easy

Prior to a vaccine mandate, governments must ensure a stable vaccine supply, effective distribution, equity of access, and convenient services. Australia's vaccine supply has been limited to date and access remains challenging. People with disabilities and aged care providers have reported ongoing vaccine access challenges.<sup>7</sup> Early inequities in access have affected certain cultural 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 failed to meet its service delivery obligations is unjust and may be ineffective without addressing the access barriers limiting uptake.

### Less restrictive and trust promoting measures should come first

Prior to a mandate being introduced, there should be sufficient time for voluntary acceptance. Non-coercive measures targeting known causes of low vaccination should be exhausted, for example, on-site vaccination, reminders and incentives,<sup>8</sup> 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.<sup>9</sup> Since mandates can undermine trust in voluntary vaccination programs, those imposing them should invest in tailored communications well in advance.<sup>10</sup>

### Procedural recommendations if a mandate is planned

#### The type of mandate chosen should not penalise the poor unfairly

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.<sup>11,12</sup>

### 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" onto 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 healthcare settings, managers have reported difficulties with identifying which staff are covered by the mandate and confusion as to why others are not included.<sup>13</sup> Mandating mask use for non-vaccination 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 due to personal belief even in the face of negative social or economic impacts.<sup>14</sup> An estimated eleven percent of Australians in a national survey in June disagreed with having a COVID-19 vaccine and a subset of them are likely to maintain that stance.<sup>15</sup> These populations should be accounted 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 step-down requirements such as mandatory documentation of recent negative tests. 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.<sup>16</sup> Exemptions that are procedurally complex to acquire reduce the rate at which people seek them, compared with easily-acquired exemptions.<sup>17</sup> 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.

Vaccine mandates, particularly without exemptions, can bring backfire effects among those more resistant to vaccination.<sup>18</sup> Mandates have also intensified anti-vaccination activism as was seen in the 19th century with the smallpox vaccine. Political polarisation about mandates may increase organised political opposition, especially amongst minor party voters.<sup>19</sup>

In boxes 1 and 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 meaningfully attempted. The benefits gained by mandates must be greater than the harms they are likely to cause. Such harms may include loss of trust in government or public health agencies and vaccination beyond the mandate, the risk of broad social divisions, and the risk of further entrenched disadvantage. 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 does not automatically make mandates acceptable for another.

One goal of vaccine mandates is to achieve a certain level of uptake in a population (e.g. >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 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.

This paper has presented two worked examples using prerequisite criteria and procedural recommendations. However, an overall guidance on thresholds for justifying mandates is beyond the scope of this paper. 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 be different over time and place and the goal of the mandate. Addressing these considerations in ways that are procedurally just can ensure that outcomes are fairer and more trusted.<sup>20</sup> Mandate decisions that are careful and responsive to context are more likely to avoid social harms while, ideally, helping to achieve a public good.

<b>Box 1. Healthcare workers</b>	
A vaccine mandate may be justified, including in situations where employees are at high-risk of infection, or infecting others who are at greater risk of severe effects of COVID-19.	
<b>Prerequisites for mandatory COVID-19 vaccination</b>	
<b>Is the mandate legal?</b>	State and territory public health orders can require certain employees to be vaccinated. Where a public health order is not in place, Fair Work Australia says individual employers' mandates are more likely to be considered reasonable where affected staff are Tier 1 or Tier 2 workers (e.g., health care workers), due to the increased risk of contracting and transmitting coronavirus to at-risk populations.
<b>Is the burden of disease high enough?</b>	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/care for, particularly when many patients are likely to be unvaccinated.
<b>Is the vaccine safe?</b>	Workers should be able to access the safest vaccine. Currently both AstraZeneca and Pfizer vaccines are generally very safe. However, in view of the TTS risk for AZ, it is preferable that workers under a mandate can access their vaccine of choice. The federal Minister for Health announced on 2 July plans for a COVID-19 Vaccine Claims Scheme backdated to the start of the national vaccine rollout that will help guide potential claimants through a no fault claims process scheme.
<b>Do the vaccines reduce transmission?</b>	A vaccinated healthcare worker is less likely to acquire a COVID-19 infection and if infected, less likely to pass on the virus according to current evidence.
<b>Is vaccine supply sufficient and accessible?</b>	Supply of the Pfizer vaccine continues to be limited in Australia at the point of writing. Access problems continue to be reported. Government and/or employers will need to improve access for workers before a mandate is enforced. According to Fair Work Australia, employers should cover employee's travel costs for vaccination and time off to get the vaccine during work hours.
<b>Have other less restrictive measures been tried first?</b>	In certain healthcare settings, it may be sufficient to require documentation of protection. All affected staff should have had prior opportunity to access vaccination with few barriers, including via onsite vaccination clinics.
<b>Procedural recommendations</b>	
<b>Does the mandate penalise the poor unfairly?</b>	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 have a vaccine, particularly those on lower incomes. Certain healthcare workers may need additional time and resources to address vaccine questions and concerns. They may include those with lower levels of health literacy and those who come from cultural backgrounds where English is not the first language.
<b>Is there a plan to support those mandating vaccination?</b>	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 to access. 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 with transition and assistance.
<b>Are affected populations considered in planning?</b>	Employers should consider the items above and develop policies in consultation with affected groups, including, peak bodies, unions and other peak bodies across all the healthcare worker groups affected.
<b>CONCLUSION</b>	A vaccine mandate may be justified for health care workers in situations where they are at high-risk of infection, or of infecting others who are at greater risk of severe effects of COVID-19. This should only occur once sufficient vaccine supply is available to enable choice of vaccine and employees have had ample opportunity to access the vaccine. Worker representatives should be consulted on the policy details and implementation.

<b>Box 2. Domestic and international travellers</b>	
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.	
<b>Prerequisites for mandatory COVID-19 vaccination</b>	
<b>Is the mandate legal?</b>	There is precedent for requiring proof of vaccination (e.g. yellow fever) for international travel to selected destinations under International Health Regulations. Some countries have announced COVID vaccine mandates for domestic air travel (e.g. Canada, Pakistan), and international travel requirements are likely to follow. There will be complexity depending on which COVID vaccines are accepted by different countries.
<b>Is the burden of disease high enough?</b>	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. State-level mandates could be based on COVID-19 cases in the state of origin at different time points.
<b>Is the vaccine safe?</b>	As per box 1 – safety applies to any vaccine a traveller is required to have.
<b>Do the vaccines reduce transmission?</b>	As per box 1.
<b>Is vaccine supply sufficient and accessible?</b>	The World Health Organization currently recommends against requirements for COVID-19 vaccination for international travel as a condition of departure or entry. 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.
<b>Have other less restrictive measures been tried first?</b>	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 COVID-19 due to travel. A step-down requirement may be a reasonable compromise. For example, the European Union’s 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.
<b>Procedural recommendations if a mandate is planned</b>	
<b>Does the mandate penalise the poor unfairly?</b>	Mandatory vaccination for global travellers will penalise those unable to access vaccination due to supply and slow country procurement. Many LMIC settings that are dependent on vaccine supply through 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 i.e., vaccination and quarantine on arrival.
<b>Is there a plan to support those mandating vaccination?</b>	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 easy to navigate 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.
<b>Are affected populations considered in planning?</b>	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 Emergency Use Listing by WHO or licensed by the national regulator; and how to account for those who seek to travel from a country without adequate vaccine supply.
<b>CONCLUSION</b>	While mandatory vaccination is not justified for travel, evidence of vaccination, negative test or previous infection is reasonable to protect travellers and reduce transmission. The implementation of these requirements needs to consider inputs from all stakeholders including those in the travel industry and travellers.



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